



Evaluation of PMTCT interventions and outcomes among HIV-positive pregnant and breastfeeding women and their HIV-exposed infants in Homa Bay County, Kenya, 2016-2019

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USG Disclaimer

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Executive Summary

Introduction

The Kenya national and county governments Ministries of Health have made a series of investments through policy and programs to accelerate elimination of mother to child transmission. Significant gains have been made in identifying HIV infected pregnant women during antenatal care visits.

In 2016, Elizabeth Glaser Pediatric AIDS Foundation, implemented the *Timiza90 project*, a five-year U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-funded project through a cooperative agreement with the US Centers for Disease Control & Prevention (CDC). Timiza90 project supported Prevention of Mother to Child Transmission (PMTCT)/pediatric treatment, through the scale-up of integrated Antiretroviral Therapy (ART)/Maternal Newborn and Child Health (MNCH) services, including interventions aimed at improving quality of services and increasing uptake.

Methods

A retrospective study was conducted with the aim of tracking HIV-related health outcomes for the mother-baby pair and determine the association between demographic, clinical, and program factors and these health outcomes. Medical records were abstracted from 13 health facilities that serve HIV-infected pregnant and breastfeeding women and their HIV exposed infants (HEIs) within Homabay county, Kenya, between Oct 2016 and Jan 2019, using a standardized case report form/chart abstraction tool.

Results

Of the 947 HIV positive pregnant women seen in antenatal care from October 2016 to January 2019 in 13 high volume facilities in Homa Bay county, a total of 857(90.5%) mothers were enrolled into PMTCT. The participants had a median gestational age of 22 weeks (IQR: 16, 28) at first ANC, with only 152(18.8%) mothers attending first ANC before 14 weeks gestation. About two thirds (634) of the mothers had at least three ANC visits before delivery and 626(86%) delivered in a health facility. In total, 652(77.6%) had been on ART for more than 3 months at enrolment into PMTCT. Most of the mothers (84.4%) were alive and active in care when the infants started HEI follow-up. Of all the 808 documented pregnancy outcomes from 857 mothers, there were a total of 774(95.8%) live births and 34(4.2%) stillbirths. The majority (98.9%) of the infants took ARV prophylaxis while 606(78.3%) infants exclusively breastfed for 6 months. At the end of study follow-up, 693(89.5%) children were alive and on follow-up, 15(1.9%) had been lost to follow-up, 63(8.1%) had been transferred-out and 3 (0.4%) had died; 12 of the live infants were HIV positive at the end of study follow up.

Conclusion

Late ANC attendance, lack of couple counseling, mixed feeding and home delivery remain a challenge among women living with HIV and are potential factors to Mother to Child Transmission (MTCT) and it is critical to enhance counselling on birth planning and preparedness in the context of HIV and PMTCT. Encouraging partner involvement would improve utilization of antenatal and postnatal services for PMTCT.

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Abbreviations

ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
BCG	Bacille Calmette-Guérin
CD4	Clusters of differentiation 4
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHVs	Community Health Volunteers
CoAg	Cooperative Agreement
DTG	Dolutegravir
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission
HEI	HIV Exposed Infant
HHS	Health and Human Services
HIV	Human Immunodeficiency Virus
IQR	Interquartile range
KEPI	Kenya Expanded Programme Immunization
LTFU	Lost to follow-up
MNCH	Maternal, Newborn and Child Health
MTCT	Mother-to-child transmission of HIV
NNRTI	Non-nucleoside reverse-transcriptase inhibitor
ODK	Open Data Kit
OI	Opportunistic infections
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother to Child Transmission
SD	Standard Deviation

TO	Transfer Out
UNAIDS	Joint United Nations Programme on HIV/AIDS
US	United States
VL	Viral Load
WHO	World Health Organization

Background

The investments by both national and county governments in prevention of mother to child HIV transmission (PMTCT) in Kenya, have yielded significant gains for working towards elimination of mother to child transmission [0]. These investments include: change of antiretroviral treatment (ART) guidelines to include test and treat [0]; provision of life-long ART for all pregnant and breastfeeding women living with HIV regardless of gestational age [0]; World Health Organization (WHO) HIV clinical stage and at any CD4 count [0]; introduction of Option B+ through the *Bring Back the Mothers* campaign; free maternity services[0]; and, Beyond Zero, the First Lady of Kenya's campaign to accelerate economic and social development through health [0]. The country developed a framework for elimination of mother-to-child transmission (eMTCT) of HIV and syphilis by 2021 and is aiming at having less than 50 cases of MTCT of HIV and syphilis per 100,000 live births [0]. National estimates indicate 96% of women who attended ANC visits self-reported knowing their HIV status [0].

In line with the above, in 2016 the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) Kenya program implemented the *Timiza90 project*, a five-year U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-funded project through a cooperative agreement with the US Centers for Disease Control & Prevention (CDC), from October 2016 to September 2021, in Homa Bay County. The purpose of this project was to support the implementation and scale-up of comprehensive, high quality, sustainable HIV and AIDS programs and contribute to epidemic control in Kenya by meeting UNAIDS 95,95,95 goals. In PMTCT/pediatric treatment, EGPAF supported scale-up of integrated ART/Maternal Newborn and Child Health (MNCH) services, including interventions aimed at improving quality of services and increasing uptake. These interventions included intensifying HIV testing for all pregnant and breastfeeding women and their partners, ensuring timely initiation of ART in MNCH clinics, and accelerating identification of HIV exposed infants(HEI) in child welfare clinics, nutrition, in-patient departments, and out-patient departments. This is done through screening of all mothers with unknown HIV status or children with unknown HIV exposure status not accompanied by their mothers, intensifying mother-baby pair follow-up, retention, defaulter tracing, and viral suppression.

