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Outcome Evaluation of Early Implementation of Option B+ in Cameroon: A Prospective Cohort Observational Survey in the Northwest and Southwest Regions

Pius Tih Muffih[1], Edouard Katayi Tshimwanga[1*], Andrew Abutu[2], Lem Edith Abongwa[1], Jacques Chirac Awa[1], Pascal Nji Atanga[1], Felix Desembuin[1], Eveline Mboh Khan[1], Kuni Esther Bonje[1], Nshom Emmanuel[1], Ebeny Francois Temgbait Chimoun[1], Thomas Welty[1], Gladys Tayong Fosah[3], Jennifer Lim[4,5], Dana Duncan[2], Leah Petit[6], Gilbert Tene[5,7], Jembia Mosoko[5], Omotayo Bolu[5]

[1]AIDS Care and Prevention Program, Cameroon Baptist Convention Health Services, Bamenda, Cameroon
[2]United States Centers for Disease Control and Prevention (CDC), Atlanta, USA
[3]Ministry of Public Health, National AIDs Control Committee, Northwest Region Technical Group, Bamenda, Cameroon
[4]Association of Schools and Programs of Public Health/Allan Rosenfield Global Health Fellowship, Washington DC, USA
[5]United States Centers for Disease Control and Prevention (CDC), Yaoundé, Cameroon
[6]Elizabeth Glazer Pediatric AIDS Foundation (EGPAF), Washington DC, USA
[7]QED Group, LLC, Washington DC, USA
Email: *edouarddr@yahoo.fr, fchimoun@gmail.com

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Abstract

Background: Mother to child transmission (MTCT) of HIV constitutes a major source of new pediatric infections in Cameroon. **Objective:** The aim of this implementation research was to assess outcomes and effectiveness of providing life-long antiretroviral therapy (ART) for HIV-positive pregnant and breastfeeding women (Option B+). **Methods:** From October 2013 to July 2014, HIV-positive pregnant and breastfeeding women, not on antiretroviral (ARV) prophylaxis and ART, were recruited from 22 purposefully selected health facilities in the Northwest and Southwest regions for a prospective, observational cohort evaluation. Option B+ was offered to participants and outcome indicators were measured. **Results:** Out of 680 women eligible for this assessment, 669 (98%) were initiated on Option B+. Retention-in-care was 90% (95% CI, 87.85 - 92.61) and 79% (95% CI, 75.20 - 81.88), and loss to follow up (LTFU) was 7% (95% CI: 4.95 - 8.90) and 15% (95% CI: 12.06 - 17.56) at 6 and 12 months respectively. Maternal mortality at 12 months after ART initiation was 2% (13). As of March 2015, 538 HIV exposed infants (HEIs) were enrolled and received postpartum nevirapine prophylaxis within

72 hours of birth and 84% (454) were on cotrimoxazole at 6 to 8 weeks. By 8 weeks of age, 498 (93%) infants had HIV DNA PCR test with 486 (97.6%) negative and 12 (2.4%) positive. **Conclusion:** In Cameroon, successful implementation of Option B+ increased retention-in-care to 79% at one year for pregnant and breastfeeding women and reduced MTCT rate below 5% for HEIs at 8 weeks of age. Long term retention, maternal and infant mortality and final MTCT rate after cessation of breastfeeding require further evaluation.

Keywords

Option B+, Implementation Research, Prevention of Mother to Child HIV Transmission, HIV Exposed Infants

