EFFECTIVENESS OF PMTCT AT NAIVASHA DISTRICT HOSPITAL: OUTCOMES OF HIV EXPOSED INFANTS.

A DISSERTATION IN PART FULFILLMENT OF MASTERS OF MEDICINE (MMED) DEGREE IN PAEDIATRICS AND CHILD HEALTH, UNIVERSITY OF NAIROBI

INVESTIGATOR

DR. EMILY WANGUI KAMAU

MBChB-NBI
Declaration

This dissertation is my original work, and has not been presented for a degree in any university nor published anywhere.

Signature

Emily Wangui Kamau, MBChB.

This dissertation is submitted with the approval of my supervisors.

Signature

Donald Oyatsi, MBChB, MMed (Paed), Dip (Neuro),
Senior Lecturer,
Department of Paediatrics and Child Health,
University of Nairobi

Signature

Elizabeth Maleche Obimbo, MBChB, MMed(Paed), MPH(Epi), FPul(Paed)
Associate Professor of Paediatrics,
Department of Paediatrics and Child Health,
University of Nairobi
Dedication:
This book is dedicated to the glory and honour of GOD, without whom I would not be alive, let alone accomplish the work in this book.

To my spiritual parents, Apostle Jane and Pastor Waithera, your labour in GOD has not been in vain.
Acknowledgments:
I would like to acknowledge GOD for giving me the strength to accomplish this work, my spiritual parents, Apostle Jane and Pastor Waithera for depositing in my life the grace to do good works, my parents Gibson Kamau, Pastor Waithera and Apostle Jane for their emotional, financial and physical support, my supervisors, Professor Obimbo and Dr. Donald Oyatsi for their meticulous yet encouraging supervision, PRIME-K for mentorship and sponsorship of the research at Naivasha District Hospital, Professor Machoki for encouraging me to take up research, Dr. John Kinuthia for your mentorship and great support in this journey-I know I can always count on you, and Francis Njiri and Philip Ayieko for statistical analysis.

Special thanks to the staff of Naivasha District Hospital, clients of Naivasha District Hospital CCC and MCH and the study participants.

Finally, I would like to acknowledge Angie Gachoka, Pastor Kabura Mwangi and Benjamin Gachoka for the numerous trips they took with me to Naivasha for data collection.

Thank you all for your wonderful support. May GOD forever remember you all for the good you have done in my life.
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List of Abbreviations

AIDS – Acquired Immune Deficiency Syndrome
ANC- Antenatal Clinic
ARVs- Anti-Retroviral Drugs
ART-Anti-retroviral Therapy
AZT- Zidovudine
CCC-Comprehensive Care Centre
CD4- Cluster of Differentiation on T helper Cells
DASCO-District AIDS and STIs Control Office
DBS- Dried Blood Spot
DH- District Hospital
DNA PCR- Deoxyribonucleic acid Polymerase Chain Reaction
HAART- Highly Active Anti-Retroviral Therapy
HIV- Human Immunodeficiency Virus
MCH-Mother and Child Health Clinic
MTCT- Mother to Child Transmission
NDH-Naivasha District Hospital
PMTCT- Prevention of Mother to Child Transmission
SPSS- Statistical Package for Social Sciences
3TC- Lamivudine
sd-NVP-Single dose Nevirapine
NVP-Nevirapine
PASCO- Provincial AIDS and STI Control Office
UN- United Nations
WHO- World Health Organization

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ABSTRACT:

Background and Significance

Effective Prevention of Mother-to-Child Transmission (PMTCT) of HIV/AIDS programme can reduce Mother-to-child transmission (MTCT) of HIV from 30-45% to 2%. Global efforts aim to reduce MTCT to less than 5% by the year 2015.

Objective:

To evaluate the effectiveness of PMTCT at Naivasha District Hospital through determination of the outcomes of HIV exposed infants, specifically HIV free survival during the first 18 months of life.

Methodology

This was a retrospective longitudinal study targeting mother-infant pairs seeking HIV care at the comprehensive care clinic. Consenting mothers completed a questionnaire that assessed socio-demographic characteristics and uptake of PMTCT interventions. Infant HIV status was obtained from records and HIV antibody testing at 18 months for previously untested infants. HIV transmission rates and mortality rates among HIV exposed infants were estimated. Kaplan Meier analysis was used to determine HIV free survival pattern.

Results

One hundred and thirteen mother-infant pairs were enrolled, 99 (87.7%) mothers and 104 (92%) infants received antiretrovirals. Although, 79 (85.6%) infants were breastfed, only 63 (55.8%) were exclusively breastfed for six months. Most 100 (88.5%) infants had HIV deoxyribonucleic acid polymerase chain reaction testing at 6 weeks, 84 (80.8%) had follow up HIV antibody testing at 18 months. Infant HIV infection was 2.7% at 6 weeks and 4.4% between 6 weeks and 18 months giving an overall MTCT rate of 7.1%. Infant mortality rate was 0.9% at 6 weeks and 7.1% between 7 weeks and 18 months giving an overall mortality rate of 8%, and an18 month HIV-free survival rate of 83.9%. Infant HIV free survival was associated with mothers’ knowledge of positive HIV status and CD4 counts before pregnancy. Mixed fed infants were more likely to turn HIV positive by 18 months. Causes of mortality were pneumonia, gastroenteritis, neonatal sepsis and cardiac failure.

Conclusion

The PMTCT programme reduced HIV infection and mortality in 83.96% of HIV exposed infants. MTCT rates increase substantially after 6 weeks indicating the urgent need for interventions to reduce breast milk transmission.

Recommendations

The PMTCT programme in Naivasha District Hospital needs to address sub-optimal ARV coverage among HIV positive women and their infants, and to encourage safe breastfeeding
by ensuring all HIV positive lactating women are on ARVS for prophylaxis or their own health.
BACKGROUND AND SIGNIFICANCE

INTRODUCTION

At the end of the year 2010, there were 3.4 million children in the world living with Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS). In addition, there were 370,000 new HIV infections in children less than 15 years and 250,000 AIDS related deaths in the same age group\(^1\). Approximately 90% of these new infections occur in children who reside in Sub-Saharan Africa\(^2\). Without treatment, one third of children living with HIV die before they reach one year of age and over 50% die by the second year of life\(^3\) (Newell 2004).

There have been modest efforts both globally and locally to reduce Mother-to-Child Transmission (MTCT) of HIV. At the United Nations General Assembly Special Session (UNGASS) in 2001, governments committed to reduce by 50% the proportion of infants infected by HIV by the year 2010. This was to be done by ensuring that 80% of pregnant women accessing antenatal care receive PMTCT services. In 2011, a new global target was set: to reduce the number of new childhood infections by 90% and in so doing reduce AIDS related infant deaths by more than 50%\(^4\).

In order to achieve these goals, it is imperative that the PMTCT programmes, world-wide and specifically in Kenya are effective. The ultimate goal of any PMTCT programme is to have a living HIV free infant. This is an end-point that should be considered when assessing these programmes. However this important end-point has not been given much emphasis in the monitoring and evaluation of PMTCT programmes in Kenya. The coverage of PMTCT services has played a larger role in terms of monitoring PMTCT effectiveness.

The overall goal of this study is to measure effectiveness of PMTCT at Naivasha District Hospital using the outcomes of HIV exposed infants. This will serve as useful information for policy makers to evaluate gains made from the programme and to further strengthen the programme so as to virtually eliminate paediatric HIV.
LITERATURE REVIEW

Mother-To-Child Transmission of HIV

According to the 2007 Kenya AIDS Indicator Survey, women aged 15-64 years are more likely to be infected with HIV, with HIV prevalence of 8.4% in comparison with 5.4% in men. Among pregnant women, the HIV prevalence is 9%. Children born to these women risk being infected with HIV via Mother-to-child transmission of HIV.

Mother-To-Child Transmission (MTCT) or vertical transmission of HIV is HIV infection from an HIV infected woman to her child during pregnancy (5–10%), labour and delivery (10-20%) and during breastfeeding (5-20%). It accounts for 90% of the HIV infection seen in the paediatric age group. The risk of transmission is particularly high if the mother herself acquires HIV infection during pregnancy or breastfeeding because viral load tends to be highest during the early stages of infection. In the absence of any intervention the rate of MTCT is about 15–30% without breastfeeding and increases to 45% with prolonged breastfeeding. These rates are higher for developing countries (25-45%) than in industrialized countries (15-30%) \(^5\). However, with an effective intervention MTCT rate can be reduced to as low as 2% \(^6\).

Pathophysiology of Mother-to-child Transmission of HIV

The timing of transmission of HIV is made based on the timing of the detection of HIV in the infant. In-utero transmission of HIV is characterized by the detection of HIV within the first 24 hours of life whereas intra-partum transmission of HIV occurs when viral studies are negative within the first week of life but becomes positive between 7 and 90 days of life. 

**In-utero transmission of HIV**

During pregnancy, the placenta provides an important physical and immune barrier between maternal and fetal circulations. It is also thought to provide protection against in-utero transmission of HIV. Evidence for in-utero HIV infection is from the findings of HIV via culture and Polymerase chain reaction in fetal tissue as early as 8 weeks of gestation. The exact mechanisms of in-utero transmission are not known, but factors that disrupt placental integrity, such as chorioamnionitis, may play a role. Furthermore, viral characteristics, such as viral subtype or cellular tropism and host genetic factors, such as HLA or chemokine
receptor genotype of the infants play a role. Majority of in-utero transmission is thought to occur late in pregnancy. Children infected during this period tend to have a rapid progression of disease towards full blown AIDS due to the efficient delivery of HIV that goes unchecked by the immature immune system of the fetus after infection of its CD4 cells. As a result, the viral load rapidly increases and peaks by 2-3 months of age and declines slowly. The viral load in this group of infants can stay high for as long as 2 years. These children will manifest symptoms of AIDS within the first few months of life. Untreated, they have a median survival time of 6 to 9 months.

**Intra-partum transmission of HIV**

The mechanisms by which intra-partum transmission occur are by direct access of cell-free or cell-associated virus to the infant systemic circulation through maternal-fetal transfusion. Maternal-fetal transfusion occurs during uterine contractions in labour, or by the infant swallowing HIV-infected genital tract secretions during delivery, with viral passage through the infant's GI mucosa to underlying lymphoid cells followed by systemic dissemination. Once infected, the viral load rapidly increases over 2-3 months and slowly declines over 2 years. Children infected during this period have a slow progression to AIDS with a median survival time of 6 years.

**Transmission through breast feeding**

Transmission of HIV infection through breast milk can occur at any point during lactation. Factors that may facilitate breast milk transmission include high maternal viral load (in plasma and in breast milk); breast milk immunological factors; maternal breast pathology such as mastitis, cracked or bleeding nipples, or breast abscess; and low maternal CD4 count. Infant gastro-intestinal pathology such as candidiasis and necrotizing enterocolitis may disrupt mucosal integrity and aid viral transmission. Infants infected during this period tend to have minimal or no progression of disease and have relatively normal CD4 counts for the first 8-10 years of life.
The prevention of mother-to-child transmission (PMTCT) is a highly effective intervention and has huge potential to improve both maternal and child health through addressing the above risk factors. This is because it can eliminate paediatric HIV and reduce maternal mortality and the negative social consequences of HIV such as orphan hood.