To strengthen retention and community-facility linkages, a mother-baby retention package and pregnancy mapping by Community Health Volunteers (CHVs) was done. The mother-baby retention package included: integration of ART in MNCH, deployment of peer/mentor mothers, psychosocial support groups, a formalized appointment system and active defaulter tracing, HEI graduation ceremonies at 18 months

and cohort monitoring for mother-baby pairs. The peer/mentor mothers were responsible for giving one-on-one support to HIV-infected pregnant/postpartum women; encourage enrollment, adherence and retention in HIV care, perform tracing for pregnant/postpartum women who miss clinic visits; and educate them on PMTCT.

The overall goal of this evaluation was to track HIV-related health outcomes for the mother-baby pair and determine the relationships between demographic, clinical, and program factors and these health outcomes in Homa Bay County.

Objectives

The evaluation objectives were:

Primary Objectives:

1. To describe ANC and PMTCT enrolment and service uptake levels for HIV positive pregnant women
2. To assess outcomes and factors associated with the outcomes for HIV-positive pregnant and breastfeeding women enrolled in the PMTCT program (adherence to ART, retention of mother baby pair, viral load access and suppression, morbidity, and mortality) at different time points.
3. To identify the demographic, clinical, and programmatic factors (age, duration on treatment, adherence to ART, regimens, clinical stage, viral suppression, and site characteristics) that are associated with infant HIV transmission.
4. To assess outcomes and factors associated with the outcomes for HEI enrolled in the PMTCT program including HIV positivity and ART uptake for HIV-positive infants.

Secondary Objectives:

1. To assess opportunistic infection (OI) screening outcomes and their care for HIV-positive pregnant and breastfeeding women and their infants. To document post-delivery family planning (FP) access and uptake.
2. To describe maternal disclosure status
3. To describe infant feeding options, immunization status, and nutritional status

Methods

Evaluation design

This evaluation used a retrospective study design. HIV-positive pregnant and breastfeeding women and their HEIs, who were enrolled in PMTCT care at EGPAF-supported facilities between October 2016 and January 2019 were enrolled into the study. Data for these women was abstracted for up to 24 months after a child's birth (until the mother exits the PMTCT program or stopped breastfeeding). HEIs were monitored until a final outcome was determined (transfer out, tests HIV positive, or discharged uninfected) following cessation of breastfeeding or is lost to follow-up.

Evaluation Location

This evaluation was conducted in 13 EGPAF-supported public health facilities within Homa Bay County. These sites were purposively selected as they contribute about twenty-five percent of PMTCT clients and were already using electronic medical records (EMR) for management of people living with HIV. The sites also had both EMR and paper records to verify data quality.

Evaluation population

The evaluation population was HIV-infected pregnant and breastfeeding women and their HEIs receiving services in EGPAF-supported facilities in Homa Bay County between October 2016 and January 2019.

Inclusion and exclusion criteria

All HIV-positive pregnant and breastfeeding women enrolled in PMTCT at the specified evaluation sites between October 2016 and January 2019) were eligible for inclusion in the evaluation.

Exclusion Criteria

PMTCT clients who were enrolled in a non-EGPAF evaluation site and mother and infant identified beyond 24 months after delivery were excluded from the evaluation.

Sample size

The evaluation enrolled all HIV-positive pregnant women who were enrolled in PMTCT between October 2016 and January 2019 in the 13 sites. Based on previous years of implementation in the selected facilities, 700 pregnant or breastfeeding women were expected to join the PMTCT program in the selected sites every year, and as such, an additional 673 infants (assuming an infant mortality rate of 38.3 per 1,000 live births) was expected to be enrolled in the infant cohort.

Data Collection

Data were abstracted from November 2020 to February 2021. This study utilized existing routine program data with client personal identifiers, which is collected as part of patient clinical records. Data were abstracted by trained research assistants from both electronic and paper-based individual patient files, ART registers, laboratory registers, and clinical cards at participating facilities. Trained research assistants entered the data into wireless-enabled tablets linked to a password-protected OpenDataKit (ODK2) database, programmed with logical and numeric checks to reduce data collection error.

Key maternal data included ANC attendance, gestation age, facility delivery, ART regimen, adherence to ART, retention in care/PMTCT, viral suppression, opportunistic infections (OIs) including tuberculosis (TB), use of family planning postpartum, partner HIV status, birth outcome and final outcomes including active in care, transfer out, loss to follow up and death. For all infants, data were collected on early infant diagnosis (EID), ART prophylaxis, growth and development, immunization, infant feeding, HIV status at PMTCT exit. HIV treatment outcomes were defined as being: active in care—documented to have collected ARVs in the last scheduled clinical visit; lost to follow up (LTFU) - if absent from the facility for more than 30 days after the last scheduled follow-up date and there was no documentation of death or transfer-out and 3 failed attempts to contact either by phone or physically; transferred out (TO)— those who were referred to another facility to continue ART care as documented on the patient charts; dead—documented in the patient chart as deceased.

Viral load (VL) monitoring was done every six months after ART initiation for children and every 12 months for the mothers.

Evaluation staff training

All study investigators had a research ethics training through CITI. Research assistants collecting data for this evaluation were trained on the protocol and standard operating procedures before implementation of the protocol. In addition to the protocol training they received research ethics training to ensure compliance with human subjects' research requirements, and signed a Confidentiality Agreement.