1. Introduction

With a population of 23.3 million and a national HIV prevalence of 4.5%, Cameroon is one of the countries most affected by the human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) epidemic in West and Central Africa [1] [2]. Accessibility of Prevention of Mother-to-Child Transmission (PMTCT) of HIV services remains low in the country. National data from 2011 showed that while 81% of pregnant women seen in health facilities received HIV testing during antenatal care (ANC), labor and delivery (L & D), and the postpartum period combined (8.4% tested HIV-positive), only 67% of these HIV-positive women received antiretroviral therapy (ART) for PMTCT [3] [4]. Although the Cameroon HIV guidelines in 2011 specified that all HIV-positive exposed infants (HEIs) were eligible for immediate ART, at the time this implementation research was initiated in 2013, only 25% of HEIs were provided antiretroviral (ARV) prophylaxis at birth, 9.3% had an HIV deoxyribonucleic acid polymerase chain reaction (DNA PCR) test at 8 weeks of age (7.1% infants testing HIV-positive), and approximately 3% of those HIV infected were initiated on lifelong ART [4]. Consequently, HIV-related deaths have contributed to a decrease in life expectancy in Cameroon from 54 years in 1990 to 51.5 years in 2010, with 10.1% of maternal deaths estimated to be HIV-related [5] [6].

In support of the national HIV/AIDS program in Cameroon, the Cameroon Baptist Convention Health Services (CBCHS), in collaboration with the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the Centers for Disease Control and Prevention (CDC), and the Cameroon Ministry of Public Health (MOPH), initiated scaling up implementation of HIV testing services (HTS), care and treatment, and PMTCT services with the aim to reduce HIV burden among these vulnerable populations [7]. The PMTCT program has evolved from the use of single-dose nevirapine (sdNVP) in 2000 to implementation of the World Health Organization (WHO) Option A regimen for pregnant and breast-

feeding women in 2010 [7] [8]. For HIV-infected pregnant women who were not eligible for lifelong ART based on CD4 count or clinical staging, Option A consisted of antepartum twice-daily zidovudine (ZDV) to HIV-infected pregnant women starting at 14 weeks of gestation and continued throughout pregnancy. At the onset of labor, sdNVP was administered with the initiation of twice daily ZDV and lamivudine (3TC) for seven days postpartum. HIV-exposed infant (HEI) prophylaxis involved neviparine (NVP) syrup from birth until one week after cessation of breastfeeding or for six weeks postpartum if not breastfeeding [9] [10]. In 2010, the government of Cameroon developed a national plan for the elimination of mother-to-child transmission of HIV (eMTCT) to align with the global eMTCT plan to reduce new pediatric HIV infections and decrease the MTCT rate to less than 5% by 2015 [11] [12].

In 2012, Cameroon's MOPH decided to implement Option B+ (life-long ART for pregnant and breastfeeding women regardless of CD4 count) nationwide using a phased approach to reach these goals [11]. With funding from the U.S. President's Emergency Plan For AIDS Relief (PEPFAR) through CDC, CBCHS piloted a rollout of PMTCT Option B+ in the Northwest and Southwest regions of the country. The aim of this study was to evaluate outcomes and effectiveness of PMTCT Option B+ service at 12 months postpartum in order to facilitate national scale-up by the MOPH. A second evaluation will describe 24 months postpartum outcomes.

2. Materials and Methods

2.1. Study Design, Settings and Population

A prospective cohort of mother-infant pairs were enrolled from maternal and child health (MCH) services across 22 health facilities in the Northwest (Bamenda) and Southwest (Kumba) regions of Cameroon and followed monthly until 12 months after Option B+ initiation. The 22 health care facilities, 12 in Bamenda and 10 in Kumba, were purposely selected. Participants enrolled for the evaluation, from October 2013 to July 2014, were newly identified HIV positive pregnant or postpartum women in ANC, L & D, and postpartum care who were not on ARV prophylaxis or antiretroviral therapy (ART). HIV positive breastfeeding women whose infants were greater than 18 months of age were excluded. As per Option B+ recommendations, clients were initiated on ART immediately after HIV diagnosis, and blood was drawn for baseline laboratory tests of CD4 cell count, full blood count, liver function test, serum creatinine, and fasting blood sugar. None of these tests delayed ART initiation. All costs associated with laboratory tests were absorbed by the project and study participants did not pay for any testing. All women who only accepted Option B received ongoing counseling throughout this period to continue ART for life.

2.2. Sample Size Estimation

Given the number of project sites with the expected population of HIV-positive

women attending ANC services in the 10 months enrolment period, facility-specific sampling targets were determined by sampling proportionally to three patient volume categories (low, medium, and high) based on ANC attendance, PMTCT services utilization rate, and geographical accessibility. Effort was made to enrol participants from all volume sites resulting in the enrolment of 100 mother-infant pairs from low and medium volume sites, and 400 from high volume sites.