**PMTCT in Kenya**

In Kenya, PMTCT programmes were initiated on a pilot basis in the year 2000, and officially launched in the year 2002. Since the year 2003, these programmes have undergone substantial scale-up with 4000 (90%) of 4400 facilities with maternal child health services offering PMTCT services. PMTCT services in Kenya are free and integrated into Maternal and Child Health (MCH) services.

There are 4 prongs of the PMTCT programme in Kenya which parallels the WHO comprehensive approach to PMTCT:

## Table 1: Risk Factors for Mother-To-Child-Transmission of HIV:

<table>
<thead>
<tr>
<th>Pregnancy</th>
<th>Labour and Delivery</th>
<th>Breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ High maternal plasma viral load (new infection or advanced AIDS)</td>
<td>✓ High maternal plasma and/or genital viral load (new infection or advanced AIDS)</td>
<td>✓ High maternal plasma/or breast milk viral load (new infection or advanced AIDS)</td>
</tr>
<tr>
<td>✓ Viral, bacterial, or parasitic placental infection e.g. malaria</td>
<td>✓ Rupture of membranes more than 4 hours before labour begins</td>
<td>✓ Duration of breastfeeding</td>
</tr>
<tr>
<td>✓ Sexually transmitted infections</td>
<td>✓ Vaginal delivery</td>
<td>✓ Early mixed feeding (e.g. food or fluids in addition to breast milk)</td>
</tr>
<tr>
<td></td>
<td>✓ Invasive delivery procedures that increase contact with mother’s blood or body fluids e.g. episiotomy, fetal scalp monitoring, frequent vaginal examinations</td>
<td>✓ Breast abscesses, nipple fissures, mastitis</td>
</tr>
<tr>
<td></td>
<td>✓ First infant in multiple birth</td>
<td>✓ Oral disease in the baby e.g. thrush or sores</td>
</tr>
</tbody>
</table>
HIV testing is routinely offered to pregnant women who access antenatal services. Those who do not access antenatal services will therefore miss out the opportunity to be tested for HIV.

As regards preventive ARV therapy, the national programme has adopted the WHO 2006 guidelines. When these WHO guidelines were revised in November 2009, the Kenyan
national PMTCT guidelines were also revised to include option A of the revised 2009 WHO guidelines. These revised guidelines are as follows:

Women with CD4 less than or equal to 350 and/or WHO HIV stage 3 and 4 irrespective of CD4 should be started on lifelong HAART for their health. The preferred first-line ART regimen should include an AZT + 3TC backbone: AZT + 3TC + NVP or AZT + 3TC + EFV. Alternative regimens that are recommended include TDF + 3TC (or FTC) + NVP and TDF + 3TC (or FTC) + EFV.

Table 2 shows guidelines for women whose CD count is above 350 and/or WHO stage 1&2:

**Table 2: Revised ARV guidelines for women whose CD4 count is above 350 and/or WHO stage 1 and 2**

<table>
<thead>
<tr>
<th></th>
<th>OPTION A</th>
<th>OPTION B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MOTHER</strong></td>
<td>Ante partum AZT from 14 weeks.</td>
<td>Triple ARV (from 14 weeks until cessation of breastfeeding (stop 1 week after complete exposure to breast milk)</td>
</tr>
<tr>
<td></td>
<td>Sd-NVP during onset of labour</td>
<td>✓ AZT+3TC+LPV-r</td>
</tr>
<tr>
<td></td>
<td>AZT+3TC during labour and delivery.</td>
<td>✓ AZT+3TC+ABC</td>
</tr>
<tr>
<td></td>
<td>AZT+3TC for 7 days post-partum.</td>
<td>✓ AZT+3TC+EFV</td>
</tr>
<tr>
<td></td>
<td>(sd-NVP, AZT and 3TC can be omitted if mother receives AZT longer than 4 weeks ante-partum)</td>
<td>✓ TDF+XTC+EFV</td>
</tr>
</tbody>
</table>
In 2009, sixty seven per cent of pregnant women living with HIV received dual ARV prophylaxis (sd NVP and AZT), while 11% received ART for their own health benefit and about one third of women received sd NVP in Kenya. Infant prophylaxis continues to lag behind maternal ARV prophylaxis with only 42% of HIV exposed infants receiving ARV prophylaxis. It is estimated that 40,000-50,000 infants annually in Kenya acquire HIV from their mothers and an estimated 117,000 children require Anti-Retroviral Treatment.

**PMTCT Cascade**

In order for ARVs to be delivered successfully to mother-baby pairs, there is a critical pathway that HIV positive women must go through. This is called the PMTCT cascade and it is as follows:

**Figure 2: PMTCT cascade**

Women attend Antenatal Clinic and are offered a HIV test on an opt-out basis. Should they accept to take the test, they are then tested and receive the results on the same day. Those who test positive are staged immunologically and clinically (using the WHO clinical staging) see APPENDIX I. ARV prophylaxis is offered to HIV positive women based on their HIV
staging. Ideally this should all be done within the 1st Ante-natal visit. This ensures that all women attending antenatal care are tested for HIV and those women who require ARVS are initiated on them as soon as they present to the ante-natal clinic.

During these visits to the ante-natal clinic, these women also receive ARV prophylaxis to take when in labour. In addition to PMTCT services, expectant women are advised on the importance of the routine focused Antenatal Care visits and delivering under supervision of skilled personnel in a health facility. Once their infants are delivered, they are required to take ARVs for a period of 6 weeks. At the age of 6 weeks, these infants undergo testing for HIV-DNA PCR method via Dried Blood Spot. In the year 2009, forty nine thousand DNA PCR tests for infant HIV diagnosis were conducted. Only 40% of all PCR tests done in that year were conducted at 6 weeks as per the recommendations. At the age of 6 weeks, these HIV exposed infants should be started on septrin and multivitamins which are discontinued only when the infant tests negative for HIV at the age of 18 months. Under the national PMTCT programme, these HIV exposed infants (infants of mothers with HIV) are followed up until the age of 18 months when they are re-tested using HIV antibody method. Those who test positive are subsequently enrolled for care in HIV clinics. The goal in follow up of HIV exposed infants is to recognize those who are HIV positive early, so as to enroll them for prompt initiation of ARVs where indicated. This serves to reduce HIV –associated mortality.

Organization of PMTCT services in Kenya

PMTCT is part of primary health care initiative intended to be offered at all levels of health facilities in Kenya.

**Level 1: Community Health Workers:**
Under the second National Health Sector Strategic Plan (NHSSP II), Community Health Workers (CHWs) carry the responsibility of advising their community members to attend ANC and deliver in health facility.

**Level 2: Dispensaries**
In these health facilities there are trained staff, test-kits and ARVS. Therefore, expectant women who attend ANC at these health facilities are offered HIV testing and counseling. ARVS are offered where indicated. In ideal situations, deliveries should not take place in these health facilities. Where it is possible, expectant mothers are referred to higher levels of health facilities to deliver.

**Level 3: Health Centers**
In addition to the services offered in level 2 health facilities, there are maternity services. However, these do not include maternity theatres and personnel trained in performing caesarean sections.

**Levels 4-6: Sub-district and District Hospitals, Tertiary Referral Hospitals and National Referral Hospitals**

These offer ANC and delivery services—normal deliveries and caesarean sections. In addition, these facilities incorporate HIV exposed infant follow up by a paediatrician where necessary.

![Image of health facility levels]

**Figure 3: Various levels of health facilities in Kenya**

There are specific national targets\(^{10}\) that have been set up by the government of Kenya for its PMTCT programme to be met by the year 2013 in the 3\(^{rd}\) Kenya National AIDS Strategic Plan. These include:

- To have 50% fewer new infections in the general population
- To have less than 1% of males and 3% of females aged 15-24 years living with HIV
- To have 80% of HIV-positive pregnant women receive ARVs for PMTCT
- To have less than 8% of HIV exposed infants getting infected with HIV

In addition, the government of Kenya is strongly committed to reducing MTCT rates of transmission of HIV to less than 5% by the year 2015.
Effectiveness of PMTCT

Effectiveness of PMTCT is defined as the prophylactic benefit of a PMTCT intervention when implemented in real practice.

It can be measured by use of several outcome indicators which include:

i. PMTCT intervention coverage—which is intended to act as a surrogate for the number of infant infections prevented

ii. Infant infections prevented

iii. Infant deaths prevented

iv. HIV-free survival

There is no consensus on which of the above outcome indicators should be the gold-standard approach of measuring population effectiveness of PMTCT. However, several studies have been conducted to assess effectiveness of PMTCT.

Table 3: Studies on effectiveness and outcomes of PMTCT

<table>
<thead>
<tr>
<th>TITLE OF ARTICLE</th>
<th>AUTHOR and YEAR</th>
<th>STUDY DESIGN and SAMPLE SIZE</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOUTH AFRICA 1. Effectiveness of the first wide district wide programme for Prevention of Mother-To-Child Transmission of HIV in South Africa</td>
<td>Coetzee D, Hilderbrand K, Boulle A, Draper B et al. 2005</td>
<td>Cross-sectional N= 658</td>
<td>✓ PMTCT coverage and MTCT rates utilised. ✓ PMTCT coverage of 77%. ✓ 8 week MTCT rates- 8.8% Maternal age strongest independent risk factor for transmission</td>
</tr>
</tbody>
</table>
**WEST AFRICA**

Outcomes of PMTCT services and factors affecting vertical transmission of HIV infection in Lagos, Nigeria\(^{12}\).