Stakeholder Engagement

EGPAF worked closely with various stakeholders throughout the course of the evaluation. The County Director of Health and County and sub county health management teams (S/CHMT) were involved at the formation of the intervention. S/CHMTs and Health Care Workers supported during data collection.

Ethical Considerations

This evaluation was implemented as part of the Patient and Program Outcome Protocol, approved by Kenyatta National Hospital-University of Nairobi-Ethical Review Committee (KNH-UoN ERC), CDC (ADS) and Advarra Institutional Review Board (IRB) in the United States. It was also reviewed in accordance with the U.S. Center for Disease Control and Prevention (CDC) human research protection procedures and was determined to be research, but the CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

Statistical Analysis

Categorical variables were presented using frequencies and percentages/proportions, while continuous variables were presented using medians and interquartile ranges (IQR) and means and standard deviations (SD) depending on their distributions. Analysis was undertaken in SAS version 9.4. Factors associated with maternal treatment outcomes (in care, died, lost to follow up and transfers-out); maternal VL suppression at PMTCT enrolment and exit (<1000 copies/ mL of blood and \geq 1000 copies/mL); birth outcome (live birth, live with birth defects, still birth/miscarriage); infant status (alive, died, lost to follow-up, transfer-out) and final HEI outcome (graduated-HIV negative) and discharged to comprehensive care center(CCC) (HIV positive) were assessed using the Pearson's Chi-square and the Fisher's Exact tests where applicable. All tests were two-sided at 5% level of significance.

Results

Mothers' Characteristics

Of the 947 HIV positive pregnant or breastfeeding women who had been seen in antenatal care from October 2016 to January 2019 in nine high volume facilities in Homa Bay county, a total of 857(90.5%) mothers were enrolled into PMTCT. Eight hundred and eight mothers (94.3%) had documented pregnancy outcomes and 774 had live births (Figure 1).

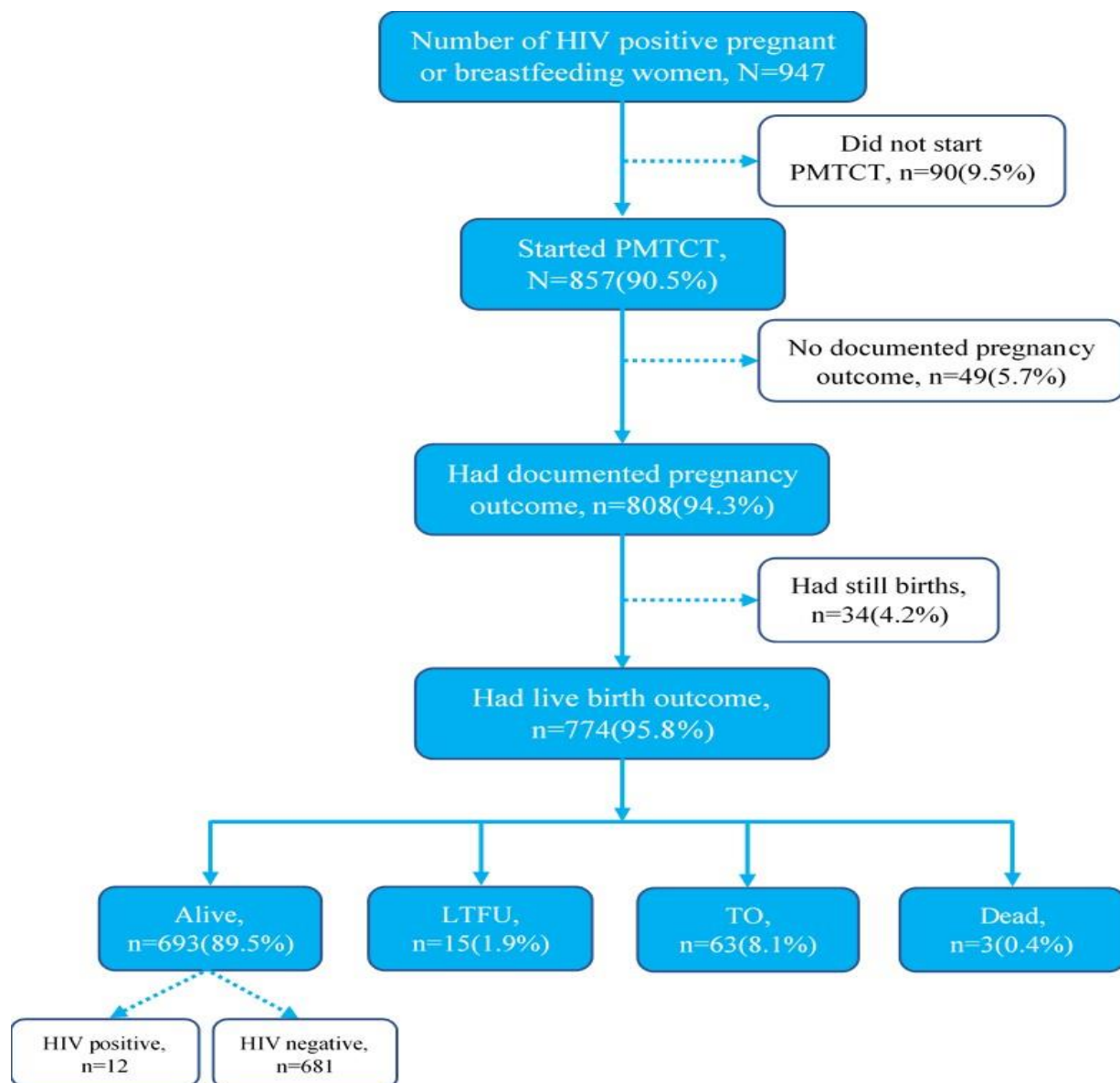


Figure 1: Study enrolment Flowchart. The flowchart shows the number of HIV+ pregnant or breastfeeding women enrolled in the study and followed up for 24 months or until final determination of HIV status.