2.3. Option B+ Implementation Support

Task shifting with nurses and midwives, a defaulter tracking system and a laboratory sample transport system were implemented in all 22 study sites. CBCHS developed a training manual adapted from materials used in Option B+ implementation in Malawi to train physicians, nurses, and midwives. Eleven ART Clinic physicians, selected from the pilot districts, were trained on patient management in the context of Option B+. These physicians trained 109 nurses and midwives from study sites and were available for consultation or referral as needed. Twenty-nine peer educators were also trained to provide additional counseling, home visits, and community sensitization. Each of them had access to a mobile phone and transportation costs to facilitate home visit or phone contact. Bikers For Health (BFH) were hired to ensure timely transportation of maternal laboratory samples, infant dried blood spots (DBS), Early Infant Diagnosis (EID) commodities and HIV test kits. Short Message Service (SMS) technology was used in addition to BFH to accelerate results return from the reference laboratory.

2.4. Data Collection and Analysis

Nursing and midwifery staff in each health facility filled out PMTCT longitudinal maternal ART and HEIs registers following each visit. The registers were reviewed monthly by monitoring and evaluation officers who extracted data into an Epi Info database. Data were cleaned and analyzed using Epi Info version 3.5.4 and Stata/SE-13 software. Data analysis was performed on a monthly basis from October 2013 to October 2015, and results were reviewed during coordination meetings by the project implementation team to identify challenges and improve implementation.

2.5. Outcomes and Definitions

Outcomes of interest among pregnant and breastfeeding women initiating Option B+ were ART uptake, ART retention, stoppage of ART, loss to follow-up (LTFU), and mortality. For HEIs, the study assessed NVP and cotrimoxazole uptake, HIV status at 6 to 8 weeks, LTFU, and mortality. For each cohort, LTFU was defined as the proportion of patients who missed their ART pick up appointment for 90 consecutive days or more at 6 and 12 months after enrollment. Maternal ART retention was defined as: the proportion of HIV-positive pregnant

and breastfeeding women on ART after initiating out of the total number of women who initiated ART and should have completed 6 and 12 months respectively. Thus, clients considered not retained or LTFU at 6 months could re-engage and be considered retained at the 12 months' time point. Clients who transferred out of the facilities were excluded from the retention analysis. Transferred out was defined as women who were referred and/or transferred to other facilities due to either miscarriage, stillbirth, infant death, or relocation, or an HIV DNA PCR positive infant. HIV infected infants were transferred to ART clinics for ART initiation but were also included in the MTCT rate computation for this evaluation. The ART retention denominator was the number of clients on ART excluding the number who transferred out for each cohort at 6 and 12 months.

2.6. Ethical Considerations

This study was approved as a public health program evaluation by the CBCHS Institutional Review Board in August 2013 and the CDC in July 2013. All participants were counseled in line with national protocols and were asked to give verbal consent before enrollment in the evaluation.

3. Results

Figure 1 shows the flow chart of participants enrolled in the study. Of 11,313 pregnant or breastfeeding women who attended maternal and child health (MCH) services in the 22 study facilities, 680 (6%) were HIV-positive and not on ART or ARV prophylaxis. Of these 680 eligible participants, 669 (98%) initiated Option B+; this included three clients who initially accepted ART only during pregnancy but later changed to lifelong ART during the course of the pregnancy. All 669 participants who initiated Option B+ were enrolled in the study.

3.1. Maternal Demographic Characteristics

The median age at enrollment was 27 years (IQR: 24 - 31 years). Of the 669 participants, 522 (78%) were either married or cohabiting, 608 (91%) owned a phone; 362 (54%) preferred to be contacted by phone, and 270 (40%) preferred to be contacted by phone or home visit. Of the 669 participants, a majority (58.7%) spent less than 200 CFA (less than $0.5 USD) to reach the health facility; 431 (64%) lived in Bamenda and 238 (36%) in Kumba. Six hundred and twenty-six (94%) enrolled in the study during pregnancy, and 454 (68%) were newly-diagnosed with HIV at their first presentation to MCH services. The median baseline CD4 count was 364 cells/mm^3 (IQR: 225 - 496) (Table 1).

