A DESCRIPTIVE STUDY OF ASPECTS OF THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV PROGRAMME AT SELECTED HOSPITALS AND CLINICS IN GAUTENG

Farrah Ismail

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DECLARATION

I, Farrah Ismail, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in Paediatrics at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

F Ismail

01 day of MAY, 2010.

DEDICATION

For all their help, support and patience, I dedicate this work to my husband Shiraz, my darling daughter Sadiyah, my parents Rayhana and Murad, my aunt Rookeya and my siblings Farzanah and Mohamed Zakkee.

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1. University of the Witwatersrand Health Sciences Research Day, August 2006.

2. All 4 Kids Conference, South African Paediatric Association, Sun City, September 2006.

ABSTRACT

AIM:

To evaluate aspects of the PMTCT programmes at selected hospitals and clinics in Gauteng.

METHOD:

A cross sectional survey of post partum women in Gauteng was undertaken during April-June 2006. Data was collected at four hospitals and eight Midwife Obstetric Units (MOUs) in four regions in Gauteng. Mothers, irrespective of HIV status, who delivered in the previous 48 hours were interviewed. This was followed by a review of the mother's and infant's records as well as relevant registers.

RESULTS:

Interviews with, and record reviews, of 182 mother-infant pairs were conducted/obtained; 69 (38%) at MOUs and 113 (62%) at hospitals. The majority (172 [95%]) of mothers were "booked" of whom 155 (85%) had undergone an antenatal HIV test. Forty-two mothers (23%) were HIV positive. Nevirapine was issued antenatally to 37/42 (89%) of eligible mothers; 30/42 (71%) took it during labour. Three women (8%) received the drug for the first time during labour; thus 33/42 (79%) of eligible mothers received nevirapine. Thirty-two (76%) of babies born to HIV positive mothers received nevirapine. However, in only 24/42 of mother-infant pairs (57%) was receipt of nevirapine by both parties, recorded. There was no significant difference in nevirapine administration rates to mothers at clinics compared to hospitals (76% vs. 81%, p=0.71). Infants were more likely to receive nevirapine at clinics compared to hospitals (90% vs. 62%, p= 0.03).

CONCLUSION:

Four years after introduction of a PMTCT programme in Gauteng, nevirapine uptake and administration rates remained sub-optimal, with at least a quarter of eligible (identified) women and infants not receiving the intervention. The findings highlight the need to prioritise and consolidate PMTCT activities in the province.

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LIST OF ABBREVIATIONS

3TC	Lamivudine
AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIDS	Acquired Immune Deficiency Syndrome
ALP	AIDS Law Project
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT/ZDV	Zidovudine
CCMT	Comprehensive Care Management and Treatment
CD4	Cluster of Differentiation 4
CDC	Centers for Disease Control and Prevention
CHC	Community Health Centre
COSATU	Congress of South African Trade Unions
DNA-PCR	Deoxyribonucleic Acid Polymerase Chain Reaction
DoH	Department of Health
ELISA	Enzyme Linked Immunosorbent Assay
HAART	Highly Active Antiretroviral Therapy
HAAST	HIV, AIDS and Sexually Transmitted Diseases
HIV	Human Immunodeficiency Virus
HST	Health Systems Trust
MCC	Medicines Control Council
MEC	Member of Executive Council
MinMEC	A committee consisting of the Health minister and nine provincial MEC's for Health
MOU	Midwife Obstetric Unit
MTCT	Mother to Child Transmission
NGO	Non-Governmental Organisation
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
PACTG	Paediatrics Aids Clinical Trial Group
PCR	Polymerase Chain Reaction
PHRU	Perinatal HIV Research Unit

PMTCT	Prevention of Mother to Child Transmission of HIV
RTHC	Road to Health Card
Sd-NVP	Single Dose Nevirapine
TAC	Treatment Action Campaign
TB	Tuberculosis
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

CHAPTER ONE

LITERATURE REVIEW

Prevention of Mother to Child Transmission (PMTCT) of HIV in the South African context

1.1 Background to PMTCT

The Prevention of Mother to Child Transmission (PMTCT) of human immunodeficiency virus (HIV) is a strategy endorsed by the World Health Organization (WHO) in 2000. It is a three pronged strategy which includes prevention of HIV among parents to be, prevention of unwanted pregnancies among HIV positive women and prevention of transmission of HIV from infected mothers to their infants.[1] The last prong of the strategy can be achieved through the provision of antiretrovirals to HIV infected pregnant women and their infants, safe delivery practices, and counselling and support for safer infant feeding practices.[1]

Mother to child transmission (MTCT) is the predominant method whereby children contract HIV.[1] In non breastfeeding populations, in the absence of any intervention, 15 to 30 percent of children born to HIV infected mothers will contract the virus,[1] with the least amount of transmission occurring intrauterine (5 to 10 percent) and most infections occurring during delivery (10 to 20 percent). Breastfeeding post delivery increases the risk of transmission by another 10 to 15 percent.[1]

Factors responsible for an increased risk of mother to child transmission include:[2]

1. Mother's viral load - with a high viral load and advanced clinical stage increasing the risk

2. Prolonged rupture of membranes
3. Infections, including chorioamnionitis
4. Prolonged exposure to maternal fluids
5. Instrumental delivery
6. Breastfeeding - where factors including high viral load, mastitis, cracked nipples and altered gut permeability of infant increases the risk of transmission.[3]

While all these factors play a role, a mother's viral load and low CD4 count are the two major factors involved; thus the need for antiretrovirals during pregnancy to decrease transmission rates.[4]

In 2007, 28.0% of South African women attending antenatal clinics were HIV positive.[5] Worldwide in 2006 it was estimated that 530 000 infants were newly infected with HIV and 380 000 children died from AIDS.[3]

With MTCT of HIV contributing significantly to the under-five mortality rate, comprehensive PMTCT packages have been developed and implemented to impact on this burden.

1.2 A Brief History of the Drug Regimens used in Prevention of Transmission of HIV from Mother to Infant

In 1994, the Paediatrics Aids Clinical Trial Group (PACTG) protocol 0760 showed a remarkable reduction in transmission of HIV (68%) in infants (tested at 18 months of age) when zidovudine (AZT) was provided from the fourteenth week of pregnancy, during labour and for six weeks thereafter to the newborn baby. Infants were not breastfeed.[6]

Since this regimen was quite intensive and costly, it would have been difficult to implement in resource poor settings.

Following on this, in 1996 the Thai-short course study using AZT from 36 weeks and during labour in non breastfeeding populations showed a 50% reduction in of the transmission of HIV.[7]

In 1999 the Centers for Disease Control and Prevention's (CDC) West African study, using the same drug regimen as the Thai short course study showed a 37% reduction in transmission rate in breastfeeding populations.[8] The PETRA study results followed in 2002. In Arm A of the PETRA study AZT and Lamivudine (3TC) were used from 36 weeks, during labour and for one week after delivery in both mother and infant the transmission rate was reduced by 63%. [9]

As impressive as these figures were, it was still costly to implement these regimens in resource poor settings.

In Arm B of the PETRA study a single dose of AZT and 3TC was administered to the mother in labour followed by a week of both drugs to mother and infant. Mothers breastfed their babies thereafter. This regimen offered a reduction in transmission of HIV of 42% (after 6 weeks).[9]

In 1999, the HIVNET 012 study in Uganda compared the use of a single 200 mg dose of nevirapine (NVP) to the mother in labour followed by a single dose of 2mg/kg to the infant, with an intrapartum dose of AZT to the mother followed by AZT to the infant for a

week. The study found a transmission rate of 13% in the NVP group versus 25% in the AZT group by 14 to 16 weeks of age in a predominantly breastfed population.[10]

Based on the HIVNET 012 study, the SAINT study was conducted during 1999 to 2000 across different centres in South Africa to compare the AZT/3TC regimen (as used in the PETRA B study) with a single dose of nevirapine (200mg) delivered to the mother in labour followed by 200mg 48 hour post partum and a single dose to the infant (6mg) 24-72 hours after delivery. The study showed a HIV transmission rate of 12.3% for NVP and 9.3% for AZT/3TC by eight weeks of age.[11]

Based on above studies, the WHO recommended in 2001 that in resource poor countries the nevirapine regimen would be the simplest regimen to deliver, but also recommended that where possible, more complex antiretroviral regimens be offered.[1]

Other data that followed included a pooled analysis by Leroy, et al. in 2005, which looked at HIV transmission rates at 6 to 8 weeks with four different antiretroviral regimens. In comparison with placebo, the adjusted odds ratio for HIV transmission was 0.23 for AZT and 3TC administered antepartum, intrapartum and seven days postpartum; 0.49 for the combination of AZT and 3TC during the intrapartum and postpartum periods only; 0.55 for AZT only, administered antepartum, intrapartum and postpartum; and 0.60 for single-dose NVP. Thus, at six to eight weeks, monotherapy with AZT and NVP had similar reductions in MTCT, and AZT and 3TC combinations had a greater efficacy in MTCT reduction.[12]

In the ANRS 1201/1202 Ditrame Plus cohort in Abidjan, Côte d'Ivoire, in 2001-2003, transmission rates at six to eight weeks postpartum were 6.5% (95% CI 3.9–9.1) with ZDV plus single-dose NVP, and 4.7% (95% CI 2.4–7.0) when mothers were given both ZDV and 3TC from week 32 of gestation, continued for one week postpartum (for both mother and child), in addition to single-dose NVP to mother and infant.[13]

Gray, et al. showed in 2005 that single-dose NVP as post exposure prophylaxis given to newborns exposed to HIV tended to reduce MTCT with transmission rates similar to those seen in the HIVNET 012 trial. At 12 weeks the cumulative HIV transmission rate was 14.3% in the NVP arm and 18.1% in babies who received AZT for six weeks post delivery. Transmission rates were higher in both groups where breastfeeding was the choice of feed.[14]

More recently in 2006, WHO published its latest recommendations on antiretrovirals in pregnancy and preventing infection in infants.[15] The guideline recommends that: (1) pregnant women eligible for Highly Active Antiretroviral Therapy (HAART) must have access to it, and (2) national programmes must adopt more efficacious antiretrovirals (ARV's) for mothers who do not qualify for HAART yet. This regimen consists of providing antepartum AZT from 28 weeks of pregnancy or as soon as possible thereafter, intrapartum AZT and 3TC plus a single dose of NVP and postpartum AZT and 3TC for seven days to mother and single dose NVP and AZT for one week to infants.

Further the guideline states that: "The length of the prophylactic regimen and optimum choice of drugs can vary depending on when a woman is identified as infected with HIV." HIV testing may have taken place before pregnancy or may occur at different times during

pregnancy, at the time of labour and delivery, or postpartum. Those women, who present later in pregnancy or at delivery, should receive the appropriate antiretroviral prophylaxis based on the time of her first visit. If the mother presents late in pregnancy and is eligible for HAART, then she should be commenced on HAART. If this is not possible, the mother should be commenced on ARV's for PMTCT. Those mothers who present in labour should receive a single dose of NVP with AZT and 3TC intrapartum, followed by AZT and 3TC for seven days. Infants born to mothers who received less than four weeks of antiretrovirals have to receive AZT for four weeks post delivery. Where countries don't have the capacity to implement the new recommendations, the guideline states that "as an absolute minimum", the single dose nevirapine (mother and infant) may be implemented with the aim of improving their programmes to provide more effective PMTCT regimens.[15]

1.3 Nevirapine Pharmacology

Nevirapine, an antiretroviral of the class non-nucleoside reverse transcriptase inhibitors (NNRTI), inhibits replication of HIV by blocking the viral reverse transcriptase enzyme. Nevirapine is rapidly absorbed when taken orally and has a long half life of approximately 45 hours after a single dose.[16,59] With multiple doses the half life is reduced to 25-35 hours as a result of self induction, i.e. the drug is an enzyme inducer and induces cytochrome P450. The most common side effects noted with prolonged use include a rash and abnormal liver function tests.[16] The risk of rash and hepatotoxicity in women on ARV treatment has been noted to be higher in women with CD4 counts greater than 250 x 10^6 cells per litre.[15] Toxicity in infants after a single dose has not been reported.[11,15]

1.4 Concerns about Nevirapine

As with other short course regimens resistance to nevirapine may develop rapidly. Resistance develops because in the presence of partly suppressive regimens the virus selects out for replication of the resistant strain. Once the drug is removed the virus returns to replication of wild type virus.[15] With nevirapine, as with 3TC, single mutations result in a high level of resistance.[15] The risk of developing resistance seems to be related to the CD4 count and viral load at the time of taking the dose, the viral subtype (more common with subtype C than with A and D), the number of doses taken during labour and, the time of sampling, i.e. from the time the drug was taken in labour.[15,17] The risk of resistance doubles when two doses are taken in pregnancy as opposed to one.[15] Previous studies, including the HIVNET 012 trial, showed resistance developing at 6-8 weeks in 25% of the women who received single dose NVP.[10] The SAINT study found that 67% of women who received two doses of NVP developed resistance.[11]

However, development of resistance has not been shown to increase MTCT in the present pregnancy; neither does exposure to nevirapine decrease the efficacy of PMTCT in subsequent pregnancies.[15] Resistance to nevirapine can be reduced by administering dual NRTIs intrapartum and for a short period following the administration of nevirapine.[15,17] WHO recommends that to prevent resistance to nevirapine, pregnant women eligible for HAART should be commenced on HAART and that mothers who receive a dose of nevirapine in false labour should not receive another dose when in established labour. The infant should be given the dose of nevirapine soon after birth followed by AZT for four weeks.[15]

1.5 PMTCT of HIV in South Africa

In 1994, the results of the first study on the use of AZT as monotherapy to prevent MTCT of HIV were published. This was a tremendous breakthrough for the reduction of HIV infection rates in children. Soon thereafter, the 1994 National AIDS Plan of South Africa stated that steps would be implemented to reduce MTCT of HIV. This included voluntary counselling and testing (VCT) and conducting research on the use of AZT and other non nucleoside reverse transcriptase inhibitors. Progress was slow and in the face of this new information being available, yet being unable to help many mothers, many organisations including the AIDS Law Project (ALP), the Aids consortium, the Perinatal HIV Research Unit (PHRU) and the Treatment Action Campaign (TAC) began lobbying of the Department of Health (DoH) to develop a programme to prevent MTCT of HIV. In 1998 the DoH announced the implementation of five PMTCT pilot sites.[18]

One of the barriers to developing a nationwide programme was the cost of AZT, and while the TAC was working to get manufacturers to reduce the cost of the drug, new opposition emerged where the Aids "denialists" sent out the message that antiretrovirals instead of improving the immune system had serious life threatening side effects. The government and the Minister of Health now questioned the safety of these drugs, and under instruction from the President, the health minister ordered the Medicines Control Council (MCC) to conduct further research on the drug. This put a halt on developing a national programme.[18]

In 2000, the MCC issued its report that stated that the benefits of AZT outweighed the risks, as suggested by the WHO, but it was rejected by the DoH requesting that more research be done on the matter. In the interim, in 1999 the results of HIVNET 012 study

became available and with the opposition to AZT at the time, the Department of Health latched onto this alternative. Nevirapine was now offered as the medicine of choice pending the results of the SAINT study. The SAINT study subsequently supported the use of nevirapine for the PMTCT of HIV, but there was minimal action by the government. In fact it declined an offer from Boehringer Ingelheim to provide the health department with a free supply of nevirapine. The TAC now considered bringing an urgent high court application for access to nevirapine. However, the medicine was not yet registered by the MCC for this purpose.[18]

In August 2000, after the International AIDS conference, the Department of Health convened a meeting to discuss new information from the conference. Thereafter, the MinMEC committee (a committee consisting of the Health minister and nine provincial MEC's for Health) decided that they would no longer use the policy with AZT, and since nevirapine was now registered by the MCC it would be tested at two pilot sites in each province over two years. The government failed to reveal information that nevirapine had been registered for PMTCT use for another six months.[18]

With pressure from many clinicians, the TAC and many affidavits later, the DoH planned to start setting up the pilot sites by March 2001. This again faced many delays and the tension between activists and DoH was rising. In June 2001 the Minister of Health met with the TAC, COSATU and a group of paediatricians who formed an organisation called "Save our Babies" to advocate for the national availability of nevirapine prophylaxis. Still their questions and pleas went unanswered.[18]

By July 2001 the DoH once again faced litigation by the TAC. The initial letter sent to the minister and the provincial MEC's demanded reasons for not making NVP available to the public sector and placement of a programme where medical practitioners in the public sector were able to prescribe NVP for their patients at their discretion where medically indicated.