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Authors</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective case control N= 733.</td>
<td>Abayomi J A, Niyi A, Abieyuwa E, Tolu F, Aruma E et al 2011</td>
<td>✓ 6 weeks MTCT rates for mothers without an effective PMTCT intervention 22.5% ✓ 9.6% with an effective intervention</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reducing Pediatric HIV Infection: Estimating Mother-to-Child Transmission Rates in a Programme Setting in Zambia\(^{13}\)

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Authors</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional study N=8237.</td>
<td>Torpey K, Kasonde P, Kabaso M, Weaver M A et al. 2010</td>
<td>✓ 0-6 week MTCT rates of 6.5% where both mother and child received interventions and 20.9% where no interventions were received. ✓ Higher MTCT rates at 6-12 months: 15.1% with PMTCT interventions and 39.3% without.</td>
<td></td>
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</tbody>
</table>

Effectiveness of a city-wide programme to prevent Mother-To-Child transmission of HIV in Lusaka, Zambia\(^{14}\)

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Authors</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anonymous cord blood surveillance for Nevirapine drug levels and HIV antibody testing. N= 8787 women.</td>
<td>Stringer et al. 2005</td>
<td>✓ 32% of HIV infected women found to be non-adherent to NVP. ✓ Concluded that process indicators (of PMTCT cascade) may substantially overestimate PMTCT programme performance.</td>
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</tr>
</tbody>
</table>

Uptake and outcomes of a Prevention of mother to child transmission (PMTCT) programme in Zomba district, Malawi\(^{15}\)

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Authors</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matched cohort study N=720( 360 HIV infected and 360 uninfected mothers)</td>
<td>Van Lettow M, Bedell R, Landes M et al 2011</td>
<td>✓ HIV free survival was 66% at 18-20 months. ✓ 6-8 weeks risk of transmission was 6.5% and cumulative risk by 24 months was 9.7% for those uninfected at 1.5 months. ✓ Poor follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Title</td>
<td>Authors</td>
<td>Study Design</td>
<td>Results</td>
<td></td>
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<tr>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| EAST AFRICA Outcomes of HIV-Exposed Children in Western Kenya: Efficacy   | Nyandiko W M, Otieno-Nyunya B, Musick B et al 2010                       | Retrospective cohort N= 2477. | ✓ 3 months MTCT rates 5%, with loss to follow up of 7.4% and mortality of 1.3% HIV exposed infants.  
✓ 18 months MTCT rates 10.5%, 27.4% loss to follow up and 3.3% mortality. |
| of Prevention of Mother to Child Transmission in a Resource-Constrained   |                                                                         |                               |                                                                                                                                         |
| Setting 16                                                                 |                                                                         |                               |                                                                                                                                         |
| Effectiveness of a PMTCT programme in rural Western Kenya 17              | Ascoaga-Lorenzo A, Ferrey C, Alvarez A et al 2011                          | Cross sectional to determine | ✓ MTCT rates of 15.86% after the breastfeeding period.  
✓ Programme coverage was estimated at 40.5%. |
| PMTCT programme coverage and case control to determine MTCT rates N= 767. |                                                                         |                               |                                                                                                                                         |
| HIV-free survival among nine- to 24-month-old children born to HIV-positive mothers in the Rwandan national PMTCT programme: a community-based household survey 18 | Ruton et al 2012                                                        | Cross sectional-community based survey N= 2982 | ✓ HIV free survival among 9-24 month old infants was 91.9%  
✓ Mortality of 3%  
✓ HIV infection rate of 4% |

**Monitoring of PMTCT Programmes**

For monitoring of PMTCT programmes to take place good data management is required. Data is collected and recorded in various levels:
1. Individual level through the use of Mother and Child Health booklet which the mother keeps and the HIV EXPOSED infant card which is used for follow-up of HIV exposed infant and this is kept in the health facility.

2. Health facility level using various standardized registers such as: Revised ANC Register, Revised Maternity Register and Post Natal Register and Workload, Other registers include: Child Health and Nutrition Information System and In-patient Morbidity and Mortality.

3. District level: the District AIDS Control Office (DASCO) summarizes data from all health facilities within a certain district.

4. Provincial level: the Provincial AIDS Control Office (PASCO) aggregates the various DASCO level data to give data for the whole province.

5. National Level: data is received from each PASCO in every province and a monitoring and evaluation manager at the National Aids and STIs Control Programme (NASCOP) aggregates this data and data from tertiary and national referral hospitals to give data for the whole country.

Data flows from the health facility level to the national level. The National AIDS Control Council steps in to control dissemination of all HIV/AIDS information for national response.

**Performance Indicators for the Kenya PMTCT programme**

Monitoring of PMTCT programmes is through the following performance indicators:

- Uptake of counseling and testing in Antenatal clinic
- Antenatal HIV sero-prevalence
- Antenatal mother ARV prophylaxis uptake
- Antenatal infant ARV prophylaxis uptake
- Uptake of counseling and testing in Maternity clinic
- Maternity mother ARV prophylaxis uptake
- Infant ARV prophylaxis uptake

Among the PMTCT outcome indicators that are missing in the Kenyan PMTCT programme performance indicators are infant HIV infection rate at 6 weeks and 18 months and HIV free survival. It is difficult to accurately estimate the performance of the programme without
establishing outcomes of HIV exposed infants. These performance indicators mainly assess PMTCT coverage until the HIV positive woman delivers.

**STUDY JUSTIFICATION**

PMTCT programmes have been operational in Kenya since the year 2000 and yet there is little information about how effective these programmes are in terms of outcomes of HIV exposed infants; trends in mother to child transmission rates and HIV free survival among HIV exposed infants. This is due to the fact that the monitoring of these programmes has placed more emphasis on programme coverage, which studies show can overestimate the success of the programme. There are

This study will provide insight on the status of the rates of infant HIV free survival which will give policymakers complete the picture of these programmes and provide justification for allocation of resources towards it.

**RESEARCH QUESTIONS**

What are the rates of HIV infection, HIV free survival and mortality at 18 months of HIV exposed infants of mothers recruited into Naivasha District Hospital PMTCT programme in the year March 2010-March 2011?

**Overall Objective:**

To evaluate the effectiveness of the Prevention of Mother to Child Transmission (PMTCT) Programme at Naivasha District Hospital through determination of the outcomes of HIV exposed infants, specifically HIV free survival during the first 18 months of life.

**Specific Objectives**

*Primary Objectives*

1. To determine HIV infection rate and HIV free survival status at 6 weeks, 9 months and 18 months among infants of HIV positive women enrolled in the Naivasha District Hospital PMTCT programme in the year March 2010-March 2011.
2. To determine the rate of uptake of PMTCT interventions among HIV infected women and their children enrolled in the Naivasha District PMTCT programme in the year March 2010-March 2011.

*Secondary Objectives*

3. To describe infant HIV testing practices among infants of HIV positive women enrolled in the Naivasha District Hospital PMTCT programme in the year March 2010-March 2011.

4. To describe causes of mortality for deceased infants of HIV positive women enrolled in Naivasha District Hospital PMTCT programme in the year March 2010-March 2011.
METHODOLOGY:

Study Design
This study was a retrospective longitudinal survey employing review of hospital records and structured interviews with mother-infant pairs. Data collection ran from November 2012 to January 2013.

Study Site
The study site was Naivasha District Hospital (NDH) Comprehensive Care Centre (CCC) and Maternal and Child Health clinic (MCH). Naivasha District Hospital is the second largest hospital in the Nakuru county area, formerly known as Rift Valley province. It is a level 4 public Hospital run by the Ministry of Medical Services, located in Lakeview Sub location of Sokoni location. Its catchment population is both rural and urban.

The facility’s Comprehensive Care Centre (CCC) serves as both a primary care centre and public referral centre for long term care of men, women and children infected and affected by HIV/AIDS. The clinic offers separate services for children and adults. Currently, the centre has approximately 4697 HIV infected adults, and 643 HIV exposed and infected children enrolled for care.

The PMTCT programme at Naivasha DH began in the year 2004. The women enrolled in the PMTCT programme at Naivasha DH are followed up at the Maternal and Child Health (MCH) clinic and the comprehensive care centre. Infants born to HIV positive women are followed up in the MCH up until the age of 18 months when rapid HIV antibody tests are done. Those who test negative are discharged from subsequent follow-up whereas those who turn positive are referred to the CCC for follow up.

Study Population

Source Population:
Naivasha district has a population of approximately 38,000 people. According to the 2007 Kenya AIDS Indicator Survey, Rift Valley province has an HIV prevalence of 6.8%. The hospital conducts an estimated 7 deliveries daily and sees approximately 150 women in its maternal and child welfare clinic on a daily basis. Hospital records showed that there were
215 HIV exposed infants born on follow up at the hospital in the years 2010 and 2011, from which the study sample was drawn.

**Study Population**
The study sample was drawn from the population of HIV exposed infants aged at least 18 months together with their mothers or guardians who had been followed at Naivasha District Hospital from March 2010 to March 2011-timed to coincide with the launching of the 3rd edition of the Kenya PMTCT guidelines, so as to include infants from the age of 18 months to 36 months of age.

**Eligibility Criteria**

**Inclusion Criteria**
1. HIV positive mothers of infants delivered between March 2010-March 2011 who had attained the age of 18 months, and had been enrolled at the PMTCT programme at Naivasha District Hospital.
2. Caretakers/legal guardians of HIV exposed children where mothers were deceased

**Exclusion Criteria**
1. Mothers who transferred into the Naivasha District CCC and therefore did not receive PMTCT interventions in NDH.
2. Mothers who were mentally impaired.

**Sample Size**
Sample size calculation was based on the primary objective of determination of HIV free survival. The sample size determined therefore depended upon the estimated prevalence of HIV survival, the power of the study-which was set at 80%, the level of precision or margin of error allowed, which was set at 5%. The sample size was corrected for, because the maximum available potential study subjects was known i.e. there were 215 HIV exposed infants on follow up at the PMTCT programme at Naivasha District Hospital from March 2010-March 2011 who were eligible as they had attained the age of 18 months.

The calculation using Fisher formula with Finite Population Correction is as follows:

\[ n = \frac{NZ^2 \cdot P \cdot (1-P)}{Z^2 \cdot P \cdot (1-P)} \]
\[ D^2 (N-1) + Z^2 P(1-P) \]

n is the minimum sample size

N is the available population of HIV positive women enrolled in PMTCT programme at Naivasha District Hospital in the year March 2010-March 2011 which is 215

D is the degree of precision used which is +5% set at 0.05.

P is the estimated prevalence of HIV free survival in HIV exposed infants which was 66% based on a similar study conducted in Zomba District, Malawi that was published in 2011 (van Lettow et al, Malawi)

Z is the table value from standard normal distribution curve at a significance level of 5% assuming a power of 80%, which is 1.96.

\[
= 215 \times 1.96 \times 0.66(1-0.66) \\
0.05^2(215-1) + 0.66(1-0.66) \\
= 133
\]

**Study Procedures**

**Recruitment**
Hospital records of mothers and infants enrolled into the PMTCT programme were perused for appointment dates for routine visits and contact information. These women were approached during routine visits for follow up at the CCC or at the MCH as they attended the HIV Exposed Infants’ clinic.

Women and HIV exposed infants registered into the PMTCT programme who were not captured at the CCC or MCH were contacted via telephone and invited to the health facility for the interview with their infants. This captured the women and infants who were lost to follow up in the PMTCT programme.

**Consenting**
Eligible mothers willing to participate in the study gave consent prior to interviews including those invited to the hospital for the interview via telephone.
**Questionnaire**

Mothers who consented to participate in the study were interviewed using a structured questionnaire by the Principal Investigator or research assistants who were clinical officers trained by the Principal Investigator. The interviews lasted 30 minutes and were conducted in both English and Kiswahili. The questionnaire contained questions which sought to obtain information on timing of HIV diagnosis, the PMTCT interventions offered to the mother and her infant, including HIV testing and current health status of her infant. HIV status of deceased infants was taken to be the last available HIV test recorded in their medical records, or in lab records or in other registers.