PMTCT Enrolment and Service Uptake

The participants in this dataset had a median age of 28.3 years (standard deviation[SD] 5.7 years) and about 25%, were 24 years and below. Overall, 755(88.1%) were married and 500 (58.3%) had HIV positive partners, while about 10% of the mothers were in discordant relationships and another one-third had partners whose HIV status was unknown and may not have benefitted from couple counseling. The participants had a median gestational age of 22 weeks (IQR: 16, 28) at first ANC, with only 152(18.8%) mothers attending first ANC before 14 weeks gestation, thereby not benefitting from the full PMTCT

package. About two thirds (634) of the mothers had at least three ANC visits before delivery and 626(86%) delivered in a health facility. Five hundred and sixty-eight (66.3%) mothers were on a non-nucleoside reverse transcriptase inhibitor (NNRTI) based regimen at enrolment into PMTCT. Over three quarters of the of the participants 652(77.6%) had been on ART for more than 3 months at enrolment into PMTCT. Most of the mothers (84.4%) were alive and active in care when the infants started HEI follow-up (Table 1).

Table 1: Demographic and clinical characteristics of mothers enrolled in the study, October 2016 to January 2019, in EGPAF supported facilities in Homa Bay County

Mother Characteristics at PMTCT enrollment		N=857(%)
Mean age – years, standard deviation (SD)		28.3(5.7)
Age group (years)		
	<15	6(0.7%)
	15-19	35(4.1%)
	20-24	171(20.0%)
	25-34	518(60.4%)
	35-44	125 (14.6%)
	45+	2 (0.2%)
Marital status		
	Single	53(6.2%)
	Married/cohabit	597(69.7%)
	Married (polygamous)	158(18.4%)
	Separated/divorced	7(0.8%)
	Widowed	42(4.9%)
Partner status		
	HIV positive	500(58.3%)
	HIV negative	98(11.4%)
	Unknown	259(30.2%)
Type of facility attended		
	County referral hospital	97(11.3%)
	Sub-county hospital	265(40.0%)
	Health center	495(57.8%)
	Dispensary	0(0.0%)
Gestational age at first ANC, n, median [IQR]		22[16, 28]
	≤14	152(18.8%)
	15-28	517(63.8%)
	29+	141(17.4%)
	Missing	47
No. of ANC visits		
	1	82(9.6%)
	2	141(16.4%)

	3	172(20.1%)
	4+	462(53.9%)
Delivered in health facility		
	Yes	626(86.0%)
	No	102(14.0%)
	Missing	80
WHO staging at enrollment in PMTCT		
	I/II	769(91.1%)
	III/IV	75(8.9%)
	Missing	13
CD4 count at enrollment in PMTCT; n, Median [IQR] cells/ml		
	<200	13(8.8%)
	200+	134(91.2%)
	Missing	710
ARV Regimen at PMTCT enrollment		
	PI based	101(11.2%)
	NNRTI	568(66.3%)
	DTG based	188(21.9%)
ART experience		
	On ART ≤3 months	188(22.4%)
	On ART >3 months	652(77.6%)
	Missing	17
Birth outcome		
	Alive – normal	773(95.7%)
	Alive – birth defects	1(0.1%)
	Still birth	34(4.2%)
	Unknown/missing	49

Birth Outcomes and EID Testing

Of all the 808 documented pregnancy outcomes from 857 mothers, there were a total of 774(95.8%) live births and 34(4.2%) stillbirths. One of the live births had a cleft palate and hydrocephalus. The median age at enrolment into HIV exposed infant follow-up was 0.2 weeks (IQR: 0.0, 5.6). About half of the infants were male (51.0%). The majority (98.9%) of the infants took ARV prophylaxis while 606(78.3%) infants exclusively breastfed for 6 months. At the end of study follow-up, 693(89.5%) children were alive and on follow-up, 15(1.9%) had been lost to follow-up, 63(8.1%) had been transferred-out and 3 (0.4%) had died. Overall, twelve children became infected with HIV by 18 months. Eight(1.0%) of them were diagnosed by DNR PCR at six weeks, three at six months and one at 12 months giving a positivity of 1.6%. Table 2.

Table 2: Characteristics of infants enrolled in the study, October 2016 to January 2019, in EGPAF supported facilities in Homa Bay County

Characteristic	N=774(%)
Age at HEI enrolment; median [IQR] weeks	0.2 (0.0, 5.6)
Gender, missing=1	
Female	378(48.8%)
Male	395(51.0%)
Type of infant prophylaxis	
NVP only	9(1.1%)
AZT+NVP	765(98.9%)
Exclusive Breastfeeding in first 6 months after birth	
Yes	606(78.3%)
No	168(21.7%)
EID uptake at 6 weeks	749 (96.8%)
HIV Status	
HIV positive	12(1.6%)
HIV Negative	762(98.5%)
Initiated on ART	12(100%)
Time to ART initiation, days(n, median (Q1, Q3)	12, 31.5(15, 37.3)
6 month VL	
Uptake	7/11(63.6%)
VL<1000	3/7(42.9%)

Characteristics of mothers by child HIV status

In total, children of 12 HIV positive mothers tested HIV positive. The median age at PMTCT enrolment of the mothers whose children turned positive was 27 years, (IQR:21, 30) compared to 29 years (IQR:24, 32) for mothers whose children turned negative. There was no difference between marital status, partners' HIV status, ART regimen and gestation age at PMTCT enrolment between the two groups. Overall, median duration on ART at PMTCT enrolment was 0 months (IQR:0, 26), and 29 months (IQR:2.7, 52) for mothers with HIV positive infants and mothers of HIV negative infants respectively. There was however a significant difference in proportions between women whose children turned positive (72.7%) and those whose children tested negative (23.3%), among women who had been on ART for less than three months ($p=0.001$). Most of the women whose children turned positive, 7/12(72.7%) had been on ART for less than three months. Of the HIV positive women whose infants tested HIV positive, only 6 women had a viral load result at the time of delivery and breastfeeding and 2/6 (33%) of these women were not virally suppressed (Table3).

