The Kabeho Study:
Kigali Antiretroviral and Breastfeeding Assessment for the Elimination of HIV

AIDSFree Webinar: Viral Load Monitoring in Pregnancy & The Postpartum Period
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Kabeho Study: Kigali Antiretroviral and Breastfeeding Assessment for the Elimination of HIV

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Introduction

• Primary Aim: To evaluate the overall 18- and 24-month, HIV-free survival in Rwanda’s Option B+ PMTCT program in a cohort of 608 HIV-positive pregnant/postpartum women and their infants in Kigali, Rwanda
  • Enrolled in the third trimester of pregnancy or within two weeks post-delivery
  • Last 24 month follow-up completed in May 2016

• The study also determined:
  • birth outcomes; including stillbirths, prematurity, low birth weight, and gross congenital anomalies
  • nutritional outcomes; as defined by lack of stunting, underweight, or wasting
  • adherence to ARVs among pregnant and postpartum women and their HIV-exposed children

• Methodology: Facility-based, prospective cohort in urban area
Maternal Viral Load and Infant HIV Testing

Maternal viral load (VL)
- Study-specific RNA-PCR testing at enrollment, around delivery, 18 months, and 24 months
- VL detection defined as <20 copies per mL (lower limit of detection with the lab assay)

Early infant diagnosis (EID)
- DNA-PCR testing at birth (retrospective, taken within two weeks) and at six weeks
- Serology testing at 9, 18, and 24 months
- Positive PCR confirmed by a second test

Maternal VL and EID:
- Samples processed at the National Reference Laboratory (NRL) in Kigali
- Conducted using Roche COBAS Ampliprep/TaqMan (V2) quantitative and qualitative tests
Maternal VL at enrollment significantly associated with duration of maternal ART

Maternal viral load at 24 months postpartum (70% available only): 78% <20 c/ml; 91% < 1000 c/ml
Factors associated with detectable VL ( >20 copies RNA/mL) at enrollment

• Logistic regression using GEE (n=603)

• Women were more likely to have a detectable VL if they:
  • Had no education (AOR=2.35, 95% CI: 1.37, 4.02)
  • Reported side effects in the past month (AOR=1.95, 95% CI: 1.38, 2.76)
  • Had been on ART less than four months
    • Compared to ART exposure ranging from 3.93 (95% CI: 2.59, 5.95) for those on ART for more than 3 years to 6.31 (95% CI: 3.03, 13.12) for those on ART 1-2 years.

• Adherence was not a significant predictor of detectable VL in our logit model
Follow-up of Kabeho study infants

Women enrolled in the cohort = 608

Women at delivery = 600

Live-born infants born = 597

Children at ~6 weeks = 577 (96.6%)

Children at ~9 months = 547 (91.6%)

Children at ~18 months = 514 (86.1%)

Children at ~24 months = 453 (75.9%)

Women terminated before delivery = 8

Sets of twins = 7
Stillbirths = 10

Live-born infants who died within 2 days of birth = 8
Infants who died between >2 days and 8 weeks = 3
Transferred out of Kabeho sites = 2
Participant withdrawal = 3
LTFU = 4

Infants who died between >8 weeks and 10.5 months = 9
Transferred out of Kabeho sites = 11
LTFU = 10

Infants who died between 10.5 and 19.5 months = 6
Transferred out of Kabeho sites = 21
LTFU = 6

Transferred out of Kabeho sites = 5
Participant withdrawal = 9
LTFU = 47

The Kabeho Study: Kigali Breastfeeding and Antiretroviral Assessment for the Elimination of HIV
### HIV infection, death, HIV-free survival