Infant HIV test results were extracted from their medical records or other registers: the Early Infant Diagnosis results book, laboratory registers and from Walter Reed Lab where DNA PCR tests were carried out. Infants who had not undergone rapid Antibody testing by the age of 18 months were tested at the CCC using Determine test kit. Positive tests were confirmed by use of Unigold test kit.

Mothers whose infants were deceased underwent verbal autopsy to determine possible causes of death and were asked the exact age at which their infants died.

**Data Analysis**

Data obtained from questionnaires was coded and entered into preformed Access spreadsheets and analysed using Statistical Package for Social Sciences computer package.

Descriptive statistics such as mean, standard deviation, mean, median and range were used for continuous variables. Categorical data was summarized using proportions and tabulated using frequency tables. Uptake of PMTCT interventions was described in terms of frequencies and percentages. Numerical data from HIV status by the age of 18 months or at last available result before death for those who died before 18 months, was used to compute HIV incidence rate among HIV exposed infants and mother to child transmission rates. Survival analysis was performed using life tables and Kaplan Meier analysis. Age-specific and Case-specific mortality rates were computed and used to describe causes of mortality among HIV exposed infants.

Infant testing practices were described in terms of frequencies of testing by DNA PCR method and HIV antibody methods with special consideration to age at which these tests are done.
Multivariate logistic regression was used to assess associations between binary outcomes: HIV infection in infants and mortality and independent variables-PMTCT interventions.

**Ethical Considerations**
The study was conducted after getting the ethical approval from the Ethics and Research Committee of Kenyatta National Hospital, the University of Nairobi and institutional approval from the Naivasha District Hospital Medical Superintendent.

**Autonomy:**
The study was carried out only after informed consent had been sought. There were no additional costs for participation in the study and the participants were free to withdraw from the study at any stage without penalty.

**Informed Consent**
Details of the study were fully explained to participants before recruitment and they provided written consent for participation in the study.

**Confidentiality**
Mothers lost to follow up were invited to the health facility for interviews to avoid disclosure of HIV status via the phone. Confidentiality of the patients was protected by ensuring that details of HIV status of both mother and baby in the study were discussed only with the mother of the child and guardians where mothers were deceased. The review of HEI cards and Early Infant Diagnosis data was done only within the respective departments at the Naivasha District Hospital. In addition, all data obtained was kept under lock and key or in password protected computer files to restrict access. Data forms did not bear patient name or clinic number and the patients were only be identified by study numbers.
RESULTS:
From September 2012 to January 2013, mothers of 113 HIV exposed infants (HEI) attending Naivasha District Hospital participated in the study, 14 declined. The results presented show basic characteristics of mother-infant pairs enrolled in the study, the rate of uptake of PMTCT interventions, HIV infection rates and HIV free survival rates at 6 weeks, 9 months and 18 months, infant HIV testing practices at Naivasha District Hospital and causes of mortality for deceased infants.

The flowchart shown in figure 4 presents the study recruitment procedures and details of enrollment or exclusion from the study.

**Figure 4: Study Flowchart**

![Flowchart](image)

**Characteristics of Mother-Infant Pairs and PMTCT intervention uptake**
Table 4 shows the basic demographics of mother and infant pairs at Naivasha District Hospital. Over half (59.3%) of the women were married. The median age of HIV positive women was 30. The ratio of male to female infants was 1.2:1 with male infants accounting for 53.7% of the participants. The median birth weight was 3 Kgs. with an IQR between 2.6 and 3.5 Kgs.
### Table 4: Characteristics of Mother-Infant Pairs (N=113)

<table>
<thead>
<tr>
<th>Maternal Characteristics</th>
<th>Freq. (% or median IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>N=113</strong></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>67 (59.3%)</td>
</tr>
<tr>
<td>Others (Single/Separated/Divorced/Widowed)</td>
<td>46 (40.7%)</td>
</tr>
<tr>
<td>Median Age in years (IQR)</td>
<td>30 (25.5-34)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infant Characteristics</th>
<th>Freq. (% or median IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>N=113</strong></td>
</tr>
<tr>
<td>Gender (N=108)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58 (53.7%)</td>
</tr>
<tr>
<td>Female</td>
<td>50 (46.3%)</td>
</tr>
<tr>
<td>Median Age in months</td>
<td>25 (23-28)</td>
</tr>
<tr>
<td>Median Birth Weight in Kilograms (N=101)</td>
<td>3 (2.6-3.5)</td>
</tr>
</tbody>
</table>

The uptake of PMTCT interventions among mother-infant pairs is presented in Table 5. The median gestational age at enrollment into PMTCT programme was 28 months (IQR 15.5 to 28). Fifty-four (48%) mothers attended ANC clinics between 3 and 4 times during the most recent pregnancy. Only 34.5% had knowledge of HIV status and CD4 counts before pregnancy (Table 5). Ninety-nine (87.7%) mothers were on ART prophylaxis, most commonly (59.6%) AZT. Majority (87.6%) of the infants were born through Spontaneous Vertex Delivery. The Caesarean section rate in HIV positive deliveries at the hospital was 12.4% (Table 5). Co-trimoxazole prophylaxis was given to 89 (78.8%) infants. Eighty-eight (77.8%) and 16 (14.2%) infants were given Nevirapine syrup and AZT+3TC respectively (table 5). Most (88.5%) infants were tested using DNA PCR between the age of 6 and 10 weeks and 84 (80.7%) were followed up for testing at 18 months. Sixty-three (55.8%) infants
were exclusively breastfed and 26 (23%) were on complementary feeding. The remaining (21.2%) infants received mixed feeds.

**Table 5: Uptake of PMTCT interventions among mother-infant pairs**

<table>
<thead>
<tr>
<th>PMTCT Intervention</th>
<th>Freq. (%), median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age at initiation of ARVs in weeks(IQR), n = 72</td>
<td>28 (15.5-28)</td>
</tr>
<tr>
<td>Knowledge of HIV status and CD4 counts before pregnancy</td>
<td>39 (34.5%)</td>
</tr>
<tr>
<td>CD4 counts taken in mother</td>
<td>65(57.5%)</td>
</tr>
<tr>
<td>CD4 counts</td>
<td></td>
</tr>
<tr>
<td>&lt;350</td>
<td>10(15.3%)</td>
</tr>
<tr>
<td>350-500</td>
<td>10(15.3%)</td>
</tr>
<tr>
<td>&gt;500</td>
<td>45(26.9%)</td>
</tr>
<tr>
<td>Total number of ANC visits</td>
<td></td>
</tr>
<tr>
<td>1-2 visits</td>
<td>33 (29%)</td>
</tr>
<tr>
<td>3-4 visits</td>
<td>54 (48%)</td>
</tr>
<tr>
<td>Above 4 visits</td>
<td>26 (23%)</td>
</tr>
<tr>
<td>Mother ART Prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>99(87.7%)</td>
</tr>
<tr>
<td>No</td>
<td>14(12.3%)</td>
</tr>
<tr>
<td>Type of ART prophylaxis in mother</td>
<td></td>
</tr>
<tr>
<td>sd-NVP</td>
<td>6 (6.1%)</td>
</tr>
<tr>
<td>AZT</td>
<td>59 (59.6%)</td>
</tr>
<tr>
<td>Triple ARVs</td>
<td>29 (29.3%)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (5.1%)</td>
</tr>
<tr>
<td>Infant ARV prophylaxis</td>
<td></td>
</tr>
<tr>
<td>NVP syrup</td>
<td>88(77.8%)</td>
</tr>
<tr>
<td>AZT +3TC</td>
<td>16(14.2%)</td>
</tr>
<tr>
<td>None</td>
<td>8 (8%)</td>
</tr>
<tr>
<td>Infant Received co-trimazole</td>
<td>89 (78.8%)</td>
</tr>
<tr>
<td>Infant HIV testing Practices</td>
<td></td>
</tr>
<tr>
<td>Infant HIV testing is as shown in table 6. HIV testing rates decline from 88.5% at 6 weeks to 80.7% at 18 months representing a 7.8% (95% CI, -1.8 to 17.4) reduction in testing rates, p =</td>
<td></td>
</tr>
</tbody>
</table>
0.11. At 6 weeks DNA PCR testing was delayed in 10 (8.9%) infants. During follow up testing at 18 months, 8 out of the initial 113 (7.1%) infants tested positive for HIV.
Table 6: Infant HIV Testing Practices among HIV exposed infants at Naivasha District Hospital

<table>
<thead>
<tr>
<th>Age of Infant and Type of HIV Test</th>
<th>Freq. /N (%)</th>
<th>95% CI for prevalence of HIV infection by age of Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age 6 weeks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA PCR Testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Done</td>
<td>100/113 (88.5%)</td>
<td>(0.1-8.5)</td>
</tr>
<tr>
<td>Positive</td>
<td>3/113 (2.7%)</td>
<td></td>
</tr>
<tr>
<td>Delayed (done at 12 weeks)</td>
<td>3/113 (2.7%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age 9 months</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid Antibody Testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Done at 9 months</td>
<td>93/105(90.4%)</td>
<td>(-0.84-2.74)</td>
</tr>
<tr>
<td>Test positive</td>
<td>1/105 (0.95%)</td>
<td></td>
</tr>
<tr>
<td>Delayed (done at 10 months)</td>
<td>2/105(1.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age 18 months</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid Antibody</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Done</td>
<td>84/104(80.8%)</td>
<td>(1.6-10.9)</td>
</tr>
<tr>
<td>Test positive</td>
<td>5/104(4.8%)</td>
<td></td>
</tr>
</tbody>
</table>

**PMTCT outcomes**

Of 113 infants born to HIV-positive mothers, 9 (8.0%) died within 18 months of birth and a total of 8 (7.1%) tested positive for HIV. A total of 7 (6.2%) infants had unknown HIV status at 18 months. The estimated HIV prevalence among HIV exposed infants at 6 weeks was 2.7% (95% CI 0.6 – 7.6%), table 7. The prevalence increased to 4.7% among infants who were still alive at 18 months (95% CI 1.5%–10%) at 18 months, with 5 additional infants testing HIV positive. This increase was however not statistically significant, difference = 2% (95% CI, -1.2 to 10), p = 0.13.

