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MINISTRY OF HEALTH

The Effectiveness of eMTCT Package Implementation in CHAK- CHAP Uzima Supported Health Facilities, Kenya

FINAL EVALUATION PERFOMANCE MEASUREMENT PLAN REPORT

Supporting the Implementation and Expansion of High Quality, Sustainable and Comprehensive HIV Prevention, Care and Treatment Programs in Faith-Based Organization Facilities in the Republic of Kenya under the President's Emergency Plan for AIDS Relief (PEPFAR)

1ST APRIL, 2017 – 29TH SEPTEMBER, 2022

STUDY TITLE: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya

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Abbreviations and Acronyms

AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	Centers for Disease Control and Prevention
CHAK	Christian Health Association of Kenya
CS	Caesarean Section
EBF	Exclusive Breastfeeding
EID	Early Infant Diagnosis
eMTCT	Eradication of Mother to Child Transmission of HIV
ERF	Exclusive Replacement Feeding
HAART	Highly Active Antiretroviral Treatment
HEI	HIV Exposed Infant
HIV	Human Immunodeficiency Virus
INSTI	Integrase Strand Transfer Inhibitors
IPD	Inpatient Department
IPV	Intimate Partner Violence
LDL	Lower Detection Limit
LTFU	Lost to Follow Up
MCH	Maternal and Neonatal Child Health
MEI	Mother Exposed Infant
MF	Mixed Feeding
MOH	Ministry of Health
NASCOP	National AIDS & STI's Control Program
NNRTI	Non- Nucleoside Reverse Transcriptase Inhibitors
OPD	Outpatient Department
OI	Opportunistic Infection
OR	Odds Ratio
PBFW	Pregnant and Breastfeeding Women
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PI	Protease Inhibitors
PHQ-9	Patient Health Questionnaire-9
PMTCT	Prevention of Mother to Child Transmission of HIV
PNC	Post Natal Clinic
SDG	Sustainable Development Goals
SVD	Spontaneous Vaginal Delivery
USG	United States Government
VL	Viral Load
WHO	World Health Organisation

Definition of Terms

HEI EID Outcome	A HIV positive or HIV negative result determined either using EID results from the 6-week, 6 month, and 12-month PCR test, or a rapid HIV test at or after 18 months of age.
Adherence	Good adherence was defined as taking over 95% pills prescribed on self-report and pill count.
Retention	Retention in care was defined as continuous engagement in HIV care without any treatment interruption exceeding 3 months.
MEI Retention Outcome	The attrition status of the mother and exposed infant at 18-24 months of follow up where alive, transfer out, dead or lost to follow up
Depression	A score of more than 5 points on Public Health Questionnaire-9 (PHQ-9) scoring
Viral Suppression	A viral load of less than 400 copies/ml (defined by the national guidelines in use during the study period)

Executive Summary

Kenya has made tremendous strides towards elimination of mother to child transmission (eMTCT) as evident from the drop in MTCT rate from 16% (2012) to 10.8% (2017), and a resultant reduction of new infections in children from 12,941(2013) to 7,878 (2017) (Ministry of Health, 2018). This is attributed to improved case identification and comprehensive intervention strategies employed by the Ministry of Health through the National AIDS & STI's Control Program (NASCOP). Despite this improvement, Kenya is off the <5% MTCT target, with missed opportunities for uptake and coverage of comprehensive eMTCT interventions including Early Infant Diagnosis (EID) due to low utilization of antenatal care and skilled delivery services; stigma and discrimination to adolescent girls and young women and HIV positive mothers, high poverty and illiteracy levels and other vulnerability of Adolescent Girls and Young Women (AGYW), as well as logistic and commodity supply chain disruptions(Chirombo et al., 2016).

The Christian Health Association of Kenya, through the Centre for Disease Control received USG-PEPFAR funding for a five-and-a-half-year project – CHAP Uzima (CHAK HIV/AIDS Project – Uzima) to implement comprehensive Prevention of Mother to Child Transmission of HIV (PMTCT) interventions that results in achieving the <5% MTCT of HIV and syphilis. This is in line with the Kenyan eMTCT Framework 2016-2021 that aims at ending new infections among children and keeping their mothers alive (Start Free, Stay Free) (UNAIDS, 2021). The strategies implemented was in line with the 4 prongs of PMTCT namely: primary prevention of HIV among girls and women of reproductive age, prevention of unintended pregnancies among Girls and Women of Reproductive Age, prevention of mother to child transmission; and lifelong care for mother, child and family members through sustained suppression and retention.

De-identified data was abstracted from routine data sources into the investigational database for the period 1st April 2017 to 30th September 2019. HIV Exposed Infant and Maternal clinical and sociodemographic characteristics were included. Descriptive statistics were calculated, bivariate and multivariate regression analysis were conducted. A total of 3,340 HIV Exposed Infants (HEI) and 3,314 mothers were evaluated from 78 project sites. Antenatal Clinic attendance (ANC), HIV testing, ART initiation and maternal viral suppression was >95% in the study cohort. EID uptake at both month 2 and 2-12 months was >95%, with an overall HIV positivity rate of 2.3%. HEI and maternal retention at 18-24months was 86% and 96.3% respectively. Factors associated with low MTCT were on schedule immunization status (OR;95% CI: 10.991(7.753-15.580), exclusive breastfeeding (OR; 95%CI: 2.509(1.103-