After much deliberation many provinces had already set up more than the two pilot sites per province. [18]

In August 2001, the TAC, Save our Babies and the Children's Rights Centre filed a constitutional claim against the government, stating that the present policy was unconstitutional and that the government should be ordered to make nevirapine available to pregnant women who delivered in the public sector and to their babies, under the judgement of a medical practitioner, and that a national programme be developed including VCT, nevirapine to mother and infant and provision of formula feeds.[18]

On 14 December 2001, a High Court judge ruled in favour of the TAC and others and ordered that nevirapine be prescribed where medically indicated and, further, the judge "ordered the government to develop 'an effective comprehensive national programme to prevent or reduce MTCT' and return to the Court with this programme for further scrutiny before 31 March 2002."[18]

The Minister then appealed to the Constitutional Court against the execution order. In her statement to the press she promised to review the present policy with input from "national stakeholders" and from the present pilot sites.[18]

By January 2002 the HST completed its initial evaluation of the pilot sites and presented their findings at a MinMEC meeting. One of the recommendations of the evaluation stated that "while a phased and systematic expansion of comprehensive MTCT services is being planned, NVP can and should be provided immediately to all pregnant women who are already known to be HIV positive, with appropriate counselling and information." This information was not made public for a few weeks after the presentation. The Minister however stated that she could not take a decision on expansion of the programme until May 2002, when the pilot programme would have been in place for one year. In the interim, two other processes were taking place, both the Gauteng and Kwazulu Natal premiers continued to expand on their PMTCT programmes, and the TAC were planning to obtain an execution order from the Pretoria High Court, on part of the judgement that ordered that nevirapine be made available where the capacity existed. Back in court in March 2002, the High Court judge ruled in favour of the execution order and dismissed the government's application to appeal to the Constitutional Court. Following this the government launched an application to appeal the judgement directly to the Constitutional Court. The TAC then filed a counter application, stating that the aim of the government's further legal action was to "stultify the execution order." The hearing took place on 3 April 2002, and the following day the court refused the government leave to appeal the execution order.[18]

The TAC case continued in court from May through to July 2002. On 5 July 2002, judgement was handed down which stated, amongst others, that the government's policy did not fulfil the people's constitutional right to health care services, that they did not have sufficient evidence to claim that nevirapine was unsafe and that the policy was discriminatory against poor people who could not pay for the service. Further the

Constitutional Court ordered government "without delay" to remove the restrictions that prevented nevirapine from being made available for the purpose of reducing the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites, to make nevirapine available for PMTCT of HIV purposes at hospitals and clinics when in the judgment of the attending medical practitioner acting in consultation with the medical superintendent of the facility concerned that it is medically indicated, and if so to ensure that the mother is adequately counselled and tested, to make provisions for counsellors at public hospitals and clinics, to extend the counselling and testing facilities at public hospitals and clinics and expedite the use of nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV.[18]

1.6 Description of the PMTCT Programme in South Africa

Implementation of the PMTCT programme began in 2001 and an increasing number of facilities are providing the service every year. By 2006, ninety percent of public health facilities provided PMTCT services.[19]

The first policy on the PMTCT of HIV was developed in 2001, and most of the implementation strategies still prevail to date. The programme involved pregnant women attending an antenatal clinic where they were offered VCT. Pre-test counselling included information about HIV and how to prevent it, information about mother to child transmission of HIV and measures to reduce this, information about the testing process, discussion about confidentiality, discussion about couple counselling, implications of the test result and the meaning of the window period, exposure to stigma and support systems. Counselling can take place in a group session and on an individual basis. Women are given

the option of "opting-in" i.e. choosing to be counselled and tested. If she so chooses, consent is obtained from the mother and her choice recorded in the counsellor's register.[20]

A HIV rapid test is performed and mother can choose to receive her result on the same day or at a subsequent visit. The result of the test is then recorded in a blood register, the counsellor's register as well as in the antenatal card by means of a share code secret table. Once she receives her result the mother is counselled – so-called post-test counselling. If found to be HIV positive, post-test counselling would include discussion regarding CD4 counts, antiretroviral prophylaxis (nevirapine at the time of the study), feeding choices, exposure to stigma, support services and safe sex practices.[21] Previously only some facilities provided CD4 count testing. If CD4 count is <200 or if the mother is clinically a WHO category C patient, then where available, mothers can be considered for Highly Active Antiretroviral Therapy (HAART) as part of PMTCT Plus.[20]

Previously, if a mother was found to be HIV positive and if she chose to be part of the PMTCT programme, a nevirapine tablet (200mg) was issued from 28 weeks of pregnancy to be taken once the mother was in labour. The nevirapine dispensed was recorded in the nevirapine register. Previously the protocol stated that if the mother presented in false labour and had taken the tablet another dose could be taken again 24 hours after the first dose at a subsequent onset of labour or if she remained in labour. (This was subsequently changed and a second dose was no longer provided to the mother because of the increased risk of inducing nevirapine resistance.) If the mother presented in labour and had forgotten to take her tablet then a dose could be administered to her at the facility where she presented. Nevirapine dispensed in labour was also recorded in the labour ward nevirapine register. The infant was to receive a dose of nevirapine (2mg/kg) within 72 hours of birth.

Feeding options were discussed with the mother again and her choice of feed was recorded and supported.[20]

In February 2008, a new policy on the implementation of a PMTCT of HIV programme was issued by the National Department of Health.[21] There have been a few changes to the previous programme, mostly however along the lines of the drugs being used for PMTCT of HIV, with improvements in the quality of VCT provided, counselling and support on feeding choices. The policy includes as a fourth prong of the strategy the provision of appropriate treatment, care and support to women living with HIV and their children and families.

Mothers attending antenatal clinic now undergo two sets of counselling, one as a group session and the second on an individual basis. The mother then chooses to have an HIV test (or not), and if she does then both verbal and written consent is obtained. A woman may refuse to be tested, and if she does then she should be encouraged at further visits to undertake the test. If she chooses to have the test done, then the test is performed with a rapid kit, and if found to be HIV positive, the rapid test is repeated to confirm the result. All mothers are given their results on the same day and undergo post test counselling as before. If there is a discrepancy in the two results, a formal HIV ELISA is sent off and mothers are asked to return for the results. The HIV test is repeated later in pregnancy at or around 34 weeks. [21]

With the new protocol, when a mother is found to be HIV positive, CD4 counts are taken on the same day; mothers undergo screening for tuberculosis (TB) and are then classified according to the WHO HIV Clinical Staging Guideline. Mothers receive continuous

support and counselling throughout pregnancy, as well as micronutrient supplementation and prophylaxis and treatment for opportunistic infections.

If a mother is found to have a CD4 count <200 or is clinically WHO Stage 4, then she should be prioritised for HAART. Note that this is different to the WHO recommendation of CD4 < 350 or WHO Stage 3. Those mothers, who do not yet qualify for HAART, receive the PMTCT regimen, which consists of AZT from 28 weeks or later followed by single dose nevirapine and AZT on a three hourly basis when in labour. Mothers already on HAART before pregnancy continue with HAART through pregnancy, labour and postnatally; with a change of efivarenz to nevirapine in the first trimester, or they may continue with their existing regimen if present later in pregnancy. Mothers who present in labour unbooked, will undergo counselling and testing only if they present in early labour and will then receive single dose nevirapine and AZT in labour. Those who present in later stages of labour will have their testing deferred till after delivery. [21]

Infants born to mothers who are HIV positive, will receive single dose nevirapine within 72 hours of delivery and AZT for 7 days or for 28 days if the mother received less than 4 weeks of HAART or AZT during pregnancy or single dose nevirapine only. The dosages of nevirapine has been changed to a standard dose of 0.6ml (6mg) for all babies >2kg, and a dose of 0.2ml/kg (2mg/kg) for babies <2kg. AZT is also given at a dose of 1.2ml (12mg) twice daily, standard for all babies >2kg.[21]

WHO recommended in 2006 that exclusive breastfeeding should be recommended for HIV infected women for the first six months of life unless replacement feeding meets five criteria (AFASS criteria) – acceptable, feasible, affordable, sustainable and safe – before

that time. When these conditions are met, avoidance of all breastfeeding by HIV infected women is recommended.[3] The other conditions to be met before replacement feeding is chosen include safe clean water, good sanitation, nutritional counselling and growth monitoring. [3] If the mother chooses to formula feed, formula is provided free from the health facility for a period of six months in South Africa.

The new South African protocol recommends that mothers undergo extensive individual, unbiased counselling on the risks of transmission of HIV through breastfeeding and the risks with formula feeding and at the same time health workers establish whether the mother fulfils the AFASS criteria.[21]

HIV negative women and women of unknown HIV status are advised to exclusively breastfeed for the first six months and then continue to breastfeed for at least two years. For HIV positive women, if the mother fulfils the AFASS criteria, then she should exclusively formula feed. Milk is provided free for the first six months. If the mother does not fulfil the AFASS criteria then it is recommended that the mother exclusively breastfeeds the infant for the first six months. Infants must be tested 6 weeks after cessation of breastfeeding. If AFASS criteria are then fulfilled then the mother should change to formula feeding if the infant tests HIV negative, but if the AFASS criteria are not fulfilled, then the mother should continue to exclusively breastfeed until in a negative infant the AFASS criteria are fulfilled. If an infant tests positive for HIV in the interim then it is advised that the infant be continuously breastfed up to two years even if the mother fulfils the AFASS criteria at some point.[21]

Postnatally, mothers on HAART are followed up until 6 weeks post delivery where they are transferred to a Comprehensive Care Management and Treatment for HIV and AIDS (CCMT) facility. On-going support to the mother and child for feeding, child health, maternal health and social security must also be provided. Infants must be tested at six weeks of age, where the HIV-PCR test is performed to confirm the infant's status, and at the same time cotrimoxazole (Bactrim) chemoprophylaxis must be commenced. Those infants who test positive must be referred for initiation of HAART.[21]

Follow up of the mother encompasses nutritional support, counselling and supportive care, and treatment of other diseases. Follow up of infant addresses adequate nutrition, monitoring growth, monitoring for signs of symptomatic infection, and prevention of opportunistic infections.[21]

1.7 Effectiveness of the South African PMTCT of HIV Programme

Effectiveness of any PMTCT of HIV programme is determined by the reduction in the number of infants infected with HIV. Stringer et al recommend that effectiveness be measured by HIV- free survival in resource poor settings.[22]

To achieve the optimal outcome in a PMTCT program there needs to be:

1. An initial high uptake of VCT coupled with a high rate of HIV testing.
2. Easily identification of mothers who are HIV positive by health care workers (midwives, neonatal, postnatal staff) to facilitate antiretroviral/nevirapine administration.

3. Adequate counselling on feeding practices so the decision made is based on the informed choice of the mother. Mothers need to be supported in their decision by health workers.

4. A system of adequate postnatal follow up of HIV positive mothers and their infants and on-going support for mother and infant.

5. A structured programme at each facility, with adequate record keeping, adequate supply of test kits, medication and milk supplements.

Therefore in the "PMTCT cascade" problems can occur at different levels.

1.7.1 Voluntary Counselling and Testing (VCT)

1.7.1.1 Uptake of Testing and Follow Up

VCT serves as an entry point for PMTCT. A high uptake of VCT should therefore increase the number of PMTCT participants. Unpublished data from South African National Department of Health's (DoH) Roll-Out Programme 2006, reported fairly low (48%) acceptance rate of an HIV test at first antenatal visit.[23] The Health Systems Trust reported a much improved figure of 75% in 2006/7.[24] Though improved, this was still much lower than the 95% VCT uptake rate reported in Malawi.[23,25] This difference may be attributed to the method of counselling and testing. In Malawi an opt-out method was used rather than the opt-in method used in South Africa.[25,23] Recent studies done in Botswana where HIV testing had been changed from voluntary to routine or opt-out have increased rates of testing from 47% to 78%.[26] In Zimbabwe, in 2006, Perez noted that 79% of women who were not tested for HIV initially reported that they would have undergone testing if the opt out method had been implemented.[27]

Doherty, et al. in the initial report on the national pilot programme noted that at that time Kwa-Zulu Natal was the only province using the opt-out method to test mother for HIV. Their rates of testing were almost double that of the national average.[28] Jayaraman, et al. in Canada in 2003 also showed an increase in the rate of HIV testing by 28% in the month after the opt-out method was adopted.[29]

Other factors to consider for low rates of testing at an antenatal visit include quality of counselling received, and the shortage of counsellors at some centres resulting in long waiting periods for the mothers.

Karamagi, et al. in Uganda in 2003, found that of the 453 women interviewed, only ten percent tested for HIV in pregnancy. The barriers to antenatal HIV testing were unavailability of voluntary counselling and testing services (44%), lack of HIV counselling (42%) and perceived lack of benefits for HIV infected women and their infants.[30]
In Kenya, Moth, et al. in 2003 looked at the utilization of PMTCT services at a provincial hospital in Kenya. They found that 52% of clients received PMTCT information at the health facility without prior knowledge about intervention. Eighty percent of clients did not present for follow up counselling, and 95% of women did not disclose their status to their spouses. They also found that inadequate counselling services led to significant drop out of the programme, with a 32% drop out at the HIV result stage, a 54% drop out at enrolment and an 81% drop out at delivery. Reasons for drop out included fear of a positive test result, chronic illness, stigma, discrimination, unsupportive spouse and inability to pay for the service.[31]

Peltzer, et al. in 2007 found that in a resource poor setting in the Eastern Cape major barriers to provision of PMTCT included access to health care centre, stigma and support, PMTCT knowledge, HIV testing and delivery preference. Reasons for lack of disclosure included fear of stigma, discrimination and violence.[32]

Bajunirwe, et al. in Uganda in 2005 showed that the strongest predictor of willingness to test for HIV was the women's perception that her husband would approve of her testing for HIV. They were six times more likely to test than those who thought their husbands would not approve (OR= 5.6, 95% CI 2.8-11.2). Other predictors of willingness to test for HIV were post-primary education (OR = 3.1, 95% CI 1.2- 7.7) and knowledge about rapid HIV tests (OR = 1.8, 95% CI 1.01- 3.4).[33]

Data from the Health Systems Trust (HST) in 2005/6 indicated that almost 100% of pregnant South African women attend an antenatal clinic. The figure may be an overestimate as the denominator used might be an underestimate.[34] However, the uptake of HIV testing was only 45% in 2005/6 and 75% in 2006/7.[35,24]

Since 2001, trials to assess the effectiveness of PMTCT programmes were conducted at some centres across the country. Sherman, et al. at Coronation Hospital in Johannesburg reported HIV transmission rates of 8.9% in 2002 and Coetzee, et al. at Khayelitsha in Cape Town reported transmission rates of HIV of 8.8% in 2003.[36,37] Nevertheless, problems regarding the functionality of the programme have been described, which included significant loss to follow up of mothers and infants due to poor record keeping.[36,37]

Bwirire, et al. in Malawi in 2004 looked at reasons for loss of mothers to follow up in their PMTCT programme, they found that the main reasons for loss of follow up included, mothers not being prepared for an HIV test and its implications, fear of stigma, discrimination and household conflict, lack of support from husbands, the social and cultural taboos that are associated with artificial feeding, long waiting times at the antenatal clinic and inability to afford the transport costs related to the long distances to the hospital.[38]

1.7.1.2 Nevirapine Administration

While the national antenatal attendance rate is approaching 100%, and the uptake of VCT being disappointingly lower (75%), nevirapine coverage was only 51.7% in 2005/6 and only 61% in 2006/7.[35,24]

The low figures reported are thought to be the result of difficulty in data collection as nevirapine administration can take place either antenatally and in the labour ward, thus collection from two places proving difficult as well as these figures cannot exclude double counting of mothers in both places. Other reasons given include mothers choosing not to disclose their status in labour and even taking the dose without reporting to the labour ward staff. While identifying an HIV positive mother is imperative to providing both mother and baby with nevirapine, the audit on the pilot programme reported that the unique identifiers that were developed to identify mother who were HIV positive were removed from antenatal cards by patients for fear of stigma.[28] None of the national program audits discussed the problems with, nor the incorrect use of the coding system, nor the effect that this might have on identifying mothers who are HIV positive.

A study conducted by Nkonki et al in 2005 in the Western Cape at three sites with different socioeconomic profiles showed that of the 58 women interviewed a quarter (15/58) reported missing their nevirapine dose. For eleven of these fifteen women women the reason for not receiving nevirapine was as a result of health system failures including not being tested for HIV (5/15) due to lack of counsellors, test kits and consent forms; two(2/15) had not been given their test results; and four(4/15) mothers were given incorrect information on how to take the Nevirapine or had not received the nevirapine.[39] Three common reasons for mothers' not taking the dose were related to personal situations including losing the tablet, forgetting the tablet and not collecting the tablet because of denial of HIV status.

