Boffin Access

Open Access Journal | Volume: 1.1

Clinical HIV and AIDS Journal

Clinical Audit on Management of HIV exposed Uninfected Infants (HEU) 0-24 months old in 2016/17 at the Lea Toto program, Nairobi, Kenya

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Abstract

Back ground: The majority of infants born to HIV-infected women are HIV-exposed uninfected (HEU). Effective clinical management of these children will prevent seroconversion, severe illness and malnutrition. To ensure quality care the Ministry of health has guidelines for standard evidence based care that all providers follow.

Objectives: A clinical audit to determine proportion of HEU children aged less than 24 months enrolled in Lea Toto program that accessed and adhered to Kenyan National guidelines in the following components: early infant HIV diagnosis (EID), anti-retroviral prophylaxis, immunization, retention in care, and management of nutrition and infectious co-morbidity.

Methods-design, setting and participants: This was a clinical audit conducted at Lea Toto program a faith based NGO which has for the past 20 years provided health services to families of children affected by HIV and currently serves up to 3,100 HIV-positive childrens and up to 15,000 family members annually. The study participants were HEU children 0 to 24 months old on follow up in 2016-2017. Children were classified as HEU on the basis of their first HIV PCR test being negative. After informed consent a standardized clinical audit tool was used to abstract data from the electronic medical records of the HEU infants. The tool was used to collect information on timing and results of the early infant HIV diagnosis, ART prophylaxis, nutrition status, morbidity, immunization and adherence to follow up.

Results: A total of 322 electronic medical records of HEU infants at Lea Toto program were evaluated. Age on enrolment into the program was from 3 days of age to 20 months of age. The mean age of first HIV PCR test was 2.01 months. A total of 287 (89.13%) of the first HIV PCR were done at Lea Toto. Overall 299 (92.8%) of the 322 participants received ART prophylaxis, 144 (44.7%) the recommended combined Zidovudine (AZT)+Nevirapine (NVP) prophylaxis, and 155 (48%) only NVP. Only 217 (67.39%) participants started ART prophylaxis on first day of life and up to 219 (68.01%) HEU were on the ART prophylaxis for 3 months, while 25 (7.8%) receive a shorter course of prophylaxis because of loss to follow-up or no longer at risk, and 78 (24.2%) received more than 3 months prophylaxis due to heightened risk of infection from maternal viral non-suppression. The 23 (7%) who did not received ART prophylaxis were enrolled into the program after they had been weaned off breastfeeding and reports of ART prophylaxis could not be verified. Overall 265 (82.3%) received Co-Trimoxazole prophylaxis. There were 214 (66.45%) participants who reported exclusive breastfeeding for 6 months, 58 (18%) for 5 months and only 10 (3%) for less than a month. Overall 72 (22.4%) had some malnutrition including 43 (13%) moderate malnutrition, 13 (4%) stunted, 9 (3%) wasted, while 7 (2%) both wasted and stunted. Only 26 (8.1%) of the 322 participants were admitted to hospital during the period of audit. Only 4 (1.2%) children seroconverted. Factors associated with seroconversion were late enrolment, inappropriate ART prophylaxis and incomplete HIV testing.

Conclusion and Recommendation: Children enrolled in the Lea Toto program are accessing the essential HIV care package. Late enrollment into the program was associated with increased likelihood of malnutrition and HIV infection. There is need for continuing medical education (CME) to address the observed low PCR testing rate at 9 months and inappropriate use of CTX before the age of 6 weeks of life.

Keywords

HIV exposed uninfected children; Clinical management; Lea Toto program; Kenya

Introduction

With increasingly effective PMTCT (Prevention of Mother to Child Transmission), the population of HEU infants is growing. HEU children are at increased risk of mortality, morbidity and slower early growth than their HIV-unexposed counterparts [1,2]. Nine out

Article Information

DOI: 10.31021/chaj.20181104
Article Type: Research Article
Journal Type: Open Access
Volume: 1 **Issue:** 1
Manuscript ID: CHAJ-1-104
Publisher: Boffin Access Limited

Received Date: 02 November 2018
Accepted Date: 21 December 2018
Published Date: 26 December 2018

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Citation: Kagunda EW, Musoke R, Nduati R. Clinical audit on management of HIV exposed uninfected infants (HEU) 0-24 months old in 2016/17 at the Lea Toto program, Nairobi, Kenya. Clin HIV AIDS J. 2018 Dec;1(1):104

of ten HIV infected children acquired the virus from their infected mothers during pregnancy, delivery, or through breast-feeding [3]. Without treatment, the likelihood of HIV passing from mother-to-child is 15% to 45%. With specific interventions such as combination antiretroviral treatment (cART) in non-breastfeeding populations, the risk of MTCT can be reduced to less than 2%, and to 5% or less in breastfeeding populations [4].