5.708), increasing maternal age (OR; 95%CI: 2.132(1.152-3.945)), the absence of maternal depression (OR;95% CI: 0.611(0.409-0.913) and optimal maternal adherence (OR;95%CI: 5.553(3.439-8.967) were the significant predictors of a HEI negative status at p<0.05. Infant retention was associated with on schedule immunization status (OR;95% CI: 2.909(1.469-5.760), exclusive breastfeeding (OR;95% CI: 0.054(0.006-0.500), maternal age above 25 years (OR;95% CI:3.482(1.250-9.702), and mother being on any ART regimen with optimal adherence (OR;95% CI: 14.124(7.661-26.039) at *p<0.05.* Maternal retention was associated with good adherence to ART (OR;95%CI: 12.166(7.118-20.794), known HIV status of the partner-HIV negative (OR;95%CI: 2.132(1.218-3.733) and an increasing age of the mother (OR;95%CI: 2.960(1.245-7.040) for age 25+ years respectively (p<0.05).

Kenya is lagging behind towards achievement of eMTCT for both HIV and syphilis, with 21 counties recording an increase in new infections for the period 2013-2015 (Chirombo et al., 2016). Structured strategies targeting the 4 prongs of PMTCT, with particular focus on young mothers and their partners, improving provider and program capacity to provide comprehensive eMTCT intervention, retention management and data use for decision making is critical to ensure that there is no room for missed opportunities. More research would be useful to further understand the factors contributing to significant MTCT and Mother Exposed Infant (MEI) pair attrition in order to inform PMTCT programming and long-term engagement in care for MEI pairs.

This evaluation project has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the CDC's Cooperative Agreement Number: 6 NU2GGH002034-01-01 with the Christian Health Association of Kenya under the CHAK CHAP Uzima program. The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the funding agencies.

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Conflict of Interest Statement

All co-investigators involved in this evaluation report no actual or potential conflicts of interest.

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1.0 Background

Globally, more than half (51%) of People Living with HIV are women. Sub Saharan Africa contributes over half of the new vertical HIV infections in 2020 (World Health Organisation, 2021). Without intervention, the risk of vertical HIV transmission during pregnancy, delivery and breastfeeding range from 20-45%(PMTCT UNGASS, 2010). Kenya has the third-largest HIV epidemic in Africa with 1.43 million People Living with HIV and 32,027 new HIV infections annually (MOH, 2021). In 2012, WHO introduced option B+, the provision of life long Antiretroviral Therapy (ART) to all HIV positive pregnant and breastfeeding women irrespective of CD4+ cell count or WHO clinical stage (WHO Summary, 2012). The Start Free, Stay Free, AIDS Free global agenda was launched in 2016, to prioritize prevention of new infections among women, strengthen retention of Pregnant and Breastfeeding Women (PBFW) living with HIV on life-long ART and accelerate identification and treatment of HIV positive infants and children. Kenya adopted implementation of option B+ in 2012, expanding Anti-Retroviral Treatment (ART) access to all PBFW Living with HIV. Infants born to HIV positive women (HIV Exposed Infants-HEI) start daily 6 weeks of Azidothymidine (AZT) + Nevirapine (NVP) and thereafter NVP continued until 6 weeks after complete cessation of breastfeeding; while the mother continues life-long ART (NASCOP, 2018). The Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 report estimates a double the HIV prevalence among women aged 15-49years compared to men at 6.6% and 3.1% respectively. Despite the adoption of the Test and Start guidelines, there is a high unmet need for treatment among PBFW Living with HIV at 7.9%. National programmatic data indicates low skilled birth attendance (77.4%) and suboptimal Early Infant Diagnosis (EID) uptake at 69% for infants < 8 weeks and overall EID at 60% (KHIS 2021); posing missed opportunities for maternal ART, skilled birth delivery and infant prophylaxis initiation, a harbinger for increased risk of vertical transmission. During the 2012-2015 period, Kenya implemented the first eMTCT strategic framework and successfully halved mother- to-child transmission of HIV from 16% to 8.3%. However, the gains have been reversed by weak devolved health systems requiring a revision of the national eMTCT framework (2016-2021) that sets bold elimination targets for HIV of fewer than 50 new HIV infections among children per 100,000 live births, less than 5% MTCT of HIV and over 95% antenatal coverage as of 2021. However, the MTCT rate stands at 11.5% against the global target of <5% (*HIV Estimates 2020_Vs 17*, n.d.). Measuring and tracking the impact of eMTCT programs is critical towards monitoring progress towards the virtual eMTCT goal, as well as informing responsive interventions and

programming. We sought to evaluate the progress and challenges towards achieving eMTCT by implementing core PMTCT interventions in the CHAP Uzima project during the period 2017 to 2019.

2.0 Evaluation Methodology and Approach

2.1 Evaluation Setting

Evaluation Settings: The CHAK-CHAP Uzima project is a 5-year PEPFAR-CDC funded project whose overarching goal is to support the expansion and provision of sustainable high-quality HIV prevention, care and treatment services in faith affiliated health facilities in Kenya from 1st April 2017 to 29th September 2022. The analyses was conducted from 78 CHAP *Uzima* supported health facilities located in 19 counties of Nairobi, Kajiado, Narok, Nakuru, Laikipia, Kiambu, Muranga, Kirinyaga, Nyeri, Nyandarua, Makueni, Machakos, Kitui, Embu, Tharaka Nithi, Meru, Taita Taveta, Kilifi and Mombasa county. These facilities are implementing a comprehensive eMTCT package as per the national guidelines.