Stringer, et al. in Lusaka, Zambia estimated city wide effectiveness of their PMTCT programme using anonymous cord blood surveillance for HIV antibodies and detectable nevirapine drug levels. They found that there were three areas of programme effectiveness that were not addressed by most studies, including that women who were HIV negative were more likely to refuse the test, laboratory errors caused a proportion of mothers who should have received prophylaxis to receive it and one third of women who were given nevirapine tablet for self administration, did not actually swallow the tablet. Thus only 30% of HIV infected women and HIV exposed infants were receiving minimum prophylaxis.[22]

In a more recent study in Lusaka, Zambia, Albrecht, et al. reviewed factors that determined adherence to nevirapine in mothers and babies. They found that mothers who delivered at home, had no high school education or delivered low birth weight babies were less likely to receive nevirapine. Babies born at tertiary centres, with low Apgar scores or who died in

the neonatal period were also less likely to receive nevirapine mainly because of other interventions that were prioritised.[40] Colvin, et al. in their study at three different socioeconomic sites in South Africa reported that the higher socioeconomic status of the mother and the better the counselling received, the higher the chance of the mother receiving nevirapine (OR1.17, p=0.03; and OR=1.55, p=0.008, respectively).[41]

According to the District Health Barometer the national nevirapine coverage for babies in 2005/6 was reported in excess of 70% with some districts reporting 100% coverage.[35] This compared favourably to the previous 2006 DoH survey, where just over a third (37%) of mother-infant pairs received nevirapine.[23] These high rates however might also be an overestimate as they account for the number of babies given nevirapine born to those mothers who are identified as being HIV positive rather than of all HIV positive women. In 2006/7 however the rates had dropped to about 47%, the lower rates thought to be as a result of better record keeping.[24]

Poor rates of nevirapine administration to babies are most likely the result of an inability to identify all HIV positive mothers. Low rates of nevirapine administration to babies was also reported in Malawi, with a rate of 45%, mainly due to the high loss to follow up of mothers by delivery (68%).[25]

Spinsley, et al. of the Elizabeth Glasier Paediatric Aids Foundation evaluated their MTCT programme in resource limited settings across different countries. Of the 2.6 million women who accessed their services, 92.9% of women were counselled and 82.8% accepted testing. Of those who had tested positive, 75% received antiretroviral prophylaxis and 45.6% of infants born to HIV positive mothers received prophylaxis.[42]

Onah, et al. at a tertiary hospital in Nigeria, showed high rates of VCT uptake (almost 100%), as well as high rates of nevirapine administration to mother and infant, where 24% (10/41) had taken their nevirapine issued to them during antenatal period and the rest (31/41) received their antiretrovirals on arrival at the labour ward. All infants received nevirapine at birth. Their high rates of VCT acceptance could be related to mothers receiving both group counselling and individual counselling (96%), and changing to the opt-out system of testing. Apart from reporting that the 10 mothers who received their antiretrovirals antenatally resided outside of town, there is no mention as to why all of the other mothers received their dose in the labour ward (perhaps this is part of the policy).[43]

Geddes, et al. at McCords Hospital in Durban over the period 2004 to 2005, also showed high rates of VCT (100% received counselling and 91% underwent testing). There was an 11% (36/338) loss of HIV positive mothers to follow up, 97% of women received prophylaxis, Ninety eight percent of the live babies born to HIV positive mothers who delivered at the hospital received nevirapine and 75% received AZT as well. [44] They demonstrated very high rates along all steps in the "cascade", in this state-aided hospital, however they also mention that there could possibly be a selection bias in their patients - they were socio-economically better off than those attending public facilities.

High rates of nevirapine administration to babies have also been described in the Health Systems Trust review of the National Pilot Programme in 2002 reported that though 55% of HIV positive mothers received nevirapine, 99% of babies born to HIV positive mothers received nevirapine.[28] Once again this is a percentage of the mothers identified as HIV positive. Sherman et al also reported figures of 95% at Coronation Women and Children's Hospital in 2004.[36]

1.7.1.3 Feeding

Since the initial recommendation that exclusive breastfeeding for four to six months reduces the transmission of HIV from mother to infant, there have been some controversy regarding the potential risk of transmission versus the benefit of breastfeeding and therefore what the optimal feed for the infant would be. There has also been concern that there has been a reduction in the number of mothers breastfeeding both in the HIV positive and HIV negative mothers and that support for breastfeeding has been reduced.

Most studies report high rates of feeding counselling received by mothers antenatally and postnatally. The 2002 audit of pilot sites reported that mothers who received counselling were given the option of choosing to formula feed exclusively for six months or breastfeed exclusively for 4-6 months with early weaning. At discharge 58% of mothers chose to formula feed and 42% chose to breastfeed. There were a higher percentage of mothers who intended to formula feed in the rural areas compared to the urban areas.[28]

Geddes, et al. were also concerned that more than 90% of mothers chose to formula feed in their sample.[44] Onah, et al. in their study in Nigeria showed that 98% of HIV positive mothers received counselling on feeding, with 100% choosing to exclusively formula feed.[43] Coetzee et al. in Khayelitsha, on interviewing mothers after 6 weeks found that only 4 mothers (<1%) were mixed feeding and the rest reported exclusive formula feeding.[37]

Buskens, et al. in 2007 looked at the infant feeding practices of mothers in low resource settings in three African countries. They found that despite PMTCT programmes, most infants underwent very early mixed feeding. Reasons for mixed feeding included the belief

that it was necessary to give infants water, disempowered mothers felt that their breast milk was insufficient and relatives and breadwinners played an authoritarian role on the modes of feeding, especially in situations where the mother did not disclose her status. [45] Sadoh, et al. in Nigeria evaluated the feeding practices of HIV positive mothers in the first six months of their babies' lives. They had two cohorts of patients, a PMTCT cohort and a non-PMTCT cohort. None of the babies in the PMTCT cohort were breastfed and all in the non PMTCT cohort were breastfed. Mixed feeding was high in the non-PMTCT cohort (70.45%). Formula was inadequately prepared in 77.4% of the non-PMTCT cohort and in 18.6% of the PMTCT cohort.[46]

Chopra, et al. in 2008, assessed the feeding components of PMTCT programmes in four African countries. They found that infant feeding options were mentioned in only 48% of observed counselling sessions and in only 5.5% was it discussed in depth. Overall there was poor knowledge of the risk of transmission from mother to child through breastfeeding by health care workers. Perceptions by the community on the dangers of HIV transmission through breastfeeding as well as the stigma associated with not breastfeeding made it difficult for mothers to sustain any optimal feeding plan.[47]

1.7.1.4 Post-natal Follow-up

Further care of the mother and the infant after delivery involves identification and management of an HIV infected infant as well as managing the mother's infection. This requires integration of health care services responsible for PMTCT and paediatric and adult care.

Most studies done on the operational effectiveness of PMTCT programmes have experienced loss of follow up of infants post delivery. Sherman, et al. at Coronation Hospital experienced a 70% loss to follow up by 4 months of age.[36] Doherty, et al. reported a 50% loss to follow up of infants.[28]

Ginsburg, et al. in 2007 assessed PMTCT programmes across 18 countries supported by the Elizabeth Glasier Pediatric AIDS Foundation. During their 18 month study period 10% of mothers tested were found to be HIV positive. Across 14 countries 86% of clinics reported having fewer than 10 patients on HAART at the time with improvement where 11 clinics reported having 25 or more patients on HAART. At most of these clinics the site where mothers obtained their HAART was separate to the PMTCT site. Approximately nine percent of infants were followed up and received cotrimoxazole prophylaxis.[48]

1.8 A Gauteng PMTCT Perspective

Gauteng has 27 hospitals offering paediatric care and over 320 provincial and local authority clinics providing antenatal and/or obstetric services, including PMTCT. Approximately 150 000 babies are born in Gauteng each year with two-thirds of births occurring in hospital and one-third at the clinics. Each of the midwife obstetric units (MOU) provides a PMTCT programme based on the national PMTCT guidelines.

The Health Systems Trust review of the National Pilot Programme in 2002 reported a 79% uptake of VCT in Gauteng, 58% administration of nevirapine to mothers and a 98% administration of nevirapine to infant. Poor rates of nevirapine administration to mothers was attributed to poor understanding of the regimen by mothers and non-disclosure of their HIV result by mothers to staff in the labour ward.[49]

According to the District Health Barometer the 2006/7 antenatal HIV prevalence in the metro regions in Gauteng ranged from 27% to 32%, the nevirapine coverage to the mother ranged from about 67% to about 90% (in the City of Johannesburg) and the nevirapine coverage for babies ranged from 24% to 42%.[24]

1.9 Conclusion

For an effective PMTCT programme there needs to be a high rate of acceptance of HIV testing, knowledge of women's status and understanding the need for PMTCT of HIV. Easy identification of mothers who are HIV positive leads to more mothers and babies receiving nevirapine. Adequate counselling and support assists mothers in making their feeding choice, and may improve follow up of infant and mother. Imperative is the early identification of HIV infected infants which is dependant on documentation of the mothers result, as well as ongoing management of the mother's and infants infection, preventing opportunistic infections and providing nutritional support. For optimal care of mother and infant there needs to be better intergration of mother and child services.

To reduce the spread of HIV and the number of deaths from HIV in the paediatric population, PMTCT services need to be strengthened. Improvement in antiretroviral regimens is but one step. We need to overcome the stigma associated with HIV, provide support and encourage mothers to know their status and understand the need for PMTCT. Changing our opt-in policy to an opt-out policy and improving our counselling services and involving partners and spouses will improve our VCT uptake rates. Optimal feeding plan for each mother must be decided individually through unbiased counselling, giving mothers all the facts they need and then providing support for their choice.

PMTCT programmes are an entry point to family care and comprehensive HIV/AIDS treatment and care. Opportunities to prevent infection cannot be missed.

CHAPTER TWO

INTRODUCTION

In Gauteng, antenatal and obstetric services are offered at both hospitals and clinics including Midwife Obstetric Units (MOUs). The Midwife Obstetric Units (MOUs) belong to the provincial authority. MOUs and hospitals provide obstetric care 24 hours a day whereas most ordinary clinics provide antenatal services during working hours, five days a week. A survey by the Health Systems Trust in 2003, looking at primary health care services in Gauteng, indicated that 22% of facilities providing antenatal care, had services available for five days a week.[50]The number of deliveries at MOUs includes anything between three and ten babies a day.

At the time of the study most facilities ran their PMTCT programmes according to the 2001 National PMTCT Protocol. This included:

- counselling, followed by voluntary testing and post test counselling,
- recording of the result on mother's antenatal card according to the coding system,
- issuing nevirapine to HIV positive mothers,
- recognising babies exposed to HIV and issuing nevirapine prophylaxis to them,
- counselling and supporting mothers' feeding choice,
- issuing of milk if the mother chose to formula feed, and
- follow up of mother and infant with infant testing by means of the HIV DNA-PCR test at six weeks of age.

In addition to this, some units were able to offer HIV positive mothers CD4 testing which enabled mothers eligible for HAART to be referred to an HIV clinic. While some facilities had their PMTCT programmes well in place and running for a long time, one facility had started their MOU service a month before this study.

When the functionality of the pilot sites was assessed by Doherty et al, many problems were found at each facility. These problems included inadequate space for the addition of dedicated rooms for counselling and testing, inadequate staff including lay counsellors to counsel and test patients as well as poor ongoing post test counselling and support. Supply of test kits often ran out. Regarding nevirapine administration to mother and baby, noted problems included inadequate information given to the mothers on when to take nevirapine, difficulty identifying HIV positive mothers and therefore their babies and recording of the administered dose. Difficulty recognising mothers was a result of failure to disclose their status and coding systems not being implemented properly. Further, rates of testing of infants at follow up were very poor, owing to discrepancy as to when to test the infant, poor referral systems, ineffective use of tracking or coding system and reluctance of mothers to disclose their status. Initially, infants were tested via the ELISA method at 12 months of age, which has subsequently changed to the DNA-PCR method.[49]

The Millennium Development Goals stress the importance of reducing the under- five mortality rates by reducing the number of cases of and the spread of HIV. Worldwide, new studies are taking place regularly to determine the most effective regimen of ARV's to prevent MTCT.

With the move towards providing mothers with dual or triple therapy, the aim of my study was to assess whether the PMTCT programme in place at the time of the study was

running effectively and whether the health system could support a more complex drug regimen.

2.1 AIM:

The aim of the study was to evaluate aspects of the PMTCT programmes at selected hospitals and clinics in Gauteng

2.2 OBJECTIVES:

Primary objective:

To determine the proportion of eligible mother-infant pairs receiving nevirapine.

Secondary objectives:

1. To establish VCT uptake and HIV positivity rates in women delivering at the selected sites.

2. To determine the feeding practices of mothers during the first 48 hours of their baby's life.

CHAPTER THREE

METHODS

3.1 Study Design

A cross sectional survey involving post partum women was undertaken across four Gauteng hospitals and eight midwife obstetric units (MOUs) between April and June 2006. The study was primarily descriptive, but had analytic components.

3.2 Study Population

The study population consisted of all mothers who delivered babies in Gauteng. Approximately 150 000 deliveries occur in Gauteng each year. At the time of the study Gauteng had 27 hospitals and 320 local and provincial clinics that offered antenatal care and/or obstetric services.

3.3 Study Sample

The study sample was obtained from mothers who had delivered babies in the preceding 48 hours from twelve PMTCT sites in Gauteng province. The sites were chosen on a convenience basis.

A sample of between 150 to 200 mother infant pairs from both the hospital and midwife obstetric unit (MOU) sites, with approximately 45 HIV positive mothers was anticipated in the study period. The study period was based on the period available for the researcher to visit the sites and complete data collection.

Exclusion criteria were: (a) mothers who had delivered stillbirths and (b) mothers who were too ill to be interviewed (e.g. being ventilated or heavily sedated).

The size of the sample was based on an estimate of the number of deliveries at each site over the time period allocated for data collection (2 months). It was estimated that the study sample would include 0.25% of the (annual) study population, i.e. mothers delivering in Gauteng in one year.

3.4 Study Sites

Four hospitals and eight MOUs were selected, with one hospital and two MOUs each from four of the five regions in Gauteng. Site selection was based predominantly on convenience but also influenced by availability and approval to conduct research at each facility. Only four regions in Gauteng were selected due to time and logistical constraints (the fifth region was the smallest and the furthest north). One hospital, and two MOUs, was selected in each region in an attempt to improve generalisability. This distribution would also allow enrolment of approximately equal number of study participants overall at hospitals and MOUs.

The sites selected included:

Johannesburg Central : Chris Hani Baragwanath Hospital

Chiawelo Clinic

Zola Clinic

Lillian Ngoyi Clinic was selected initially instead of Zola Clinic. However when permission was requested from Gauteng Health Regional Office to conduct research at MOUs, permission was denied for Lillian Ngoyi Clinic but granted for Zola Clinic (which was recommended by the Gauteng Office). The reason for refusal of permission was not stated in their response.

I anticipated that this change in the study site would influence the sample size calculation as Lillian Ngoyi Clinic has on average more deliveries per month than Zola Clinic.

West Rand: Leratong Hospital

Mohlakeng MOU

Bekkersdaal MOU

The West Rand has only three facilities providing midwife/obstetric services. The two selected for study were chosen on a convenience basis.

East Rand: Tembisa Hospital

Phola Park MOU

Esangweni MOU

The East Rand has four facilities providing midwife/obstetric services and the two chosen were convenient in terms of travelling distance.

Tshwane: Pretoria West Hospital

Laudium CHC

Shoshanguve CHC

Laudium CHC had opened its MOU section one month prior to our study. I anticipated that implications of this on the study could be both positive and negative. Staff would be very

familiar with the PMTCT programme as they would have recently received in-service training (positive), but 'teething problems' were to be expected (negative).

Three of the four hospitals selected were secondary (regional) hospitals. Chris Hani Baragwanath Hospital served both secondary and tertiary roles in its region. Both Chris Hani Baragwanath and Pretoria West hospitals had an independent research unit monitoring their PMTCT programmes. Pretoria West Hospital was one of the facilities included in the initial national PMTCT pilot study.

3.5. Study Procedures

A study tool consisting of four parts was designed by the researcher (Appendices A-D). The first part involved an interview with each mother (conducted by the researcher). The second part involved a review of each mother's and baby's records. The third part included a cross-check of nevirapine administration in the mother/baby's file with hospital and clinic records. The fourth part consisted of an interview with the manager in charge of the PMTCT programme at each centre.

Part 1- Interview with mother

The postnatal wards were visited and all mothers who had delivered babies in the preceding 48 hours were approached for consent to participate in the study. Mothers were selected on a convenience basis, but an attempt was made to interview all eligible women present in the ward/unit on the study day. Mothers received both an information sheet as well as a verbal description of the purpose of the study prior to enrolment.

A series of questions (Appendix A) were asked to each mother in order to determine:

1. If the mother had received antenatal VCT and if she was aware of her results
2. If the mother was provided with nevirapine at an antenatal visit
3. Details regarding the administration of nevirapine in labour
4. Whether the mother was aware of her baby receiving nevirapine
5. Whether the mother had received any feeding counselling before or after delivery
6. If the mother was aware of what her baby had been fed and what her intended feeding choice was.

Part 2- Record Review

The second part (Appendix B) included an assessment of:

A) The mother's hospital/clinic file and antenatal card to:

1. Determine whether the mother received VCT, and whether she opted to have an HIV test (data from antenatal card).
2. Assess the recording of a HIV test (in antenatal card).
3. Determine whether the mother was given nevirapine antenatally (to ingest when in labour).
4. Determine whether the mother's receipt of nevirapine in labour was documented in her file.
5. Assess if any record existed of the baby's initial feeding method and whether any record was made of postnatal counselling regarding feeding present.

B) The mother's or baby's file, to determine if a dose of nevirapine administered to the baby had been recorded as well as to determine the feed offered to the infant immediately after, and following, birth.

Part 3- Cross checking

The third part (Appendix C) included a cross-check of the hospital or clinic's nevirapine registers with the mother's or baby's file to validate the administration of nevirapine.

Part 4- Interview with unit manager

The fourth part (Appendix D) included an interview with the manager or person in charge of the PMTCT programme at each site to understand the availability of protocols and how they were being followed at each site.

