

An early assessment of Uganda's roll-out of Option B+: Service capacity and infant outcomes

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BACKGROUND

Uganda was one of the first countries in sub-Saharan Africa to implement Option B+ as its national strategy for prevention-of-mother-to-child transmission (PMTCT) of HIV, doing so in 2013. We report on two evaluations designed to assess the capacity of the health care system to implement Option B+, and to obtain preliminary information on the maternal-to-child-transmission rate of HIV.

METHODS

We performed: 1) a cross-sectional assessment in 2014 of 505 health care facilities (49 district hospitals, 83 Health Center [HC] IVs, and 373 HCIIIs) in 62 of Uganda's 112 districts to evaluate whether services and commodities required for Option B+ were being provided; and 2) a retrospective record review of 283 HIV-exposed infants enrolled in post-natal care in 2013 in the Central Region to evaluate infant outcomes at 18-months of age.

RESULTS

Less than 50% of HCIIIs performed routine diagnostics, including syphilis, hemoglobin, and urinalysis testing, required at all ante-natal clinics; almost all facilities performed a baseline CD4 cell count, but only 44.5% of HCIIIs and 60.2% of HCIVs performed follow-up testing. The proportion of facilities monitoring antiretroviral therapy (ART) (47.2-69.4%) and clinic adherence (50.0-67.3%) was low. Many facilities (20.4-45.8%) reported stock-outs of ART and HIV test kits in the prior month. At 18 months, 53.7% of HIV-exposed infants were lost to follow-up (LTFU). Among those retained, 6.5% were HIV infected.

CONCLUSION

Significant shortcomings in service provision and high LTFU of HIV-exposed infants are barriers to Uganda's ability to implement Option B+ successfully.

Key words: HIV, Uganda, prevention, maternal to child transmission, Option B+

INTRODUCTION

For almost two decades, the elimination of new HIV infections among children has been of paramount concern to the global HIV community (World Health Organization [WHO], 2010). New drug regimens and more comprehensive treatment guidelines for the prevention of mother-

to-child transmission (PMTCT) of HIV have helped mitigate pediatric infection rates, especially in high-burden, low-resource settings (WHO, 2012; Joint United Nations Programme on HIV/AIDS [UNAIDS], 2013). In 2012, the WHO updated their recommendations for reducing vertical transmission, which accounts for the majority of pediatric infections (WHO, 2012). WHO's recommenda-

tion, referred to as Option B+, requires that all pregnant and breastfeeding HIV-sero-positive women be initiated on lifelong antiretroviral therapy (ART) regardless of their immunologic or clinical status.

Uganda was among the first countries in sub-Saharan Africa to incorporate Option B+ into its national PMTCT strategy, doing so in 2013 (Uganda Ministry of Health [MoH], 2013). With one of the world's highest birth rates and a disproportionately high HIV prevalence among women, Uganda required a robust and multi-pronged PMTCT strategy to stem the tide of new pediatric infections (Uganda Bureau of Statistics [UBOS] and ICF International, 2012). Appropriate uptake of Option B+ among breastfeeding mothers can reduce maternal-to-child-transmission (MTCT) to less than 5% and to as low as 2% among those infants who do not breastfeed (WHO, 2010). Widespread roll-out of PMTCT has additional benefits, such as improving mothers' overall health, reducing HIV transmission in future pregnancies, and decreasing transmission in sero-discordant couples (WHO, 2012; UN-AIDS, 2011).

In adopting Option B+, the Uganda MoH revised its national clinical guidelines. Pregnant and breastfeeding women with HIV, in addition to initiating a lifelong course of ART, are to receive baseline hemoglobin, urinalysis, and syphilis tests, as well as a CD4 cell count repeated every six months (Uganda MoH, 2011b; Uganda MoH, 2012; Uganda MoH, 2013). HIV-exposed infants are to receive six weeks of prophylaxis with daily nevirapine and a test for the presence of viral DNA, also known as a polymerase chain reaction (PCR) test, at six weeks of age. Exposed infants with a negative first PCR test are to be re-tested after the cessation of breastfeeding. At 18 months, all exposed infants are to undergo a rapid antibody test. Finally, the updated guidelines mandate that health care workers regularly monitor medication adherence and retention to clinic appointments among both mothers and infants (Uganda MoH, 2013). The success of Option B+ in reducing pediatric infections hinges on the Ugandan health system's capacity to implement these guidelines.

The MoH, the Makerere School of Public Health, Kampala, the University of California, San Francisco, and other implementing partners supporting Option B+ conducted two surveys to assess the ability to provide health services for PMTCT and to obtain initial information on the success of the Option B+ program. The first, conducted in 2014, was an evaluation of service capacity of health facilities in Uganda; the second was a retrospective record review of HIV-exposed infants born during 2013 to determine retention and obtain preliminary information on the MTCT of HIV. Together they provide a picture of the implementation and effectiveness of the program shortly after initial roll-out.