Since 2011 to 2015 globally the annual number of HIV-infected children has declined by 50%. Kenya reduced number of new HIV infections among children by 49% between 2013 and 2015 [5].

The purpose of this study was to conduct a clinical audit to determine proportion of HEU children aged less than 24 months enrolled in Lea Toto program that accessed and adhered to Kenyan National guidelines in the following components:

a) Recommended infant ART prophylaxis for 12 weeks, with Zidovudine and nevirapine for 6 weeks, followed by nevirapine for 6 weeks.

b) Early infant HIV diagnosis-at 6 weeks age or first contact if seen after 6 weeks age using DNA PCR.

c) Co-Trimoxazole prophylaxis-from 6 weeks of age to 6 weeks after exclusive breastfeeding stops.

d) Adherence exclusive breastfeeding for 6 months then addition of appropriate complementary feeds while continuing to breastfeed for at least 12 months.

e) Recommended immunization schedule as per National Vaccination and Immunization Programme.

Methods

Study design

This was a clinical audit to evaluate management of HEU children according to Kenyan national HIV guidelines.

Study site

The study was conducted within the Lea Toto program in Nairobi, Kenya. The charity has 8 health facilities located in informal settlements of low socioeconomic status in Nairobi. The program manages children who are HIV infected or HIV exposed but uninfected according to the Kenya National guidelines. The program's clinics are run by a multidisciplinary team of clinical officers (known as physician assistants in some countries), nurses, nutritionists, social workers and counselors.

Study population

The study population was HEU children followed up in the first 2 years of life in 2016 and 2017 in Lea Toto program and had been in the program for at least 3 months and were confirmed HIV negative on initial PCR testing. Potential study participants were identified by proportionate stratified random sampling from the 8 facilities.

Data abstraction

A standardized structured questionnaire was used to abstract de-identified data from electronic medical records of the patients. Specifically the tool collected data on the demographic characteristics (age, sex, whether orphaned, maternal education status and use of cART), early infant HIV diagnosis (defined as DNA PCR testing at 6-8 weeks of life), subsequent HIV testing, ART prophylaxis (drugs used and duration), feeding and nutrition status (duration of exclusive breastfeeding, timing of complementary feeds, anthropometric measurements of the child), morbidity (cause of illness and hospitalization), immunization and adherence to follow up.

Statistical analysis

Electronic data was cleaned before embarking on data analysis. We used STATA 9.2 for statistical analysis. Descriptive statistics were used to summarize the study population characteristics, ART prophylaxis, early infant and subsequent HIV testing. Adequacy of care was estimated by level of adherence to Kenyan HIV treatment guidelines. Prevalence was tabulated and association between incomplete HIV care and poor outcomes (including seroconversion, malnutrition and sever illness) was determined using Chi square test of independence.

Ethical considerations

Written consent was obtained from custodians of electronic medical records (board of management-Lea Toto program) before data collection. The study was conducted after approval from the Research and Ethics Committee of Kenyatta National Hospital and the University of Nairobi.

Results

A total of 322 electronic medical records of HEU infants at Lea Toto program were evaluated. The study was conducted in January and February 2018. The current age of the children was from 3 to 24 months during study period. The median age of enrolment into program of 1.5 months and there was a male to female ratio of 1:1. Just over half of the children had been referred to the program, 125 (38.8%) by community health workers and 58 (18.1%) from other health facilities. Half of the mothers 151(51.7%) were unemployed, while 47 (31.12%) were single parents.

Early infant diagnosis HIV testing

The timing of the first HIV PCR test among study participants was from 3 days to 20 months of age, and 251 (91.5%) had first PCR done at 6 weeks as recommended. The mean age of first HIV PCR test was 2.0 ± 0.5 months and the median was 6 weeks age (IQR 3) (Table 1).

There were 6 patients enrolled when 3-8 weeks old but had 1st PCR done at 9 weeks-6 months. There were 12 children enrolled when 7-24 months old and had PCR done at 9 weeks-6 months at other facilities before enrolment. The PCR testing at first contact was from 57-96%, highest among children enrolled at 3-8 weeks. Some children enrolled later had PCR done before enrolment.