3.6 Study Measurements

1. The rate of VCT uptake was calculated based on the interview with mother as well as from the mothers' records (both accepted as "proof").
2. The confirmed HIV positivity rate was calculated based on a record of a positive result or disclosure from the mother.
3. The rate of nevirapine administration to a mother was obtained from mother's report of nevirapine receipt either antenatally or in labour, as well as from a record of administration in either the antenatal card, the labour file or the nevirapine register.
4. The rate of nevirapine administration to baby was obtained from a record of administration in the baby's records and/or from the unit's nevirapine register.
5. Initial feed to baby data was obtained from the baby's records and/or from the mother's history.

All interviews were conducted by a single researcher (FI) to avoid interviewer variability.

For open questions, pre-empted answers were coded by the researcher to maintain uniformity. For example, with questions where more than one answer would be possible, the possible responses that the researcher anticipated would be offered by participants were pre-emptively allocated numbers, e.g. 1-6 and the mother's response would be captured as a number, unless the response was unique and unexpected, in which case it would be captured verbatim.

3.7 Pilot Study

A pilot study was conducted at two sites, Alexandra Health Centre (a MOU) and Johannesburg General Hospital, to test the study tool and to incorporate any changes before the main study, and to provide the researcher with a guide to the time needed to complete the four components of the study. A total of thirty mothers were interviewed. With the initial questionnaire the flow of questions regarding testing for HIV till taking nevirapine in labour was poor. Further questioning on when nevirapine was issued to the mother and when nevirapine was taken were necessary to assess where in the process the problem arose. The initial questionnaire was not specific in this matter. The changes made to the study tool after the pilot study included adding on questions on disclosure of mother's HIV status, rephrasing the questions on nevirapine receipt antenatally and in labour to make the question clearer to the participant, and including more detailed questions or post delivery counselling, feeding practices and follow up of the infant.

3.8 Statistical Analysis

Data was initially entered onto an Excel spreadsheet (Microsoft, Seattle, USA), then analysed using Statistica statistical software version 6.0 (Statsoft, USA) and Epi Info version 3.3.2 (CDC, Atlanta, USA). Most data was descriptive but comparison of data was done using standard statistical tests such as the chi-square test (or Fisher exact test, if <5 observations per cell) for categorical data. A p-value <0.05 was considered significant.

3.9 Ethical Considerations

Ethical approval was obtained from the University of Witwatersrand's Committee for Research on Human Subjects (Medical) (Clearance No. M060328). (Appendix E). Permission was obtained from Gauteng Regional Office, Pretoria Regional Office, Ekhuruleni district, West Rand Regional Office and the Chief Executive Officers of all the hospitals.

Memos were sent to each facility providing them with the dates of the scheduled visits and the unit managers were phoned a few days in advance to obtain their permission and remind them of the visit.

Information sheets were provided to all mothers and facility managers (Appendices F-G), and written consent was obtained from all those who chose to participate (Appendix H).

3.10 Financial Considerations

A Faculty Research Committee Individual Grant was obtained from the University of Witwatersrand Health Sciences Research Committee. This covered stationery, printing, telephone and transport expenses.

CHAPTER FOUR

RESULTS

Two hundred and twelve mothers were approached for consent to participate in the study. Thirty (14%) mothers refused to participate. One hundred and eighty two mother-infant pairs (86% of those approached) were included in the study.

Of the 182 participants, 113 (62%) delivered at hospitals and 69 (38%) delivered at clinics, a hospital: clinic ratio of 1.6, which approximated the general ratio of hospital to clinic deliveries in Gauteng at the time. However, the hospital: clinic ratio differed in the various regions. Table 1 shows the distribution of participants who delivered infants at the different regions.

Table 1: Distribution of study participants between hospitals and clinics, per district, in Gauteng

	No. of patients	*Hospital*	*Clinic*	*Hospital:Clinic ratio*
Johannesburg Central	59	40	19	2.1
East Rand	33	17	16	1.1
West Rand	49	36	13	2.8
Tshwane	41	20	21	0.95
Total	182	113	69	1.6

4.1 Demographics.

The demographic details of mothers included in the study are displayed in Table 2. Their mean age was 26.2 years, most (73%) were unmarried, two-thirds (65%) had attended secondary school, few (20%) were employed and the vast majority (93%) lived in Gauteng.

Table 2: Demographic details of mothers included in study (n=182)

Detail	*Result*
Age	Mean: 26.2 ±5.9 years Range: 17-47 years
Marital status:	**N (%)**
Unmarried	133 (73)
Married traditionally	16 (9)
Married legally	32 (17)
Separated/Divorced	1 (1)
Education:	**N (%)**
Secondary school education	120 (66)
Primary school education	13 (7)
Tertiary level of education	33 (18)
No formal education	16 (9)
Employment:	**N (%)**
Mothers employed	36 (20)
Partners employed	152 (84)
Place of Residence:	**N (%)**
In Gauteng	169 (93)
Other Province	13 (7)

4.2 Booking During Pregnancy

One hundred and seventy two (95%) of study participants had "booked" during their pregnancy. Ninety-two percent of mothers (168/182) attended an antenatal clinic during their pregnancy, 26% (48/182) attended a hospital, 30% (55/182) attended a general practitioner and 4% (7/182) visited a traditional healer. Many had attended more than one point of service delivery during the pregnancy.

4.3 Voluntary Counselling and Testing (VCT)

An HIV test was offered to almost all (95%) of mothers attending an antenatal clinic; 45% of women attending a hospital, 37% attending a general practitioner and none of the

mothers attending a traditional healer. The mothers' partner was present at the time of VCT session in 12% of instances. Eighty five percent (155/182) of mothers had their HIV test performed antenatally, 2% (3/182) tested postnatally and 13% (24/182) failed to receive VCT or chose not to test throughout their pregnancy or post delivery.

4.4 HIV Seroprevalence

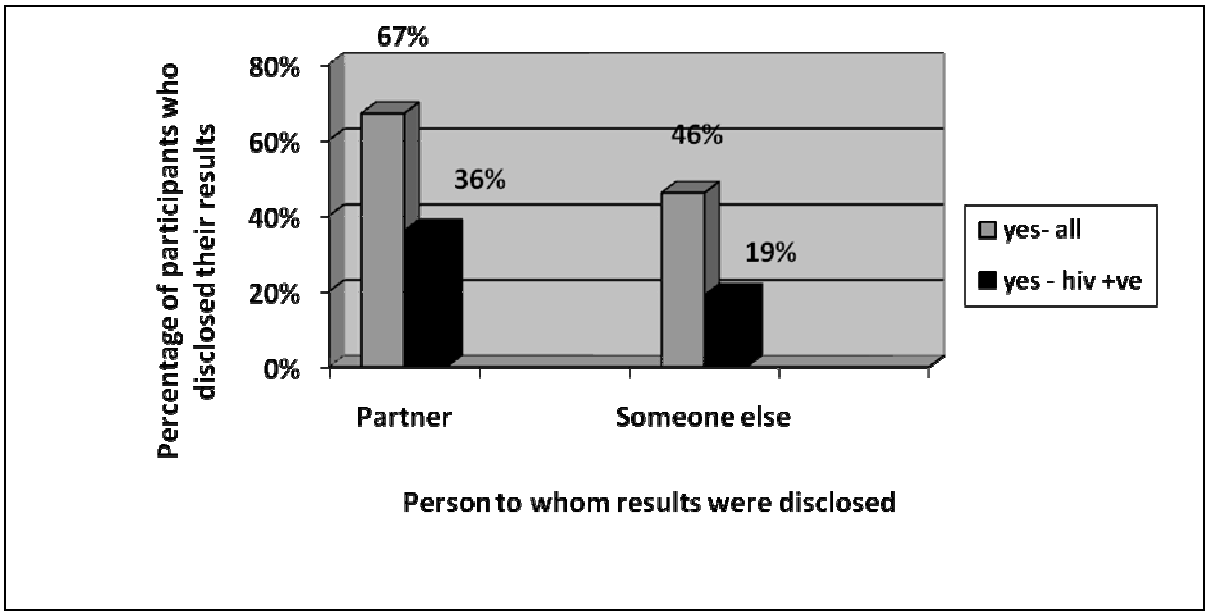
The confirmed HIV positivity rate in this study sample was 23% (42/182). The HIV positivity rate was much lower in the West Rand region (12%), compared to the other regions which ranged from 22% to 27%. This was statistically significant (6/49[12%] vs. 36/133[27%], p=0.04).

Of those participants who had tested for HIV, most received their result from a counsellor (46%) followed by a nurse (37%), while few received their result from the clinic doctor (3%) or a general practitioner (6%). More than three-quarter (77%) of participants received their results immediately after counselling and testing. About the same number (73%) of those who tested antenatally reported that they received post test counselling, leaving more than a quarter of the sample who claimed that they did not receive this service.

4.5 Disclosure

Of all mothers who tested for HIV, 67% (106/158) had disclosed their results to their partners and 46% (72/158) disclosed to another person. However of the mothers who tested positive for HIV, only 36% (15/42) disclosed their results to their partner and 19% (8/42) disclosed to someone else (Figure 1). This difference between HIV status and disclosure was statistically significant, with participants who tested positive much less likely to disclose their status to their partner (15/42 [36%] vs. 91/116 [78%]; p<0.001).

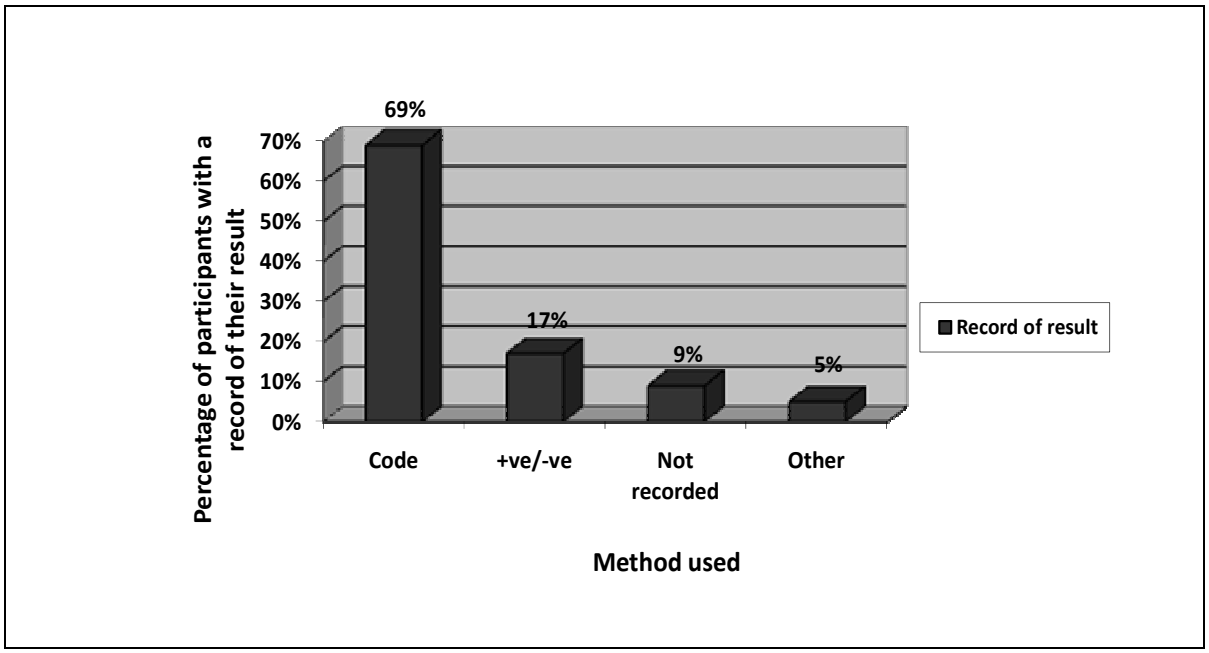
Figure 1: Number of women who disclosed their HIV result to their partner and/or someone else



4.6 Recording of Test Result

Mothers' HIV results were recorded in the antenatal card and/or in the admission files. This was either in the form of the national PMTCT coding system, or marked as positive or negative in admission files, or the specific unit had its own coding system, e.g. "VCT positive" or "VCT negative". In some cases more than one method was present, coded in the antenatal card and marked as positive or negative in the admission file. Figure 2 shows the distribution of the various methods used. The "other" category included facility specific coding methods, e.g. VCT +ve, IC +ve.

Figure 2: Methods used to record the mother's HIV result in her records



4.7 Nevirapine

During the interview with the mothers, they were asked about their knowledge of nevirapine. Their response was recorded and immediately coded by the researcher as either acceptable or not acceptable. An acceptable explanation was considered to be one where anything to do with the prevention of transmission of HIV from mother to infant was mentioned. Sixty four percent (116/182) of all mothers interviewed claimed that they knew what nevirapine was; however only 53% (97/182) of all mothers had a reasonable explanation for its use. All the HIV positive mothers could adequately explain nevirapine's function. There was a significant difference found between HIV positive and HIV negative mothers with regard to adequate knowledge on nevirapine and its uses, with HIV positive mothers having a better knowledge overall (42/42 [100%] vs. 55/140 [39%], p=0.0002).

4.7.1 Nevirapine Administration to the Mother

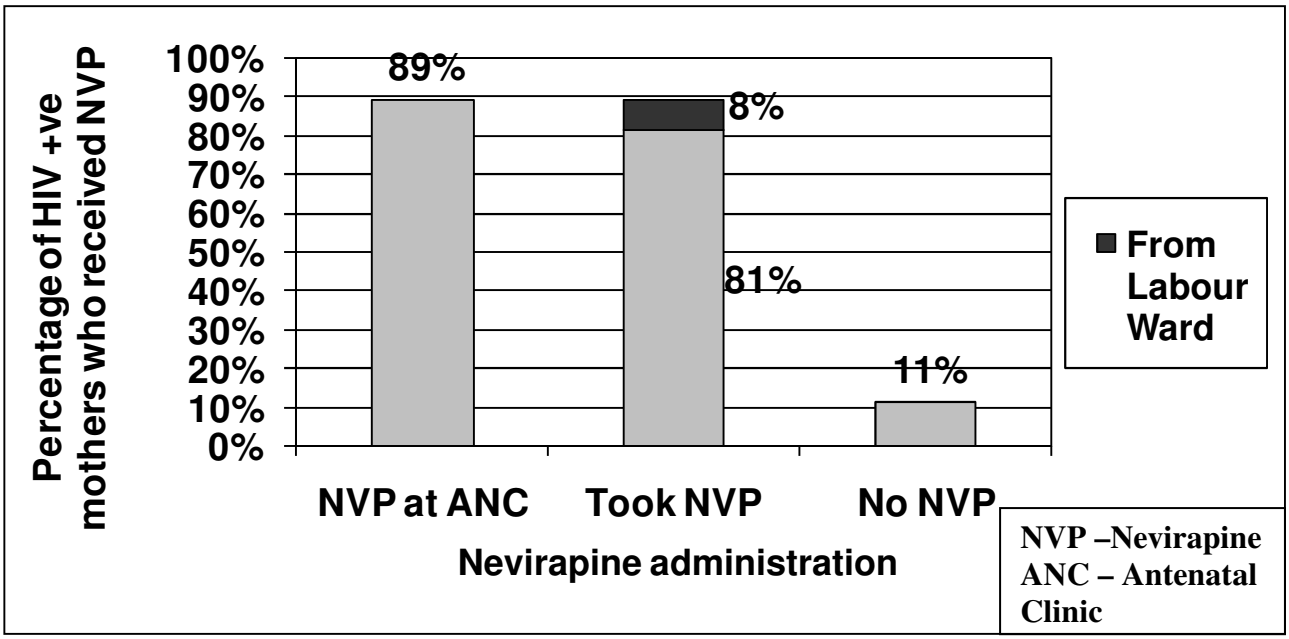
Forty two mothers were identified as HIV positive. Of the 42 mothers, 37 (89%) received nevirapine antenatally. Reasons for the five mothers not receiving nevirapine antenatally included:

- failure of health care workers to recognise the mother as being HIV positive (n=2),
- failure of mother to disclose her status to health care workers (n=2),
- mother was tested early in pregnancy and asked to come back at a later stage (28 weeks of pregnancy) to collect her nevirapine (n=1).

Almost all of the mothers who received their tablet antenatally were adequately counselled about when to take the tablet in the researcher's opinion. Once again this counselling was offered by either a nurse or a counsellor.

Of the 37 HIV positive mothers who received nevirapine antenatally, 30 (81%) took the tablet (given to them at antenatal clinic) when they went into labour, and 3 (8%) took their tablet in the labour ward (tablet given to them when they presented in labour). Four mothers (11%) did not take the medication (figure 3).

Figure 3: Administration of nevirapine to HIV +ve mothers during pregnancy and labour



The seven mothers who did not take the dose given to them at antenatal clinic reported losing the tablet or forgetting the tablet at home, or that they were visiting at a place away from home and had not had the medication with them when they went into labour.

Some of the reasons for the four mothers who received nevirapine antenatally but presented in labour without having taken the tablet, and had not been given another dose of nevirapine included:

- a mother presented fully dilated and about to deliver it was too late for her to receive the dose,
- inconsistencies with what to do if a mother presented in true labour after having presented in false labour more than 48 hours prior and had taken her initial dose,
- hesitancy to give a mother who disclosed her status on presentation in labour ward a dose of nevirapine without proof of a positive status,

- some mothers who had booked at another province and presented in labour at a facility in Gauteng without a record of an HIV result, were not retested; reasons for failure to retest mother is unknown.