Table 7 shows the infant infection and mortality infection rates at 6 weeks, 9 months and 18 months respectively among HIV exposed infants at Naivasha District Hospital.
Table 7: Infant HIV infection and mortality rates at 6 weeks, 9 months and 18 months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>6 weeks N=113</th>
<th>9 months N=105</th>
<th>18 months N=104</th>
<th>Total N=113</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV infection</td>
<td>3 (2.7)</td>
<td>1(0.95)</td>
<td>4(3.8)</td>
<td>8(7.1%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>1(0.9)</td>
<td>6(5.7)</td>
<td>2(1.8)</td>
<td>9 (8%)</td>
</tr>
<tr>
<td>HIV free and alive*(N=107)</td>
<td>102(96.2)</td>
<td>95 (89.6)</td>
<td>89(83.96)</td>
<td>89(83.96)</td>
</tr>
</tbody>
</table>

*7 infants excluded from this analysis as their HIV status was unknown

HIV free survival analysis

Out of the 113 HIV exposed infants, 7 (6.2%) had unknown HIV status. This represents the number of infants in whom we were unable to reach for testing out of the 19.2% who had not been tested by the age of 18 months within the PMTCT programme at Naivasha District Hospital PMTCT programme.

Table 8 shows a life table HIV free survival analysis in the 106 HIV exposed infants whose HIV status is known. We analyze survival of mortality and HIV infection.

Table 8: Life table showing 18 month HIV free analysis of 106 HIV exposed infants at Naivasha District Hospital

<table>
<thead>
<tr>
<th>Time (months) since birth</th>
<th>Number alive at beginning of interval</th>
<th>Events* during interval</th>
<th>Number at risk</th>
<th>Chance of surviving interval</th>
<th>Risk of event</th>
<th>Cumulative HIV free survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2</td>
<td>106</td>
<td>3</td>
<td>106</td>
<td>0.9717</td>
<td>0.0161</td>
<td>0.9717</td>
</tr>
<tr>
<td>3 to 5</td>
<td>103</td>
<td>1</td>
<td>103</td>
<td>0.9623</td>
<td>0.0185</td>
<td>0.9623</td>
</tr>
<tr>
<td>6 to 8</td>
<td>102</td>
<td>3</td>
<td>102</td>
<td>0.934</td>
<td>0.0241</td>
<td>0.943</td>
</tr>
<tr>
<td>9 to 11</td>
<td>99</td>
<td>3</td>
<td>99</td>
<td>0.9057</td>
<td>0.0284</td>
<td>0.9057</td>
</tr>
<tr>
<td>12 to 14</td>
<td>96</td>
<td>1</td>
<td>96</td>
<td>0.8962</td>
<td>0.0296</td>
<td>0.8962</td>
</tr>
</tbody>
</table>
The highest risks of event (turning HIV positive or death) were experienced at ages 15 to 19 months followed by 12 to 14 months. From the life table above we see that the cumulative risk of HIV infection and/or death was 16%.

The cumulative survival at 18 months in HIV exposed infants at Naivasha DH, regardless of HIV status, was 92% whereas the HIV free survival was 83.9% as presented in figure 5 below. This graph compares the cumulative survival among HIV exposed infants to the HIV free survival.

Figure 5: Survival curves for HIV exposed infants at Naivasha District Hospital
Figure 6 shows the Kaplan Meier analysis for HIV free survival in the infant cohort.

Figure 6: Kaplan Meier analysis of HIV free survival among HIV exposed infants at Naivasha District

Causes of Death
The overall mortality rate was 8%. The identified causes of deaths occurring within 18 months of birth were pneumonia, gastroenteritis, neonatal sepsis and meningitis (table 9).

Table 9: Causes of mortality among HIV exposed infants at Naivasha District Hospital

<table>
<thead>
<tr>
<th>Causes</th>
<th>N=113</th>
<th>Freq. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia</td>
<td></td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td></td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>Neonatal Sepsis</td>
<td></td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Cardiac Failure</td>
<td></td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>3 (2.7%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>9 (8%)</strong></td>
</tr>
</tbody>
</table>
Associations between PMTCT outcomes and PMTCT interventions

Univariate analysis of PMTCT outcomes and the association with PMTCT interventions is shown in table 10. Infant feeding method showed a statistically significant association with HIV status at 18 months ($p = 0.026$). Up to 50% of the HIV positive children were on mixed feeding compared to 25% of infected children fed either through exclusive or replacement feeding.

Eighteen-month mortality was also significantly associated with infant ARV prophylaxis therapy ($p = 0.003$). Most (44.4%) of the infants who had died by 18 months had been on NVP therapy.
Table 10: HIV infection and mortality by PMTCT interventions

<table>
<thead>
<tr>
<th>PMTCT intervention</th>
<th>HIV Positive by 18 months</th>
<th>P value</th>
<th>Deceased by 18 months</th>
<th>P value</th>
<th>HIV free survival by 18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freq. (%) (N=8)</td>
<td></td>
<td>Freq. (%) (N=9)</td>
<td></td>
<td>Freq. (%) (N=89)</td>
</tr>
<tr>
<td>Knowledge of HIV status and CD4 count before pregnancy (n=39)</td>
<td>1(12.5%)</td>
<td>0.25</td>
<td>3 (33.3%)</td>
<td>1.00</td>
<td>34(38.2%)</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SVD (n = 94)</td>
<td>7(87.5%)</td>
<td>1.00</td>
<td>9(100%)</td>
<td>0.6</td>
<td>77 (86.5%)</td>
</tr>
<tr>
<td>C/S (n = 14)</td>
<td>1(12.5%)</td>
<td></td>
<td>0</td>
<td></td>
<td>12 (13.5%)</td>
</tr>
<tr>
<td>ARV prophylaxis in mother</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triple ARVs</td>
<td>4(50%)</td>
<td></td>
<td>4(44.4%)</td>
<td></td>
<td>25 (28.0%)</td>
</tr>
<tr>
<td>AZT</td>
<td>3(37.5%)</td>
<td></td>
<td>2(22.2%)</td>
<td></td>
<td>57 (64%)</td>
</tr>
<tr>
<td>Sd-NVP</td>
<td>0</td>
<td></td>
<td>1(11.1%)</td>
<td></td>
<td>5 (5.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td></td>
<td>0</td>
<td></td>
<td>5 (5.6%)</td>
</tr>
<tr>
<td>None</td>
<td>0</td>
<td></td>
<td>2(22.2%)</td>
<td></td>
<td>12 (13.4%)</td>
</tr>
<tr>
<td>ARV prophylaxis in infant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NVP</td>
<td>2(25%)</td>
<td>0.65</td>
<td>4(44.4%)</td>
<td>0.003</td>
<td>70 (78.7%)</td>
</tr>
<tr>
<td>AZT +3TCsyrup</td>
<td>5(62.5%)</td>
<td></td>
<td>2(22.2%)</td>
<td></td>
<td>13 (14.6%)</td>
</tr>
<tr>
<td>None</td>
<td>1(12.5%)</td>
<td></td>
<td>3(33.3%)</td>
<td></td>
<td>6 (6.7%)</td>
</tr>
<tr>
<td>Infant Feeding method</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exclusive Breastfeeding (n =60)</td>
<td>2(25%)</td>
<td>0.029</td>
<td>4(44.4%)</td>
<td>0.58</td>
<td>54 (60.7%)</td>
</tr>
<tr>
<td>Mixed feeding (n =21)</td>
<td>4(50%)</td>
<td></td>
<td>3(33.3%)</td>
<td></td>
<td>16 (18.0%)</td>
</tr>
<tr>
<td>Replacement feeding (n = 20)</td>
<td>2(25%)</td>
<td></td>
<td>2(22.2%)</td>
<td></td>
<td>19 (21.3%)</td>
</tr>
</tbody>
</table>

As shown in Table 11 HIV-free survival was associated with knowledge of HIV positive status and CD4 count before pregnancy. Infants whose mothers did not know the CD4 cell count were 17% (Adjusted OR 0.83, 95% CI 0.71-0.96) more likely to die within the first 18 months of life compared to infants born to mothers with knowledge.
Infant feeding practices were also significantly associated with HIV status at 18 months. Infants on mixed feeds were approximately twelve times more likely to turn positive at 18 months compared to exclusively breastfed infants (Adjusted OR 12.26(1.25-120.19).

Table 11: Age adjusted multivariate regression of outcomes of HIV exposed infants by PMTCT interventions

<table>
<thead>
<tr>
<th>PMTCT intervention</th>
<th>HIV Positive by 18 months (N=8) RR (95% CI)</th>
<th>Deceased by 18 months (N=9) RR (95% CI)</th>
<th>HIV free survival by 18 months (N=89) RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of Positive HIV status and CD4 count before pregnancy (N=39)</td>
<td>7.91(0.67-93.32)</td>
<td>1.23(0.23-6.56)</td>
<td>0.83(0.71-0.96)*</td>
</tr>
<tr>
<td>ARV prophylaxis in mother</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triple ARVs (N=29)</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>AZT and sd-NVP (N=65)</td>
<td>3.55(0.56-22.4)</td>
<td>2.32(0.54-9.93)</td>
<td>0.85(0.72-1.01)</td>
</tr>
<tr>
<td>Infant Feeding method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exclusive Breastfeeding (N=60)</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Replacement feeding (N=21)</td>
<td>11.74(0.91-151.69)</td>
<td>0.82(0.09-7.39)</td>
<td>0.85(0.63-1.14)</td>
</tr>
<tr>
<td>Mixed feeding (N=20)</td>
<td><strong>12.26(1.25-120.19)</strong></td>
<td>0.98(0.15-6.25)</td>
<td>0.87(0.66-1.14)</td>
</tr>
</tbody>
</table>

*95% CI do not include 1.00 indicating statistically significant associations
DISCUSSION
This study provides an evaluation of the PMTCT programme at Naivasha District Hospital. We set to determine the effectiveness of the PMTCT programme through outcomes of HIV exposed infants. The overall Mother-to-Child Transmission rate for the programme is 7.1% with a HIV free survival of 83.9%. Bearing this in mind, this discussion tackles rates of uptake of PMTCT interventions among mother-infant pairs enrolled in the study, infant HIV testing, the rates of infant HIV free survival, infant HIV infection and mortality among HIV exposed infants.

For PMTCT programmes to succeed, women must have knowledge of their HIV status. It is preferable that HIV status is known before pregnancy and this forms the basis for the first two prongs of PMTCT: primary prevention of HIV and prevention of unintended pregnancies among HIV infected women. At Naivasha District Hospital in this study, only 39.5% of women enrolled in the PMTCT programme had knowledge of their HIV status and CD4 counts before their last pregnancy while 60.5% had their first HIV test done during the last pregnancy. This shows that HIV testing rates before pregnancy are low and that majority of the women who test for HIV are tested at the Ante-natal clinic. This is comparable to the 2007 Kenya AIDS Indicator Survey (KAIS 2007) findings that of women who had been tested for HIV, 66.1% were tested at the Ante-natal Clinic.