<table>
<thead>
<tr>
<th>Time of infection/death</th>
<th>Number of Events in Interval (n)</th>
<th>Cumulative Number of Events (n)</th>
<th>Transmission/Death Rate % (95% CI)</th>
<th>Cumulative Survival % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth 1,2 (n=597)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Infection (n=517)</td>
<td>2</td>
<td>2</td>
<td>0.3 (0.08-1.3)</td>
<td>99.7 (98.7-99.9)</td>
</tr>
<tr>
<td>Death (within 2 days)</td>
<td>8</td>
<td>8</td>
<td>1.4 (0.7-2.7)</td>
<td>98.7 (97.3-99.3)</td>
</tr>
<tr>
<td>6 weeks (n=577)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection (n=556)</td>
<td>1</td>
<td>3</td>
<td>0.5 (0.2-1.6)</td>
<td>99.5 (98.4-99.6)</td>
</tr>
<tr>
<td>Death &gt;2 days - 8 weeks</td>
<td>3</td>
<td>11</td>
<td>1.9 (1.0-3.4)</td>
<td>98.1 (96.7-99.0)</td>
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<tr>
<td>9 months (n=547)</td>
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</tr>
<tr>
<td>Infection (n=512)</td>
<td>2</td>
<td>5</td>
<td>0.9 (0.4-2.2)</td>
<td>99.1 (97.8-99.6)</td>
</tr>
<tr>
<td>Death &gt;8 weeks-10.5 months</td>
<td>9</td>
<td>20</td>
<td>3.5 (2.3-5.4)</td>
<td>96.5 (94.6-97.7)</td>
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<tr>
<td>18 months (n=514)</td>
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</tr>
<tr>
<td>Infection (n=454)</td>
<td>0</td>
<td>5</td>
<td>0.9 (0.4-2.2)</td>
<td>99.1 (97.8-99.6)</td>
</tr>
<tr>
<td>Death 10.5-19.5 months</td>
<td>6</td>
<td>26</td>
<td>4.8 (3.3-6.9)</td>
<td>95.3 (93.1-96.8)</td>
</tr>
<tr>
<td>24 months (n=453)</td>
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</tr>
<tr>
<td>Infection (n=416)</td>
<td>1</td>
<td>6</td>
<td><strong>2.2 (0.7-7.0)</strong></td>
<td><strong>97.8 (93.0-99.4)</strong></td>
</tr>
<tr>
<td>Death 19.5-&lt;28.0 months</td>
<td>0</td>
<td>26</td>
<td>4.8 (3.3-6.9)</td>
<td>95.3 (93.1-96.8)</td>
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<td>24-month HIV-free survival</td>
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HIV infection, death, HIV-free survival
In-depth interviews conducted with a subset of cohort women (n=112) whose children were 0-6, 7-12, 13-18, or 21-24 months of age

Trend toward poorer adherence around the time of breastfeeding cessation (when child no longer exposed to HIV)

Mothers of children 13-18 months were least often virally suppressed and had been on ART the longest (though small sample size)
  – Also reported fewest number of factors facilitating their adherence and reported inhibiting factors more frequently than mothers of children 0-6 and 7-12 months

Fewer women with children 21-24 months indicated that they were comfortable with lifelong ART compared to mothers with children at other ages
Conclusions and Lessons Learned

• Low HIV transmission and high HIV-free survival rates can be achieved within national PMTCT programs in breastfeeding populations.

• However, loss to follow-up of HIV-positive women and their exposed infants within MCH/PMTCT services during the two-year postpartum period significantly affects the accuracy of HFS rates and the determination of final HIV status in the child.

• This study showed high rates of viral suppression in women in PMTCT programs, but greater vigilance is needed for those who are on ART for longer durations.

• More attention is needed to ensure results of VL testing are appropriately integrated into PMTCT clinical consultations and suspected treatment failure can be more swiftly addressed in pregnant women.
THANK YOU!

For questions, please contact Michelle Gill: mgill@pedaids.org

For further reading:

24-month HIV-free survival among infants born to HIV-positive women enrolled in Option B+ program in Kigali, Rwanda

Detectable Viral Load in Late Pregnancy among Women in the Rwanda Option B+ PMTCT Program: Enrollment Results from the Kabeho Study

Understanding Antiretroviral Treatment Adherence Among HIV-Positive Women at Four Postpartum Time Intervals: Qualitative Results from the Kabeho Study in Rwanda

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