Overall, 33/42 (79%) of mothers who were HIV positive took nevirapine during labour (on history or by record review). However, for only 29/33 participants (88%), was receipt of nevirapine by the mother recorded in her file or in the nevirapine register.

Nevirapine and place of delivery: There was no difference demonstrated between nevirapine administration to a mother at a clinic as opposed to a hospital during labour, (16/21[76%] vs. 17/21[81%], p=0.71).

Nevirapine and employment: No statistical difference was demonstrated between being employed or unemployed and taking nevirapine in labour, (8/10 [80%] vs. 25/32 [78%], p= 0.90).

Nevirapine and any level of education: No statistical difference was demonstrated between receiving any formal education versus no formal education and taking nevirapine in labour, (27/34 [79%] vs. 6/8 [75%], p=0.79).

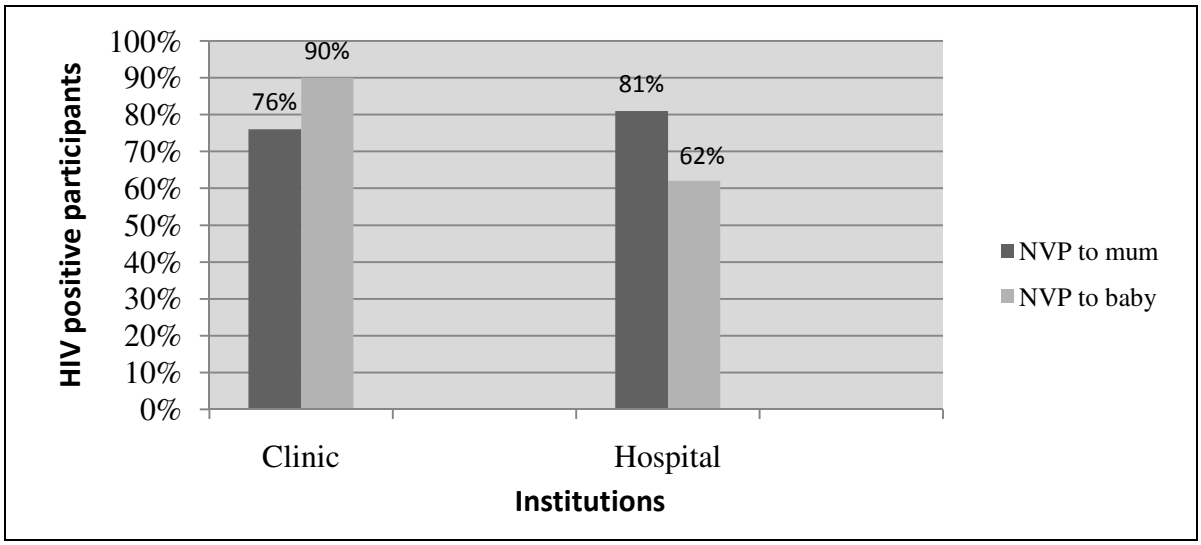
Nevirapine and living with partner: No statistical difference was demonstrated between living with a partner, or not living with a partner, and taking nevirapine in labour, (21/25 [84%] vs.12/17 [71%], p=0.3).

4.7.2 Nevirapine Administration to Infant

Figure 4 shows the difference in nevirapine administration to mother and infant at clinics and hospitals. The rate of nevirapine administration to infants was based on a record of nevirapine administration in the infant's file or in the nevirapine register.

Figure 4: Nevirapine administration to mothers and infants at the clinics and hospitals

Differences Between Clinics and Hospitals:



There were a total of 63 clinic deliveries. Twenty one (33%) of the mothers at clinics were HIV positive (half of all HIV positive mothers in the full study sample). Of those who were positive, overall, 16/21 (76%) women received nevirapine in labour. Nineteen (90%) of the infants born to HIV positive mothers received nevirapine. There were a total of 113 hospital deliveries, of whom 21 (19%) were HIV positive. Overall 17/21(81%) of the HIV positive mothers received nevirapine in labour and 13 (62%) of the infants born to HIV positive mothers received nevirapine. Infants were more likely to receive nevirapine at a clinic than at a hospital, (19/21 [90%] vs.13/21 [62%], p=0.03).

Overall:

- 79% (33/42) of HIV positive mothers received nevirapine,
- 76% (32/42) of infants born to HIV positive mothers received nevirapine, and in
- 57% of cases was receipt of nevirapine by both mother and infant recorded.

Only 26/33 mothers (78%) who had received nevirapine were aware or informed after delivery that their infant had received nevirapine. Table 3 summarises the above data:

Table 3: Summary of receipt of nevirapine by mother and infant at the clinics and hospitals

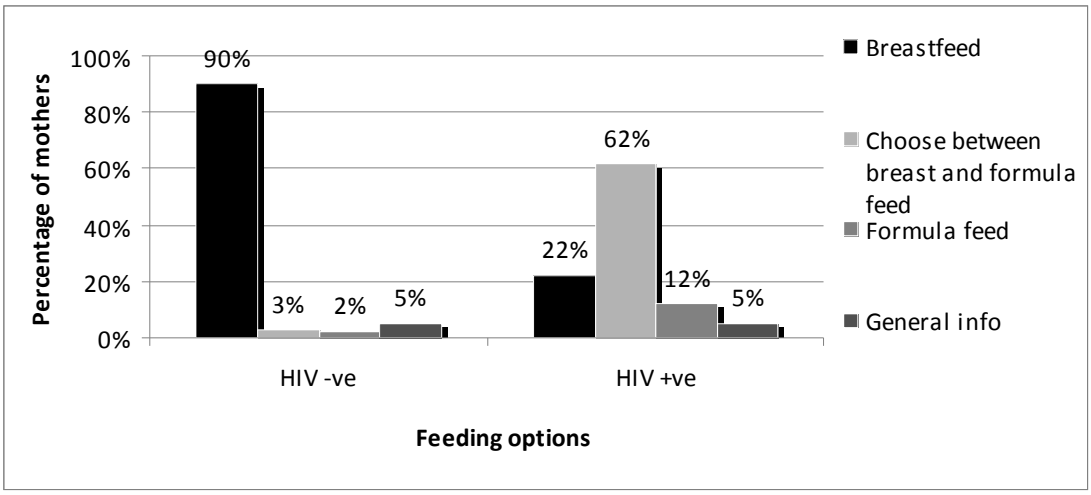
	Total N (%)	***Clinic N(%)***	***Hospital N(%)***	***p-value***
HIV positive	N=42	N=21	N=21	
Mothers who received nevirapine	33 (79)	16 (76)	17 (81)	p=0.7
Infants who received nevirapine	32 (76)	19 (90)	13 (62)	p=0.03

4.8 Feeding

4.8.1 Counselling

All mothers were asked if they had received any infant feeding counselling during pregnancy and about their future infant feeding choices. Seventy eight percent (142/182) reported to have received some form of counselling.

Figure 5: Feeding options recommended to HIV positive and negative mothers by staff during antenatal counselling



Of all the HIV negative mothers counselled, 90% reported that they were advised to breastfeed only or exclusively breastfeed for four to six months, 3% were advised to choose between formula and breastfeeding and 2% were advised to formula feed only. Five percent could only recall general information about feeding, namely how to position infant when feeding, how frequently to feed infant, how to sterilise bottles, etc. (figure 5).

Amongst the HIV positive mothers, 22% (9/42) were advised to breastfeed only or exclusively breastfeed for 4-6 months, 62% (26/42) were advised to choose between formula and breastfeeding, 12% (5/42) were advised to formula feed only and 5 % (2/42) recalled receiving general information only (figure 5).

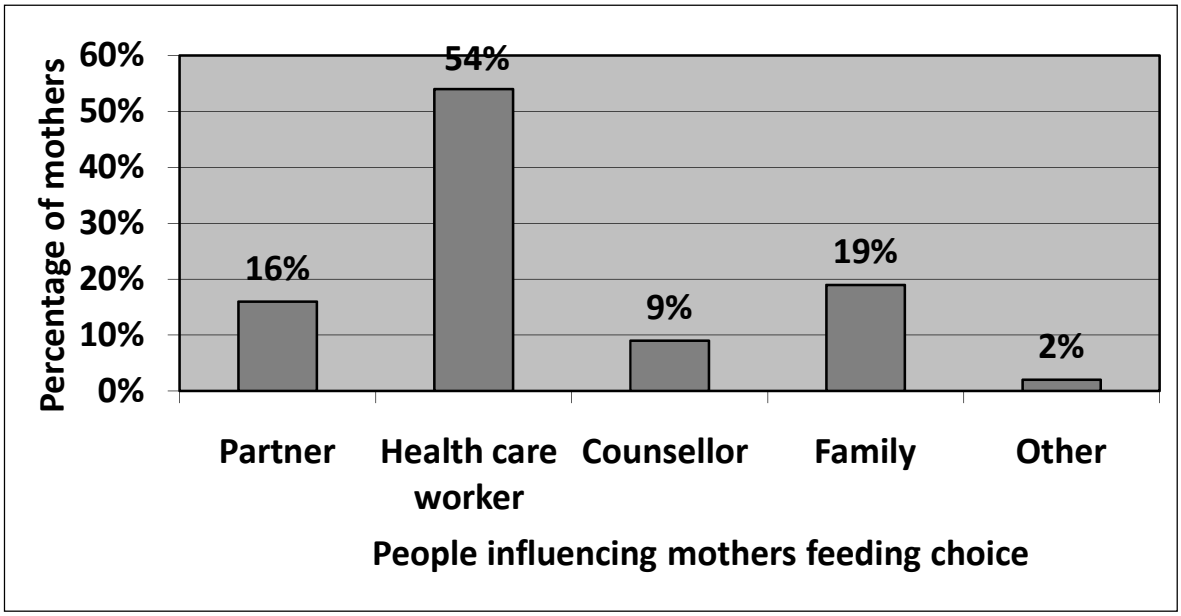
Significantly more HIV negative mothers were advised to breastfeed only or exclusively for 4 to 6 months than HIV positive mothers (90/100 [90%] vs.9/42 [22 %]; $p<0.001$), and more HIV positive mothers were advised to choose between formula feeds and breastfeed than HIV negative mothers (26/42 [62%] vs. 3/100 [3%], $p<0.001$).

After delivery, 141/182 mothers (77%) reported that they received some information or counselling on feeding which included just being asked what their feeding choice was, being told to start breastfeeding, the advantages of breastfeeding, advice on maintaining breastfeeding, or advice on sterilisation of bottles. Thirty six (86%) of mothers who were HIV positive reported to have received some form of advice or counselling post delivery including just being asked what their feeding choice was. The majority (93%) of all mothers who were counselled post delivery claimed to have received the counselling from the nurse or midwife who attended the delivery.

4.8.2 Mothers' Choice

During the interview, mothers' were asked what their feeding choice was before delivery and what they had decided to feed the infant after delivery, as well as whether anyone had influenced their decision making. Of the HIV positive mothers, 10/42 (24%) decided to breastfeed and 29/42 (69%) decided to formula feed during pregnancy and a further 3/42 (7%) made their choice to formula feed post delivery. One hundred and twenty four HIV negative mothers (89%) decided to breastfeed and 6/140 (4%) decided to formula feed during pregnancy. A further 8/140 (6%) and 2/140 (1%) made their decision to breast and formula feed respectively, post delivery. Fifty seven mothers (31%) reported that their decision was influenced by another person. Health care workers influenced feeding choice in more than half of these participants (figure 6).

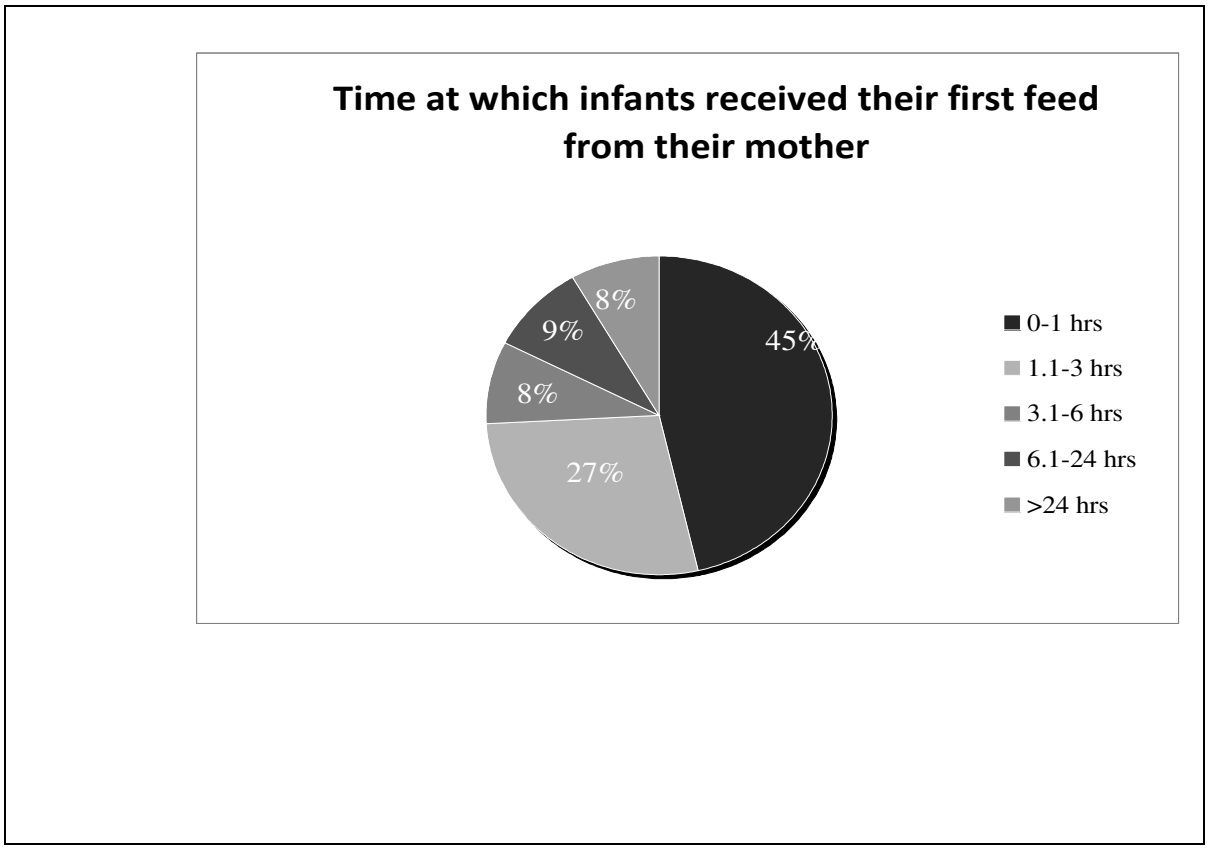
Figure 6: Percentage of mothers whose feeding choice was influenced by another person



4.8.3 Timing of First Feed

Less than one-half of mothers (82/182 [45%]) fed their infants within the first hour. The majority of infants were fed by their mothers within the first three hours (131/182 [72%]) (figure 7).

Figure 7: Time at which infants received their first feed from their mother



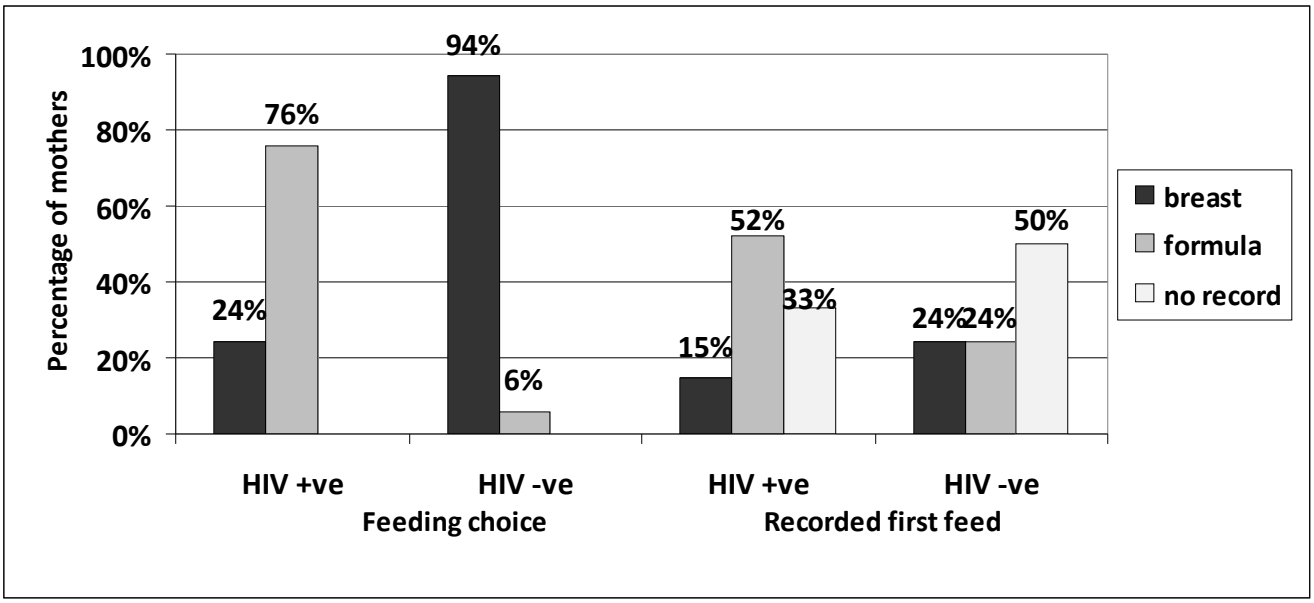
4.9 Recording of Feeds and Feeding Choice

Of the 140 HIV negative mothers, 132 (94%) chose to breastfeed, and 8 (6%) chose to formula feed. A record of the mother's feeding choice was present in only 43/140 (31%) of the bedletters, of whom 40/43 (93%) selected breastfeeding and 3/43 (7%) formula feeding. The infant's first feed was recorded in 67/140 (48%) of the participants records, with almost equal number of infants recorded as being breast (33/67 [49%]) and formula fed (34/67 [51%]). (figure 8).