Table 3: Characteristics of Mothers stratified by Infant HIV status, October 2016 to January 2019, in EGPAF supported facilities in Homa Bay County

Factor	Level	Mothers with HIV +ve babies, (N=12) N (%)	Mothers with HIV -ve babies, (N=845) N (%)	P-value
Age at PMTCT enrollment, years	Median (IQR)	27(21, 30)	29(24, 32)	Na
	<24	4(33.3%)	208(24.6%)	0.487
	25+	8(66.7%)	637(75.4%)	
Marital status	Married	12(100.0%)	741(87.7%)	0.195 ^a
	Not married	0(0.0%)	104(12.3%)	
Sexual partner HIV status	HIV positive	5(45.5%)	500(59.2%)	0.358 ^a
	HIV negative	3(25.0%)	96(11.3%)	
	Unknown status	3(25.0%)	249(29.5%)	
ART at PMTCT enrollment	Non-PI based	8(72.7%)	582(68.9%)	0.783 ^a
	PI based	2(18.2%)	75(8.8%)	
	DTG based	1(9.1%)	188(22.3%)	
WHO stage at PMTCT enrollment	I/II	10(90.9%)	762(91.0%)	0.988 ^a
	III/IV	1(9.1%)	75(9.0%)	
CD4 at PMTCT enrollment, cells/ml of blood	Median (IQR)	*	482(329, 649)	Na
Gestation at PMTCT enrollment, weeks	Median (IQR)	20(18, 26)	23(16, 28)	Na
ART experience	Median (IQR), months	0(0, 26)	29(2.7, 52)	<0.05 ^a
	≤3 months	8(72.7%)	195(23.1%)	<0.001 ^a
	>3 months	3(27.3%)	650(76.9%)	
ANC attendance, expected to have 4-5 visits based on median gestation at PMTCT enrollment	1-3	7(100.0%)	388 (45.9%)	<0.004 ^a
	4+	0(0%)	457 (54.1%)	
Place of delivery	Health care facility	7(58.3%)	656(77.6%)	0.504 ^a
	Non-health care facility	5(45.5%)	189(22.4%)	
Birth outcome	Live birth	12(100.0%)	762(95.7%)	0.464 ^a
	Still birth	0(0.0%)	34(4.3%)	
Facility type	County Referral Hospital/Sub-County Hospital	6(54.5%)	459(54.4%)	0.988 ^a
	Health Centres	4(36.4%)	258(30.6%)	
	Dispensary	1(9.1%)	128(15%)	

Viral load	Had VL result at delivery	6(50.0%)	545(64.0%)	0.298 ^a
	Suppressed	2(33.3%)	510(93.6%)	<0.001 ^a
	Not suppressed	4(66.3%)	35(6.4%)	
	No VL results	6 (50.0%)	300 (35.5%)	
Breastfeeding in first 6 months post-delivery	Had breastfeeding information	6(50.0%)	629(74.4%)	0.055 ^a
	EBF	5(83.3%)	601(95.5%)	0.154 ^a

^aChi-square test, Na-Not available, *CD4 at PMTCT enrollment not documented

Family Planning and Maternal Opportunistic Infections

Post-delivery, about 68% of the women received family planning interventions with over 86% on either implants or injectable birth control methods. Fifty (50) women were reported to have experienced OIs with over a quarter of them (26%) experiencing oral thrush. Four percent (4%) of the women had TB while 8% had chronic diarrhea. Figure 2