2.2. Study Design

Using a maximum variation sampling, we conducted a retrospective study of PMTCT interventions in the CHAP Uzima Program. The study analyzed all HIV positive PBFW and HEI identified at 78 project sites between 2017 to 2019.

2.3 Study Participants

All HIV positive pregnant and breastfeeding women, and HIV Exposed Infants identified and enrolled from routine clinical visits and reviews in the period April 2017 to December 2019 and were enrolled for longitudinal follow up within the supported facilities were included in the study population. HIV positive PBFW or HEI identified but linked for follow up in non-project sites were excluded.

2.4 Data Collection Methods and Rationale

Health care workers at the project sites implement the PMTCT package of care as per MoH recommendations with documentation in patient charts and registers (HEI card, HEI register, MOH 257 Green Card, ANC, Maternity and Post Natal Care Registers). Site specific data was abstracted and subsequently aggregated for assessment of clinical and sociodemographic variables. Analysis of routine data can inform descriptive features (prevalence or incidence of

MTCT, ART options and risk factors), associations with putative risk factors and/or treatment effects of interventions (e.g. ART, skilled delivery, exclusive breastfeeding etc.).

The primary dependent variable was HEI EID outcome (whether HIV positive or HIV negative) determined using EID results from the 6week, 6-month, 12-month PCR tests, or a rapid HIV test at 18-24 months. The secondary dependent variable was MEI pair retention at 18-24 months. Independent HEI variables evaluated were: age at enrolment into HEI care, entry point to HEI care, ARV prophylaxis given, infant delivery options-home vs facility delivery, infant feeding options (exclusive breast feeding, replacement feeding, mixed feeding); immunization status, and infant retention status at 24months.

The maternal predictor variables were: age at HEI enrolment, entry point into HIV care, duration on ART at HEI enrollment, maternal ARV regimen, adherence to ART, maternal VL in pregnancy and at 24mo, partner HIV status, IPV/GBV screening outcomes, PHQ-9 depression score, Opportunistic Infections (OIs) during PBFW period, maternal retention at 24 months. Good adherence was defined as taking over 95% pills prescribed on self-report and pill count. Retention in care was defined as continuous engagement in HIV care without any treatment interruption exceeding 3 months.

De-identified data was abstracted from routine data sources into the investigational database with role-based access to specific data by evaluation staff who had undertaken human subjects' protection training and signed protocol specific data use and confidentiality agreements.

2.5 Data Analysis

Statistical analyses were performed using STATA V.14. All variables were initially examined for distribution, range, outliers and the extent of missing data. Descriptive analyses consisting of mean, median, interquartile range for continuous variables and proportions (95% confidence intervals) for categorical variables was conducted. Chi-squares and T-tests were computed for categorical and continuous variables respectively. Multivariate logistic regression analysis for binary outcomes and cox proportional hazards regression model for time to event outcomes was computed. All statistical tests were 2-sided and p-values less than 0.05 considered significant.

2.6 Evaluation Strengths and Limitations

The evaluation data was collected under real-world circumstances, maximizing representativeness and generalizability, minimizing costs and effort, and allowing the capture

of information in large populations and many clinical events in large datasets that are continuously updated and cover long periods (Lars G. Hemkens, 2016). The limitations in use of this retrospective datasets includes errors and biases in data processing (due to data misclassification, missing data sets, data linkage problems), inability to control for exposure, and lack of a comparison group limiting the strength of association and causality. This was however controlled for using instrumental variable analysis and missing data imputation.

2.7 Stakeholder Engagement

Stakeholder engagement was embedded in the program design, implementation, monitoring and evaluation. Key stakeholder and their roles were: The MoH at national and county levels who provided guidance and supportive supervision for implementation of comprehensive MTCT interventions; CDC-Kenya who provided programmatic guidance, budgetary support and technical assistance; CHAK management and project management team who provided the requisite project leadership for successful implementation; Facility health care providers who served as frontline service providers and assisted in data collection; Patients and communities who were the primary beneficiaries of project interventions; and project staff who provided mentorship and supportive supervision to facility staff, as well as data validation, analysis, interpretation and dissemination. Periodic reports were disseminated on routine and ad hoc basis to keep all stakeholders abreast of the project progress; with continuous learning and adaptation from stakeholder feedback.

2.8 Ethical Considerations

The Investigators and evaluation staff undertook human subject protection training and signed confidentiality agreement forms before role-based access to de-identified investigational database. The study was approved by the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee (KNH-UON ERC), protocol number P753/12/2O17 and by CDC. The protocol 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 non-research. The CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes. A waiver of informed consent was applied according to Section 45 CFR 46 (d) guidance on use of routinely collected data.

2.9 Use of Evaluation Findings

This project activity will provide important information for public-health decision makers and HIV service delivery; enabling review of the progress on implementation of eMTCT package of care and highlight critical interventions for successful programming.

3.0 Findings

For the final analysis, we reviewed a total sample of 3,340 HEI, of whom 3,054 (91.4) were enrolled into the PMTCT program at <8wks of age; with the primary entry point being the Maternal and Neonatal Child Health Clinics 2,093(62.7%) and the Comprehensive Care Clinic-1,147(34.3%). The median age for enrolment was 6wks. ARV prophylaxis was provided to 3,267(98%) infants and 3,239 (97%) were exclusively breastfed, whereas 47 (1.4%) and 54 (1.6%) had exclusive replacement feeding and mixed feeding respectively *(Table 1)*. Immunization status was up to date for 3,140 (94%) infants as per the Kenya expanded program on immunization schedule. A total of 9,168 EID and 2,826 rapid tests were conducted, whereby 78 infants were confirmed HIV positive, posting an overall MTCT rate of 2.3%. The MTCT rate was 2% (61/3233), 0.1% (5/2,963), 0.2% (7/2,972), 0.2% (5/2826) at 6wk, 6 months, 12 months and 18 months respectively. The majority of infants were exited from the program at 18-24 months as HIV negative 2,871(85.9%), 75(2.3%) as HIV positive enrolled in care, 141(4.2%) as LTFU, 42 (1.3%) as mortalities, 184 (5.5%) as transfer-outs; posting a crude retention rate of 91.3%. 27 infants had not been exited from care at due to continued breastfeeding beyond the 24-month follow up period.

