

Research Article

Uptake of PMTCT Option B-plus among HIV-Infected Women Attending Antenatal Clinics and Labor Wards at Mulago National Referral Hospital in Kampala, Uganda

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Abstract

Objective: Option B-plus strategy was adopted and implemented by Uganda's Ministry of Health (MOH) in 2012. We aimed to describe Prevention of Mother-To-Child HIV Transmission (PMTCT) programmatic findings on uptake, initiation, missed opportunities and reasons for non-initiation of Option B-plus among HIV-infected pregnant women at Uganda's Mulago National Referral and Teaching Hospital.

Methods: We extracted and evaluated routine PMTCT programmatic data collected from pregnant women attending for the first time to either Mulago Hospital Antenatal Care (ANC) clinics or Labor Wards (LWs) from 16th October 2012 to 31st May 2014. Data were collected in MOH logs/forms, entered in Microsoft Access and analyzed using Stata Version 10.1.

Results: Overall, HIV prevalence was 11.0% (7,496/68,053) among first-time ANC and LW attendees to Mulago Hospital and of these, 30.3% (2,269/7,496) were newly diagnosed with HIV. Of all the HIV-positive women, 89.9% (6,739/7,496) were on ART including 54.0% (4,046/7,496) initiated on Option B-plus and 36% (2,693/1496) who presented as already being on ART. A further 3.7% (277/7,496) enrolled in a PMTCT research study and 6.4% (480/7,496) not initiated Option B-plus. Among the 480 non-starters: 69.3% (333/480) presented to Hospital LW but did not progress to delivery, 13.3% (64/480) opted to be screened for a research study but never returned for follow up, while 17.3% (83/480) declined Option B-plus. The main reasons for opting out were: declining to take lifelong ART; preferring to receive drugs from another facility; and denial of HIV-positive test result.

Conclusion: Overall, Option-B plus ART was highly acceptable and very few women opted out over the first 19 months of implementation of the Option B-plus programme at Mulago Hospital in Kampala, Uganda. There is urgent need to maximize retention in care and ART adherence.

Keywords: HIV-Infected; Initiation; Option B-Plus; Pregnant Women; Uganda

Introduction

Preventing Mother-To-Child HIV Transmission (PMTCT) is crucial to curb the global pediatric HIV epidemic and promote maternal and infant health. The World Health Organization (WHO) PMTCT guidelines have evolved over the years and Uganda has adopted and updated its national PMTCT guidelines according to evolving WHO recommendations since 2003 [1,2].

In 2012, WHO updated the PMTCT guidelines and recommended that HIV-infected women identified during pregnancy and breastfeeding could start triple Antiretroviral Therapy (ART) irrespective of their CD4 cell count and WHO clinical staging, and then either stop ART after complete breastfeeding cessation (Option B) or continue to take ART for the rest of their lives (Option B-plus) [3]. The guidelines also recommended that all HIV-exposed infants receive 6 weeks of daily Nevirapine syrup from birth. The Option B-plus 'Treatment as Prevention' strategy was adopted by the Uganda Ministry of health (MOH) in September 2012 [2]. In 2013, WHO updated the harmonized adult and pediatric treatment guidelines and recommended either Option B or B-plus as national PMTCT programme options [4]. With the target of achieving below 5% vertical HIV transmission, PMTCT programmes became known as elimination of Mother-To-Child HIV Transmission (eMTCT) programmes.

The Option B-plus MTCT strategy presents advantages at several levels. Programmatically, eligibility and treatment initiation are simplified as CD4 cell count testing and WHO clinical staging are no longer required before ART initiation; adult prevention and treatment ART regimens are streamlined as they are identical; and dosing is simplified and adherence enhanced as the recommended Option B-plus first line regimen is available in a well-tolerated, once-daily, single-pill, fixed-dose combination. The benefits to the woman, her infant, future infants and sexual partners include: strong and life-long PMTCT for both current and future pregnancies; maternal HIV treatment to keep the mother healthy and able to care for her children; consequent reduction in maternal and infant morbidity and mortality, and a reduction in sexual transmission to HIV-negative spouses and other sexual partners. Further, a single message can be given to health providers and communities regarding both eMTCT and ART, making it simpler to deliver and easier to understand. Finally, the individual prevention and treatment benefits result in public health benefits at the population level with reduced HIV transmission and acquisition [5].