3.2. ART, Retention, and Mortality among Pregnant and Breastfeeding Women

Of the 669 participants, 43 (6%) and 64 (10%) clients were transferred out during the 0 - 6 and 0 - 12 month maternal cohort. Thus, 626 and 605 pregnant

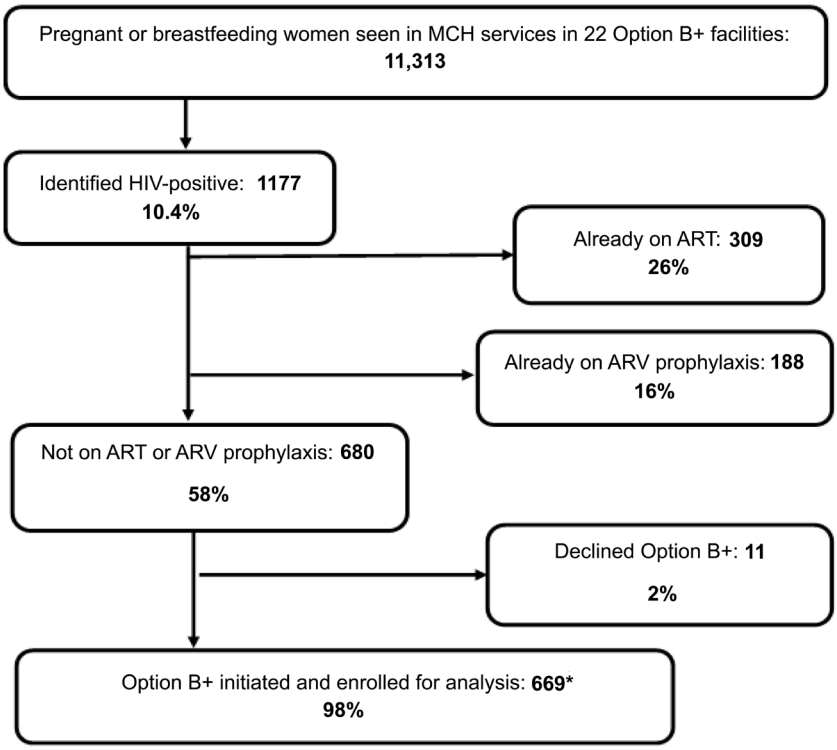

Figure 1. Enrolment flow chart of participants in Option B+ evaluation.

Table 1. Socio-demographic and clinical characteristics of ARV naïve pregnant and breastfeeding women enrolled for Option B+ evaluation.

Variables	Frequency (N = 669)	%
Age (years)		
Median (IQR)	27 (24 - 31)	
<25	252	37.7
25 - 30	217	32.4
>30	200	29.9
Marital Status		
Single	144	21.5
Married/Cohabiting	522	78
Others (widow, divorced)	3	0.5
Ownership of telephone		
Yes	608	90.9
No	61	9.1
Preferred means of contact		
Telephone call	362	54.1
Home visit	24	3.6
Both telephone and home	270	40.4
Refused contact	2	0.3
No means of contact	3	0.5

Continued

Unknown	8	1.2
Transport to site		
≤200 CFA	393	58.7
>200 CFA	276	41.3
Health district		
Bamenda	431	64.4
Kumba	238	35.6
Entry point		
Antepartum (ANC/L & D)	626	93.6
Postpartum	43	6.4
HIV status at enrolment		
Known positive but not on ARVs	215	32.1
Newly diagnosed	454	67.9
WHO stage		
I	570	85.2
II	72	10.8
III	27	4
CD4 (cells/mm^3) at enrolment		
Median (IQR)	364 (225 - 496)	
≤350	234	34.4
>350	257	38.4
Unknown	178	26.6

and breastfeeding women were included in the cohort at 0 - 6 and 0 - 12 months respectively. The average retention after ART initiation among participants who did not transfer out was 566 (90%) (95% CI, 87.85 - 92.61) at 0 - 6 months and 476 (79%) (95% CI, 75.20 - 81.88) at 0 - 12 months (Figure 2). Details of maternal outcome at 0 - 6 and 0 - 12 months after ART initiation are presented in Table 2.

