Impact of expanded screening and POC on infant diagnosis and ART initiation

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Background

- High incidence among pregnant and breastfeeding women is associated with higher HIV vertical transmission. Furthermore, limited access and long turnaround time of early infant diagnosis can delay ART initiation in children.
- Limited data on Mother To Child Transmission rate and outcomes of infants on treatment since roll-out of Option B+
- We assessed the impact of expanded women/child HIV testing outside PMTCT coupled to the introduction of decentralized near Point of Care early infant diagnosis devices on children diagnosis and ART initiation.

Objectives

- To measure MTCT rate among infants age 6 weeks and 9 months
- Among HIV+ infants, to assess prospectively linkage to care, time to ART initiation and survival
- To measure the proportion of HIV-positive infants virally suppressed 6 months after diagnosis

Methods

Settings and duration This study took place in Ndhiwa, a sub-county of Homa bay county in western Kenya from February 2016 to January 2017. Out of the 33 health facilities providing ART and PMTCT services at the time of the study, 26 were included: 1 hospital, 3 health centers and 22 dispensaries

Design Cross sectional facility-based survey at expanded programs of immunization (EPI) and maternity with prospective home-based and/or facility follow-up of HIV+ infants.

Study population and Inclusion criteria Infants aged 0 (at birth), between 2 to 10 weeks and 8 to 10 months were eligible

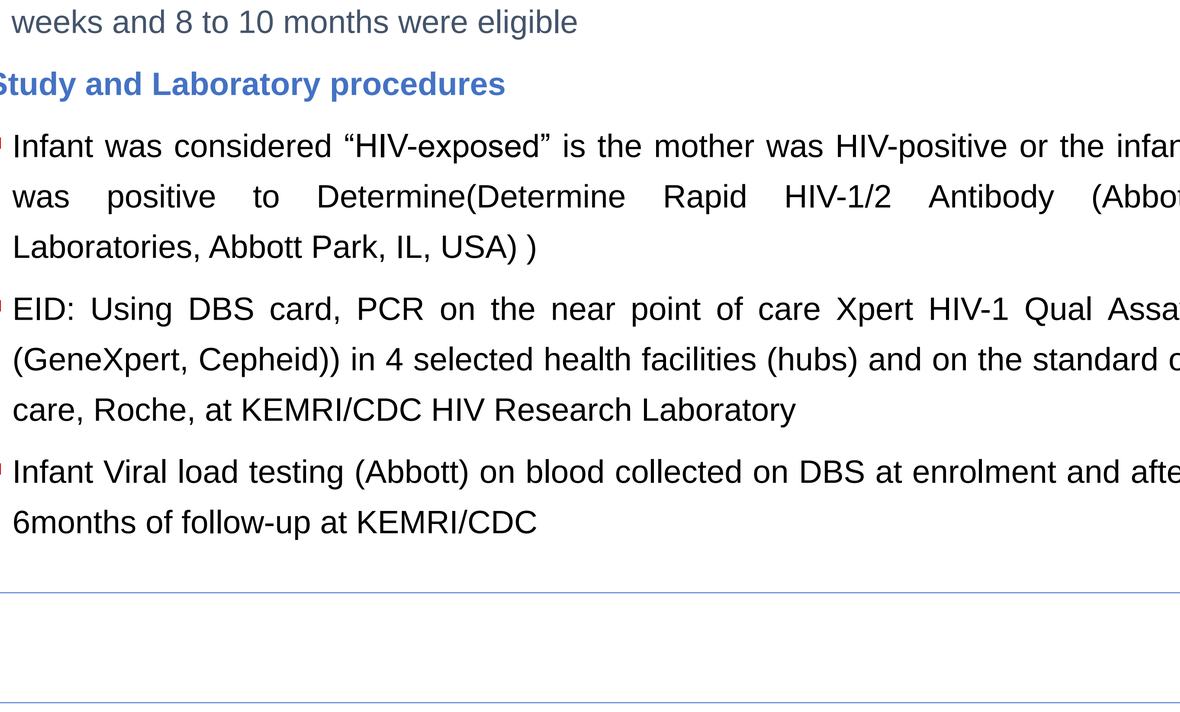
Study and Laboratory procedures

- Infant was considered "HIV-exposed" is the mother was HIV-positive or the infant was positive to Determine(Determine Rapid HIV-1/2 Antibody (Abbott Laboratories, Abbott Park, IL, USA))
- EID: Using DBS card, PCR on the near point of care Xpert HIV-1 Qual Assay (GeneXpert, Cepheid)) in 4 selected health facilities (hubs) and on the standard of care, Roche, at KEMRI/CDC HIV Research Laboratory
- Infant Viral load testing (Abbott) on blood collected on DBS at enrolment and after 6months of follow-up at KEMRI/CDC