Despite the benefits of the Option B-plus MTCT strategy, research and public health questions remain as to its programmatic effectiveness due to a number of operational challenges. Option B-plus implies starting and adhering to life-long ART by HIV-infected women. ART may carry risks of side-effects in the short

and long term including the development of virological resistance and reduced therapeutic options [6-8]. In addition, women may not have disclosed to partners or other family members and consequently need strong psychosocial and economic support [9] at a time of heightened vulnerability during pregnancy and lactation with potential risks of social harm including discrimination and stigma [10]. To date, limited monitoring and evaluation data are available from resource-constrained settings that have adopted the Option B-plus MTCT strategy. In most programmes, pregnant women are routinely counselled, tested, given their HIV result and offered lifelong ART if found HIV-positive, all within a few hours on the same day. Women generally learn about their HIV-positive status while seeking routine antenatal care. Issues regarding same day ART acceptability and initiation have been raised in similar settings. In South Africa, some of the barriers to initiation of ART identified among pregnant women were disclosure and limited time to accept dual challenges of being diagnosed HIV-positive among others [11]. Given these circumstances and that the pregnant women are usually asymptomatic; it is not clear whether or not these women are psychologically and practically prepared to start ART for life with good adherence and retention in care. We describe findings from a very large PMTCT programme cohort from Uganda's National Referral and Teaching Hospital regarding the uptake and acceptability of Option B-plus among HIV-infected women and the reasons why some of these women did not receive Option B-plus ART on the same day of their clinic attendance.

Methods

We extracted and evaluated routine PMTCT programmatic data collected from pregnant women attending for the first time to either Mulago Hospital Antenatal Care (ANC) clinics or Labor Wards (LWs) from 16th October 2012 to 31st May 2014. Each year, approximately 30,000 women seek Antenatal Care (ANC) and a similar number deliver their babies at Mulago National Referral and Teaching Hospital in Kampala, Uganda. The PMTCT programme at Mulago began in April 2000. Routine services are offered at the multiple ANC clinics, Labor Wards (LWs) and Post-Natal Care (PNC) clinics and include routine HIV testing and counselling and ART initiation (or continuation) for HIV-infected women. The Option B-plus strategy was implemented at Mulago Hospital as of October 2012, shortly after adoption of the revised Uganda national eMTCT/ART guidelines.

All women attending the clinics were screened to identify those referred from other health centers with a documented/known HIV-positive test result, including those already on ARV drugs, as well as those coming in with a recent documented/known HIV-negative result within the last 3 months, and those without a recent HIV-negative test. Routine free group counselling was conducted for women requiring a further HIV test. They were then offered an HIV test using the nationally recommended rapid HIV testing algorithm, and provided their HIV result as part of post-test indi-

vidual counselling on the same day. All women newly diagnosed with HIV and all HIV-positive women referred from other health centers who were not yet on ARV drugs, were given information about the PMTCT programme and the Option B-plus recommendation to start ART for life. They were also provided with information about relevant ongoing PMTCT research studies, and, if interested, were referred to research staff for further information and screening. Women already on ART were also counselled about Option B-plus and encouraged to adhere to their medication and attend for ongoing health care.

Programme Population

The programme population for this analysis consisted of pregnant women attending Mulago Hospital ANC or LW for the first time in that pregnancy and who were diagnosed with HIV during the time period 16th October 2012 to 31st May 2014. All newly diagnosed HIV-infected women were given information and counselled on the benefits of Option B-plus as per the Uganda 2012 Integrated National ART, eMTCT, Infant and Young Child Feeding (IYCF) Guidelines [2].

Data Collection and Analysis

According to the Uganda 2012 Integrated National Guidelines on ART, eMTCT and IYCF [2], pregnant and lactating mothers freely give out information as part of care. PMTCT activities are routine in all hospitals and health facilities accredited by the Uganda MOH and these activities do not require obtaining an informed consent from human subjects receiving PMTCT services. At Mulago, specific MOH monitoring tools were used by PMTCT counsellors to collect data and identify clients opting out of Option B-plus ART so as to provide follow-up and ongoing supportive counselling and interventions to these women. These tools include HIV counselling and testing client cards and delivery logs. There was no written or oral informed consent obtained from patients for either the ARV treatments provided or for the use of their data in this programme as counselling, testing and treatment was part of a routine national MOH programme. HIV status, ART initiation and opt out information were captured as routine. Data were extracted and reviewed retrospectively to identify and evaluate pregnant women who attended Mulago Hospital's ANC clinics or LW for the first time in that pregnancy.