Subsequent HIV testing

This evaluated children currently eligible for tests during study period and received the test within the recommended age (Figure 1).

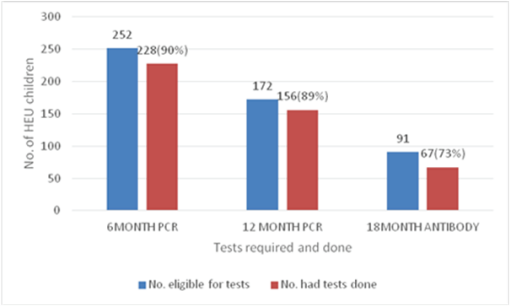
ART prophylaxis

Overall 299 (92.8%) of the 322 participants received ART prophylaxis, 144 (44.7 %) the recommended combined Zidovudine (AZT)+Nevirapine (NVP) prophylaxis, and 155 (48%) only NVP (Figure 2).

There were 25 (7.8%) children received a shorter course of prophylaxis because of loss to follow-up, orphaned children whose HIV test was negative and children who were on follow up in other institutions where prophylaxis was done for shorter duration of time. Another 78 (24.2%) children received more than 3 months prophylaxis due to heightened risk of infection because their mothers had not achieved viral suppression, mothers not on HAART or diagnosed in the postnatal period.

Co-Trimoxazole prophylaxis

The national guidelines recommend that all HIV exposed infants



The 6 month PCR had the most uptake (90%) with the 18 month antibody test having the least uptake (73%).

Figure 1: Subsequent recommended HIV tests N=322

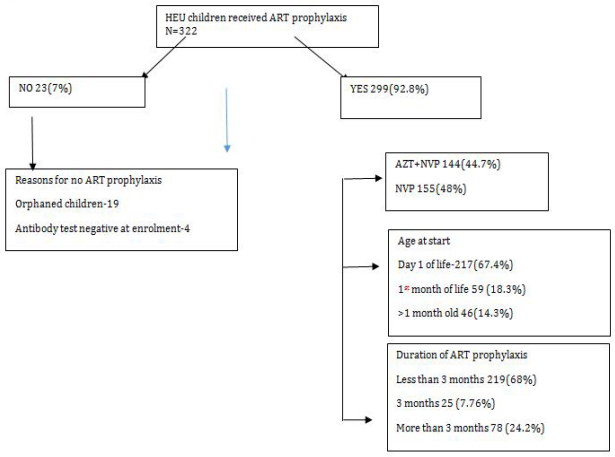


Figure 2: ART prophylaxis given to participants

should receive Co-Trimoxazole prophylaxis from 6 weeks of age to 6 weeks after exclusive breastfeeding stops.

Majority of the participants at 265 (82.3%) were on Co-Trimoxazole prophylaxis. The prophylaxis was started as early as day 1 of life to 9 months of age. The majority of participants 178 (55.28%) were started at 4-6 weeks of age. There were 57 children whose records didn't include Co-Trimoxazole prophylaxis received. This was especially for children lost to follow up.

Morbidity of HEU infants at Lea Toto program

The common diseases affecting the participants were as shown in Table 1. Overall 303 participants experienced at least one episode of acute respiratory infection (ARI), 12 (3.7%) severe enough for hospital admission. From the medical records, the severity of ARI was not clarified. Only 3 (0.9%) children were diagnosed with tuberculosis. Other than TB, median age at diagnosis of these conditions was in the first year of life. Most of these conditions were managed as outpatient. The children received free treatment at Lea Toto facilities (Table 2).

There were 26 (8.1%) children admitted to hospital in the period of observation among them 16 (4.9%) with diagnosis of gastroenteritis, 12 (3.7%) ARI, 2 (0.6%) for tuberculosis, 4 (1.5%) for neonatal conditions as seen in Table 3.

Feeding history and nutrition status of the participants

Overall 282 participants reported that they exclusively breastfed their infants among them 214 (66.45%) who reported 6 months of exclusive breastfeeding, 58 (18%) for 5 months and 10 (3%) for less than a month. None of the mothers had chosen replacement feeding. Overall 254 (78.8%) children were breastfed as recommended i.e. exclusive breastfeeding for 6 months then addition of appropriate complementary feeds while continuing to breastfeed for at least 12 months. The total duration of breastfeeding even after introduction of complementary feeding was not documented.