Table 1: Infant Clinical and Sociodemographic Characteristics: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 1: Infant Characteristics Clinical and Sociodemographic Characteristics

Characteristic	n(%)
Infant Age at Enrolment (wks)	
<=8	3054(91.4)
9-52	237(7.1)
>52	49(1.5)
Entry Point	
IPD	13(0.3)
OPD	69(2.1)
MAT	18(0.5)
CCC	1147(34.3)
MCH	2093(62.7
PCR Results (6 wks)	
Neg	3172(98)
Pos	61(2)
Received Infant Prophylaxis	
No	73(2)
Yes	3267(98)
Infant Feeeding Option	
EBF	3239(97)
ERF	47(1.4)
MF	54(1.6)

Characteristic	n(%)
PCR Results (6 months)	
Neg	2958(99.8)
Pos	5(0.1)
Not documented	2(0.1)
PCR Results (12 months)	
Neg	2785(99.8)
Pos	7(0.2)
Antibody Results (18-24 months)	
Neg	2821(97.9)
Pos	5(0.2)
Not documented	56(1.9)
Immunization Status	
On schedule	3140(94)
Not on schedule	200(6)
Infant Outcome	
HIV Neg and excited	2871(86)
POS and enrolled	75(2.3)
LTFU	141(4.2)
TO	184(5.5)
Dead	42(1.3)
Not discharged	27 (0.8)

Key: IPD-Inpatient Department, OPD-Outpatient Deaprtment, MAT-Maternity, CCC-Comprehensive Care Clinic, MCH-Maternal and Neonatal Child Health, PCR-Polymerase Chain Reaction, EBF-Exclusive Breast feeding, ERF-Exclusive Replacement Feeding, MF-Mixed feeding; LTFU-Lost to Follow Up, TO-Transfer Out.

A total of 3,314 mothers were enrolled into the study, of whom 435(13.2%) were young mothers aged <25yrs whereas 2,879 (86.8%) mothers were >24yrs, with the median age being 33yrs (IQR 28-37) *(Table 2)*. The majority of mothers 2,911(87.1%) were known positive (KP) on ART at HEI enrolment. The cumulative total of KP and new positives on ART was 3,314, with 2,270 (68%), 896 (26.8%), 145 (4.3%) on NNRTI, INSTI and PI based ARV regimens respectively. Maternal viral suppression in pregnancy and breastfeeding period was 97.8% (n=2,443), with significant optimal adherence to ART at 96.3% of the study population. A total of 2,153 (64.9%) women had partners with known status, with 44.1% in sero-discordant relationships. There was a high prevalence of IPV and depression elicited at 19.1% and 6.9%, and minimal opportunistic infections during the PBFW period at 0.5% respectively in the study population.

Table 2:Maternal Clinical and Sociodemographic Characteristics: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 2: Maternal Clinical and Sociodemographic Characteristics

Characteristic	n(%)	Characteristic	n(%)
Maternal Age		**Mode of Delivery**	
<20	82(2.5)	C/S	457(13.7)
20-24	353(10.7)	SVD	2,883(86.3)
>24	2879(86.9)	**Place of Delivery**	
ANC Attendance		Home	53(1.6)
No	95(2.8)	Hospital	3287(98.4)
Yes	3245(97.2)	**Adherence**	
HIV Status		Good	3187(95.4)
Known Positive	2911(87.1)	Poor	153(4.6)
New Positive	403(12.1)	**IPV Present**	
Not documented	26(0.8)	N	2707(81)
Partner Tested for HIV		Y	633(19)
Yes	2164(64.8)	**Alcohol and Substance abuse**	
No	882(26.4)	N	3304(98.9)
Not documented	294(8.8)	Y	36(1.1)
Partner HIV Status		**Depression**	
HIV Positive	1205(36.1)	N	3111(93.1)
HIV Negative	949(28.4)	Y	229(6.9)
Not documented	1186(35.5)	**OI's during PBFW Period**	
Maternal ARV Regimen		N	3327(99.6)
INSTI	896(26.8)	Y	13(0.4)
NNRTI	2270(68)	**Maternal Retention**	
PI	145(4.3)	Alive	3216(96.3)
Not documented	29(0.9)	Dead	26(0.8)
Maternal VL Status (18-		LTFU	98(2.9)
>1000	45(1.4)		
400-1000	8(0.2)		
<400	216(6.5)		
LDL	2175(65.1)		
ND	896(26.8)		

Key: ANC-Antenatal Clinic; INSTI-Integrase Strand Transfer Inhibitors, NNRTI-Non Nucleoside Reverse Transcriptase Inhibitor, PI-Protease Inhibitors, VL-Viral Load, CS-Caeseran Section, SVD-Spontaneous Vaginal Delivery, IPV-Intimate Partner Violence, LTFU-Lost to Follow Up.