Regarding interventions to reduce transmission of HIV from pregnant and lactating mothers (prong 3), 87.7% of women enrolled in the PMTCT programme at Naivasha District Hospital used ARVs for PMTCT. For virtual elimination of Mother-child transmission of HIV (MTCT rates less than 5%) there should be at least 90% of women who test positive for HIV on ARVs. Therefore, it is necessary to find out if there are barriers to ARV usage among these women and to eliminate these barriers to ensure all women who test positive for HIV not only receive but are adherent to ARVs for prophylaxis. Majority of women on prophylactic ARVs were on Zidovudine monotherapy (59.6%) as is stipulated in the 3rd edition of the PMTCT guidelines of March 2010. The 2nd most common ARV regimen among these women was HAART (29.3%). This exceeds the number of women whose CD4 counts were below 350 (15.3%) which is the cut-off for initiation of triple ARVS (HAART). The surplus may have been on HAART prior to pregnancy or may have been initiated on
HAART because they were in WHO stage 3 or 4. In line with the national PMTCT goal to achieve virtual elimination of MTCT of HIV by 2015, the 4th edition of PMTCT guidelines which were released in 2012, encourage facilities with ability to initiate and monitor patients on HAART to initiate triple ARVs (HAART) for life (uninterrupted) on all HIV positive pregnant mothers regardless of their WHO clinical stage or CD4 count in order to attain maximal viral load suppression. Naivasha District Hospital can certainly take up this new directive to eliminate mother-to-child-transmission of HIV.

As regards PMTCT interventions in infants, prophylactic ARV usage among HIV exposed infants was higher than maternal ARV usage at 92% and majority of these infants were on Nevirapine (77.8%). Co-trimoxazole prophylaxis among these infants was much lower than ARV prophylaxis at 78.8%. This may be explained by the fact that Nevirapine syrup is given at the time of delivery whereas co-trimoxazole is given at the 6 week visit. Drug stock-outs may have occurred at the 6 week visit, or it may have been omitted while the other activities such as vaccination and DNA polymerase testing were done at this period.

Infant HIV testing practices revealed highest testing rates at 9 months (90.4%) which coincides with measles vaccination in the National Immunization Schedule. It is at this time that those who may have been missed at 6 weeks testing period (HIV DNA testing) could have been captured. Infants who received follow-up Anti-body testing at 18 months were 80.4%. We managed to test 13% of the 19.2% who had not been tested by the 18 month of life because we approached mothers enrolled for care at the CCC at Naivasha District Hospital. Attrition along the PMTCT cascade needs to be addressed in Naivasha District Hospital. One way to address it is by integration of PMTCT services within the other services in the Maternal and Child Health Clinic such as immunization, such as is seen with the 9 month HIV testing rates. Secondly, is to track down infants lost to follow up in the PMTCT programme. Mothers enrolled at CCC can be used for tracing these infants when they come for routine HIV care and ARV refill. Other ways include defaulter tracing using telephone contacts and/or community health workers. Through the study we were able to reduce the number of infants not tested for HIV at 18 months from 19.2% to 6.2% using telephone for inviting mothers and infants to the health facility for testing.

Infant feeding practices showed a higher prevalence of exclusive breastfeeding in this population of HIV exposed infants at Naivasha District at 55.8% than the country prevalence which is 32% from the 2008 Kenya Demographic Health Survey. There were high rates of
mixed feeding-21.2% and these infants were 12 times more likely to turn HIV positive than infants who were exclusively breastfeed. This is higher than what Bobat et al\textsuperscript{23} found in South Africa in 1997 where mixed fed infants were approximately 1.5 times more likely to turn positive-an additional 9.5% MTCT rate was conferred by breastfeeding (MTCT rates among infants exclusively breastfed was 14.6% versus 24.1% for mixed feed infants). Illif et al in Zimbabwe\textsuperscript{24} (the ZVITAMBO study) found that mixed feeding was associated with a fourfold rise in post-natal transmission of HIV and threefold increase in the risk of postnatal transmission plus death at 6 months compared with exclusive breastfeeding. Cumulative risks of HIV transmission/death at 18 months in Naivasha District Hospital was 16%. This is comparable to the Kisumu breastfeeding\textsuperscript{25} which was 15.7% at 18 months among infants whose mothers were on Zidovudine and whose infants used Nevirapine. The 6 week and 18 month MTCT rates of 2.7% and 7.1% respectively seen at Naivasha District Hospital are close to those seen in the Kisumu Breastfeeding study among this same group of mother-infant pairs which were 4.2% and 7.0% respectively.

The risks of mortality and HIV infection were higher after 6 months, which is the period during and after weaning. Possible explanations for this could be the abrupt weaning and cessation of breastfeeding at 6 months therefore withdrawal of protective maternal antibodies and for those who do continue breastfeeding it could be due to the dilution of these protective maternal antibodies once they begin complementary feeds.

Infants whose mothers had knowledge of HIV status and CD4 counts before pregnancy were more likely to survive within the first 18 months of life than mothers who did. Possible explanations for this is that these women have had the opportunity to be enrolled in care and where necessary have had ARVs initiated to suppress viral load. They are also more likely to have received more information on ways to reduce HIV transmission to their infants and also prolong survival in their infants due the fact that they are privileged to frequent health facilities more and benefit from health talks and counseling because they are enrolled in HIV clinics for care and follow up.

The causes of mortality are similar to the major causes of childhood mortality and are pneumonia, gastroenteritis and neonatal sepsis. One infant was reported to have died from cardiac failure. It is not known if this was developed from a concurrent respiratory tract infection or from an intrinsic cardiac defect. This is one of the limitations of verbal autopsy we experienced. 2.7% of mortality had unknown causes as the primary caregivers were not
present at the time the infants succumbed and could not provide information on circumstances surrounding death.

The MTCT transmission rates are higher than that which is required to have virtual elimination of Mother-to-child Transmission of HIV. In order to bring these rates to less than 5%, the programme must ensure that at least 90% of mothers and infants enrolled use ARVS for treatment or PMTCT. In addition, for enhanced survival in infants mothers should be encouraged to exclusively breastfeed their infants for the first 6 months of life and to continue to do so for up to 1 year.

CONCLUSIONS

1. In this study, 83.96% of infants born to HIV positive women enrolled in the PMTCT programme at Naivasha District Hospital survived both death and HIV infection. This gives a cumulative risk of HIV infection and death at 16%. The infant HIV infection rate of 7.1% is above that required for virtual elimination of mother to child transmission of HIV.

2. The PMTCT intervention uptake with specific reference to ARV usage for PMTCT shows higher uptake in infants than in mothers. However, the uptake of ARVs in mothers falls below targets required for virtual elimination of mother to child transmission of HIV despite the fact that it meets the targets set in the 3rd Kenya National AIDS Strategic Plan.

3. Infant HIV testing rates are highest at 9 months with most HIV infection occurring between 6 weeks and 18 months, coinciding with breast milk transmission. A fifth of infants born to HIV positive mothers enrolled in the PMTCT programme at Naivasha DH are lost to follow up.

4. Major causes of mortality among HIV exposed infants at Naivasha District Hospital are Pneumonia, Gastroenteritis, Neonatal Sepsis and Cardiac Failure.

RECOMMENDATIONS

1. We need to address the sub-optimal ARV coverage among HIV positive women and their infants by identifying barriers to ARVs usage in these groups and eliminating these barriers.
2. We should encourage safe breastfeeding practices at Naivasha District Hospital by ensuring all HIV positive lactating women are on ARVs for prophylaxis or treatment and counseling them on the importance of exclusive breastfeeding of their infants for the first 6 months of life. Mixed feeding should be highly discouraged in our counseling. Mothers should also be counseled on proper weaning practices and encouraged to breastfeed their infants until they are 1 year to enhance infant survival.

3. We need to trace infants lost to follow up in the PMTCT service cascade. This can be aided by approaching their mothers who frequent the Hospital CCC for their own HIV care.

**STUDY LIMITATIONS**

Self-reported data is susceptible to recall and reporting biases. To overcome these biases, we used maternal and infant health records to cross check information gathered from mothers.

Retrospective studies rely heavily on complete records. Incomplete records may present a challenge in data collection. To enable us to get adequate information even with incomplete records we held corroborative interviews with mothers. We also reviewed other registers in the pharmacy department and maternal and child health clinic.

Missing contact information and incorrect contact information presented a challenge in tracking down mothers who were lost to follow up.

Due to the lack of information on 87 mothers who tested positive for HIV in the year 2010, the study findings cannot be generalizable to all women who tested positive for HIV in 2010 but only to those who were enrolled for PMTCT at Naivasha District Hospital.
REFERENCES:

2. UNAIDS Global Report 2010
10. The Kenya National AIDS Strategic Plan III


APPENDIX I: WHO CLINICAL STAGING OF HIV

Primary HIV infection

Unrecognized/Acute Retroviral Syndrome

Stage 1

Asymptomatic

Persistent generalized lymphadenopathy

Stage 2

Unexplained moderate weight loss (< 10% of body weight)

Recurrent upper respiratory infections (current event plus one in the last 6 months)

Herpes zoster

Angular cheilitis

Recurrent oral ulceration (2 or more episodes in last 6 months)

Papular pruritic eruption

Seborrhoeic dermatitis

Fungal nail infection

Stage 3

Unexplained severe weight loss (> 10% body weight)

Unexplained chronic diarrhea longer than one month

Unexplained persistent fever (i.e. above 37.6°C intermittent or constant lasting > 1 month)

Persistent oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis
Severe bacterial infections (pneumonia, pyomyositis, empyema, bone and joint infections, meningitis or bacteremia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Unexplained anaemia < 8g/dl, neutropenia < 0.5 * 10⁹ per litre and chronic thrombocytopenia < 50*10⁹/litre

Stage 4

HIV wasting syndrome

Pneumocytis pneumonia

Recurrent severe bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital, anorectal of more than 1 month duration or visceral at any site

Esophageal candidiasis or candidiasis of the trachea, bronchi or lungs

Extra pulmonary tuberculosis

Kaposi’s sarcoma

Cytomegalovirus infection (retinitis, or infection of other organs)

CNS toxoplasmosis

HIV encephalopathy

Extra pulmonary cryptococcosis including meningitis

Disseminated non tuberculous mycobacterial infection

Progressive multifocal leukoencephalopathy

Chronic cryptosporidiosis (with diarrhea)

Chronic isosporiasis

Disseminated mycosis (coccidiomycosis and histoplasmosis)

Recurrent non typhoidal salmonella bacteremia

Lymphoma (cerebral or B cell non Hodgkin) or other solid HIV assoc tumors
Invasive cervical carcinoma
Disseminated atypical leishmaniasis
Symptomatic HIV assoc nephropathy or symptomatic HIV associated cardiomyopathy

APPENDIX II: QUESTIONNAIRE
To be used in interviewing mothers or guardians of HIV exposed infants where mothers are deceased. Utilize records in addition.