METHODS

Survey of health facility capacity to provide Option B+ services

We performed a cross-sectional assessment of 505 health care facilities in 62 of the 112 districts of Uganda; these districts were located in 9 of the 10 health regions of the country. The survey took place between April and July 2014 and was part of an initial plan by the MoH to perform periodic assessments of all health facilities providing Option B+. Sites were selected in districts where Option B+ was first implemented, since the national program was expanded in a phased manner. Site selection was also designed to obtain a fairly representative sample of the range of facilities providing PMTCT services. Facilities that were evaluated included 373 (74%) HCIIIs, 83 (16%) HCIVs, and 49 (10%) district hospitals. HCIIIs and HCIVs are lower level health facilities in comparison to district hospitals. HCIIIs, the lowest level of facility, usually staffed by nursing assistants, do not provide PMTCT services, and therefore were not surveyed.

The MoH PMTCT Program developed the assessment tool, which was a checklist of the availability and implementation of services recommended to be provided when initiating and following women on Option B+. At each site, the assessment team interviewed health care workers in charge of ante-natal care, the laboratory, and supply stores. The checklist was comprised of 24 items that asked about: 1) the availability of laboratory diagnostic services (CD4 cell count testing or referral of specimens, and syphilis testing, urinalysis, and hemoglobin levels for pregnant women), 2) whether health facilities were conducting retention and adherence monitoring, 3) the availability of family support groups, and 4) stock-outs of ART and HIV test kits in the month prior to the assessment.

Evaluation of retention of HIV-exposed infants and maternal-to child-transmission of HIV

The MoH selected two districts in the Central Region of the country to obtain preliminary information on the effectiveness of the Option B+ strategy, which was first rolled out in this area. The two districts were selected because they were among the very first to implement Option B+. Within each district, the five facilities with the greatest number of HIV-infected pregnant women in care were identified. This included one regional referral hospital, three district hospitals, two HCIVs, and four HCIIIs. De-identified data from all 283 HIV-exposed infants who had been enrolled in post-natal care at these sites from April through June 2013 were abstracted from clinic registers onto standardized forms. Data abstraction took place in late 2014.

Data from both surveys were entered onto Excel spreadsheets and analyzed using SPSS (version 10). Frequencies were calculated, stratified by level of health facility. As both the health facility survey and retrospective record review were routine MoH activities for the purposes of programmatic monitoring, and neither

one included collection of personal identifiers, the local human subject ethical review board considered the protocols to be exempt from review.

RESULTS

Health facility survey

We categorized health facility services into those that related to diagnostic testing, patient monitoring, and drug and test kit availability (Table 1). All district hospitals and HCIVs and 83.9% of HCIIIs performed baseline CD4 testing. However, repeat six-month CD4 cell counts were being performed much less frequently, particularly at HCIIIs (44.5%). Standard evaluations of pregnant women, including syphilis testing and urinalysis, were only performed in half or less of all facilities. All HCIVs and district hospitals evaluated hemoglobin levels, in contrast to HCIIIs, in which only 33% performed them. ART adherence monitoring and tracking of client retention

varied by level of health facility: 67.3-69.4% of hospitals conducted this type of monitoring, compared to about 50% of HCIIIs. Family support groups were available in almost all HCIIIs (91.4%), but much less so at higher-level facilities. Recent stock-outs of ART occurred across all health facilities (20.4-22.4%); nearly half (45.8%) of HCIIIs, 41.0% of HCIVs, and 24.5% of district hospitals experienced a stock-out of HIV test kits in the previous month.

Retrospective record review

Among the 283 HIV-exposed infants whose records were evaluated, only 124 (43.8%) were still being seen in care at 18 months of age; 152 (53.7%) were lost-to-follow-up (LTFU), and 7 (2.5%) were recorded as having died (Table 2). The LTFU was highest among infants seen at HCIVs (77.5%) followed by those at HCIIIs (62.2%). Even at the regional hospital, over half (52.5%) of the HIV-exposed infants were LTFU by 18 months. At 18 months of age, 93.5% of infants in care were listed as

Table 1: Availability of services required for provision of Option B+ at 505 public health facilities, Uganda, 2014