Of the 42 mothers who were HIV positive, 10 mothers (24%) chose to breastfeed and 32 mothers (76%) selected formula feeds. For only twenty five (60%) mothers, was a record

of her feeding choice present in the bedletter, of which 18/25 (72%) selected formula feeding and 7/25 (28%) breastfeeding. In the infants' records there were 28/42 records (67%) of the infants first feed, with 22/28 (79%) being formula fed and 6/28 (21%) breastfed (figure 8).

Figure 8: Mothers' feeding choice (verbal) and infant's first feed (from infant's record) in HIV positive and HIV negative mothers



From the formula fed infants' records it was noted that 27/56 infants (48%) were initially fed formula by the healthcare worker. Of those born to HIV positive mothers, 12/22 infants (55%) who were formula fed were fed initially by the healthcare worker.

4.10 Post Delivery Counselling

Fifty five percent of HIV positive mothers received further counselling after delivery from the midwife or nurse in the unit, including counselling on feeding, risk of transmission of opportunistic infections.

Seventeen percent (7/42) of HIV exposed infants' Road to Health Cards had an indication that the infant was HIV exposed and in only 3/42 (7%) of cases did their Road to Health cards indicate that they were to receive formula milk.

4.11 Interview with the Unit Manager

The unit managers of each facility were interviewed and asked a series of questions regarding the operation of the PMTCT programme. All of the managers reported that their unit followed the national PMTCT protocol and all units provided VCT. One facility did not provide partner counselling. Counselling at all the units was provided by either a counsellor or nurse or midwife; no doctors were involved in VCT. The counselling included discussion about the risk of transmission of HIV to the infant, preventing new infections in pregnancy, the use of nevirapine, feeding choices, cotrimoxazole prophylaxis, and follow up care of mother and infant. Eight units (67%) claimed that they discussed all of the above aspects; four units (33%) did not include a discussion on feeding choices during antenatal counselling.

4.11.1 Testing

All 12 units used the rapid HIV testing method and testing was done by nurses or counsellors. Results were recorded according to the protocol coding system in all units (However, this claim was contradicted during the record review as some units had their

own system of coding/ recording results). All managers reported that results were given to the mothers immediately after testing, and three units also disclosed results to the mother at a later stage if there was some discrepancy with the results, or if the mother preferred to be given her results later. Ten units were able to perform CD4 counts once a mother tested positive for HIV, the other two units did not have the facilities or the support services to carry out CD4 testing on the mothers.

4.11.2 Antiretroviral Therapy

All 12 units dispensed nevirapine antenatally. Nevirapine was dispensed by the health care workers at all units, and in two units counsellors dispensed the medication as well. The dispensation of the drug to the pregnant women was recorded in the nevirapine register. Only one unit provided mothers with an information leaflet describing the drug and indicating when to take the drug. Seven of the twelve facilities were able to provide HAART to those mothers who qualified for it. After CD4 testing was done, those who qualified for HAART were referred to that facility's ARV clinic. Mothers with a CD4 count less than 200 or clinical category stage C qualified for HAART, based on national guidelines at the time.

4.11.3 Labour

When mothers presented in labour their HIV results were obtained from the antenatal card. In the event that there was no result recorded on the card, the result was obtained from the results register if the mother booked at the same clinic (8 units), provided that mothers presented during the day shift, i.e. before 4pm. If not, mothers would be asked if they were aware of their result (6 units) or mothers were counselled and tested after delivery (3 units). None of the units tested unbooked mothers without results, when they were in

labour. Once the mother was established to be HIV positive the health care worker attending the delivery was responsible for ensuring that the mother received or took her dose of nevirapine at all units, and this was recorded in the mothers' file according to protocol in eight of the twelve units. The subsequent dose given to the infant was recorded according to protocol in the mother's or infant's file in 9 units, in the maternity or birth register in 4 units, in the nevirapine register in 8 units and on the Road to Health Card in 2 units.

4.11.4 Feeding

Managers claimed that feeding choices were discussed antenatally and postnatally at all units. It was policy that the mother decided on the initial feeding choice and was the first to feed the infant except if the mother was extremely ill. The midwife was the first to feed the infant in two units and the mother was the first to feed the infant in the other ten units. Free formula milk was available at all facilities as part of the PMTCT programme. Only one unit manager was not in favour of mothers receiving free formula milk as her personal preference was for mothers' to exclusively breastfed their infants.

4.11.5 Post Delivery Counselling

Managers at all units claimed that their service provided post delivery counselling which included feeding choices, cotrimoxazole prophylaxis, testing infants for HIV, and general follow up of infants initially at three days, and then at six weeks for immunisation and for HIV testing. Most unit managers (11/12) were aware of the earliest age of testing (6 weeks), however fewer (8/12) were aware of what test was usually carried out. The three unit managers who were unsure of the test carried out, believed that infants were also tested by either the HIV Elisa of HIV Rapid test. The declared reason for their uncertainty

was that they themselves were not involved with testing of the infants at six weeks, and that at that moment not all facilities were able to provide the service.

CHAPTER FIVE

DISCUSSION

5.1 Summary of the Key Findings

All twelve units had a PMTCT programme in place that closely followed the national PMTCT protocol according to their managers. There were high overall rates of VCT uptake and high acceptance of testing; however disclosure rates of a positive result to a partner or someone else were poor. The rate of nevirapine administration to the mother antenatally (for use at the time of labour) was good but actual administration of the drug to both mother and infant at the time of birth were disappointingly poor. The mother's preferred choice of feed and the initial feed received by the infant were both poorly recorded. Clinic managers provided an inappropriately optimistic perspective of their clinics functioning.

5.2 Findings on Aspects of the PMTCT Programme

5.2.1 Entry into the System

Some 95% of participants attended an antenatal service during their pregnancy. This correlates with national figures of antenatal clinic attendance in 2006 of 100%.[34] However these national figures are an overestimate, with attendance rates across the different provinces ranging from 76% in the Eastern Cape to 120% in Kwa-Zulu Natal. The figure for Gauteng was 115%. In 2004, the Health Systems Trust reported the national antenatal attendance rate as 95.5%.[34]

Mothers obtain antenatal care from different sectors of the health care system during their pregnancy, including from general practitioners (private sector), antenatal clinics and hospitals. With the strong influence of traditional health care on African societies, some might attend traditional healers during their pregnancy. However, there was low (4%) reported usage of the services of a traditional healer during pregnancy by participants, a much lower rate than that described by Banda et al in Zambia, where 21% of women interviewed reported to have visited a traditional healer in that pregnancy.[51] This might possibly be a result of a reporting bias on the part of mothers owing to the possible displeasure they anticipated revealing this fact may have elicited from the researcher.

5.2.2 Voluntary Counselling and Testing (VCT)

Only 85% of mothers in the study accepted testing. Nevertheless, this figure is higher than that reported by the Department of Health's National Roll-Out programme (56%) [28] or that reported by the Health Systems Trust in 2006/2007 (75%).[24] Factors that have been reported to influence the rate of acceptance to test for HIV include, the method of testing, the availability of counsellors and quality of counselling received, fear of stigma, discrimination and chronic illness and unsupportive spouse.[30, 33, 52]

According to the South African PMTCT protocol, HIV counselling and testing is recommended on an opt-in basis as opposed to an opt-out basis.[21] The latter approach has been shown to improve the uptake of testing for HIV, as in Malawi where antenatal HIV testing increased to 95%,[25] and in Botswana where antenatal testing increased to 78%.[26] Walmsley, in her commentary on screening for HIV infection quotes other studies where the proportion of women tested increased from 33-74% to 81-88% with the opt-out method.[53] Jayaraman, et al. in 2003, in a study in Alberta, Canada also showed an increase

in the rate of HIV testing by 28% in the month after the opt-out method was adopted.[29] In the report on the initial evaluation of the national PMTCT pilot programme in 2002, Kwa-Zulu Natal was the only province where testing had been done on an opt-out basis and their rates of testing for HIV was almost double that of the national average.[28] Changing the national protocol for HIV testing from opt-in to opt-out should contribute to much higher rates of testing.

Less than three quarters of participants who had tested antenatally received post test counselling. The reasons or barriers to not receiving counselling and the quality of the counselling received were not examined in this study. Neither can this study offer comment on the availability of counsellors or the quality of counselling.

Bajunirwe, et al. in Uganda in 2005 showed that women whose partners approved of them testing for HIV were six times more likely to undertake testing.[33] In my study, there were only 12% of reported instances where the partner was present at the time of testing, despite all but one facility claiming that they offered partner counselling and testing. Promotion of partner testing is another area that could improve the uptake of antenatal VCT.

Just over a third of women who tested positive for HIV disclosed their results to their partner and 17% disclosed their result to someone else. Disclosing one's result is known to positively impact on the care of the child, possibly by improving support from the spouse and improving care for the family.[54] Fear of stigma, discrimination and lack of support from one's spouse are the usual reasons for not disclosing one's result.[54] However, the poor disclosure rates noted in this study may also indicate that the quality of counselling

might not be adequate to provide the mother with sufficient support and confidence to overcome these barriers.

5.2.3 HIV Positivity Rates

The HIV positivity rate in this sample was 23%. This is much lower than what was expected - the reported 2007 Gauteng seroprevalence rate was 30.3% [5] A likely explanation is that the sample statistic is biased as those mothers who feared disclosure of their result to an unknown person (the researcher) or stigmatisation might have chosen not to participate. Thirty mothers refused to participate; if all of these were considered to be HIV positive, the sample positivity rate would have been 34%. This might also be the reason for much lower HIV positive rates in the West Rand region (12%), compared to the other regions which ranged from 22% to 27%. There were more participants who declined participating in the study from the West Rand. There was an impression that the participants in that region were less open or more hesitant to discuss issues of PMTCT, possibly for fear of stigmatisation.

5.2.4 Recording of HIV Result

Most mothers' HIV results (when recorded) were recorded by means of a code, usually according to the national PMTCT coding system. The coding system uses a # sign followed by a number (usually 1), then the first alphabet of the maternal grandmother's name which is followed by the first alphabet of the mother's name. The coding system is quite complex and requires training for its proper use, and not all staff use the coding system correctly. It was introduced to allow communication between health care workers while at the same time keeping the mother's result confidential. However using any coding system may actually promote the fear of stigmatisation and discrimination rather than

promoting acceptance of one's status and encouraging awareness. It may also contribute to poorer quality of care being delivered, owing to misclassification and misinterpretation.

5.2.5 Nevirapine to the Mother and Infant

On a positive note, the great majority (89%) of mothers who tested HIV positive received nevirapine antenatally, for use during labour. The reasons for the 11% not receiving nevirapine antenatally included failure to recognise the mother as being HIV positive. Ultimately 33 mothers (79%), received nevirapine in labour (30 of whom took the dose given to them antenatally and three received a dose in labour ward). This percentage is similar to Spensley, et al's multi country study figure of 75%,[42] but much lower than that reported by Onah, et al. at a south-eastern Nigerian tertiary care facility (98%).[43] Though the current study's number was much higher than the national figure of 51.7%,[35] it is inadequate for optimal prevention of mother to child transmission of HIV. This level of coverage would still leave 20% of infants born to mothers at risk of contracting HIV with at least 7/100 infants contracting the virus. At a provincial level, this would mean that at least 2000 additional HIV infected infants would be expected per annum. The actual nevirapine coverage figure would be expected to be still lower as the study estimate did not account for those mothers who did not test for HIV but were actually positive.

Nkonki, et al. in their study in the Western Cape looked at reasons for missed opportunities in the PMTCT programme. They found that most missed opportunities were health system related or personal. The personal factors given were loss of the tablet, forgetting the tablet and avoiding collecting the tablet because of denial of their result.[39] The health system factors included incorrect information given to the mothers on how to take the tablet and health staff not supplying the women with the tablet, both as a result of poor

communication and lack of a locus of responsibility.[39] Seven patients in this study also reported losing or forgetting the tablet or not having the tablet with them when going into labour as they were visiting away from home. The four patients in this study who failed to receive nevirapine in labour were the

result of health system related factors including failure by health staff to accept a mother's verbal report of her positive status, and the failure to test mothers who presented without a test result having booked elsewhere or at another province. Patient related factors included receiving a dose 48 hours previously when in false labour and presenting too late in labour to receive a dose. Communication problems did not come across as a reason for the health system related factors.

Two-thirds of HIV-exposed infants received nevirapine. This is higher than the national average (less than 50%)[24] and the rates reported by Spensley, et al. in their multi country study (45.6%),[42] but much lower than that reported by Geddes, et al. at McCords Hospital in Durban (98%)[44] and Onah, et al. in Nigeria (100%)[43]. Health service administration is poorer in the study settings in comparison to the latter two studies quoted. These include activities such as not identifying mothers who were HIV positive and poor record keeping. Since nevirapine administration to the infant was assessed by identification of any record of administration in the infants file, mother's file or the nevirapine register, it is possible that the true rate of administration may be higher than that described here (because of failure by health workers to capture the administration of the drug).

Only 57% of mother-infant pairs had a record of nevirapine administration to both mother and infant. Once again this low statistic may partially be the result of poor record keeping.

Nevertheless, this dismal statistic compares favourably to the DoH report indicating that 37% of mother-infant pairs received nevirapine country-wide.[23]

Albrecht, et al. in 2006 in Lusaka, Zambia, showed that mothers who delivered at home, had no high school education, delivered low birth weight infants or who had infants born in a tertiary centre with low Apgar scores were all less likely to receive nevirapine.[40] While this study did not include any home deliveries, we identified that infants were more likely to receive nevirapine at a clinic than a hospital. Higher rates of nevirapine administration to infants at a clinic setting was probably the result of better attention to identifying HIV positive mothers there (if for no other reason than that they had fewer women to care for) . The poorer rate of nevirapine administration to infants at the hospitals may also be the consequence of poorer record keeping (resulting in a false negative). There was no difference demonstrated between nevirapine administration to mothers in labour at a clinic as opposed to a hospital.

Delvaux, et al. in 2009 at 12 PMTCT sites in Rwanda, showed that mothers who were unmarried, less educated, had two or less antenatal visits and those who were offered HIV testing after the first antenatal care visit were more likely not to adhere to taking nevirapine at the recommended time.[55]Non-adherence was defined as mother and/or infant not ingesting single dose nevirapine at the recommended time or not at all. This study was unable to demonstrate any difference in nevirapine administration related to the mother's level of education, employment status or if they were living with their partner.

5.2.6 Infant Feeding and Counselling

The previous South African PMTCT protocol (2001) recommended that mothers should be counselled and given the choice to exclusively breastfeed for six months or formula feed where feasible from the beginning.[20] Counselling was an ongoing process and feeding choices was to be emphasised at each encounter with a health care professional. Free formula was provided by the PMTCT centre.[20] In 2006, the WHO infant feeding recommendation changed and the new protocol recommended that after extensive unbiased counselling, if HIV positive mothers fulfilled the AFASS criteria they should exclusively formula feed. If the criteria were not met, mothers were encouraged to exclusively breastfeed for the first six months or continue breastfeeding until the AFASS criteria were met.[3]

In 2008, across 29 districts in Botswana, Kenya, Malawi and Uganda, Chopra, et al. found that in their observed PMTCT counselling sessions, for only 48% of the time were feeding options discussed or mentioned. The only recommended feeding option given to the mothers was breastfeeding in 85% of case and formula feeding in 10% of cases. In 60% of consultations, no mention of the benefit of early cessation of breastfeeding and early weaning was made.[47]

Just over three-quarter of all mothers in this study reported to have received counselling on feeding during their pregnancy. We did not assess the quality of the counselling they received. Of the HIV positive mothers, more than a third were directed (rather than counselled based on individual circumstances) to use either breastfeed or use formula. Based on the reported evidence, it is possible that up to 40% of mothers received

inadequate or inappropriate advice. The quality of the counselling provided at health services requires auditing and monitoring.