It was then entered in Microsoft Access and analyzed in Stata version 10.1 (Stata Corp, College Station, Texas, USA). Among first-time antenatal attendees and women presenting in labor without prior documented antenatal attendance at Mulago Hospital, we aimed to establish:

- All HIV-infected women including those newly diagnosed and those already known to be HIV-positive.
- Those previously started on ART for PMTCT as well as those newly initiated on Option B-plus ART.

- Missed opportunities or system failures which resulted in women not initiating ART.
- Those women who opted out of or declined Option B-Plus ART and their stated reasons.

Results

Data on first ANC and LW attendance collected over the 19-month study period are shown in (Figures I) for ANC attendance and (Figure II) for LW attendance. Overall median age was 24 years (IQR: 21 - 28). The median age of all women attending ANC for the first time was 25 years (IQR: 22 - 29 years), while the median age of all women attending LW for the first time was 23 years (IQR: 20 - 27 years).

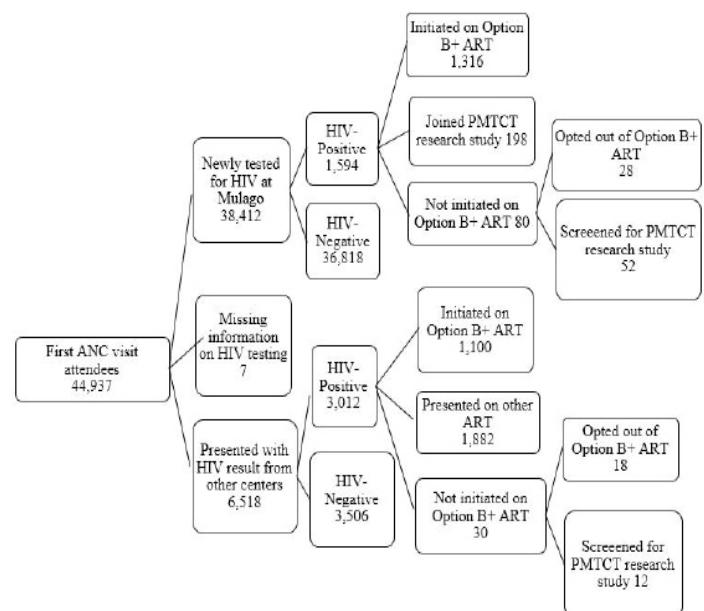


Figure I: HIV status and Option B-plus Initiation Among Women Attending ANC for the First-Time at Mulago Hospital from 16/10/2012 to 31/5/2014, N = 44,937.

As shown in (Figure I), a total of 44,937 women attended Mulago Hospital ANC for the first time over the 19-month period; of these, 85.5% (38,412/44,937) were newly tested for HIV while 14.5% (6,518/44,937) presented with a documented recent HIV test result. Overall in ANC, 10.3% (4,606/44,937) of all women who attended for the first timewere HIV-infected with almost two-thirds (65.4% [3,012/4,606]) previously diagnosed and just over one third (34.6% [1,594/4,606]) newly diagnosed with HIV. Of these HIV-infected women, 40.9% (1,882/4,606) were already on ART, hence we could not initiate them again on Option-B plus at Mulago, and a further 52.5% (2,416/4,606) were initiated on Option B-plus ART including 1,316 women who were newly diagnosed and 1,100 women who were already known to be HIV-infected but who were not on ART at the time of the clinic visit.

Of the remaining women, 1.0% (46/4,606) opted out of Option B-plus for various reasons, a further 4.3% (198/4,606) enrolled in a PMTCT research study, and 1.4% (64/4,606) opted to be screened for a PMTCT research study but did not return for enrolment in the study or for care at Mulago Hospital.

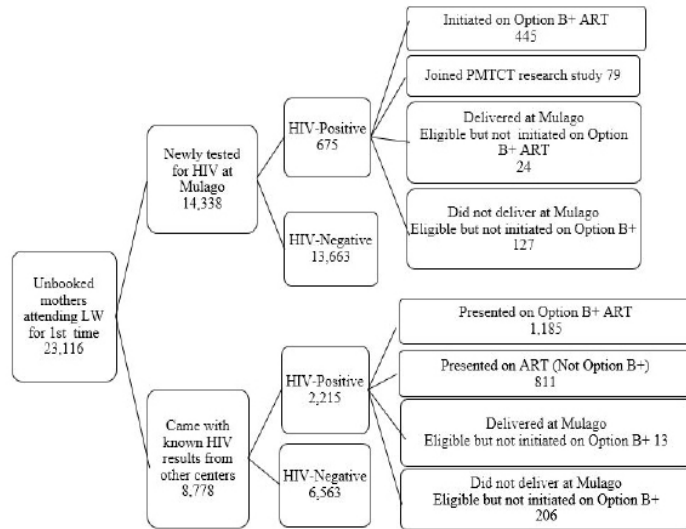


Figure II: HIV Status and Initiation of Option B-plus Among Women Presenting for the First-Time at Mulago Hospital Labor Wards from 16/10/2012 to 31/5/2014, N = 23,116.