Spontaneous vaginal delivery accounted for 83.6% of all the deliveries, with only 52 (1.5%) of women delivering at home without any skilled birth attendance. Twenty-four-month maternal retention was 96.8%, with a 2.5% LTFU and 0.6% mortality rate.

On univariate analysis, HEI characteristics associated with a HIV negative outcome and infant retention were infant enrolment at age <8wks; on schedule immunization status; exclusive breastfeeding; infant receiving any ARV prophylaxis (p<0.001) *(Table 3)*. Maternal characteristics associated with HIV negative HEI outcome and retention were: mother being on a NNRTI ARV regimen backbone; maternal age above 25 years; a suppressed maternal VL status <400 copies/ml; >95% adherence to ART and skilled birth attendance. Absence of maternal depression and substance abuse was associated with HIV negative HEI outcome but no correlation with infant retention. ANC attendance was associated with improved retention.

Table 3: Factors Associated with Infant HIV Outcome and MEI Retention: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 3: Univariate Factors Associated with Infant HIV Outcome and MEI Retention

	Infant HIV Outcome				MEI Retention Outcome			
Factor	**Other (Pos, TO, Dead)**	**Neg**	**Chi-value**	**P-value**	**Not retained**	**Retained**	**Chi-value**	**P-value**
Infant Age at Enrollment								
<=8weeks	394(12.9%)	2660(87.1%)	39.399	**<0.001**	98(3.2%)	2956(96.8%)	29.774	
9-52 wks	60(25.3%)	177(74.7%)			19(8.0%)	218(92.0%)		**<0.001**
>52 wks	15(30.6%)	34(69.4%)			7(14.3%)	42(85.7%)		
Entry Point								
IPD	5(38.5%)	8(61.5%)			2(15.4%)	11(84.6%)		
OPD	17(24.6%)	52(75.4%)	13.934	**<0.001**	4(5.8%)	65(94.2%)	6.152	
MAT	3(16.7%)	15(83.3%)			1(5.6%)	17(94.4%)		0.188
CCC	165(14.4%)	982(85.6%)			43(3.8%)	1104(96.3%)		
MCH	279(13.3%)	1814(86.7%)			74(3.5%)	2019(96.5%)		
Immunization Status								
On schedule	346(11.0%)	2794(89%)	396.967	**<0.001**	83(2.6%)	3057(97.4%)	167.714	**<0.001**
Not on schedule	123(61.5%)	77(38.5%)			41(20.5%)	159(79.5%)		
Maternal ARV Regimen								
INSTI	103(11.5%)	793(88.5%)			25(2.8%)	871(97.2%)		
NNRTI	330(14.5%)	1940(85.5%)	53.127	**<0.001**	74(3.3%)	2196(96.7%)	348.887	**<0.001**
PI	19(13.1%)	126(86.9%)			5(3.5%)	140(96.6%)		
Not Documented	17(58.6%)	12(41.4%)			20(69%)	9(31.0%)		
Maternal Age								
15-19 yrs	23(28.1%)	59(72%)	29.785	**<0.001**	9(11%)	73(89.0%)	22.558	**<0.001**
20-24 yrs	71(20.1%)	282(79.9%)			18(5.1%)	335(94.9%)		
25+ years	361(12.5%)	2518(87.5%)			78(2.7%)	2801(97.3%)		
Infant Feeding Option								
EBF	437(13.5%)	2802(86.5%)	52.917	**<0.001**	113(3.5%)	3126(96.5%)	15.878	**<0.001**
ERF	6(12.8%)	41(87.2%)			6(12.8%)	41(87.2%)		
MF	26(48.2%)	28(51.8%)			5(9.3%)	49(90.7%)		
Received Infant ARV Prophylaxis								
No	32(43.8%)	41(56.2%)	54.885	**<0.001**	13(17.8%)	60(82.2%)	41.481	**<0.001**
Yes	437(13.4%)	2830(86.6%)			111(3.4)	3156(96.6%)		
Maternal VL Status 18-24mo								
LDL	244(11.2%)	1931(88.8%)	103.57	**<0.001**	36(1.7%)	2139(98.3%)		
<400	16(7.4%)	200(92.6%)			2(0.9%)	214(99.1%)	109.132	**<0.001**
400-1000	5(62.5%)	3(37.5%)			1(12.5%)	7(87.5%)		
>1000	20(44.4%)	25(55.6%)			6(13.3%)	39(86.7%)		
ND	184(20.5%)	712(79.5%)			79(8.8%)	817(91.2%)		
Depression								
Yes	48(21%)	181(79%)	9.751	**<0.001**	12(5.2%)	217(94.8%)	1.605	0.205
No	421(13.5%)	2690(86.5%)			112(3.6%)	2999(96.4%)		
Alcohol & Substance Abuse								
No	456(13.8%)	2848(86.2%)	14.685	**<0.001**	121(3.7%)	3183(96.3%)	2.174	0.14
Yes	13(36.1%)	23(63.9%)			3(8.3%)	33(91.7%)		
Place of Delivery								
Home	22(41.5%)	31(58.5%)	33.663	**<0.001**	14(26.4%)	39(73.6%)	77.647	**<0.001**
Hospital	447(13.6%)	2840(86.4%)			110(3.4%)	3177(96.7%)		
Mode of Delivery								
C/S	59(12.9%)	398(87.1%)	0.562	0.454	8(1.8%)	449(98.3%)	5.701	**0.017**
SVD	410(14.2%)	2473(85.8%)			116(4%)	2767(96%)		
Adherence								
Good	382(12%)	2805(88%)	243.586	**<0.001**	64(2%)	3123(98%)	565.385	**<0.001**
Poor	87(56.9%)	66(43.1%)			60(39.2%)	93(60.8%)		
OIs during PBFW Period								
No	462(13.9%)	2865(86.1%)	17.131	**<0.001**	121(3.6%)	3206(96.4%)	13.69	**<0.001**
Yes	7(53.9%)	6(46.2%)			3(23.1%)	10(76.9%)		
IPV Present								
No	374(13.8%)	2333(86.2%)	0.604	0.437	102(3.8%)	2605(96.2%)	0.123	0.726
ANC Attendance								
					32(33.7%)	63(66.3%)	245.715	**<0.001**
					92(2.8%)	3153(97.2%)		