Onah, et al. at a tertiary facility in Nigeria, reported that 98.9% of their mothers received infant feeding counselling which is a more acceptable figure. However, all their mothers chose breast-milk substitutes for their infants. This suggests a bias in the counselling the mothers were provided, unless the setting was extremely under-resourced.[43]

Most mothers had made their feeding choice during their pregnancy with 76% of all HIV positive mothers choosing to formula feed. Of the HIV negative mothers 94% chose to breastfeed which is reassuring. According to the mothers' report more than half of the mothers feeding choices were influenced by a healthcare worker, indicating the importance of the health care workers opinion to the mother, and thus the need for adequate unbiased counselling to be offered in the ordinary antenatal programme.

Irrespective of the mother's choice, there were significant differences in what the first feed that the infant received was. With the HIV negative mothers a record of the infants first feed was recorded for less than one-half of cases, with equal numbers of infants being breast or formula fed. This is unacceptable and a cause for concern. In most local hospitals it is standard practice to take the infant to the nursery for routine procedures and examination while the mother undergoes the third stage of labour. Infants are often fed formula during this period while awaiting transfer to the mother. Infants who are ill are reviewed by the paediatric team and may be admitted to neonatal unit if necessary. In such cases infants might receive formula from a health worker as the initial feed.

Apart from improving the bonding between mother and infant, early skin to skin contact has a positive effect on continuing breastfeeding at one to four months, maintaining the newborns temperature in the thermo-neutral zone, reducing the infants crying and has effects on stabilizing the infants glucose.[56]

Recording of feeding choices was poor. HIV negative mother's choice of feed was recorded for 31% of the mothers and 48% of the infants' first feeds were recorded. With the HIV positive mothers, the mothers feeding choice was recorded for 60% of the mothers, 67% of infants' first feeds were recorded, with 79% of infants being formula fed.

It is concerning that less than half of the mothers had fed their infants within the first hour of life, and just about three-quarters of infants were fed their first feed within the first three hours of life. This is contrary to one of the ten recommended Baby-Friendly steps, that is to initiate breastfeeding within the first half hour of birth.[57] Based on records, 48% of all formula fed infants and 55% of formula fed infants who were born to HIV positive mothers received their first feed from a health care worker. This is probably as a result of hospital protocol and procedures as mentioned above. This is a clear violation of the Baby-friendly code. Breastfeeding within the first hour has also been shown to reduce the rates of sepsis in newborn infants.[58]

Half of the HIV positive mothers received further counselling after delivery. All of them received information about the risk of transmission and the need for prophylaxis, cotrimoxazole prophylaxis and testing the infant for HIV. However, on the infant's Road to Health Cards in only 17% of cases was there an indication that the infant was exposed to HIV, contrary to the national coding system which demands that a code to indicate that the

infant is exposed should be transcribed on every Road to Health card. In 7% of cases there was a specific milk code transcribed indicating that the infant was eligible for free formula milk. In none of the cases was there any indication for the need for cotrimoxazole prophylaxis charted, as is required according to the national protocol.

Failure to record these probably arises out of health workers fear of the patient being stigmatized but is also as a result of protocol not being carried out correctly. This impacts on the care of the infant where he/she might only be diagnosed once he presents at a facility and requires admission, which impacts on the management he/she receives. The diagnosis might also be overlooked in a well child attending a facility for a well infant (immunization) visit, where infection might not be suspected and therefore the opportunity for opportunistic infection prophylaxis and nutritional support missed.

5.3 Interview with Unit Managers

Although all units claimed to follow the national PMTCT protocol, the interviews with the unit managers highlighted a few concerns. A third of the units for instance did not include any discussion on feeding options in their initial VCT counselling. Only after a mother had tested and was found to be HIV positive were feeding options discussed; thus HIV negative mothers were denied information on the benefits of breastfeeding.

Some units had designed their own methods of recording the mothers HIV results, though they were all familiar with the national PMTCT coding system. This poses a problem where a mother might not deliver at the same facility that she booked at, and thus her HIV

status is not recognized, resulting in a missed opportunity to prevent mother to child transmission of HIV.

Nevirapine was dispensed at all units and no record of shortages of the drug was reported. One unit provided the mothers with pamphlets with information on the purpose of the drug as well as when to take the drug. While this practice should be encouraged to improve adherence to taking nevirapine, this study could not demonstrate that it made a difference. Most mothers reported that they were offered adequate information on when and how to take the drug.

If mothers presented in labour without a HIV result recorded on the antenatal card, most units were able to obtain the mothers' HIV result from clinic registers during working hours if the mother had booked at the same clinic. However, if the mother had booked elsewhere or presented without an HIV result, apart from the mother disclosing her result, the result could only be obtained post delivery. This conforms to the national protocol that recommends that testing only take place post delivery in such instances. This, however, is less than satisfactory as it only allows only for post exposure prophylaxis to be administered to the infant, and misses a vital opportunity to reduce the transmission burden.

All unit managers reported that feeding choices were discussed with mothers both antenatally and postnatally. This was not confirmed in our interview with the mothers as just over three-quarter of mothers reported to have received some information on feeding antenatally and postnatally.

Two unit managers admitted that infants received their first feed from the health care worker due to unit protocols and procedures. However, in this study 44% of recorded infant feeds were from a health care worker, which is more than would be expected if only two units had adopted that policy. The other units reported that health care workers fed infants if mothers were too ill, but this study excluded mothers who were too ill to be interviewed.

Free formula milk was available at all units and there was no report of shortages of supply. All except one unit manager were in favour of HIV-exposed infants receiving formula milk for six months. Health care workers strongly influenced the mother's feeding choice (in 54% of cases).

All twelve unit managers reported routine follow up of infants at 3 days and then at six weeks at which time testing of the infant took place and cotrimoxazole prophylaxis was commenced. The validity of these claims could not be tested in the study.

5.4 Limitations of the Study

The study had a number of limitations as outlined below:

Study design

1. The study sites were chosen by convenience rather than random sampling. Four out of the five regions in Gauteng were chosen based on ease of travel and time constraints. This limits generalisability of the study findings to the whole Gauteng PMTCT population. Nevertheless, it is unlikely that different clinics, hospitals and

regions in the province are likely to display major differences in PMTCT performance from that described in the study, particularly as an attempt was made to include the correct proportion of MOU and hospital deliveries.

2. Owing to time constraints the sample size had to be limited. A larger sample would have improved the confidence limits around the study statistics.

Bias

1. Clinics and hospitals were informed in advance about the visit and the exact dates of the visit. This might have biased the staff to improve on practices such as nevirapine administration, record keeping and initiated a protocol review by the unit manager. However, this is unlikely to have occurred, in the researcher's view.
2. Records or interviews may inaccurately reflect actual practice. The participants may have been inclined to please the interviewer and report personal behaviours and health worker practices that were untrue (positive bias). Alternatively, poor record keeping negatively biases reported coverage, since good practices such as nevirapine administration may have occurred, but were simply not recorded. The researcher tried to compensate for both these biases, by encouraging participants to honestly report behaviours and attempting to review records as thoroughly as possible.
3. Mothers who were actually HIV positive may have chosen not to participate in the study, thus reducing the HIV seroprevalence in this sample of patients, while also biasing conclusions. This situation is considered to have been quite likely.
4. This study could not identify possible HIV positive mothers in the group of patients who had not tested for HIV or refused to reveal their status. This may have

unduly inflated the true nevirapine coverage statistics, i.e. the situation appears better than what it really was.

5.5 Further Research Questions

- Could replacing the coding system, with a more open description of HIV status improve identification of HIV positive mothers?
- Can opt-out VCT succeed in South African settings?
- Can the implementation of testing mothers for HIV in early labour, for those who present without a recorded HIV test result, improve PMTCT of HIV?

CHAPTER SIX

CONCLUSION

This study emphasises that the quality of the PMTCT programme needs revising and the quality of ongoing support and care received needs improvement. Some even argue that a more complex regimen, involving introduction of antiretrovirals earlier in pregnancy and more drugs, improves adherence and reduces the number of missed opportunities.[39]

Emphasis needs to be placed on improving the number of participants entering into the programme by improving the number testing for HIV, recognising both positive mothers and exposed babies, improving the counselling on feeding choices and providing ongoing support and incorporating PMTCT programmes into mother and child health services. Families need to receive ongoing health and social support and measures must be introduced to ensure that they do not fall through the cracks in the present system.

As of February 2008, PMTCT facilities around the country began implementing the new national PMTCT programme, with improvements on many aspects of the previous programme, the most remarkable being the introduction of dual antiretroviral therapy for both the mother and baby. While improving the antiretroviral regimen will reduce the transmission of HIV from mother to child, there are still many problems along the different steps in the PMTCT cascade that need to be improved on, as described in this study.

Recommendations

1. Each region (district) and sub-district, including its associated hospitals and clinics, should set explicit PMTCT targets, for areas such as VCT coverage, nevirapine administration to mother, nevirapine administration to infant, feeding options for the mother and follow up care of infant and mother with infant testing at six weeks of age. The achievement of these targets must be monitored by the sub-districts, districts and province. Well functioning health centres should be rewarded, while underachieving centres should be supported, and if necessary reprimanded. The underlying principle is that there has to be accountability.

2. There has to be clear responsibility for the implementation of PMTCT programme within the different service levels. Thus, at the provincial level the role of the HIV, AIDS and Sexually Transmitted Diseases (HAAST) and Maternal and Child Health (MCH) directorates in managing the programme, including how they co-operate, needs to synchronised. Similarly, integration of the antenatal and child health services needs to be developed and supported at district level.

3. In addition to the ordinary monitoring and evaluation activities, the health care manager in charge of the PMTCT programme at each facility needs to conduct regular unplanned audits on the different components of the PMTCT programme, using a standard guideline or drawing up a checklist based on the present national programme recommendations. Audits on the quality of counselling, testing, post-test counselling, drug dispensing, feeding choices, post delivery counselling and ongoing follow up should be done at irregular, but frequent, intervals to prevent

expectation of the audit by staff. An external (provincial) auditor should be allocated to audit each district.

4. Regular in-house, in-service training and updates needs to take place at all facilities to update staff on changes to the programme and to reinforce present polices to ensure effective running of the programme.

5. Those involved in antenatal counselling of mothers should undergo regular training to improve their skill. Counsellors should be provided with a support service for themselves.

6. The Department of Health needs to adopt and implement the opt-out method of testing as part of the national protocol, to increase the number of mothers testing for HIV.

7. Partner counselling rates need to be improved. Although eleven of the twelve facilities provided partner counselling and testing, only 12% of partners were tested in this sample. Apart from the counselling received at an antenatal visit, partners need to become more aware of the need for PMTCT of HIV. NGOs promoting HIV testing and treatment can assist by including questions about partners: “Is your partner pregnant? Have both of you tested for HIV? What about your baby?” as part of their health communication strategy.

8. Identifying mothers who are HIV positive must be standardised and simplified. The coding system presently used can be incorrectly used and results misinterpreted if

one is not trained to use the table. A suggestion is to include on the antenatal card a section on PMTCT, as follows (Table 4):

Table 4: Suggested method of recording mother's HIV result and relevant PMTCT data on the mother's antenatal card

PMTCT: (Circle the relevant blocks)

HIV Result	+	_
CD4 Count	Date:	Date
Eligible for HAART	Yes	No
Dual Therapy	Yes	No
	Date started:	
Nevirapine only	Yes	No
Feeding Counselling received	Yes	No
Feeding Choice		
AFASS criteria met?	Yes	No

9. Mothers who present in labour without evidence of a HIV result, must have a rapid test performed immediately and offered nevirapine if appropriate, provided the mother is in the first stage of labour. The opt-out system will assist here as well, as the test done would be part of "routine blood taking". Mother's declaration of their positive status, even in the absence of documented evidence of this, should be an indication for providing antiretroviral prophylaxis during labour.

10. The labour ward admissions file, which is a standardised file used by clinics and hospitals for mothers admitted in labour, needs to also include a specific section (perhaps on the inner aspect of the front cover of the file) indicating the mothers status, her antiretroviral regimen antenatally, the antiretrovirals used in labour and antiretrovirals administered to the baby and choice of feeding. A suggested format is presented below (Table 5):

Table 5: Suggested method to document PMTCT data in labour admissions file

PMTCT: (Circle the relevant blocks)

HIV Result	+	–
CD4 Count	Yes	No
HAART	Yes	No
Dual Therapy	Yes	No
	Date started:	
Nevirapine only	Yes	No
AZT in labour	Yes	No
Nevirapine in labour	Yes	No
Nevirapine to baby	Yes	No
AZT to baby	Yes	No
Feeding Counselling received (post delivery)	Yes	No
Feeding Choice		
AFASS criteria met?	Yes	No

11. All those involved in post delivery counselling must undergo regular training to practice unbiased counselling on feeding as well as counselling mothers on follow up care. Unless a mother fulfils the AFASS criteria, they should be encouraged to breastfeed.

12. Facilities, mostly hospitals, where mothers and babies are separated soon after birth, need to be pressurised by health authorities into changing this policy. Except where a mother is too ill or has received a general anaesthetic, all babies must be fed by their mother in the first hour of life. Adoption of the ten baby-friendly steps will go a long way to achieving this.

13. Documentation of the mothers feeding choice and the babies first feed must be compulsory for both the mother's and the baby's health service record to ensure that mixed feeding practices do not commence at health centres.

14. Identifying HIV exposed infants must also be simplified. The easiest method would be to document this on the Road to Health Card (RTHC) which is the present recommendation, however this is seldom done and mothers are also not counselled on when their babies need to be tested nor on the need for cotrimoxazole prophylaxis. The Road to Health Card needs to be modified as well to include a section on PMTCT, either by including it on the present card system or changing it to the booklet form used in other countries such as Botswana. The following is a suggested table to include on the RTHC (Table 6):

Table 6: Suggested table to include on the Road to Health Card to indicate PMTCT information

PMTCT: (Circle the relevant blocks)

Is infant exposed?	Yes	No
Received nevirapine	Yes	No
Received AZT	Yes	No
	How long? _____days	
Feeding	Breast	Formula
PCR testing	Date:_____	Where? _____
Bactrim prophylaxis	When to start? _____	

15. PMTCT services needs to be integrated into existing paediatric and maternal health care services. It would be best for the mother to attend one facility for herself and her child as this would improve follow up and would cost the mother less to attend on one day than on different days. An ideal situation would be one where the follow up service occurs at the same place as antenatal clinic, however this is not the situation at most facilities, as these facilities have their own HIV units for paediatrics and adults. An adequate referral system post delivery must be in place at every unit where mothers would be given the same follow up dates for both herself and her baby, to ensure that they both achieve and retain optimal health.

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APPENDIX A

PART ONE: INTERVIEW WITH MOTHER:

Note highlighted questions refer only to participants who are HIV positive.

Date:___/__/2006

Study no: _____

Hospital/Clinic:_____

Demographics

I would like to start by asking you some questions about yourself

1.	How old are you?	
2.	What is your marital status?	1=unmarried 2=married, traditional 3=married, legal 4=widow 5=divorced 6=separated 9=other
3.	How many children do you have?	
4.	Have any of your children passed away? If yes, how many?	1=No 2=Yes
5.	What is your highest level of education? If school, write actual grade:_____	1=None 2=primary school 3=secondary school 4=tertiary education
6.	Are you working?	1=No 2=Yes
7.	Is your partner working?	1=No 2=Yes
8.	Where do you live? (Town/township name: _____)	1=In Gauteng 2=Outside Gauteng
9.	Do you live with your partner?	1=All the time 2=Most of time (>50%) 3= Some of the time (20-50%) 4= No

Antenatal visits

I now want to ask you about the care you received while you were pregnant

a) Did you visit any of the following?
If yes to any, then ask the following:
b) At what stage of your pregnancy (weeks)?
c) Were you offered counselling (advice) about HIV at any of the visits?
d) Were you offered an HIV test?
e) Did you choose to have the test?

		A		B	C		D		E	
20.	General practitioner (GP)	1=no	2=yes		1=no	2=yes	1=no	2=yes	1=no	2=yes
21.	Traditional healer	1=no	2=yes		1=no	2=yes	1=no	2=yes	1=no	2=yes
22.	Antenatal Clinic	1=no	2=yes		1=no	2=yes	1=no	2=yes	1=no	2=yes
23.	Hospital	1=no	2=yes		1=no	2=yes	1=no	2=yes	1=no	2=yes

If answer yes to any of c, d or e above continue. If no, go to Q30

24.	When you received VCT was your partner with you at the time	1=no 2=yes
25.	Are you aware your HIV result? (please do not tell me the result) If no, why not? **(proceed to Q30)**	1=no 2=yes
26.	Who gave you your result?	1=nurse 2=clinic doctor 3=GP 4=counsellor 9=other
27.	When did you receive the result?	1=immediately after VCT 2=follow up visit 3=admitted in labour 9=other
28.	Did you receive any further counselling (advice) at the time you got your HIV result (post test counselling)?	1=no 2=yes
29.	Have you told your result to your (i) partner or (ii) anyone else?	 1=no 2=yes 1=no 2=yes

30.	Do you know what Nevirapine is?	1=no 2=yes
30a	If yes, please tell me what it is?	
30b	Researcher code: acceptable	1=no 2=yes
31.	Did you or your baby receive Nevirapine? If no, proceed to Q **36**	1=no 2=yes
32.	Were you given Nevirapine to take home when you were pregnant?	1=no 2=yes
33.	Were you told when to take the Nevirapine?	1=no 2=yes
34.	What were you told?	
35.	Who gave you this information?	1=nurse 2=clinic doctor 3=GP 4=Instruction sheet/ Pamphlet 5=Other mothers

		9=other
36.	Did you receive any counselling about the feeding of your baby while you were pregnant? If no, continue to Q38	1=no 2=yes
37.	What were you told?	