Results

A/ Study inclusion, HIV exposure and infection

Figure 1: Inclusion flow chart



- Out of 3,452 infants, 24.7% (95%CI 23.6-26.5) were exposed

B/ Post Natal care among HIV-exposed infants

- Among HIV-exposed children, 89.0% (95%CI 86.7-90.9) received Nevirapine within 48 hours following birth.
- Among 305 HIV exposed children age 9 months, 94.1% (95% CI 90.8-96.3) had received Bactrim from the age of 6 weeks.
- Among the 311 HIV-children age 9 month who should have all been tested for HIV, testing coverage was as follow: 77.1% (95% CI 72.0-81.4) had a previous PCR and 49.2% (95% CI 43.6-54.8) ever received their results.

C/ Mother to Child Transmission rate

Table 1: MTCT rate by mothers' biological characteristics

	Exposed	Infected	MTCT rate
Mother HIV status			
Known positive	818	23	2.8
Newly diagnosed	34	5	14.7
Mother on ART			
Yes	787	18	2.3
No	65	10	15.4
Mother time to ART intiation and Viral Load (cp/mL)			
<1000	**693**	**10**	**1.4**
Before last trimester of pregnancy	568	2	0.3
Last trimester of pregnancy	78	3	3.9
After delivery	35	4	11.4
Never	19	1	5.3
≥1000	**148**	**18**	**12.7**
Before last trimester of pregnancy	76	6	7.9
Last trimester of pregnancy	23	2	8.7
After delivery	9	1	11.1
Never	40	9	22.5
TOTAL	852	28	**3.3**

- Overall MTCT rate among all HIV exposed-children attending EPI and maternity was **3.3% (95%CI 2.3-4.7)** ranging from 2.3% (3/129) in maternity, 3.3% (14/419) at EPI 6 weeks and 3.5% (11/311) at EPI 9 months.
- Time to ART initiation in mothers and mother's viral load was associated with MTCT (p<0.01 each). MTCT was 1.4% and 12.7% among infants whose mother had VL<1000 and ≥1000 cp/mL, respectively. MTCT was even as low as 0.3% among those who achieved a viral load <1,000 cp/mL and initiated ART before the last trimester of pregnancy.
- MTCT increased with time to ART initiation among mothers, from 1.2% among mothers who initiated ART before the last trimester of pregnancy, 4.5% for those who initiated during the last trimester and 11.4% for those who initiated after delivery and 17.0% for those who never initiated.

D/ Time to ART intiation

- Of the 28 children identified, 24 were undiagnosed and had not started ART. More specifically among HIV-exposed infant age 9 months, out of 14 HIV-positive infants, only 4 were diagnosed and on ART and 2 only had a viral load <1,000cp/mL.
- Median time between first test and ART initiation was 34 days [IQR 19-58]. After 2 weeks, 4 weeks, 8 weeks and 12 weeks, the proportion of infants on ART was 21.7%, 43.5%, 82.6% and 100%, respectively.
- A total of three infants died and one was transferred out before the end of the study. Two infants died after the 2nd monthly follow-up visit and a 3rd infant died after the 4th follow-up visit (2 of the infants who died were already on treatment).
- Six months following diagnosis, 50% (10/20) infants achieved a VL<1,000 cp/mL

Discussion

- This is the first study measuring MTCT rate at population level in Kenya since the scale-up of option B+
- Elimination of MTCT is within reach but residual transmission remained suggesting a need to speed diagnosis and ART initiation among women as well as preventing treatment failure while on ART.
- Nevirapine and Cotrimoxazole coverage was good but EID is not yet completely rolled-out as close to half of the children age 9 months never received any EID results.
- Scale-up of POC EID assays and expanding infants testing (e.g. birth testing) should be implemented
- Point of Care EID and testing at EPI allowed early diagnosis including children of undiagnosed mothers, faster linkage to care and ART initiation. However, 6 months following the first test, we found a poor viral suppression and survival, highlighting the need to invest in friendly treatment and supportive adherence models for infants
- Strengths and limitations
  - Strengths: high inclusion rate, sample representativeness
  - Limitations: final MTCT rate (18-24months) not measured and short infants follow-up, facility based survey.

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