At six months after ART initiation, 6 women (1%) had died and 9 (1%) had stopped ART. At twelve months after ART initiation, a total of 10 women (2%) had died; 17 (3%) had a still birth, and 15 (2%) had a miscarriage. Of the 10 women who died, 2 died of HIV-related disease, 3 died of obstetrical complications, and the cause of death of five was unknown. An additional 12 women stopped their ART after six months for a total of 21 (3%) women who stopped ART at 12 months (Table 2).

Table 3 shows the twelve-month distribution of LTFU among HIV-positive pregnant and breastfeeding women enrolled in the evaluation. Of the 98 (15%) women who were LTFU at 12 months after ART initiation, 50 (51%) never returned for their first ART refill (failure of ART initiation), and 48 (49%) were LTFU after delivery. Spending less than 200 CFA (less than $0.5 USD) to reach a

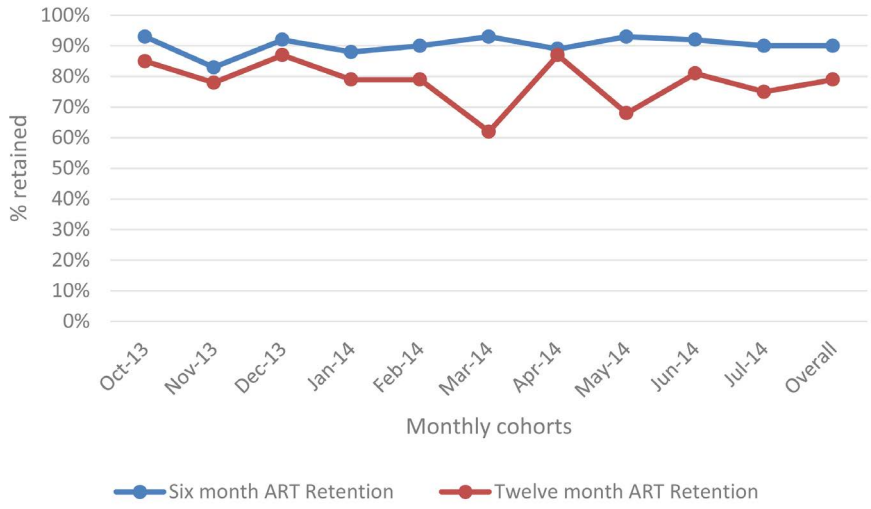

Figure 2. Retention for monthly cohorts of pregnant and breastfeeding HIV-positive women enrolled in Option B+ evaluation.

Table 2. Six and twelve month's maternal retention on ART among HIV-positive pregnant and breastfeeding women enrolled in Option B+ evaluation.

Variables	0 - 6 months after ART	0 - 12 months after ART
	N = 669	
Transfer out of study[a]	Transfer out: 43 (6%)	Transfer out: 64 (10%)
Because of miscarriage	14 (2%)	15 (2%)
Because of still birth	12 (2%)	17 (3%)
Because of relocation	7 (1%)	14 (2%)
Because of infant death	7 (1%)	11 (2%)
Because of HIV DNA PCR positve infant[b]	3 (<1%)	6 (1%)
Because of severe ART side effect	0	1 (< 1%)
Retention denominator[c]	626	605
Lost to follow up (LTFU)	LTFU: 45 (7%)	LTFU: 98 (15%)
Voluntarily discontinued ART (voluntary withdrawal from study)	9 (1%)	21 (3%)
Died	6 (1%)	10 (2%)
Retained	566	476
Retention (95% CI)	90.4% (87.9 - 92.6)	76.7% (75.2 - 81.9)

a. Transferred out: defined as women who were referred and/or transferred to other facilities due to either miscarriage, stillbirth, infant death, or relocation, or a PCR positive infant; b. Infants with a positive HIV DNA PCR result were transferred to ART clinics for ART initiation but were also included in the MTCT rate for this study; c. Retention denominator was the number of clients on ART excluding the number who transferred out for each cohort at 6 and 12 months.