Labour Ward

I now want to ask you some questions about your labour and delivery

38.	**When you went into labour which clinic or hospital did you go to?**	1=this clinic 2=another clinic 3=this hospital 4=another hospital 5=at home 9=other
39.	Where was your baby born?	1=this clinic 2=another clinic 3=this hospital 4=another hospital 5=at home 9=other
40.	How was your baby delivered?	1=normal vaginal delivery 2=assisted delivery 3=caesarean section
41.	Did you take Nevirapine when you were in labour? If no, proceed to Q41 If yes, proceed to Q42	1=no 2=yes
42.	Why not?	1=forgot tablet 2=lost tablet 3=did not receive tablet 9=other
43.	When did you take the Nevirapine?	
44a.	Was the Nevirapine tablet that you took, the one given to you at the antenatal clinic / during your pregnancy?	1=no 2=yes
44b.	Was the Nevirapine tablet that you took, the one given to you when you were in labour?	1=no 2=yes
45.	Did the midwife ask you if you had taken nevirapine in labour?	1=no 2=yes
46.	Did you tell the midwife that you had taken the tablet?	1=no 2=yes
47.	Did you take Nevirapine before at any time before, for example if you had labour pains at an earlier time? If no, proceed to Q48	1=no 2=yes
48.	How many tablets?	

Post delivery

I now want to ask you some questions about what happened after your baby was born

49.	Do you know if your baby received Nevirapine? If no, proceed to Q50	1=no 2=yes
50.	How do you know this for sure?	1= Enquired from staff 2= Was informed by staff 3= Was informed by counsellor 4= Looked through file 9= other
51. 51a	Did you receive any counselling after your baby was born? If no, proceed to Q54 Did you receive any counselling/after the baby was born about: a) how best to feed your baby (your choices) b) bactrim prophylaxis c) testing your baby for HIV	1=no 2=yes 1=no 2=yes 1=no 2=yes 1=no 2=yes
51b	Did you receive any counselling/advice after your baby was born about how best to feed your baby? (your choices)	1=no 2=yes
52.	Who counselled you?	1=midwife/nurse 2=doctor 3=counsellor 9=other
53.	When were you counselled?	1=immediately after delivery 2=within one hour of delivery 3=within three hours of delivery 4=within six hours of delivery 5=within 24hours of delivery 6=24-72 hours after delivery 9=other
54.	Where were you counselled?	1= labour ward 2= postnatal ward 9= other
55.	How long after your baby was born did you first see your baby?	1= immediately 2= less than one hour 3= one to three hours 4= more than three hours 5= more than 24 hours 6= more than two days 9=other
56.	How long after birth did you first feed baby? **If answer to Q55 is 1 or 2 proceed to Q57, if not then**	1= within the first hour 2= within 3 hours 3= within 6 hours 4= more than 6 hours 5= more than 24 hours 9=other
57.	Do you know if baby was fed before	1=no 2=yes

	this? **If no, proceed to Q58**	
58.	What was baby's first feed?	1= breast milk 2= formula milk 3= unsure 9= other
59.	What have you decided to feed your baby?	1= breast milk 2= formula milk 3= unsure 9= other
60	If answer to Q58 is 2, Where will you get milk from?	1=buy milk 2=from clinic 3=from hospital 9=other
61.	When did you decide what you are going to feed your baby?	1= before birth 2= after birth
62.	Did anyone help you to make this decision? **If no, proceed to Q63**	1=no 2=yes
63.	Who?	1=partner 2=health care workers 3=counsellors 4=family members 9=other
64.	Do you know when to take/bring your baby back to clinic for "check up"?	1=no 2=yes
65.	Have you been given a Road to Health Card for your baby?	1=no 2=yes
66.	Should your HIV status be reflected on the baby's Road to Health card? a) If yes, what should it say? b) If no, why not?	1=no 2=yes
67.	Has the clinic or hospital told you anything about free formula milk being available for some babies? If no, go to Q68?	1=no 2=yes
68. 69.	What have they told you? Do you think that some babies should be offered free milk? If yes, which babies should receive free milk?	 1=no 2=yes

Thank you very much for your time and help.
Do you have any questions for me?
Please accept this present from me.

APPENDIX B

PART TWO; SECTION A; MOTHERS RECORDS:

Study Number: _____

Date: _____/___/2006

Hospital/Clinic: _____

101.	Age	
102.	Parity/Gravidity:	P G
103.	Date of delivery:	___/___/2006
104.	Antenatal Card present in file: If no, proceed to Q106	1=no 2=yes
105a	Where booked?	
105b	How many antenatal visits?	
106	Record of VCT: Date pre test counselling received: Date post test counselling received:	 ___/___/2006 ___/___/2006
107.	When was HIV test done:	1=antenatally 2=labour ward admission 3=postnatally 9=other
108.	What is the result of the test?	1= positive 2= negative 3= unknown/ no result
109.	How is result recorded?	1= Code 2= Marked as positive or negative 3= Not recorded 9= Other
110.	Where is result recorded?	1= Antenatal card 2= File 3= Admission form 4= Not recorded 9= Other
111.	Record of Nevirapine/HAART given to mother?	1=no 2=yes
112.	Record of CD4 count present?	1=no 2=yes
113.	Record of post delivery counselling by any health care worker or counsellor to mother? (about anything) If no, proceed to Q115	1=no 2=yes
114.	Was the following discussed? a)Risk of transmission and need for prophylaxis b)Feeding choices c)Bactrim prophylaxis d)Testing baby For HIV	 1=no 2=yes 1=no 2=yes 1=no 2=yes 1=no 2=yes
115.	Record of mother's choice of feeding?	1=no 2=yes
116.	What is mother's choice recorded as?	1=Breast milk 2=Formula milk 9=Other

SECTION B: BABY'S RECORDS

Study No: _____

Date: _____/____/2006

Hospital/Clinic: _____

201.	Hospital No	
202.	Date of Birth	
203.	Gestational Age (_____ weeks)	1=term 2=preterm
204.	Weight (g)	
205.	Apgar score at 1 minute	
206.	Apgar score at 5 minute	
207.	Clinical Condition of Baby	1=well (with mother) 2=ill (admitted to neonatal unit) 3=very ill (high care/NICU)
208.	Reason for admission	1=respiratory distress (non-term) 2=birth asphyxia 3=preterm 4=sepsis 5=surgical 6=congenital abnormality 9=other
209.	Where are baby's details being obtained from?	1=mother's file 2=neonate admission file 3=newborn clinic card 4=Road to Health card 9=other
210.	Record of mother's HIV result present?	1=no 2=yes
211.	Is answer to Q210 no, then	1=awaiting result 2=refused testing 3=not yet tested 4=not recorded
212.	Record of Nevirapine administered to baby If yes, when administered	1=no 2=yes Date:___/___/____ Time:
213.	Record of baby's first feed?	1=no 2=yes
214.	What was baby fed?	1=Breast milk 2=Formula milk 9=Other
215.	Who fed baby initially?	1= Health care worker 2= Mother
216.	Is a Road to Health Card available?	1=no 2=yes
217.	If answer to Q217 yes, AND baby HIV exposed, does Road to Health Card indicate a) Exposure b) nevirapine given c) milk code d) due for bactrim prophylaxis	 1=no 2=yes 1=no 2=yes 1=no 2=yes 1=no 2=yes

APPENDIX C

PART THREE:
REVIEW OF CLINIC OR HOSPITAL NEVIRAPINE REGISTER FOR BABY'S DOSE

Study No: _____

Date: ___/____/2006

Hospital/ Clinic: _____

301.	Where are records of Nevirapine administration to baby found?	1=birth register 2=maternity register 3=nevirapine register
302.	Is baby's hospital number present in register?	1=no 2=yes
303.	Is mothers hospital number present in register?	1=no 2=yes
304.	Is mother's HIV result recorded in register?	1=no 2=yes
305.	How is the mother's result recorded	1=code 2=marked as positive or negative 9=other
306.	Is the dose of Nevirapine administered to baby recorded?	1=no 2=yes
307.	Is the name of the person who gave the dose recorded?	1=no 2=yes

APPENDIX D

PART FOUR:
FUNCTIONING OF HEALTH SERVICE SYSTEMS;
INTERVIEW WITH UNIT MANAGER

Hospital/Clinic: _____

401.	What protocols available for your hospital/clinic's PMTCT programme?	
402.	Who is responsible for ensuring that the programme runs effectively?	
403.	Is VCT offered at your clinic/hospital	1=no 2=yes
404.	Is partner counselling offered at your clinic/hospital?	1=no 2=yes
405.	Is counselling offered: a) antenatally b) in labour c) postnatally	 1=no 2=yes 1=no 2=yes 1=no 2=yes
406.	Who provides the counselling?	1= counsellors 2= nurses/midwives 3= doctors 9= other
407.	Where does counselling take place?	
408.	What does pre-test counselling include:	1=risk of transmission of HIV from mother to baby? 2=preventing new infections during pregnancy? 3=the use of Nevirapine 4=feeding choices 5=bactrim prophylaxis 6=follow up care of mother and baby
409.	Who performs HIV test on mother?	1=nurses/midwives 2=counsellors 3=doctors 9=other
410.	What method of testing is used?	1= HIV rapid test 2= HIV Elisa
411.	When are the results given to the mother?	1= immediately 2= follow up visit
412.	Who gives the results to mothers?	1=nurses/midwives 2=counsellors 3=doctors 9=other
413.	How are the results recorded?	1= Code 2= positive/negative 3= other
414.	Where are the results recorded? a= clinic register b= antenatal card	 1=no 2=yes 1=no 2=yes

	c= admission file	1=no 2=yes
415.	Is Nevirapine issued to mother antenatally?	1=no 2=yes
416.	When?	
417.	Who dispenses the Nevirapine to the mother?	1=health care workers 2=counsellors 9=other
418.	What information is given to the mother?	
419.	Does mother receive some form of information leaflet with the drug?	1=no 2=yes
420.	Where is the dispensing of drug recorded?	
421.	Are CD4 counts done after testing for HIV?	1=no 2=yes
422.	Does your facility provide HAART to pregnant mothers?	1=no 2=yes
423.	Who qualifies for HAART?	
424.	When mothers present in labour, how is the mother's HIV result established?	
425.	What is done if there is no record of mother's result on the antenatal card?	
426.	Who is responsible for ensuring that Nevirapine was given to the mother?	
427.	When is Nevirapine given?	
428.	Where is the dose of Nevirapine recorded?	1=mother's file 2=nevirapine register 9=other
429.	Who is responsible for giving Nevirapine to the babies?	
430.	Where is the dose of Nevirapine given to the baby recorded?	1=mother's/baby's file 2=birth register/maternity register 3=Nevirapine register 4=RHC Card 9=other
431.	Are feeding choices discussed with the mother antenatally? If no, proceed to Q434	1=no 2=yes
432.	By whom?	
433.	When?	
434.	Are feeding choices discussed with the mother postnatally? If no, proceed to Q437	1=no 2=yes
435.	By whom?	
436.	When?	
437.	Who makes the decision about what the baby's first feed will be?	
438.	What if the mother is too ill?	
439.	Who gives the baby its first feed?	1=nurse/midwife 2=mother 9=other
440.	What is the baby fed routinely for its first feed?	1=breast milk 2=formula milk

		9=other
441.	Is free formula milk (as part of the PMTCT programme) available at your clinic/hospital?	1=no 2=yes
441.	Who qualifies for free PMTCT formula milk?	
442.	Are you in favour of baby's of HIV positive mothers being offered free formula milk for six months?	
443.	When are mothers told to bring their babies back for first "check-up"?	
444.	At what age are infants first tested for HIV?	
445.	What test is performed?	

APPENDIX E

ETHICAL CLEARANCE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ismail

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M060328**
PROJECT	A Descriptive Study of Aspects of the Prevention of Mother to Child Transmission of HIV Programmes at Selected Hospitals...
INVESTIGATORS	Dr F Ismail
DEPARTMENT	Dept of Paediatrics & Child Health
DATE CONSIDERED	06.03.31
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 06.04.04 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr H Saloojee

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.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX F

A DESCRIPTIVE STUDY OF ASPECTS OF THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV PROGRAMME AT SELECTED HOSPITALS AND CLINICS IN GAUTENG

INFORMATION SHEET AND INFORMED CONSENT FOR PARTICIPANTS

Hello,

I am Dr Farrah Ismail, a doctor in the Department of Paediatrics and Child Health at the University of Witwatersrand. I am presently carrying out a study on the Prevention of Mother to Child Transmission of HIV Programme in Gauteng.

I would like you to read this information sheet to understand what is involved in this study.

Why am I doing this study?
To assess whether the programme is running properly and to find out if there are any problems with the programme that we can try and fix.

What do we expect from the participants of this study?
You are invited to participate in this study. It is completely voluntary meaning that you can decide whether you want to talk to me or not. I am asking all mothers who have delivered babies at this clinic/ hospital to take part in this study, irrespective of whether they are HIV positive, HIV negative or if they do not know their HIV result.

What do I expect from you if you agree to take part in the study?
I will be asking **you 67** questions about the care you received during your pregnancy (including voluntary counselling and testing for HIV), what medicines you received during labour (specifically the medicine called Nevirapine) and how you are feeding your baby. This should not take longer **than 30** minutes.

I am also requesting to look through your file and antenatal card..

May I withdraw from the study?
Your participation in this study is completely voluntary and you may withdraw from the study at any time. You can choose not to answer any question I ask that you do not wish to answer. If you withdraw or choose not to participate this will not affect the care you receive in this ward.

What about confidentiality?
Whatever I discuss with you or read in your file will remain confidential. This means that I will not tell or discuss this with anybody else. I will only record your study number on my question paper. No records will be kept of your name, address or any other personal details.

Should there be anything on this sheet that you do not understand, please ask me to explain the words or information to you.

I will not receive any direct benefits from doing this study.

If you are unhappy to participate in this study please inform me and I will leave. This will have no effect on your or your baby's care in the ward.
If you are happy to participate please read and sign the attached consent form.

If you have any queries afterwards you may contact me at (011) 481 5196, or you may contact the chairperson of the Human Research Ethics Committee at the University of Witwatersrand, Prof Cleaton-Jones at (011) 717 2229.

Thank you

Dr F Ismail
Department of Paediatrics and Child Health
University of Witwatersrand

APPENDIX G

A DESCRIPTIVE STUDY OF ASPECTS OF THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV PROGRAMME AT SELECTED HOSPITALS AND CLINICS IN GAUTENG

INFORMATION SHEET FOR THE MANAGER OF THE PMTCT PROGRAMME

Good Day Sir/Madam

I am Dr Farrah Ismail, a registrar in the Department of Paediatrics at the University of Witwatersrand. I am currently carrying out a research study describing the delivery of prevention of mother to child transmission of HIV programmes (PMTCT) at selected hospitals and clinics in Gauteng. My supervisor is Professor Haroon Saloojee.

Why am I doing this study?
I am doing this study to assist in improving the effectiveness of the programme in delivering Nevirapine to babies born to mothers who are HIV positive
Your Midwife Obstetric Unit(MOU)/hospital is one of the twelve sites that we have randomly chosen to be part of this study.

You are invited to participate in this study.

What is expected from the participants of this study?
I would like to conduct an interview the manger of the PMTCT programme at your facility. My interview will consist of 31 questions about the running of the programme. I would also like to interview mothers who have delivered babies in the last 48 hours and review their files and antenatal cards and would like to review clinic/hospital registers.

The duration of the entire evaluation will be no longer than two to three days.

May I withdraw from the study?
Your participation is completely voluntary. You may withdraw from this study at any time. If you choose to withdraw or not to participate in the study it will have no negative effects on your work relationship in any way.

What about confidentiality?
Patient and provider information will remain confidential. Allocating study numbers will protect anonymity of participants.

I have acquired permission from the Local and Provincial health authorities to conduct this study.

A summary of the findings from all the sites combined will be available to your MOU/hospital once the research is completed. I will not receive any direct benefits from doing this study.

If you have any queries you can contact me at (011) 481-5196 or the chairperson of the Human Research Ethics Committee at University of Witwatersrand, Prof Cleaton-Jones at (011) 717-2229.

If you are happy to participate please read and sign the attached consent form.

Thank you for your time.

Dr F Ismail
Department Of Paediatrics and Child Health
University of Witwatersrand

APPENDIX H

A DESCRIPTIVE STUDY OF ASPECTS OF THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV PROGRAMME AT SELECTED HOSPITALS AND CLINICS IN GAUTENG

CONSENT FROM PARTICIPANT

I, _____hereby consent to participate in the Prevention of Mother to Child Transmission of HIV Programme evaluation study.
The study has been explained to me and I understand what the study will entail.
I consent to an interview and a review of my records.
I understand that all information will be kept confidential
I understand that I can withdraw from the study at any time and this will not affect my or my baby's care in the ward.

Signed_____

Date: _____

Place: _____

Witness: _____