



# Evaluating the Impact of Prevention of Mother to Child Transmission of HIV

## (PMTCT) in Malawi: Piloting an Immunization Clinic-Based Surveillance Approach

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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
  - ANC sites offering PMTCT: 6% (2005) → 88% (2008)

# 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

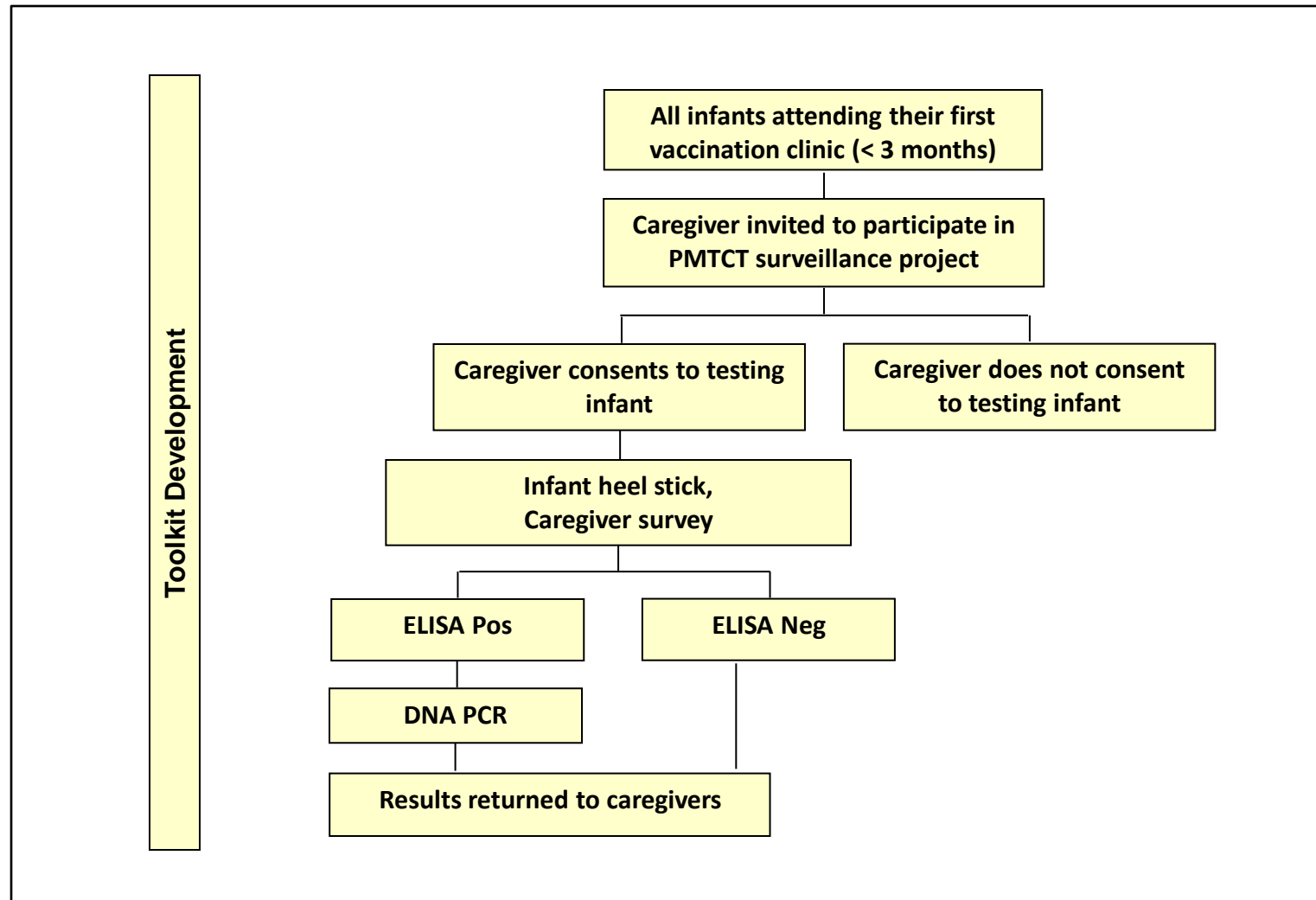
## Benefits of this method:

- 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





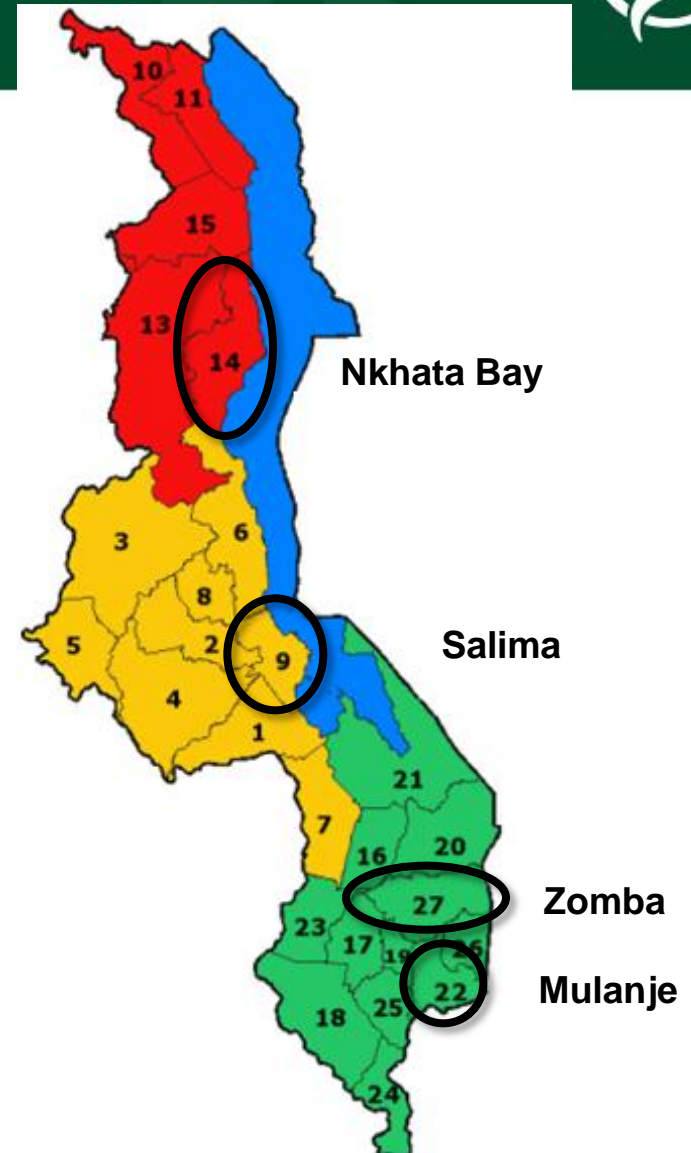
# Implementation Flow Diagram





# 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





# Data Collection

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

District	# sites sampled per district
Nkhata Bay	10
Salima	10
Mulanje	15
Zomba	18
Total	53



# 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

- ( $\# \text{ HIV positive infants} / \# \text{ exposed infants}$ )

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

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



# Preliminary Results

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

<b>MTC Transmission Rate [(B)/(A)]</b>	8.3%
<b># ELISA-pos infants (A)</b>	794
<b># DNA-PCR-pos infants (B)</b>	66





# 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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