Part I: MOTHER
Socio-demographic Data of Mother

Study Code: _______________

Hospital Number: _______________

Section A: Socio-demographics

1. Age: _______________ years

2. Number of years of education __________

3. Level of education
   o Primary school
   o Secondary school
   o College/University
   o None

4. Marital status
   o Single
   o married
   o Separated/divorced
   o Widowed
Section B: Knowledge about HIV status self and partner

5. If married, is your partner aware of your HIV status?
   o Yes
   o No

Partner HIV status
   o Positive
   o Negative
   o Not done
   N/A

6. Where were you tested for HIV?
   o At ANC visits during pregnancy with this child
   o At ANC visits during a previous pregnancy
   o At a VCT center before I fell pregnant
   o At hospital when my child fell ill
   o In a hospital ward when I fell ill before pregnancy
   o Other, please specify _________________________

7. How long have you lived with HIV? __________

Section C: Pregnancy intention
8. Are you currently pregnant?
   o Yes
   o No

9. If you are not pregnant, are you on any family planning method?
   o Yes
   o No

10. If please state method

    Method
    o Injectable – depo provera
    o Permanent methods-Tubal ligation, husband had a vasectomy
    o Oral contraceptive pills
    o Implants
    o IUCD
    o Condoms
    o Herbal
    o Dual method (any of the above in addition to condoms)
    o Other, please specify __________________________

11. If no, why not? __________________________

    Use the codes

    1. Fear of side effects
    2. I am currently not sexually active
    3. My partner is reluctant for me to use it
    4. Other __________________________
12. Did you the plan pregnancy with this infant?
   - Yes
   - No

13. Before knowing your HIV status, were you on FP?
   - Yes
   - No

14. How has knowledge of positive HIV status affected your Family planning decisions?
   1. I now use family planning to prevent pregnancy and didn’t before
   2. I now use condoms in addition to other methods
   3. It had not made any difference
   4. Other __________________________

15. Do you desire to have more children?
   - Yes
   - No

16. Do you know what your husband would feel about another pregnancy?
   - Yes
   - No

17. Have you discussed intentions to have another pregnancy with your husband?
   - Yes
   - NO

18. Have you received any advice from hospital on steps to take before you fall pregnant?
Yes

No

If yes, please specify

Use the codes below:

1. Take ARVs until CD4 counts are above 500

2. Come to hospital and have CD4 counts taken before considering falling pregnant

3. Have the doctor examine you and determine you are healthy enough to fall pregnant

4. Other

19. How has knowledge of your HIV status affected your desires for having children

Use the codes below

1. I don’t desire any more children now

2. I fear falling pregnant because of transmission of HIV to my child

3. It has not made any difference

4. Other

Section D: Care before pregnancy

20. Did you have CD4 counts loads taken before your last pregnancy?

Yes

No

If yes, what was the CD count?

a. ______/mm3

Did you have viral load taken before your last pregnancy?

Yes

No
III. If yes, what was the viral load ____________ copies/mm^3

21. Have you had your CD4 count taken after pregnancy?
   If yes, please state the new level ______________

22. Were you advised on any measures you need to take before getting pregnant when living with HIV/AIDS?
   o Yes
   o No

23. Did you attend antenatal care clinic
   a. Yes
   b. No
      If yes, where, how many visits

   How many times did you attend ANC in the pregnancy with your infant? __________

24. Where did you attend ANC?
   o Dispensary
   o Health Centre
   o Naivasha District Hospital
   o Private hospital
   o Other

25. Did you receive any counseling about how to prevent HIV infection in your infant during your ANC visits?
   o Yes
   o No

26. Were you counseled on how to feed your infant?
27. I. Were you on ARVs prior to pregnancy with this infant? Place in right place

- Yes
- No

II. Which regimen?

- AZT+3TC+LPV-r
- AZT+3TC+ABC
- AZT+3TC+EFV
- TDF+XTC+EFV
- AZT+NVP+3TC
- AZT+d4t+NVP
- Other, please specify ________________

28. When were ARV drugs initiated __________

- Before conception
- While attending the ANC
- After delivery of my infant

29. If you were not on ARVS prior to pregnancy, did you take any ARVS during your pregnancy?

- Yes
- No

30. If yes

- during pregnancy
- during labor/delivery
- after delivery for a short period of time
- during breastfeeding

Please specify which ones
31. When in your pregnancy did you begin to take ARVs? ____ weeks

32. Did you have any illness during your pregnancy?
   
   o Yes
   
   o no

   If yes specify

   o TB
   
   o UTI
   
   o STI
   
   o Malaria
   
   o Other, please specify ________________

   If yes, were you hospitalized?

   o Yes
   
   o No

33. Were you counseled on place of delivery?

   o Yes
   
   o No

34. When was the date of delivery _____________

35. When was the EDD _______________
36. Where did you deliver (place of delivery)

- Public health facility
- Private health facility
- Home
37. How did you deliver your child?

- Normal Delivery
- Elective C/S
- Emergency C/S
- Assisted delivery (use of forceps, vacuum)

If C/S reason for operation

- Complicated delivery
- Had a previous C/S
- Planned for PMTCT purposes
- Planned before delivery for other obstetric reasons besides PMTCT or previous C/S

38. For mothers who delivered via emergency C/S or via normal delivery, how long did labour pains last until time of delivery? _________

39. Did your water break before delivery of your child?

- Yes
- No

   If yes, what was the duration between your water breaking (drainage of liquor) and delivery of your child? _________

40. Did you experience any complications during delivery?

- Yes
- No

41. Please choose complication experienced.

1. Perineal tear
2. Severe bleeding after delivery-requiring fluids or blood transfusion
3. Retained placenta

4. Other ___________________

PART II: INFANT

Information to be obtained from mother and infant health records
42. Is infant alive?
   - Yes
   - No

   If infant is deceased, at what age did infant die?
   - Less than 60 days
   - 2 months-6 months
   - 6-12 months
   - 12-18 months

43. Gender of infant
   - Male
   - Female

44. Current Age of infant  

45. What was the child’s birth weight?  

46. Did you child receive ARVs after delivery?
   - Yes
   - No.

47. If yes when were the drugs started?  

48. What drugs were given?
   - NVP syrup
   - AZT syrup
   - AZT+3TC

49. Is child still taking drugs?
50. Has your child tested for HIV?
   - Yes
   - No

51. If yes, what is the HIV test result
   - negative
   - positive
   - no result

52. If positive, has CD4 been done?
   - Yes
   - No

53. If CD4 test done, please state the result ___________

54. Is child on ARVs for treatment?
   - Yes
   - No

55. If on treatment, please state drugs given
   - AZT, 3TC, NVP
   - AZT, 3TC, LPV/R
   - ABC, 3TC, NVP
   - ABC, 3TC, LPV/R
   - Other ________________
56. Apart from ARVs did your infant take any other medication?

- yes
- no

If yes, please specify

- Septrin
- Multi-vitamins
- Other, please specify ________________

57. When were these other medications started? ________________

58. Did you breastfeed your child?

- Yes
- No

59. How long did you breastfeed your baby without addition of any other fluids such as water?________

60. When did you introduce other feeds to your child’s diet? ________________

61. Please state the method of feeding for your baby’s first 6 months of life

- Breastfeeding only without any other fluid even water
- Breastfeeding with water only
- Breastfeeding sometimes, cow’s milk other times
- Cow’s milk only without breast feeding
- Formula milk only without breast feeding
- Does infant breastfeed after weaning
  - Yes
  - No
  -
62. At what age was DBS (DNA PCR) done? ________________

63. What was the DBS result?
   - Positive
   - Negative

64. Has your child had an HIV antibody test done?
   - Yes
   - No

How many Antibody tests have been done? ________________

Age at 1st HIV antibody test ________________

Age at 2nd and final HIV antibody test ________________

65. What were the results of rapid antibody tests:
   - Positive
   - Negative

Part III: PMTCT Cascade checklist (as verification from documents/record)
Using mother and baby’s health records where information is not gotten from interview and code as follows:

Code as follows: 1=yes, 2=no,

For questions 1-9 use ANC visits 1=1st visit 2=2nd visit 3=3rd visit 4=from 4th onwards

Gestational age at which mother was enrolled into PMTCT ________________

HIV status of the infant ________________

PMTCT CASCADE CHECKLIST

<table>
<thead>
<tr>
<th>PMTCT intervention</th>
<th>Received</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. HIV testing and counseling during ANC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Received results on the same day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>WHO staging done</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>CD4 counts done</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Provision of preventive ARVs</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Counseled on infant feeding</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Counseled on FP for PMTCT</td>
<td></td>
</tr>
</tbody>
</table>
| 8. | Delivery of infant in hospital  
(others column: 1=C/S, 2=normal delivery, 3=assisted delivery) |
| 9. | Took ARVs during labour  
(others column: 1=HAART 2=AZT+3TC 3=others) |
| 10. | Took ARVs post-partum  
(others column: 1=HAART 2=AZT+3TC for 1 week, 3=others) |
| 11. | ARV prophylaxis in infant  
(others column: 1=NVP syrup until 6 months, 2=NVP until cessation of breastfeeding, 3=AZT for 6 months) |
| 12. | Infant on septrin  
(for others column 1=appropriate dosage 2=overdose 3=under dose) |
| 13. | Mode of infant feeding  
(others column: 1=exclusive breastfeeding 2=mixed feeding, 3=complementary feeding) |
| 14. | Attendance of scheduled visits for mother  
(others column write it as a fraction e.g. 14/15) |
| 15. | Attendance of scheduled visits for infant  
(others column: write as a fraction) |
| 16. | HIV testing in infant at 6 weeks  
(for others column: 1=done on schedule 6-8 weeks, 2=above 8 weeks) |
| 17. | Results of PCR received  
(for others column: 1=within 2 weeks 2=received in 3-4 weeks 3=above 4 weeks later) |
| 18. | Mother currently on family planning |

**Part IV: Verbal autopsy**
For those whose infants who are deceased

Was DNA PCR done?

- Yes
- No

If yes, what was the result?

- Positive
- Negative

What were symptoms in child prior to death or diagnosis of child prior to death?

____________________________________________________

____________________________________________________

Code:

A: AIDS-like symptoms: severe wasting, recurrent pneumonias, oral thrush, failure to thrive, delayed milestones

B: Pneumonia: cough, difficulty in breathing, nasal flaring

C: Gastroenteritis: diarrhea, vomiting

D: Meningitis: convulsions, fever, loss of consciousness

E: Malaria: fever, history of travel, convulsions, pallor, anemia, positive blood slide

F: Malnutrition: severe wasting with or without oedema, frequent infection

G: TB: cough for longer than 2 weeks, night sweats, fever, history of contact with PTB, severe wasting, failure to thrive

H: Other: ___________________

Part V: Loss to follow up

For mothers who ceased to attend PMTCT programme.