health facility (OR: 1.76, 95% CI 1.14 - 2.71) was identified as a factor that influenced LTFU. LTFU was not influenced by timing of enrollment, ownership of a telephone, HIV status at enrollment, newly diagnosed HIV-positive status at enrollment, or WHO clinical stage of disease (Table 3).

Table 3. Twelve months distribution of LTFU among HIV-positive pregnant and breast-feeding women enrolled in Option B+ evaluation.

Variables	Frequency (N = 669)	LTFU (n = 98)	% (n/Nx100)	OR (95% CI)	P-value
Age (years)					
Median (IQR)	27 (24 - 31)	26.5 (23 - 29)			
<25	252	42	16.7	1	-
25 - 30	217	38	17.5	1.06 (0.69 - 1.72)	0.81
>30	200	18	9	0.49 (0.28 - 0.89)	0.02
Marital Status					
Single	144	25	17.3	1	-
Married/Cohabiting	522	73	13.9	0.77 (0.47 - 1.27)	0.31
Others (widow, divorced)	3	0	0	-	-
Ownership of telephone					
Yes	608	84	13.8	1	-
No	61	14	9.1	0.53 (0.28 - 0.99)	0.05
Preferred means of contact					
Telephone call	362	52	14.3	1	-
Home visit	24	5	20.8	0.89 (−7.33 - 28.61)	0.35
Both telephone and home	270	38	14	0 (−5.60 - 5.82)	1
Refused contact	2	0	0	0.32 (−70.26 - 18.01)	0.57
No means of contact	3	1	33.3	0.88 (−13.44 - 76.53)	0.35
Unknown	8	2	25	0.77 (−11.18 - 51.23)	0.38
Transport to site					
≤200 CFA	393	46	11.7	1	-
>200 CFA	276	52	18.9	1.76 (1.14 - 2.71)	**0.01**
Health district					
Bamenda	431	63	14.6	1	-
Kumba	238	35	14.7	1.01 (0.64 - 1.76)	0.98
Entry point					
Ante partum (ANC/L & D)	626	83	13.2	1	-
Post-partum	43	15	34.9	0.94 (0.39 - 2.29)	0.89
HIV status at enrolment					
Known positive but not on ARVs	215	31	14.4	1	-
Newly diagnosed	454	67	14.7	0.12 (−5.23 - 6.66)	0.73
WHO stage					
I	570	88	15.4	1	-

Continued

II	72	7	9.7	0.59 (0.26 - 1.33)	0.2
III	27	3	11.1	0.71 (0.21 - 2.43)	0.59
CD4 (cells/mm^3) at enrolment					
Median (IQR)	364 (225-496)				
≤350	234	26	11.1	1	-
>350	257	32	12.5	0.12 (−5.01 - 6.92)	0.73
Unknown	178	-	-	-	-

3.3. ARV and Cotrimoxazole Uptake, Retention and Mortality, among Enrolled HEIs

Of the 669 women enrolled in the study, 120 women either died, had miscarriage, stillbirth or withdrew from care before delivery. The remaining 549 women gave birth to 568 HEIs; of these, 538 enrolled in the study. All 538 enrolled HEIs received postpartum NVP within 72 hours of birth, and 454 (84%) received cotrimoxazole per national recommendations at 6 to 8 weeks of age. By 8 weeks of age, 498 (93%) infants had results from an HIV DNA PCR test with 486 (97.6%) tested negative and 12 (2.4%) tested positive. All HIV-infected children were referred to ART clinics for immediate treatment. Details on enrollment and outcome of HEI are shown in **Figure 3**.

