Evaluating the Impact of Prevention of Mother to Child Transmission of HIV (PMTCT) in Malawi: Piloting an Immunization Clinic-Based Surveillance Approach

Scott Kellerman MD, MPH
Erik Schouten, MD, MSc
Michele Sinunu MPH
Enock Kajawo Diploma ClinMed
Frank Chimbwandira MBBS, MPH
Management Sciences for Health
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Project Goal

Evaluate the effectiveness of prevention of mother-to-child transmission (PMTCT) efforts in reducing vertical HIV transmission in Malawi and generate population-based vertical transmission rates
Project Aims

1. Through appropriate sampling, determine population-based vertical transmission rate of HIV from mother-to-child
2. Determine the rate of participation in PMTCT
3. Develop a Toolkit to communicate practical facilitators and barriers for implementing a routine surveillance system at immunization sites
Background on PMTCT

Without intervention, the estimated transmission rate of HIV from mother to child is between 30% to 35%

- 5% to 10% during pregnancy
- 5% to 20% during labor and delivery
- 5% to 20% during breastfeeding

PMTCT is the primary strategy to reduce vertical transmission of HIV

PMTCT interventions have reduced transmission to <2% in developed countries
Background on PMTCT

PMTCT in Malawi

- Top 10 highest-burden countries in terms of vertical transmission
- Significant progress in scaling up PMTCT services
Methods

Measure vertical transmission rate by collecting dried blood spots (DBS) from infants attending their first immunization visit* scheduled at 6 weeks

- Test DBS with ELISA (maternal seroprevalence)
- Test ELISA+ for PCR (infant seroprevalence)
- Ratio of Ab + to HIV + (Vertical Transmission Rate – VTR)

Inclusion Criteria

- Infants
  - < 3 months of age; first immunization at first immunization clinic visit
- Caregivers; Parent or legal guardian; >17 years of age

*This approach was developed by Dr. Nigel Rollins in South Africa, now with the WHO; references available upon request
Methods

Survey caregivers for information relevant to vertical transmission

- Questions on: health status of mother, ANC, delivery, HIV testing, HIV prophylaxis & treatment

Screening questions at start of survey form
Survey form also prompts to obtain informed consent
Methods

Benefits of this method:

- Dried blood spots (DBS) easy to collect
- One DBS sample sufficient to assess exposure, positivity, & transmission rate
- In settings where immunization rates are high population based estimates of transmission can be acquired
  - We implemented sampling scheme to obtain random sample
- Data collected by existing clinic staff trained to recruit, screen, obtain informed consent, & collect data
Implementation Flow Diagram

All infants attending their first vaccination clinic (< 3 months)

Caregiver invited to participate in PMTCT surveillance project

Caregiver consents to testing infant

Infant heel stick, Caregiver survey

ELISA Pos

DNA PCR

Results returned to caregivers

Caregiver does not consent to testing infant

ELISA Neg
Sampling

• Multi-stage cluster design
  • Stage 1: Sampling districts
    • Purposive selection
  • Stage 2: Sampling health facilities
    • Random selection (some exclusions made)
    • In facilities: consecutive sampling of infant-caregiver pairs who meet the inclusion criteria
Samples collected from 53 health facilities
Target sample size 5,445

- Each facility was given a target sample size based on immunization rates from the previous year

<table>
<thead>
<tr>
<th>District</th>
<th># sites sampled per district</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nkhata Bay</td>
<td>10</td>
</tr>
<tr>
<td>Salima</td>
<td>10</td>
</tr>
<tr>
<td>Mulanje</td>
<td>15</td>
</tr>
<tr>
<td>Zomba</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>53</strong></td>
</tr>
</tbody>
</table>
Implementation

2-day trainings for data collectors
  ▪ 5 trainings total

Data collected over 8 weeks (Sept-Nov 2011)

Supervision visits
  ▪ Every two weeks (4 visits total)
  ▪ Every health facility visited
  ▪ Samples & surveys collected
  ▪ Quality assurance activities conducted
  ▪ Retraining & mentorship provided as needed
Implementation

Laboratory analysis

- DBS samples sent to National HIV Reference Laboratory for ELISA testing
- Samples that tested antibody positive sent to UNC Laboratory in Lilongwe for DNA-PCR testing

Results returned to clinics to be provided to caregivers at infants subsequent immunization

Survey data entry

- Double-entered into a Microsoft Access database
Analysis

Frequencies to characterize the sample

Transmission rate
  - (# HIV positive infants / # exposed infants)

Identify variables associated with HIV transmission

Examine participation in PMTCT by district
Preliminary Results

- Collected complete data from 5,544 caregiver-infant pairs
  - Exceeding target sample size of 5,445 caregiver-infant pairs

Number of samples by district & ELISA positive

<table>
<thead>
<tr>
<th>District</th>
<th>Total (%) N=5,544</th>
<th>ELISA-pos (%) N=794 (14.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nkhata Bay</td>
<td>557 (10.0)</td>
<td>47 (8.4)</td>
</tr>
<tr>
<td>Salima</td>
<td>1,078 (19.4)</td>
<td>112 (10.4)</td>
</tr>
<tr>
<td>Mulanje</td>
<td>1,976 (35.6)</td>
<td>308 (15.6)</td>
</tr>
<tr>
<td>Zomba</td>
<td>1,933 (34.9)</td>
<td>327 (16.9)</td>
</tr>
</tbody>
</table>
Preliminary Results

• Overall Transmission rate of HIV from mother-to-child

<table>
<thead>
<tr>
<th>MTC Transmission Rate [(B)/(A)]</th>
<th>8.3%</th>
</tr>
</thead>
<tbody>
<tr>
<td># ELISA-pos infants (A)</td>
<td>794</td>
</tr>
<tr>
<td># DNA-PCR-pos infants (B)</td>
<td>66</td>
</tr>
</tbody>
</table>
Successes

Close collaboration with local partners

- Solicited input from Ministry partners early & often

Using clinic staff as data collectors worked well

- Supported sustainability & capacity building

Strong likelihood methodology will be replicated & scaled up country-wide

- Through CDC support to the MOH & we have contributed to the development of the protocols
Challenges

Create explicit criteria for selecting data collectors
  ▪ Better to use Health Surveillance Assistants (medical assistants) than Nurses as data collectors

Adapt training & all instructions into Chichewa

Need to identify a process to collect samples from outreach clinics
  ▪ Excluded outreach clinics in this effort, hurts representativeness and sample size

Lab delays
  ▪ Make sure all laboratory terms are explicit in a signed contract prior to data collection
Next Steps

Share results with Community
  - IAS Poster (primary results) & presentation (secondary analysis) accepted; CCABA presentation

Continue data analysis
  - Currently cleaning data & creating variables

Continue to develop the Toolkit

Developing a final report with local collaborators

Peer-reviewed papers should be ready by fall

Dissertation (Michele Sinunu)
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