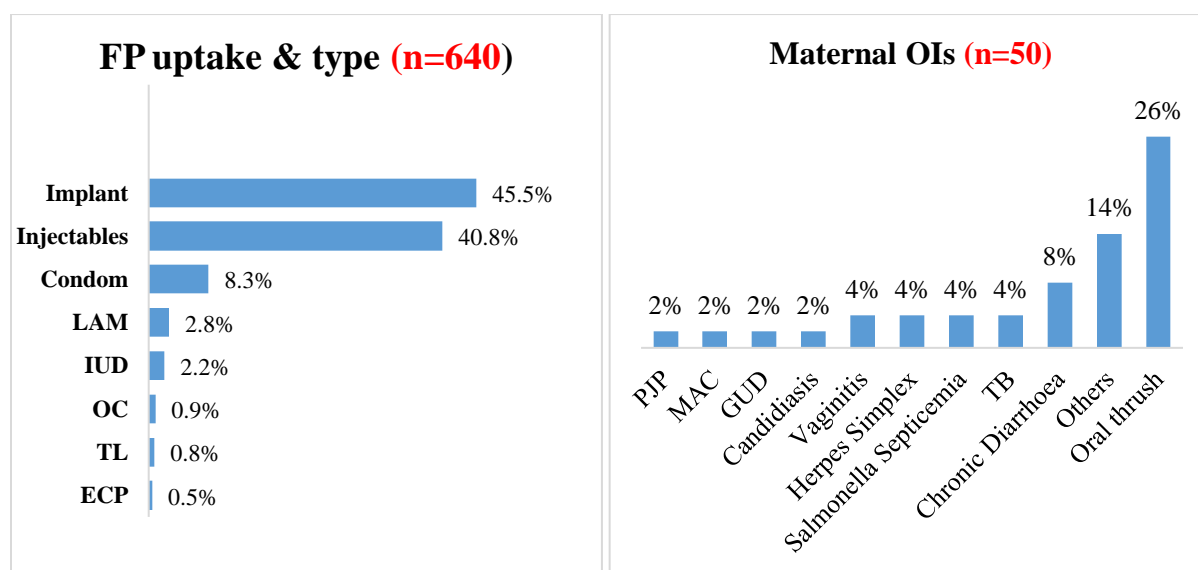


Figure 2: Family planning and Opportunistic Infections among women enrolled in the study in EGPAF supported sites in Homa Bay County

Infant Immunization

Overall, 92% of the infants had at least the initial Bacille Calmette-Guérin (BCG) immunization and 87% completed the immunizations as per the Kenya Expanded Programme for Immunization (KEPI) schedule. Similarly, 92% of the HIV positive and HIV negative infants had at least the initial BCG immunization, while 82% of the HIV positive and 87% of HIV negative infants completed the KEPI scheduled of immunizations.

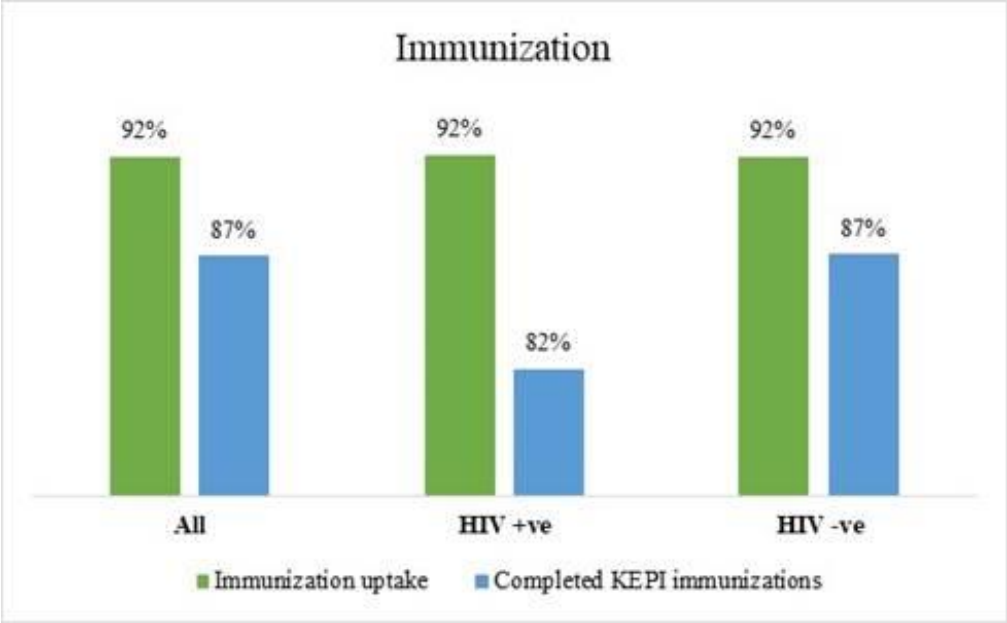


Figure 3: Immunization among infants Born to women enrolled in the study in EGPAF supported facilities in Homa Bya County

Infant Nutrition Status

Figure 4 below shows the weight and height of infants born to women enrolled in the study. HIV positive infants had a median weight below the expected for age. Likewise, the HIV positive infants had lower median height compared to the expected for age.