Similarly, as shown in (Figure II), a total of 23,116 pregnant mothers presented for the first time at the Mulago Hospital Labor Ward (LW) over the 19-month period; of these, 62.0% (14,338/23,116) were newly tested for HIV while 38.0% (8,778/23,116) presented with a known HIV test result. Overall in LW, of all women who first presented, 12.5% (2,890/23,116) were HIV-infected with more than three-quarters (76.6% [2,215/2,890]) previously diagnosed and less than one-quarter (23.4% [675/2,890]) newly diagnosed with HIV. Of the 2,890 HIV-infected women, 69.1% (1,996/2,890) were already on triple therapy (Option B-plus or other ART), and a further 15.4% (445/2,890) were initiated on Option B-plus ART in the LW. Of the remaining 449 women, 8.2% (37/449) opted out of Option B-plus for various reasons, a further 17.6% (79/449) of women opted to enroll in a PMTCT research study, and 74.2% (333/449) did not progress to deliver at Mulago Hospital and were not documented to have started on Option B-plus ART including 127 newly HIV-diagnosed and 206 with already known HIV-positive status.

Overall, 68,053 pregnant women attended Mulago Hospital for the first time either in ANC clinics or in the LW and of these, 11.0% (7,496/68,053) were HIV-infected. Of the 7,496 HIV-positive women, 69.7% (5,227/7,496) were previously diagnosed with HIV, 30.3% (2,269/7,496) were newly diagnosed with HIV at that visit, 51.7% (3,878/7,496) were already on ART, and 38.2% (n

= 2,861/7,496) were initiated on Option B-plus ART during their first clinic visit including 2,416 women in ANC and 445 in LW. Of the remaining 757 women, 11% (83/757) opted out of Option B-plus for various reasons shown in (Figure III); 44% (333/757) did not progress to deliver at Mulago Hospital and were not documented to have started on Option B-plus ART; 36.6% (277/757) of women opted to enroll in a PMTCT research study; and 8.5% (64/757) opted to be screened for a PMTCT research study but did not subsequently return to Mulago Hospital.

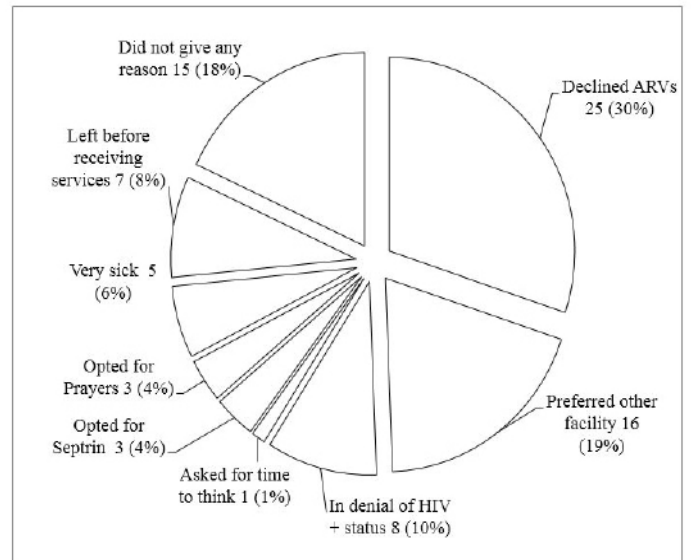


Figure III: Reasons for Opting-Out of Option B-plus among HIV-positive Women Attending Mulago Hospital Antenatal or Labor Services (N=83).