Key: IPD-Inpatient Department, OPD-Outpatient Department, MAT-Maternity, CCC-Comprehensive Care Clinic, MCH-Maternal and Neonatal Child Health, PCR-Polymerase Chain Reaction, EBF-Exclusive Breast feeding, ERF-Exclusive Replacement Feeding, MF-Mixed feeding; PBFW- Pregnant and Breasfeeding Woman, LTFU-Lost to Follow Up, TO-Transfer Out, OI-Opportunistic Infection

Treatment of the mother for any opportunistic infection during the PBFW period was associated with higher infant attrition. The entry point into HEI care and presence of reported IPV did not have any association with attrition (p>0.05).

On multivariate regression analysis incorporating the significant covariates identified on univariate analysis, on schedule immunization status, exclusive breastfeeding, increasing maternal age, the absence of depression, optimal maternal adherence and suppression were the significant predictors of a HEI negative status (p<0.05) *(Table 4).* Infants of mothers with good adherence were almost 6 times more likely to have a negative outcome compared to those with poor adherence (OR;95%CI: 5.553(3.439-8.967), p<0.001. Infants of mothers with depression during pregnancy were 42% less likely to have a HIV negative status compared to those without

Table 4: Multivariate Factors Associated with HIV Negative Status in HEI: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 4: Multivariate Factors Associated with HIV Negative Status in HEI

Factor	Odds ratio(95%CI)	SE	P-value	Factor	Odds ratio(95%CI)	SE	P-value
Infant Age at Enrollment(ref>52 wks)				**Received Infant Prophylaxis**			
<=8wks	1.164(0.495-2.739)	0.508	0.727		1.089(0.501-2.369)	0.432	0.829
9-52 wks	0.748(0.315-1.776)	0.33	0.511	**Maternal VL 18-24mo(ref>1000)**			
Entry Point				LDL	1.748(1.342-2.275)	0.235	**<0.001**
IPD	0.371(0.083-1.663)	0.284	0.196	<400	3.911(2.151-7.112)	1.193	**<0.001**
OPD	0.730(0.363-1.466)	0.26	0.376	400-1000	0.280(0.054-1.464)	0.236	0.131
MAT	1.792(0.291-11.030)	1.661	0.53	ND	0.908(0.406-2.030)	0.372	0.814
CCC	0.821(0.634-1.064)	0.109	0.137	**Depression**			
Immunization					0.611(0.409-0.913)	0.125	**0.016**
(On schedule)	10.991(7.753-15.580)	1.957	**<0.001**	**Alcohol and Substance**			
Mother Regimen					0.745(0.319-1.738)	0.322	0.496
INSTI	0.630(0.482-0.824)	0.086	**0.001**	**Place of delivery (Hospital)**			
NNRTI	0.863(0.479-1.554)	0.259	0.624		1.225(0.575-2.610)	0.473	0.598
Age of the				**Adherence (Good)**			
20-24 years	1.282(0.656-2.503)	0.438	0.467		5.553(3.439-8.967)	1.357	**<0.001**
25+ years	2.132(1.152-3.945)	0.669	**0.016**	**OIs During PBFW**			
Infant Feeding Option(ref=MF)					0.850(0.224-3.229)	0.579	0.811
EBF	2.509(1.103-5.708)	1.052	**0.028**				
ERF	6.633(1.698-25.911)	4.612	**0.006**				

Key: IPD-Inpatient Department, OPD-Outpatient Deaprtment, MAT-Maternity, CCC-Comprehensive Care Clinic, MCH-Maternal and Neonatal Child Health, EBF-Exclusive Breast feeding, ERF-Exclusive Replacement Feeding, MF-Mixed feeding; OI-Opportunistic Infection, PBFW-Pregnant and Breatfeeding Woman

depression (OR;95% CI: 0.611(0.409-0.913). Infants whose immunization status was on schedule were 10 times more likely to have a HIV negative outcome status compared to those who were not on schedule (OR;95% CI:10.991(7.753-15.580), p<0.001.

On multiple logistic regression for factors associates with infant retention, on schedule immunization status, exclusive breastfeeding, maternal age above 25 years, mother being on any ART regimen with optimal adherence, were significant predictors of retention *(p<0.05) (Table 5).* Infants of mothers with good adherence were almost 14 times more likely to have been retained compared to those with poor adherence (OR;95% CI: 14.124(7.661-26.039). Infants whose immunization status was on schedule were almost 3 times more likely to have

been retained compared to those who were not on schedule (OR;95% CI: 2.909 (1.469-5. 760); p 0.002.