4. Discussion

Historically, PMTCT coverage and ART retention along the PMTCT cascade have been poor in Cameroon [4]. UNAIDS reported a 6 weeks MTCT rate of 5.2% in Cameroon, which is higher than the global eMTCT targets of less than 2% and 5% at 6 weeks and after cessation of breastfeeding respectively [13]. To achieve these targets, ART uptake and maternal retention on ART are essential. Early implementers of Option B+ have reported high ART uptake, yet many countries have struggled with maternal retention [14] [15]. In this evaluation, early retention at 6 months after ART initiation was high at 90% and then declined at 12 months after ART initiation to 79%. The 12 months ART retention rate was high when compared to 60% from a nationwide survey of Cameroon's adult ART program in 2014 [16]. Among women in Option B+ programs, the 6 months retention rate in Cameroon was higher than the rate seen in Uganda and the Democratic Republic of Congo (DRC), while the 12 months retention was similar to data from Malawi Option B+ program [14] [17] [18]. To identify effective strategies to improve maternal retention, it was important to first understand which patients were at highest risk of LTFU. Similar to results from Malawi [17] and Ethiopia [15], this study found that clients with higher transport cost to the facility were twice as likely to become LTFU at 12 months compared to those with lower transport cost. To minimize LTFU after ART initiation and after delivery, we used appointment diaries and peer educators throughout the

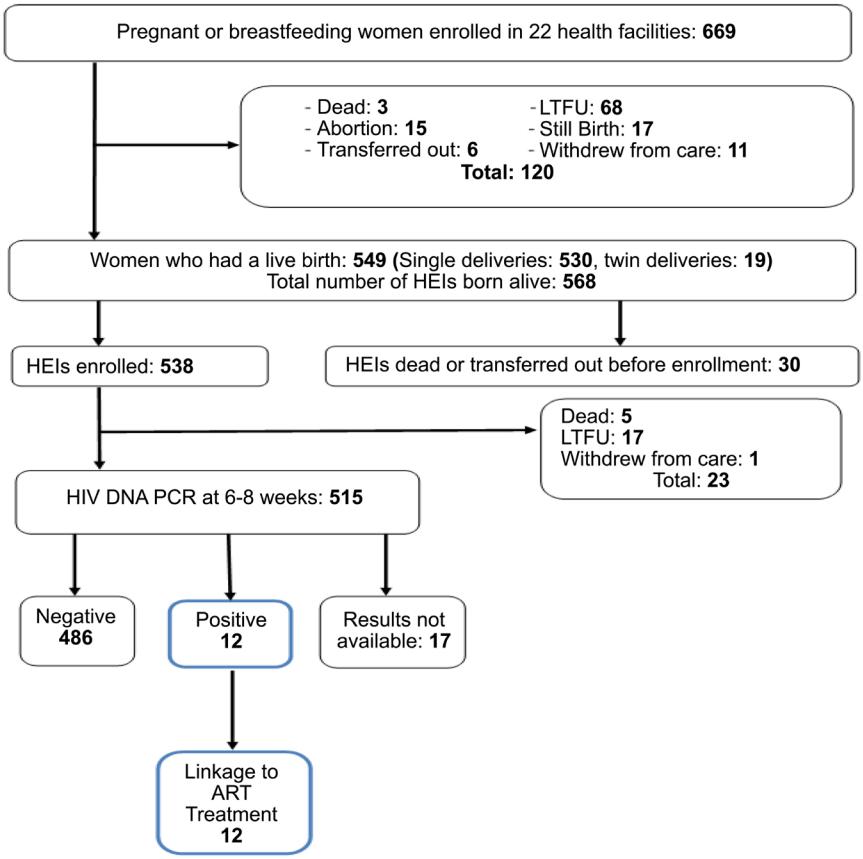

Figure 3. Enrollment and outcome of HIV exposed infants selected for Option B+ evaluation.

duration of the study, to closely monitor clients with missed appointments and to re-engage defaulters and patients with more than one month since the last ART refills. We did not experience high LTFU immediately after ART initiation and among women who initiated Option B+ while breastfeeding. Compared to the Cameroon adult ART retention data, our study suggested that women involved in the Option B+ program had a better 12 months ART retention, and this may be due to the interventions in place. However, this evaluation was limited to only 2 regions of Cameroon and was not nationwide as the Cameroon adult ART retention data.