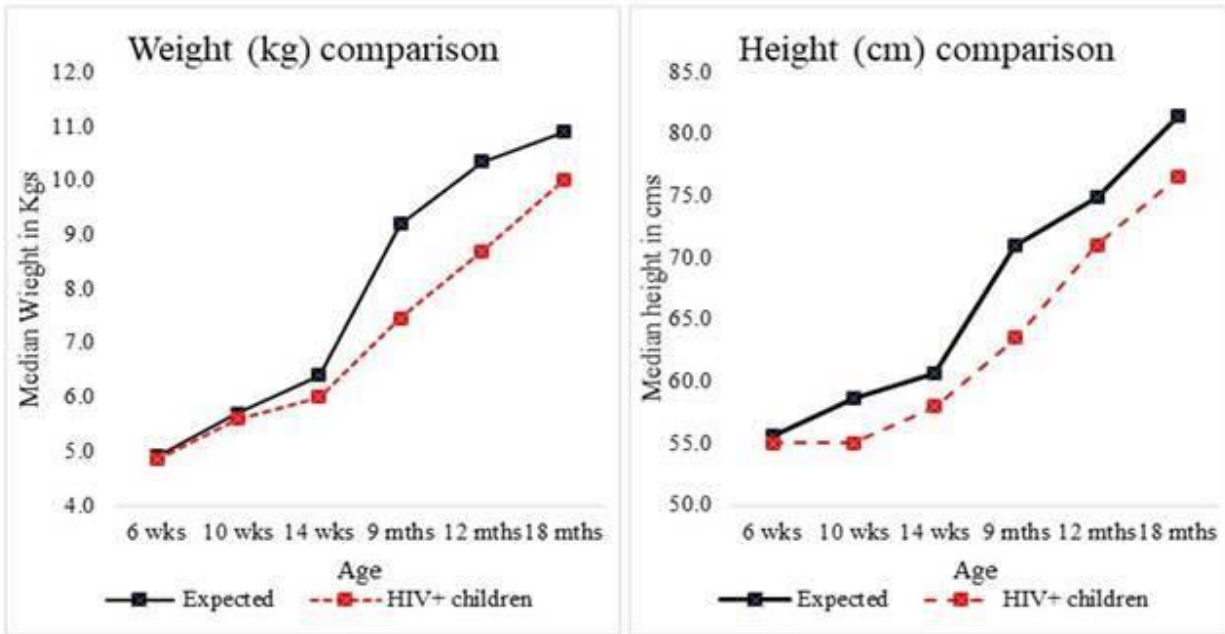


Figure 4: Nutrition Status by weight and Height of Infants born to women enrolled in the study in EGPAF supported facilities in Homa Bay County

Discussion

This study examined a cohort of HIV positive pregnant and breastfeeding women and HIV exposed infants in Homa Bay, Kenya and factors associated with MTCT. In our sample, we observed majority of women (60.7%) were married, had median age of 28.3 years with a median gestational age of 22 weeks at first ANC, which is similar to other studies conducted in Kenya [25, 25].

In our study, the majority of women (91.1%) in ANC were in WHO clinical stage I, which is consistent with literature from South Africa and Ethiopia reporting 96.7% and 82.3% of women in ANC in WHO clinical stage I [25], [25]. Over half (69.8%) of the women in our sample knew the status of their partner, with 58.3% of their partners being HIV positive. These sample characteristics are consistent with other published studies in South Africa [25]. Our study found no evidence of the partners HIV status to be significant concerning MTCT which was similar to the study from South Africa [25].

In regards to ANC attendance, our study found 53.3% of women in ANC to have completed 4 or more ANC visits with 20.1% having completed three. An evaluation conducted in western Kenya additionally reported a little over half (54%) of women in ANC in their sample to have completed a minimum of 4 visits [26]. These percentages seem to be higher than those reported among cohorts of pregnant women

in other settings such as Lesotho and Zimbabwe (33.9% and 36.7% for 4ANC visits respectively) [25], [25]. Consequently, an analysis among low income women in three counties in Kenya found that with each week of delayed ANC enrollment, the likelihood of ANC attendance reduced by 3%, highlighting the significance of early and consistent engagement with women through this platform [25].

Two-thirds (66.3%) of women in our sample were on NNRTIs at the time of enrolment in PMTCT, with 29.1% on DTG. Other studies report similar compositions of treatment with one study reporting 80.2% [25] and 78.0% [26]. ART regimen at time of PMTCT enrollment was not found to be associated with MTCT in our study. Findings from a study based in Zimbabwe demonstrated being on second-line ART compared to first-line treatment was associated with increased likelihood of viral suppression [26].

Our study found the majority of pregnant women (86%) gave birth at a health facility. Compared to published literature, the proportion of pregnant women delivering in health facilities is high. In western Kenya, an evaluation reported 54% of women in their cohort delivered in a health facility setting [26], though they were not in PMTCT. Our analysis did not find the place of delivery to be a significant factor pertaining to the likelihood of delivery of an HIV positive infant. Other evaluations have found place of delivery such as delivery at a health facility compared to home delivery to be protective against MTCT of HIV for infants [26], [26], [26].

Throughout the course of our study, 12 out of 808 children born became infected with HIV before reaching 18 months of age, resulting in a positivity of 1.4%. This percentage is consistent with other reported seroconversion findings in Tanzania (1.58%) [26] and India (1.29%) [26]. However other MTCT have been reported at higher and lower rates. In Kenya, a longitudinal study found the seroconversion incidence to be 0.41% with 2 infants becoming infected with HIV out of 1403 women in the sample [26]. Similarly, the HIV transmission rate among infants in a study in Ethiopia was 0.61% and 0.80% in South Africa with 2 cases of HIV infected infants out of 356 and 248 infants, respectively [26,25].

The factors that were shown to be significantly associated with HIV positive infants included mothers being on ART for less than three months. Over half (77.6%) of pregnant women attending ANC in our study had more than three months of experience in taking ART; the women with less than 3 months experience were at increased risk of having their child infected with HIV. Among a sample of pregnant women on ART in Malawi, the proportion of women with poor adherence were found to be higher among those that had been on ART for less than 12 weeks which affected their viral load at the time of

delivery[26]. High viral load and non-adherence to ART have been shown to be significant predictors of MTCT [26].

Comparable to our study, no significant difference in HIV positivity among women who exclusively breastfed compared to those that did not (though it was borderline significance, most likely due to the small number) was found in an evaluation conducted in Kenya [26]. This is in spite of a study that detailed the existence of stigma impacting the ability to exclusively breastfeed, described among both HIV positive and negative women [26]. In our sample, 78.3% of women exclusively breastfed their infant the first 6 months during the postnatal period. This is lower than other studies that have shown exclusive breastfeeding within the last 7 days of 88.1% among a sample of post-partum women and their infants in Rwanda [26]. However, other studies have reported much lower proportions of women (34.9%) predominantly breastfeeding their infants, with the predominate feeding method being formula as indicated in a study from South Africa[26].

Our findings showed no adverse outcomes among pregnant women in ANC. In alignment, a study investigating outcomes for pregnant women on ART in Kenya found no factors associated with treated HIV and adverse pregnancy outcomes such as pregnancy loss, premature birth, or low birth weight [26]. Among the births included in our study, 4.2% were stillbirths. This figure is consistent with other findings that reported a 4% [26] and 4.6% stillbirth occurrence[26]. HIV positive pregnant women not consistently taking ART however has been shown to have higher likelihood of low birth weight among their infants [27].