Category	Service	HCIIIs ¹ n (%)	HCIVs n (%)	Hospitals n (%)
Diagnostic Testing of HIV-infected Mothers	CD4 cell count, baseline	313 (83.9%)	83 (100%)	49 (100%)
	CD4, every 6 months	166 (44.5%)	50 (60.2%)	35 (71.4%)
	Syphilis testing	86 (23.1%)	31 (37.3%)	26 (53.1%)
	Urinalysis	116 (31.1%)	39 (46.9%)	25 (51.0%)
	Hemoglobin level	123 (33.0%)	83 (100%)	49 (100%)
Patient Monitoring	ART adherence monitoring, mothers	176 (47.2%)	54 (65.1%)	34 (69.4%)
	Retention monitoring, mothers & infants	185 (50.0%)	47 (56.6%)	33 (67.3%)
	Family support groups	341 (91.4%)	77 (92.8%)	20 (40.8%)
Service Availability	ART stock-out in prior month	76 (20.4%)	18 (21.7%)	11 (22.4%)
	HIV test kit stock-out in prior month	171 (45.8%)	34 (41.0%)	12 (24.5%)

¹ Health Center

Table 2: 18-month outcomes of HIV-exposed infants enrolled in care; Central Region, Uganda, 2013-2014

Health Facility	Enrolled at Birth	Status at 18 months				
		LTFU ¹ n (%)	Dead n (%)	Retained n (%)	HIV uninfected n (%)	HIV infected n (%)
RRH ²	97	51 (52.5%)	3 (3.0%)	43 (44.3%)	41/43 (95.3%)	3/43 (4.7%)
DH ³	101	42 (41.6%)	4 (3.9%)	55 (54.5%)	52/55 (94.5%)	3/55 (5.5%)
HCIV ⁴	40	31 (77.5%)	0 (0%)	9 (22.5%)	8/9 (88.9%)	1/9 (11.1%)
HCIII	45	28 (62.2%)	0 (0%)	17 (37.8%)	15/17 (88.2%)	2/17 (11.8%)
All	283	152 (53.7%)	7 (2.5%)	124 (43.8%)	116/124 (93.5%)	8/124 (6.5%)

¹ Lost to follow up ; ² Regional Referral Hospital ; ³ District Hospital ; ⁴ Health Center

being HIV-uninfected, and this did not vary by type of health facility. Seven of the eight HIV-infected children had been started on ART (data not shown).

DISCUSSION

Integrating Option B+ into the national PMTCT strategy has been a critical step in advancing Uganda's commitment to reduce pediatric HIV infections. However, results from two MoH-commissioned assessments revealed serious shortcomings in operationalizing the national guidelines. We surveyed nearly a third of all the 1600+ facilities accredited to provide updated PMTCT services in the country and identified significant gaps in basic diagnostic testing, routine patient monitoring, and the availability of HIV tests kits and antiretroviral drugs.

Although initiation of women on Option B+ does not require a CD4 cell count to be obtained, and Uganda is working to implement routine viral load testing more widely, immunological monitoring remains the primary method by which adherence and the effectiveness of ART are evaluated. Results of the capacity survey were unable to determine whether the failure of many facilities to perform follow-up CD4 testing was due to a lack of awareness of its importance or to limited resources, such as funds to pay for sample transport to the Central Public Health Laboratory. In addition, the failure to perform simple tests, such as urinalysis and hemoglobin levels during ANC visits, increases the risk of poor pregnancy outcomes and jeopardizes the health of the mother and the infant (Allen, 2000; Schneeberger, Gerlings, Middleton, & Crowther, 2015). These tests are inexpensive and easy to perform. Refresher training with review of guidelines for ante-natal care and PMTCT, as well as ongoing supervision of health care workers and facilities, all need to occur.

Stock-outs of HIV test kits occurred across all levels of health facilities, and ART medications were also not available regularly. Stock-outs of either commodity hinder prompt initiation of women on Option B+. The lack of a regular supply of ART can contribute to the development of drug resistance if women are not taking their medication regularly (Gardner et al., 2008). Stock-outs may also result in poor patient retention if patients lose interest in returning to clinics that don't have drugs (Gourlay, Birdthistle, Mburu, Iorpenda, & Wringe, 2013).

Family support groups are part of the national guidelines, because such community-based groups are useful in encouraging women to initiate Option B+ and to be retained in care (Lifson et al., 2015; Lubega et al., 2015; Poudel, Buchanan, Amiya, & Poudel-Tandukar, 2015). They help women overcome feelings of stigma and discrimination and remind them of the steps that HIV-infected pregnant and breastfeeding women need to take to protect their infants. In our assessment of health facility capacity, we found that at almost all lower-level health facilities, family support groups were available

and functional, but less than half of district hospitals had them. This may be because lower-level health facilities are more closely connected to the communities they serve. Family support groups, as well as village health workers, are vital for community engagement and client follow-up. However, many barriers to effectiveness of village health workers in Uganda exist, including poor incentives, low salaries, and out-of-pocket transportation costs for themselves and their clients.