Table 5:Factors Associated with HEI Retention at 18-24 months: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 5: Factors Associated with HEI Retention at 18-24months

Factor	Odds ratio(95%CI)	SE	P-value	Factor	Odds ratio(95%CI)	SE	P-value
Infant Age at Enrollment(ref>52 wks)				**Mode of Delivery (ref=CS)**			
<=8wks	3.665(0.906-14.820)	2.613	0.068	SVD	1.509(0.676-3.370)	0.619	0.316
9-52 wks	3.171(0.702-14.330)	2.44	0.134	**OIs during PBFW**			
Immunization Status					1.032(0.165-6.449)	0.965	0.973
(On schedule)	2.909(1.469-5.760)	1.014	**0.002**	**Infant Feeding Option(ref=MF)**			
Age of the Mother(ref=15-19)				EBF	0.054(0.006-0.500)	0.061	**0.01**
20-24 years	1.754(0.561-5.478)	1.012	0.334	ERF	0.045(0.003-0.625)	0.6	**0.021**
25+ years	3.482(1.250-9.702)	1.82	**0.017**	**Mother ARV Regimen (ref= Not Documented)**			
Place of Delivery				INSTI	13.212(2.689-64.912)	10.731	**0.001**
	1.265(0.436-3.672)	0.688	0.666	NNRTI	8.878(1.947-40.477)	6.872	**0.005**
Adherence (Good)				PI	12.973(2.023-83.193)	12.3	**0.007**
	14.124(7.661-26.039)	4.408	**<0.001**	**Mother VL Status 24 months (ref=>1000)**			
ANC Attendance(Yes)				LDL	1.079(0.355-3.282)	0.612	0.893
	1.984(0.622-6.328)	1.174	0.247	<400	2.291(0.393-13.352)	2.06	0.357
Received Infant Prophylaxis (Yes)				400-1000	0.286(0.023-3.550)	0.368	0.33
	0.654(0.119-3.591)	0.568	0.625	Not documented	0.415(0.141-1.219	0.228	0.11

Key: ANC-Antenatal Clinic, CS-Caeseran Section, SVD-Spontaneous Vaginal Delivery, OI-Opprotunistic Infection, PBFW-Pregnant and Breatfeeding Women, EBF-Exclusive Breast feeding, ERF-Exclusive Replacement Feeding, MF-Mixed feeding; ARV-Antiretroviral,INSTI-Integrase Strand Transfer Inhibitors, NNRTI-Non Nucleoside Reverse Transcriptase Inhibitor, PI-Protease Inhibitors, VL-Viral Load.

Regarding 18-24month maternal retention, the age of the mother, partner HIV status and adherence were significant predictors of attrition outcome. *(Table 6).* Mothers who reported good adherence were 12 times more likely to be alive compared to those with poor adherence (OR;95%CI: 12.166(7.1118-20.794), p<0.005.

Table 6: Multivariate Factors Associated with Maternal Retention: The Effectiveness of eMTCT Package Implementation in CHAK-CHAP Uzima Supported Health Facilities, Kenya, April 2017-September 2019

Table 6: Multivariate Factors Associated with Maternal Retention

Factor	Odds ratio(95%CI)	SE	P-value	Factor	Odds ratio(95%CI)	SE	P-value
Age of the Mother(ref=15-19)				**Partner HIV Status (ref=Unknown)**			
20-24 years	1.800(0.673-4.810)	0.903	0.241	Neg	2.132(1.218-3.733)	0.609	**0.008**
25+ years	2.960(1.245-7.040)	1.309	**0.014**	Pos	1.495(0.861-2.595)	0.42	0.153
Place of Delivery (Hospital)				**Depression (Yes)**			
	2.646(1.086-6.447)	1.202	**0.032**		0.887(0.416-1.888)	0.341	0.756
Immunization (On Schedule)				**ANC Attendance(Yes)**			
	4.577(2.667-7.855)	1.261	**<0.001**		3.114(1.380-7.031)	1.293	**0.006**
Mode of Delivery (CS)				**Adherence (Good)**			
	1.509(0.676-3.370)	0.619	0.316		12.166(7.118-20.794)	3.327	**<0.001**
Infant Feeding Option (ref =MF)							
EBF	0.522(0.155-1.757)	0.323	0.294				
ERF	0.475(0.068-3.311)	0.47	0.453				

Key: ANC-Antenatal Clinic, CS-Caeseran Section, EBF-Exclusive Breast feeding, ERF-Exclusive Replacement Feeding, MF-Mixed Feeding

Mothers with a partner of known HIV status had better retention; with those whose partner was HIV negative 2 times more likely to be retained if partner was HIV negative (OR; 95%CI: 2.132 (1.218-3.733), p <0.008. Having a HIV positive partner was not shown to have significant effect on improving retention (OR;95%CI 1.495(0.861-2.595), p 0.153. The likelihood of mother being retained increased with age of the mother, with mothers aged 25yrs+ three times more likely to be retained than teenage mothers 15-19yrs (OR;95% CI: 2.960(1.245-7.040), p<0.01.