In Malawi, 6 months retention data demonstrated that women initiating ART during pregnancy were five times more likely not to return to the clinic after they initiated ART compared to non-pregnant women (OR: 5.0, 95% CI 4.2 - 6.1) and those who started Option B+ while breastfeeding were twice as likely to miss their first follow up visit compared to women who initiated during ANC [17].

During this evaluation, CD4 testing was used since the Cameroon national guidelines on management of HIV recommended CD4 testing at baseline and every 6 months while on ART. Despite cost subsidies and laboratory sample transportation systems to improve uptake of laboratory tests, we noted a drop in

CD4 testing uptake greater than 50% at 6 months and almost 90% at 12 months after ART initiation. Reliance on ongoing CD4 monitoring for PMTCT Option B+ for a test and start approach may not be feasible in the Cameroon setting.

Some of the challenges noted in this evaluation included systemic barriers (such as long waiting times for sample collection, stock out of reagents, frequent break down of equipment) and distance to testing site; these have been described in other countries as well [9] [10]. The results of this study stressed the importance of addressing programmatic challenges related to laboratory equipment and supply chain system of reagents and other commodities to ensure high uptake of routine laboratory testing.

In Cameroon, HIV is a large contributor to maternal mortality rates. A 2012 study attributed 10% of pregnancy-related deaths to HIV [6]. However, in this current study which took place in an Option B+ setting, a mortality rate of 2% was found among enrolled women at 12 months post-ART initiation; this is similar to 1.7% found in a study in Malawi [17] and 2.6% found 6 months after initiation of Option B in the Cameroon DREAM study [19].

Rates of infant NVP uptake after birth, HIV DNA PCR testing at 6 to 8 weeks of life, and MTCT at 6 weeks captured by PCR were similar to those found in Malawi, where 95% of HEIs received ARV prophylaxis (NVP) after birth, 82% received a DNA PCR test at 6 to 8 weeks of life, and 2.6% tested positive [20]. We put systems in place to track defaulters and improve retention along the PMTCT cascade and early infant diagnosis (EID) uptake using community workers.

The uptake of EID of 95.7% and the HIV transmission rate among infants tested at 8 weeks of 2.4% reported in this study are 3 times better than the 2014 overall country EID uptake of 24% and MTCT rate at 6 weeks of 7%, identified shortly before Option B+ was implemented nationwide in Cameroon [21] The 2015 estimated uptake of EID at 8 weeks was 30% while the HIV transmission rate among infants tested at 6 weeks was 5% [22].

5. Strengths and Limitations

This evaluation follows a large prospective cohort of mother-infant pairs across 22 busy PMTCT sites predominantly in semi-urban and rural areas of Cameroon. The descriptive evaluation of the outcomes of mother-infant pairs was not designed as an experimental study that would allow causal inferences to be made. The selection strategy of participating health facilities and eligibility of participants may limit the generalizability of findings and the ability to be a model for a complete Option B+ policy. Because many HEIs were still breastfeeding at the time of the 6 weeks HIV DNA PCR testing, our results may underestimate final HIV rates in this cohort after cessation of breastfeeding. Additionally, we only know the HIV status of HEIs who were retained during the reporting period; HEIs who were not retained might have been more likely to become HIV infected or to have died. Final outcomes of enrolled HEIs are not included since many had not yet reached 18 months of age at the time of analysis.

However, HEIs continued to be followed, and the HIV transmission rate among those tested at 24 months of age and/or after cessation of breastfeeding will be addressed in a subsequent analysis.

6. Conclusion

We describe the outcome evaluation of early implementation of PMTCT Option B+ in Cameroon. Our data demonstrate that it is possible to achieve high 12 months ART retention rate among pregnant and breastfeeding women who start ART after they are diagnosed with HIV. In addition, reduction of MTCT was also achieved. Longer-term ART retention, infant mortality, and HIV transmission rate among HEIs after cessation of breastfeeding need further evaluation.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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