Discussion

Identifying a pregnant woman's HIV status is the key entry point into PMTCT for HIV-infected women to receive care and treatment. These data show over 50 percent uptake of Option B-plus ART with a few women not initiated over the first 19 months after introduction of Option B-plus strategy at Mulago National Referral Hospital in Kampala, Uganda. In the context of Option B-plus, our data reveals a decreasing proportion of women who are newly diagnosed with HIV during pregnancy. Among first-time ANC or LW visit attendees, nearly two-thirds of HIV-positive pregnant women and more than three-quarters of HIV-positive women presenting in labor knew their HIV status before attending. The trend for an increasing proportion of pregnant women to know their HIV status prior to the current pregnancy is also being widely observed in facility based data, demographic and HIV population-based surveys [12] as well as other resource-constrained settings [13]. The shrinking pool of newly diagnosed women may allow PMTCT programmes to concentrate their counselling and psycho social services on this subgroup of newly HIV-diagnosed women to support them to accept their HIV status, access support and

effectively engage in treatment. The larger pool of women with known HIV status are likely to be at a different stage in acceptance and disclosure, thus services for them may be more effectively targeted at ART initiation and adherence.

In a typical eMTCT programme, including that at Mulago Hospital, HIV-positive women are advised to start ART on the same day they are diagnosed, so there is almost no time for them to absorb the shock of their new diagnosis with all its social, health and other ramifications. In our programme, some women were not initiated on ART due to a number of issues and we were able to identify potential missed opportunities for eMTCT and maternal care. There was a small group of women who chose to join an eMTCT research study through which they would have accessed ARV interventions and care, however a small proportion of them did not come back to hospital for their enrollment appointment after screening. These women became lost to follow-up. Efforts were made by both research and programme staff to contact them through phone calls, tracing them using locator forms and home visits but with no success. There were also missed opportunities to initiate (or continue) ART among late presenters in labor ward who are at high risk of vertical transmission. Our data indicated that 4.4% of HIV-infected women presented to the labor ward and did not go on to deliver at that time, and while some were documented as having received their HIV results, they had no documentation that they received ART. Some of the reasons contributing to this include but are not limited to the following: poor triage in LW, women in false labor and those coming with sickness like malaria leaving LW before being attended to by PMTCT staffs who initiate them on ART. Furthermore, nearly two-thirds of these women knew their HIV-positive status prior to attending the LW suggesting a double missed opportunity to start them on Option B-plus, both prior to, and at the labor ward. Upon investigation, we found that records management and retrieval was poor especially at night and on weekends, so that if an antenatal client record could not be found, a new one was created in labor ward which introduced opportunities for double-counting as well as over- or under-estimating clinic attendance and ART coverage, which could be neither excluded nor quantified due to the programmatic nature of our data.

Initiation of ART at the first health care contact during pregnancy is only the beginning step in the eMTCT cascade. Although it is reassuring that ART appeared highly acceptable, but there was also a small proportion (1.1%) of HIV-positive women opting out of Option B-plus initiation during pregnancy. The primary reason cited for opting out of Option B-plus at Mulago was lack of interest in taking lifelong ARV drugs. Our methodology did not allow us to explore what lay behind this response because these women did not return for follow-up despite numerous phone calls and attempts to engage them in care. Other studies have already raised alarm bells about disengagement from care after ART initiation. A study carried out in South Africa between January 2011 and Sep-

tember 2012 showed that 32% of HIV-infected pregnant women initiated on ART had disengaged from care by 6 months postpartum [14]. Although there are many potential benefits of Option B-Plus [5], other implementing sites have reported challenges associated with this strategy. At the 7th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention held in Kuala Lumpur, Malaysia in 2013, speakers from Malawi and Uganda highlighted loss to follow-up of HIV-infected women after initiation of Option B-plus as a major implementation challenge. In Malawi, 17% of all Option B-plus patients were reported lost to follow-up six months after ART initiation [15], and in Uganda 18% of women initiated on ART in antenatal care and 80% initiated on ART during labor did not return to receive their baseline CD4 results [16], which is important to assess ART adherence and to direct ongoing counselling support. In 2015 at the 8th IAS conference in Vancouver Canada, an abstract presented from Malawi showed that same-day integration of HIV diagnosis and treatment with antenatal care affected retention in Option B-plus PMTCT services [17]. In South Africa, an observational study found that nearly 60% of women who tested HIV-positive during pregnancy were lost to follow-up between HIV testing and 6 months post-delivery [18].