Overall 72 (22.4%) experienced some malnutrition including 43 (13%) with moderate malnutrition [Weight for age (W/A) range -1 to -2 standard deviation (SD)], 13 (4%) stunted [height for age (H/A) Z score<-3], 9 (3%) wasted [weight for height (W/H/) Z score<-3], while 7 (2%) both wasted and stunted. The median age for diagnosis of wasting was 13 months and the range was 2-24 months. The median age of stunting was 14 months with a range of 10-24 months. Out of 29 participants with severe malnutrition, 26 (89.65%) were appropriately diagnosed and managed. The plotting of child's weight and height in recommended growth charts was not regularly done (Table 3).

The HEU children with severe malnutrition were compared to those that were well nourished. They were comparable in terms of mother's education status as well as employment status. A similar proportion of children (both well-nourished and not) were exposed to exclusive breastfeeding for 6 months. The only difference between well-nourished and poorly nourished HEU was the age at which they enrolled into the program. Only 20% of the malnourished HEU enrolled into the program by 6 months of age compared to 93.4% of the well-nourished HEU. Children enrolled in the program after the age of 6 months had 27 fold increased risk of being malnourished-OR=27.5 [(95% CI 11.2, 65.5), p<0.001 Fischer's exact test].

Seroconversion to HIV

There were 4 children whose subsequent HIV tests turned positive. Their characteristics are described in Table 4. Three of the four HIV infected children were aged 13-24 months and they had been enrolled when they were aged 13-24 months. Again 3 of the 4 infected children did not receive the appropriate ARV prophylactic regimen and they did not access EID. All 4 children who seroconverted were malnourished and 2 of them were admitted into hospital. The 4 children who seroconverted were of similar age to those that did not. However among the infected, 3 (75%) out of 4 children were enrolled in the second year of life compared to 7 (2%) of 318, OR 13.8 [(95% CI 12.3-1445), p=0.001]. All 318 children who did not seroconvert received appropriate ARV prophylaxis compared to the 3 (75%) of the 4 who were infected (p=0.02) (Table 4).

All children who seroconverted were malnourished compared to 77 of the 318 children who were not infected and this difference was significant (p=0.008 Fischer's exact test). The infected children experienced a higher hospital admission rate compared to those who were not infected 2 (50%) compared to 19 (5.9%) OR=15.7 (2.1, 117.9).

Patient follow up and defaulting rate

The program has a very high retention rate of the enrolled children. Only 12 (3.7%) of the 322 children were completely lost to follow-up. At the time of the audit 246 (76.3%) had uninterrupted continuity of care and had not missed any clinic appointments, 53 (16.4%) were officially discharged after negative antibody test at 18 months, and 11 who had missed an appointment by a week and therefore classified as lost to follow-up had resumed care and were currently on follow-up. The median age of loss to follow up was 9 months. The reasons for loss to follow up include: lack of transport means/monies, relocation, and mother's illness or too busy at work.

Immunization status of participants according to KEPI

The immunization status was up to date for 301 (93.7%) of participants on their first visit to the program. Out of 301 participants, only 204 (67.77%) had their immunization status updated to the last

Age groups	No. of HEU enrolled N=322	No of HEU who had first PCR N=322	%PCR at first contact
0-2 weeks	50	44	88%
3-8 weeks	189	183	96.8%
9 weeks-6 months	55	73	132%*
7-24 months	28	16	57.1%

Table 1: Comparison of age at enrolment and HIVPCR done at first contact

Diagnosis	No. of children affected	%	Median age at diagnosis
Acute respiratory illness	303	94.1	9 months
Gastroenteritis	153	47.5	7 months
Eye discharge	67	20.8	2 months
Skin rash	40	12.4	8 months
TB	3	0.9	13 months

Table 2: Morbidity and age at diagnosis

Variable	HEIs with severe malnutrition n=29	HEIs without severe malnutrition n=291	O.R (95% C.I)	*p* value Fischer's exact test
Age at enrolment				
0-6 months	9(20.1)	272(93.4%)	1.0 (ref)	<0.001
7-18 months	20(68.9%)	22(7.6%)	27.5 (11.2,65.5)	
Age at diagnosis				
0-6 months		8(2.48%)		
7-18 months		21(6.52%)		
Mother's education				
Primary & Never attended	18(62%)	158(54.3%)	1	0.3
Secondary & Tertiary	8(38%)	112(38.5%)	0.6(0.3-1.5)	
Mother's occupation				
Unemployed	17(58.6%)	151(51.9%)	2.01(0.8-4.8)	0.2
Working mother	8(41.4%)	143(49.1%)	1.0(ref)	
Exclusive breastfeeding for 6 months				
Yes	14(48.2%)	184(63.2%)	1	0.2
No	15(51.8%)	107(36.8%)	1.84(0.8-3.9)	
Nutrition management				
Appropriate	26(89%)	-	-	
Inappropriate	3(11%)	-		