Limitations

The primary limitation of this evaluation is that the data are derived solely from routine clinical documentation. Due to varying quality of clinical documentation there may be errors in what is documented, errors in data entry, and/or clinical information may be omitted. For this reason, we were not able to assess all the study objectives due to missing or incomplete data. In addition, while the program intends to track patients for the full time period and to capture final outcomes for patients (transfers, lost to follow up, and deaths), it may not be possible to track and ascertain final outcomes for any patients who may have provided false contact information, transferred under a different ID, or relocated without informing the clinic. Final outcome for women and infants who were lost to follow up or transferred out could not be determined as this was not documented. We were also not able to assess factors associated with HIV transmission due to the few numbers of positive infants. This study collected

data from health facilities that implemented EMR at the time of data collection. As such, the study findings might not be entirely reflective of the actual situation in terms of PMTCT implementation within Homa Bay County.

Finally, the variable set itself is a limitation in that many dimensions of comprehensive care are not routinely documented, particularly the social and behavioral characteristics of patients such as disclosure, changes in sexual partners, alcohol and drug use, etc. Similarly, some variables are not comprehensively captured by providers, such as anthropometric measurements in infants, adherence, which currently relies upon subjective provider assessments of adherence and pill pickups rather than objective measures such as pill counts.

Conclusion

We observed an enrollment rate of HIV positive pregnant women into PMTCT at slightly over 90%. Almost 6% of those enrolled to ANC did not have documented pregnancy outcomes. The participants were of a relatively young age. The results also reported almost a third of the participants' partners had unknown HIV status. This presents missed opportunities for couple counseling, potential gaps in disclosure as well as risk for seroconversion for HIV negative infants whose mothers are in discordant relationships. Additionally, from the results, the number of women attending all four ANC sessions is relatively low, and most women begin their ANC clinics during the second trimester. This also indicates that newly diagnosed HIV positive women may be initiating ART late, and interventions to address prevention of mother to child transmission may also be delayed. For the known HIV positive women, late ANC attendance presents missed opportunities for pregnancy screening at CCC as well as verification of viral suppression prior to PMTCT enrolment. Furthermore, about 14% of the mothers did not deliver in a health facility, possibly leading to missed opportunities. Again, this presents gaps in comprehensively addressing prevention of mother to child transmission opportunities. Lastly, among the infants who sero-converted, most (72.7%) of their mothers were relatively new to HIV medication (less than three months). Consequently, newly identified women living with HIV during pregnancy may require more intense follow up and adherence to strengthen the prevention of mother to child transmission. It is important to encourage women to know their HIV status before pregnancy.

Key Take Away

	Key findings	Take away	Who/when to implement
1	Median gestational age at 1st ANC was 22 weeks and about half of women completing 4 ANC visits	<ul style="list-style-type: none"> Strengthen early ANC uptake Completion of minimum ANC visits 	Community level Facility level
2	About a quarter of women do not know the HIV status of their partners	<ul style="list-style-type: none"> Strengthen couple counselling and testing 	Community level Facility level
3	A quarter of women gave birth away from the health facility	<ul style="list-style-type: none"> Patient education and birth planning Strengthening uptake of PMTCT 	Community level Facility level
4	8 of the 12 infants who had a positive EID result did so in the first 6 weeks after birth	<ul style="list-style-type: none"> Strengthen early uptake of PMTCT Repeat HIV testing during ANC 	Community level Facility level

Dissemination

The findings have been disseminated in the County to the CHMT, HCWs and other implementing partners in the county. These findings have also been presented to representatives from CDC who were also present during the dissemination meeting. The findings will be disseminated through a manuscript in a peer review journal. The final report will be shared with CHMT, NASCOP and partners and will be posted on a public website.

	Target Audience	Action Point	Channel of Communication	Time and Place
1	CHMT, Facility In-charges, health care workers	Share evaluation findings and key recommendations to strengthen program implementation	Power point presentation	Homa Bay County, meeting on 27 th July 2022

2	NASCOP, County Director of health, CASCO	Submit signed copies of the report	Report	October 2022
3	Peer reviewed Journal		Manuscript	Under preparation

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Appendices

1. Protocol, Evaluation of PMTCT interventions and outcomes among HIV-positive pregnant, breastfeeding women, and their HIV-exposed infants in Homa Bay County, Kenya. V 3.1, 21 May 2021
2. Data abstraction tools
3. CVs and RETC
- 4.



MBP tool.xlsx



Kenya MBP cohort
protocol_v3.1 21Ma



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As an employee with the Elizabeth Glaser Pediatric AIDS Foundation, a subcontracted employee, partner or governmental personnel, consultant, intern, or visiting professional, I understand that I will be exposed to privileged participant/patient information in the conduct of my duties as a member of a research team. Examples include but are not limited to medical conditions, HIV status, medical treatments, finances, living arrangements, and sexual orientation. The study participant/patient's right to privacy is not only a policy of the Elizabeth Glaser Pediatric AIDS Foundation, but is specifically guaranteed by research ethical and governmental regulations. I understand that intentional or involuntary violation of the confidentiality policies is subject to appropriate disciplinary action(s) that could include being discharged from my position and/or being subject to other penalties. By signing this document, I further agree that:

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4. I will maintain my computer protected by power on and screen saver passwords. I will not disclose my computer passwords to unauthorized persons.
5. I understand that I am responsible for preventing unauthorized access to or use of my keys, passwords, and other security codes.
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