In our study of HIV-exposed infants, significant LTFU occurred; only half of all infants brought into care were still being seen at 18 months, the recommended age for cessation of breastfeeding. We didn't collect data on HIV-infected mothers. It is possible that mothers were still being seen, but were not bringing their infants in for care; they may not have understood that if an HIV-exposed child has a negative PCR test result in the first few months, he/she may still become infected through breastfeeding. Overall, the combination of health system failure and high attrition can have a negative impact on the effectiveness of the new policy guidelines.

Other studies and reports have described breakdowns in the provision of ART, treatment adherence, and patient retention throughout sub-Saharan Africa, including Uganda (Mbonye, Hansen, Wamono, & Magnussen, 2010; Phillips et al., 2014; Tuller et al., 2010; Weiser et al., 2003). The causes are multi-factorial and include supply-chain mismanagement; insufficient training of health care workers about treatment protocols; patients' fear and experience of stigma and discrimination from family, community, and health care workers; patients' inability to pay transport costs to health facilities; and poor tracking and management of patients throughout the continuum of HIV care and treatment (Clouse et al., 2013; Kalembo & Zgambo, 2012; Nuwagaba-Biribonwoha, Mayon-White, Okong, & Carpenter, 2007). Exploration of factors driving the observed LTFU and PMTCT service gaps in Uganda require further inquiry.

The record review found a MTCT HIV transmission rate of 6.5%, which is higher than the national and global goal for Option B+, which is 5% or below. However, we do not know whether this rate is an under- or over-estimation due to the high rate of LTFU. It is possible that this calculation excludes lower-risk infants if those with an initial negative PCR test were likely to return for further follow-up.

These assessments had several limitations. The data tools were limited in scope; reasons for lack of services at health facilities were not explored, and we were unable to collect any information on possible reasons for high LTFU. Only data at 18 months were collected on infants. It is possible that a much larger proportion of children had an initial PCR test that was negative, and therefore did not return for a final test. In addition, we collected information only on those infants who had an initial health facility record, thereby excluding those who may not have returned for even an initial check-up and/or who had

been delivered at home, further reducing the reliability of the HIV MTCT estimates. It is also possible that mothers and infants transferred their care to other facilities. Since a mechanism to track patients between facilities does not currently exist, we don't know whether mother- infant pairs were being seen elsewhere. Finally, ascertainment of death is incomplete in Uganda. Knowledge of whether an infant dies depends on whether health care workers attempt to trace women who don't return for care, and such active tracing does not happen regularly. In other instances, family members coming to the clinic may inform the facility of a death. Therefore, our report of the proportion of infants who died may be an underestimate.

Following the analysis of the health facility survey data, a PMTCT stakeholders meeting was convened, which included district medical officers and representatives from the mostly non-governmental organizations involved in Option B+ implementation, to discuss the implication of the results for the success of the program. The data presented on the high LTFU of infants motivated the MoH to require that post-natal appointments be combined for both mothers and infants to reduce the number of follow-up visits required of mothers. However, a formal re-evaluation of the extent to which this improved retention has not been done. A more extensive evaluation of the MTCT rate was later undertaken by performing a comprehensive record review of a representative sample of health facilities throughout the Central Region in 2014. Findings were presented to the MoH in the form of a report (META, 2015). This evaluation found an MTCT rate of less than 5%, although infant retention at 18 months was still only about 50%. It is unknown whether any specific actions have been taken to address the gaps in services for basic ante-natal care and to ensure monitoring of response and adherence to ART. The MoH should be encouraged and supported to routinely perform such surveys and evaluations, as well as to implement solutions to address deficiencies.

The results of the assessments reported here reinforce the necessity of closely monitoring the early stages of Option B+ roll-out to ensure that facilities have the capacity to implement the program. For countries like Uganda, with a strong commitment to addressing pediatric infections, investing in robust monitoring and evaluation systems alongside the adoption of more stringent treatment recommendations are instrumental. As PMTCT treatment guidelines continue to evolve and the global HIV community looks beyond Option B+, these monitoring and evaluation systems will ensure greater confidence that Uganda and other countries are making real progress towards achieving an HIV-free generation.

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CONFLICT OF INTEREST

The authors have no conflicts of interest.

AUTHORS' CONTRIBUTIONS

RB: Contributed to conceptualization of the study, the development of the tools, implementation, and made significant contributions to the analysis, writing and editing of the manuscript.

EK: Contributed to conceptualization of the study, the development of the tools, implementation, analysis, and provided edits to the manuscript.

CK, SM, EA: Contributed to manuscript development and editing.

LK and JM: Contributed to the study conceptualization, development of tools, facilitated implementation, and reviewed the manuscript.

WB: Reviewed the draft manuscript.

JC: Made significant contributions to manuscript development, presentation of results, and editing.

CL: Made significant contributions to the analysis, manuscript development, writing and final editing.

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