Table 3: Factors associated with nutrition status of HEU infants

clinic visit. Lack of proper documentation of immunization status was noted .This may be attributed to children being immunized at other clinics (Lea Toto doesn't offer immunization services) and immunization card/book not presented during consultations at Lea Toto. The reasons for missed immunization were home delivery, hospital admissions and abandoned, orphaned children.

Table 5 shows the performance of the program over the period of observation. There was effective coverage of the essential HIV care package for the children enrolled into the program other than the 9 month HIV test.

Discussion

The majority of study participants 294 (91.3%) were enrolled at 0-6 months of age, mainly at 6 weeks of age 86 (26.8%). This corresponds to the timing of first or second HIV PCR test. These children also come for refill of their prophylaxis and adjusting of doses at 6 weeks of age.

The children's caregivers were mainly both parents 182 (56.5%) but majority were separated. Most parents were unemployed or in casual labor. Most mothers at 151 (51.7%) were unemployed, 47 (31.12%) of these mothers were single parents. The socioeconomic status of the families of HEU children is critical for their care.

The program receives children after they have been delivered in other facilities and already on ART prophylaxis. This proved to be challenging. Sometimes one has to rely on mother's history on when prophylaxis was started and if the medicines are adhered to.

The program is different from research based programs. The program's facilities are located in the community, increasing accessibility. Furthermore the program works with CHWs to ensure community involvement. It is also run by local (Kenyan) technical staff, with guidance from national guidelines. This makes the model more sustainable.

Despite the national HIV guidelines amendment to include zidovudine (AZT) as part of prophylaxis, most children enrolled early 2016 were on nevirapine (NVP) prophylaxis only. There were only 144 (45%) on AZT+NVP. The program staff then has to start the zidovudine later than recommended. This is critical as appropriate ART prophylaxis ensures HEU children don't seroconvert. The program needs to give feedback to referring health facilities if the children are not on appropriate ART [6-8].

The duration of ART prophylaxis for some participants was not appropriate. For instance its recommended if a breastfeeding mother refuses to start ART but agrees to provide infant ARV prophylaxis, provide 6 weeks of AZT+NVP, followed by daily NVP until 6 weeks after complete cessation of breastfeeding. If mother has viral load ≥ 1,000 bcopies/micromoles, continue infant prophylaxis until confirmed viral suppression or 6 weeks after complete cessation of breastfeeding. These special recommendations were not followed in the above mentioned circumstances and these children were put on similar prophylaxis as children whose mothers were on HAART and virally suppressed. This is challenging since the mothers are not managed at the program.

The national guidelines recommend that all HIV exposed infants should receive Co-Trimoxazole prophylaxis from 6 weeks of age to 6 weeks after exclusive breastfeeding stops. WHO estimate that only 8% of children exposed to HIV were initiated on Co-Trimoxazole prophylaxis by two months of age. Similarly at the program some children (17%) were not on Co-Trimoxazole prophylaxis at any point of management.

There were challenges with early infant HIV diagnosis. The tests were conducted when the child was enrolled at first contact, for 287 (89.13%) participants especially if not done at referring facility. This may not be the same timings as recommended by national guidelines. For instance a child enrolled at 5 months age will have a PCR test at

Variable	Seroconversion N =4	No seroconversion N =318	O.R	CI 95%	*p* value Fischer's exact test
Mother's education					
Primary & Never attended	2	165	1.7	0.24 to 1.2	0.05
Secondary &Tertiary	2	92			
Mother's occupation					
Unemployed	3	148	2.9	0.3 to 2.8	0.07
Working mother	1	144			
Exclusive breastfeeding for 6 months					
Yes	1	213	6	0.6 to 5.9	0.1
No	3	105			
Current age					
0-12 months	1	159	3	0.30-29	0.6
13-24 months	3	159			
Age at enrolment					
0-12 months	1	311	13.3	12.28-1445	0.001
13-24 months	3	7			
ART prophylaxis-					
Appropriate	1	318	undefined	-	0.02
Not appropriate	3	-			
EID					
Complete	1	238	8.7	0.8-84.5	0.1
Incomplete	3	80			
Nutrition status					
Normal	-	241	undefined		0.008
malnutrition	4	77			
Hospital admission					
Yes	2	19	15.7	2.1-117.9	0.04
No	2	299			