Additional reasons for opting out of Option B-plus at Mulago were preference for other health facility and to be prayed for rather than taking Option B-plus ART for treating HIV infection. At the 20th IAS Melbourne Conference in 2014, a speaker from Malawi brought to light the outcomes and reasons for loss to follow-up among women attending the Option B-plus programme and concluded that most such women had stopped ART or self-transferred to another clinic [19]. In our programme, we found out that other women were living in denial of HIV-positive results and this has been a challenge in various settings worldwide [20]. Many studies have revealed that sociocultural factors such as religion, culture and stigma can constitute barriers to ART access and adherence [21,22]. Self-care practices whereby HIV-infected people use herbs and prayers to help them mitigate or even cure HIV have also been reported as a challenge to take up appropriate care. Musheke, et al. [23] concluded that, while self-care practices may promote physical and psychosocial well-being and lessen AIDS-related symptoms for a short term, these practices undermine the ability of people living with HIV to access HIV care thereby putting them at risk of early AIDS-related mortality.

While over 50 percent rates of acceptance of Option B-plus ART initiation are very encouraging, we propose interventions to mitigate the missed opportunities identified in our programme. The first is to reinforce clinic-based efforts to educate, sensitize and strengthen counselling services about the benefits and risks of Option B-plus so that women can make and sustain informed rational choices with the support of their families and communities. There is also need to improve the longitudinal follow-up of HIV-infected pregnant women including use of proven strategies

such as short text and phone reminders and psychosocial support from peer mothers. The second is for an improved system of triage and referral of HIV-infected women presenting to, or newly diagnosed in ANC and LW so that they can be retained in care at LW and linked to appropriate care if they do not require ongoing LW services. There is therefore urgent need to improve records management and retrieval which, in this very large tertiary hospital, should include electronic records management given the size of the patient population and the various service delivery points. "At the moment, data collection is paper based and there is a tendency of files getting lost".

Our programme evaluation study had some limitations. We want to point out that although the Uganda clinical guidelines of 2010 recommend four routine antenatal care visits as follows: the first visit between 10-20 weeks of pregnancy; the second visit between 20-28 weeks of pregnancy; the third antenatal care visit between 28-36 weeks and fourth antenatal care visit after 36 weeks, we were not able to determine the time of gestation at which pregnant women attended their first antenatal care [24]. Due to weaknesses in the hospital paper-based records management, there may have been a misclassification of women as 1st attending LW and double-counting among those who attended LW without an ANC card (when they had actually attended ANC). Further, we recognize the possibility of a social desirability bias with women seeking to 'Please' providers who are recommending Option B-plus to them and thus not disclosing their true intentions or feelings [25]. It is reassuring that the counselling programme does allow women to express themselves and captures some of the reasons for opting out. However, we cannot exclude that there might not be a larger pool of clients who have also opted out by taking ART medications home but with no intention to take them.

Despite these limitations, the analyses also have a number of strengths, including the data available on the large numbers of women from this large and long standing PMTCT programme who provided reasons for opting out of option B-plus which are included in these analyses. Moreover, as Mulago hospital attendees account for a substantial subgroup of all women attending ANC and delivering each year at the national level in Uganda, we believe that this program evaluation provides valuable insights into the acceptability, feasibility and effectiveness of implementing Option B-plus in similar settings within and outside Uganda. It also points to opportunities to improve our implementation strategies. Further studies are required to evaluate Option B-plus implementation comprehensively, including evaluations of mother-infant retention in care, adherence and virologic suppression during pregnancy and breastfeeding, and linkages to ongoing reproductive and HIV care as well as infant HIV-free survival at Mulago Hospital and in other settings.

Conclusions

The results of this retrospective data analysis show that over the first 19 months of implementation of the Option B-plus programme for eMTCT at Mulago National Referral Hospital in Kampala, Uganda, uptake of Option B-plus was very high with a very small subgroup of around 1% of HIV-positive women who chose to opt out from Option B-Plus ART.

Data from this eMTCT programme evaluation underscore the urgent need to strengthen pre-pregnancy interventions given the large and increasing proportion of women with known HIV positive status prior to their current pregnancy. Efforts to improve records management and longitudinal follow-up of HIV-positive pregnant women are also essential to improve care and evaluate program effectiveness. Documentation, care and referral systems need to be improved so that all eligible HIV-infected women are offered Option B-plus and women referred between antenatal, labor and postnatal services receive continuity of care and are counted just once.

Among the many women who started Option B-plus, it will also be critical to evaluate individual ART adherence and viral suppression, systematic linkages between PMTCT, reproductive health and ongoing HIV care; and effective longitudinal monitoring systems to support continued care through any further pregnancies and for the women's lifetime.

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