4.0 Discussion and Recommendations

The rate of MTCT of HIV in this study was low at 2.3%, which falls within the virtual MTCT target of <5%. This study shows that CHAP Uzima has achieved the MTCT target within the project sites due to programmatic efforts that deliver a robust MTCT program with near universal coverage of life-long HAART for all HIV positive pregnant and breastfeeding women, with appropriate HEI prophylaxis and EID testing. Nationally, the MTCT dropped from 16.3% in 2012 to 8% in 2015 in Kenya due to national efforts to increase the number of women accessing antiretroviral treatment to prevent transmission of HIV during pregnancy, delivery, and breastfeeding; as well as reducing the unmet need for family planning among women, especially those living with HIV and increased access to delivery by skilled birth attendants (Chirombo et al., 2016). Kenya seems to have reversed on the gains made, with the MTCT rate at 11.5% and a PMTCT need of 69,497 as per the 2020 NASCOP Spectrum Estimates. Elimination of Mother to Child Transmission of HIV and syphilis, is an agenda year marked for 2030 and is in line with the Sustainable Development Goals (SDG)3 to ensure healthy lives and wellbeing for all, with national commitment to the ambitious targets set in Kenya Framework for Elimination of Mother-To-Child Transmission of HIV and Syphilis 2016-2021 (ref). Further investments and efforts are critical to achieve universal access to integrated eMTCT services that would lead to virtual eMTCT as seen in the nations of Cuba, Malaysia, Sri Lanka and Dominica among others (On, 2021; Rajapaksa et al., 2021)

4.1 Factors Associated with MTCT

This study shows that HIV transmission was associated with off schedule immunization status, mixed feeding practices, young maternal age, maternal depression and sub-optimal maternal

adherence to ART. The findings are collaborated by results from other studies conducted in similar resource limited settings in Uganda, Tanzania, Malawi (Hunduma & Gebrehanna, 2017; Kahungu et al., 2018; Nydal et al., 2021; Operto, 2020; Van Lettow et al., 2018). The maternal ARV regimen used, alcohol and substance abuse and being treated for any opportunistic infection during the PBFW period had no association with HIV transmission to the infants. This is a deviation from other studies that show that incident opportunistic infections, alcohol and substance use have the potential to compromise host immunity and facilitate viral replication and perinatal transmission of HIV (Brocklehurst & Volmink, 2002; Deschamps et al., 1999; Kabapy et al., 2020; Mbatha TL,Dube A, 2021;Vogler et al., 2011; Wang & Ho, 2011). Unlike other studies (Kasede et al., 2021; Kassa, 2018), lack of skilled birth attendance did not have an association with HIV transmission in this study. This can be attributed to the low proportion of HEI delivered at home (n=59, 1.8%) and the implementation of infant ARV prophylaxis provision at first ANC contact, or on first post-natal contact which often occurred immediately after birth. Infant ARV prophylaxis was associated with reduced MTCT of HIV.

4.2 Factors Associated with MEI Retention

There was an association of HEI retention throughout the 18-24 months of longitudinal follow-up with early on-schedule immunization status, exclusive breastfeeding, an increasing maternal age, mother being adherent to ART; which is collaborated in other studies from low to middle income countries settings (Puchalski R et al., 2019; Vrazo et al., 2018). These factors can be linked to mothers who attended ANC and were more likely to deliver in hospital, indicating a general compliance to focused antenatal care standards and post-natal follow up. The association of maternal attrition with young maternal age could be attributed to the stigma and discrimination faced by young mothers and weak socio-economic support structures that would hinder access to health services(Ronen K et al., 2017). Mothers who had a HIV positive partner had better retention than those with partners of unknown status or HIV negative partners; underscoring the psychosocial support systems available in relationships where there is disclosure of HIV status. Male partner involvement has been linked to better uptake and completion of the PMTCT cascade interventions (Lumbantoruan et al., 2020; Obai et al., 2017; Vrazo et al., 2018). Mothers who attended ANC and delivered in hospitals had better retention, a reflection of access. Mothers with good adherence to ART had superior retention outcomes; which implies good appointment keeping and on time ARV drug pick up.

4.3 Conclusion

Our study showed MTCT rates below the <5% eMTCT target at 2.3% and good retention rates for both Mother and Exposed Infant at 96.3% and 86.8% respectively. These results demonstrate the effectiveness of implementing comprehensive PMTCT interventions; where all HIV positive mothers are targeted with life-long ART and the HEI with ARV prophylaxis and EID testing. Targeting young mothers and their partners is a critical pillar for the national government, program planners and facility service providers to achieve eMTCT. In addition, capacity building and support to frontline providers to routinely conduct depression assessment with appropriate treatment and referral would not only enhance optimal mental health for mothers, but also affect HIV outcomes for HEI and retention for MEI pairs. Robust treatment counseling and adherence support for all PBFW is important to ensure compliance to appropriate infant feeding practices, immunization standards, and adherence to ART. More research may be useful to further understand the factors contributing to significant MTCT and MEI pair attrition in order to inform PMTCT programming and long-term engagement in care for MEI pairs.

5.0 Dissemination

The results of the evaluation will be presented to the Ministry of Health and CDC. An oral debriefing and a report will be provided for participating clinics/health care providers and other stakeholders and feedback collected and reviewed. Findings from the evaluation that directly impact patient care will be disseminated through patient education forums such as health talks and support group sessions in a view of identifying program specific priorities and interventions to improve eMTCT outcomes. Results will also be presented at national, regional, and international meetings, and submitted to international peer-reviewed journals; as well as published on the CHAK website. A final evaluation report will be produced in alignment with the PEPFAR ESoP requirements and posted (in English) on a publicly accessible website within 90 days of clearance.

Budget

This evaluation was conducted in kind by existing project staff and their costs covered in the project's approved personnel budget.

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CDC authorship disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention and other funding institutions.

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7.0 List of Appendices

Appendix i: CDC Protocol Determination

Appendix ii: KNH- UoN Ethics and Research Committee Approval Letter

Appendix iii: Good Clinical Practice Certificates

Appendix iv: Protecting Human Subjects Research Certificates

Appendix v: Evaluation Team Curriculum Vitae's