Timing of loss to follow up ___________________
o During pregnancy
o Within 6 weeks of delivery
o After DNA PCR testing

Was child born in a health facility?
  o Yes
  o No

Has child received vaccinations?
  o Yes
  o No

Are vaccinations received on schedule?
  o Yes
  o No

If no, please list vaccinations missed_____________________

Use the code below
  o BCG at birth
  o Polio at birth
  o Pentavalent 1-DTP, Hib, HBV, Oral polio
  o Pentavalent 2, Oral polio
  o Pentavalent 3, Polio
  o Measles
  o Pneumococcal

What are the reasons for loss to follow up?
  o Infant deceased
APPENDIX IIIA: ENGLISH INFORMED CONSENT FORM

**Title:** Effectiveness of PMTCT at Naivasha District Hospital: outcomes of HIV exposed infants

**Investigator:** Dr. E. Wangui Kamau

**Supervisors:** Dr. Donald Oyatsi and Prof. Elizabeth Maleche Obimbo

**Investigator Note:** Thank you for agreeing to read this form. It offers information about this study which will help you decide if you will take part in this study or not. Appropriate translation will be carried out in the language you are most comfortable with.

**Introduction:** Prevention of mother to child transmission is very important. If these programmes are implemented and adhered to they can eliminate HIV in children. This study aims at finding out how effective PMTCT is in Naivasha District Hospital using the outcomes of infants born to women who enrolled in the PMTCT programme there.

**Procedure:** If you agree to be part of this study, I will ask you personal questions, some of which may be sensitive, about some of the PMTCT interventions you went through, since the time you were enrolled in the PMTCT programme at Naivasha District Hospital. I will also look at your Mother and Child Welfare Booklet, and child’s records to assist in collecting this information.
**Benefits:** Findings of this study will be interpreted to you, the hospital management team and the University of Nairobi. This will help those involved in PMTCT programme to improve the quality of the programme. We will provide you with nutritional assessment and nutritional counseling for your baby.

**Confidentiality:** If you agree to be part of this study, the information you give will be held in strict confidence and only used for the purpose of the study.

**Reassurance:** The management of your child will in no way affected by your decision to decline or to participate in this study. The cost will in no way change through this study. At any time you are free to drop out of the study without penalty.

**Ethical consideration:** I have been granted approval from the Research and Ethics Committees to conduct this study.

I confirm that I have explained the study to the participant and answered any questions and concerns.

Investigator’s signature

Inquiries on ethical considerations can be gotten from:

Prof. A.N. Guantai,
Secretary, KNH/UON-ERC,
Kenyatta National Hospital,
Hospital Rd, along Ngong Rd,
P.O.Box 20723, Nairobi
Tel: (020) 726300-9
Fax: 725272

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumbprint in the space provided below.

I confirm that the study has been fully explained to me and I give full consent to participate in it.
Signature/thumbprint________________________________________

Investigator's signature____________________________________
APPENDIX IIIB: KISWAHILI INFORMED CONSENT FORM
Fomu ya Idhini

Kichwa: Ufanisi wa PMTCT katika Naivasha matokeo Hospitali ya Wilaya ya Naivasha: kupitia wazi watoto wachanga

Mpelelezi: Dr E. Wangui Kamau

Wasimamizi: Dr Donald Oyatsi na Prof Elizabeth Maleche Obimbo

Mpelelezi angependa kukushukuru kwa wakati wako na kumpa nafasi ya kusoma fomu hii. Fomu hii itakupa maelezo kuhusu utafiti huu ambayo itakusaidia kuamua kama utahusika katika utafiti huu. Usiopelewa lugh hii, utatafsiriwa katika ile lugha ambayo unaelewa.


Utaratibu: Kama utakubali kuwa sehemu ya utafiti huu, nitakuuliza maswali, mengine yatakuwa nyeti, kuhusu baadhi ya hatua za PMTCT ambazo ulipita tangu wakati ambao uliandikishwa katika programmeu hii ya PMTCT. Maswali haya yatachukua muda ya dakika ishirini tu.

Matokeo ya faida: Utafiti huu kufasiriwa kwa wewe, timu ya usimamizi ya hospitali ya Naivasha and pia Chuo Kikuu cha Nairobi. Hii itasaidia wale wanaohusika katika mpango wa PMTCT kuboresha ubora wa mpango huu. Tutapima kilo ya mwanao na kukupa mawaidha kuhusu vile unavyofaa kumlisha mwanap.

Usiri: Kama utakubali kuwa sehemu ya utafiti huu, taarifa ambayo utatoo utatumiwa katika utafiti huu peke yake na wasiohusika kaatika kuchukua taarifa huu hawatapata kujua taarifa unayotupa. Majina yako hayatatumiwa katika fomu ya taarifa, na yataonekana tu katika fomu ya idhini.

Ningependa kusingatia kuwa matibabu yakono au ya mtoto wako hautaaithrika kutokana na uamuzi wako wa kukataa au kushiriki katika utafiti huu. Umepewa uhuru na nafasi ya
kuacha kuhusika katika utafiti huu bila gharama yoyote wakati wowote utafiti huu una poendelea.

Mimi mpelelezi wa utafiti huu ninathibitisha kuwa nimemwelezea mhusika wa utafiti huu kwa ukamilifu kuhusu kuhusika kwa utafiti.

Sahihi ________________________________

Nimepewa kibali kutoka Utafiti na Kamati za Maadili ya Kituo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta ya kufanya utafiti huu. Maoni juu ya masuala ya kimaadili inaweza kupatikana kutoka:

Prof. A.N. Guantai,
Katibu, KNH/UON-ERC,
Hospitali kuu ya Kenyatta,
Hospital Rd, karibu na Ngong Rd,
S.L.P. 20723, Nairobi

Nambari ya simu: (020) 726300-9

Fax: 725272

Kuonyesha ya kwamba umeelewa hali ya utafiti huu na umetupatia ridhaa ya kushiriki katika utafiti huu, tafadhali saini au weka kidole chako katika nafasi iliyotolewa hapo chini:

Mimi ninathibitisha kuwa utafiti huu umeelezwa kwangu mimi vizuri na ninaitikiea na kupeana ridhaa ya kuhusika katika utafiti huu

Sahihi yangu au kidole cha sahihi ________________________________

Sahihi ya mpelelezi ________________________________

Tarehe ________________________________

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# HIV Exposed Infant (HEI) Follow-up Card

**MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES**

**OCTOBER, 2010**

**INFANT PROFILE**

- **HEI ID Number**
- **NAME (FIRST, MIDDLE, LAST)**
- **SEX: M ☐ F ☐**
- **Date of Birth:** /
- **Birth Wt. (kg):**
- **Date of Enrollment:**  
  - **Age of Enrollment:**
- **Source of Referral:**  
  - Paediatric Ward ☐  
  - OPD ☐  
  - Maternity ☐  
  - CCC ☐  
  - MCHPMTCT ☐  
  - Other Specify ☐
- **ARV Prophylaxis:**  
  - Sd NVP only ☐  
  - NVP for 6 weeks (mother on HAART or No BF) ☐  
  - Sd NVP + AZT + 3TC ☐  
  - NVP during breastfeeding ☐  
  - None / Other (Specify) ☐
- **History of TB Contact in Household?**  
  - Yes ☐  
  - No ☐  
  - If "YES", Screen for TB, and Appropriately refer for HIV prophylaxis ☐

**PARENT PROFILE**

- **Name of Mother**
- **Alive?**  
  - Yes ☐  
  - No ☐
- **Mother received Drugs for PMTCT?**  
  - Yes ☐  
  - No ☐
- **If Yes, Selected Drug Combination**  
  - Sd NVP Only ☐  
  - AZT + NVP ☐  
  - AZT + 3TC ☐  
  - Interruped HAART ☐  
  - HAART ☐  
  - None / Other (Specify) ☐
- **on ART at Enrollment of Infant?**  
  - Yes ☐  
  - No ☐
- **If "YES" Enter Regimen:**
- **Mode of Delivery:**  
  - SVD ☐  
  - C-section ☐
- **Place of Delivery:**  
  - Facility ☐  
  - Home ☐

**IMMUNISATION HISTORY**

- **BCG** ☐  
- **OPV / Penta 1** ☐  
- **OPV / Penta 2** ☐  
- **OPV / Penta 3** ☐  
- **Measles 6 Mths** ☐  
- **Measles 9 mths** ☐  
- **Pneumococal** ☐

**LABORATORY INFORMATION**

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Date of Test</th>
<th>Results</th>
<th>DBS Sample Code</th>
<th>Date Results Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st PCR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat PCR (For Rejections)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st Antibody @ 8 mths</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirmatory PCR, if AB ++</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat PCR (For Rejections)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Antibody @ 16 mths</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PATIENT LOCATOR**

- **Address 1:**  
  - Current ☐  
  - Permanent ☐
- **Parent:**  
  - Guardian ☐
- **Address 2:**  
  - Current ☐  
  - Permanent ☐
- **Parent:**  
  - Guardian ☐

- **Name:**
- **Telephone Number:**
- **District:**
- **Division:**
- **Location:**
- **Estate / Village:**
- **House No:**
- **SubChief's Name:**
- **Landmark:** (e.g School / Church / Mosque)

---

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## APPENDIX V: BUDGET

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>CHARGES</th>
<th>NUMBER</th>
<th>OTHER DETAILS</th>
<th>TOTAL COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESEARCH ASSISTANT</td>
<td>500/-</td>
<td>60 DAYS</td>
<td>WILL REQUIRE 2 MONTHS TO COMPLETE DATA COLLECTION</td>
<td>30,000</td>
</tr>
<tr>
<td>DATA ENTRY CLERK</td>
<td>300/-</td>
<td>60 DAYS</td>
<td></td>
<td>18,000</td>
</tr>
<tr>
<td>TRANSPORT FOR PRINCIPAL INVESTIGATOR</td>
<td>500/-</td>
<td>40 DAYS</td>
<td>TO SUPERVISE AND CONDUCT INTERVIEWS</td>
<td>20,000</td>
</tr>
<tr>
<td>STATIONERY</td>
<td>50/-</td>
<td>150</td>
<td>PRINTING AND PHOTOCOPYING QUESTIONNAIRES</td>
<td>7,500</td>
</tr>
<tr>
<td>PHONE CALLS AND COMMUNICATION</td>
<td>5,000</td>
<td></td>
<td>FOR PRINCIPAL INVESTIGATOR TO KEEP IN TOUCH WITH RESEARCH ASSISTANT</td>
<td>5,000</td>
</tr>
<tr>
<td>MISCELLANEOUS</td>
<td></td>
<td></td>
<td></td>
<td>15,000</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>96500</strong></td>
</tr>
</tbody>
</table>

SOURCE OF FUNDING: MEPI GRANT
APPENDIX VI: KNH/UON-ERC APPROVAL LETTER

Dear Dr. Kamau,

Research proposal: "Effectiveness of PMTCT at Naivasha District Hospital: Outcomes of HIV exposed infants (P115/03/2012)"

This is to inform you that the KNH/UoN-Ethics & Research Committee (ERC) has reviewed and approved your above cited research proposal. The approval period is 4th May 2012 to 3rd May 2013.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN-ERC website www.uonbi.ac.ke/activities/KNH/UoN