Table 4: Factors associated with seroconversion in HEIs

	ART	CTX	EID	6 months PCR	9 month PCR	18 month antibody testing
Number receiving service at enrollment (a)	217	178	298	216	81	81
Number eligible for the service (b)	322	293	322	252	202	91
Number provided the service (c)	295	265	322	239	135	86
Effectiveness of the program c/b	91%	90.4%	100%	94.8%	66.8%	94.5%
Service coverage (a+c)/ a+b	95.7%	94.05%	100%	97.2%	76.3%	97.1%

Table 5: Program performance

enrolment. The same child is expected to have HIV PCR at 6 months age. Some children were no longer brought to the clinic once their PCR test turned negative and child was not breastfeeding. This resulted in low turnout for the 18 month antibody tests. However the social worker and CHWs organize for home visits to ensure children resume follow up.

The turnaround time for HIV PCR results was as long as 2 months. For instance there were 3 infants who were initially managed as HEU as results were pending, but their first HIV PCR turned positive. These children had initial high viral loads due to late start of HAART.

The above mentioned challenges hindered full turn out of the recommended HIV tests. In our study there was only 79% uptake of the 6 week PCR test. Similarly in a review by Celleti [9] only 39% of children in low-income countries were estimated to have access to HIV testing within the recommended 2 months of birth.

According to a study by Ashiono E et al. [10] in a retrospective cross-sectional study that analyzed 2,642 records of HIV-exposed infants in north rift Kenya, (42.4%) infants had DNA PCR within the first 6 weeks of age. In that study only 72.1% infants received prophylactic antiretroviral, in this study ART prophylaxis was given to 92.8% of participants at Lea Toto program.

According to the ZVITAMBO trial [11] compared with not-exposed infants, sick clinic visits were 1.2 times more common among HEU infants. In this current study at Lea Toto HEU children were seen severally for various diseases, some even before scheduled appointments. There were study participants who ended up being admitted due to the severity of their illness. There were others who required further specialized treatment e.g. recurrent eye discharge not responding to treatment.

In a study by Gichuhi et al. [12] that followed 351 HEU infants from neonatal period up to 1 year of age, common medical conditions included bronchopneumonia, diarrhea and failure to thrive. These were similar to the medical conditions leading to hospital admissions in this current study at Lea Toto.

Malnutrition was observed in majority of study participants. The children who were not exclusively breastfed had higher risk of malnutrition OR=1.84 95%CI 0.85-3.96 and severe illness. More than half (56%) of the participants with wasting were not exclusively breastfed. Among the children who were treated for severe illness requiring admission and specialist follow up, 58.1% (OR: 1.22; 95% CI: 0.99 p) were not exclusively breastfed for 6 months.

The immunization status of the children was mainly recorded in the first visit to the program. The follow up immunizations after first visit was not recorded for most of the children. The immunization of HEU infants is critical in ensuring disease prevention. HEU infants have altered cell-mediated and humoral immunity, this coupled with lack of immunization increases their risk to acquire severe childhood illnesses which are preventable.

The children lost to follow up before official discharge, majority 13 out of 23 did not resume follow up. There was no documentation on home visits or phone call to ascertain child's whereabouts.

The seroconversion rate in this study was 1.24% (95% CI: 0.34, 3.15). Factors associated were late enrolment to program, incomplete EID and inappropriate ART prophylaxis. A meta-analysis including 9 studies, 3688 mother-baby pairs in Ethiopia [13], the pooled prevalence of MTCT of HIV was 9.93%. Associated factors with MTCT of HIV include: mixed feeding, absence of infant ARV prophylaxis, home delivery, and absence of maternal PMTCT intervention.

Acknowledgements

I would like to acknowledge the Board of management and staff at Lea Toto program for their support. Of special mention are Prof. Rachel Musoke and Prof. Ruth Nduati who have provided critical guidance and supervision throughout the duration of this study. I would also like to thank the data team at Lea Toto program for all the assistance with data collection and analysis.

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