Case Study: A Rapid Rollout of Universal Maternal HAART Improves Outcomes among HIV-Positive Women and Their Infants in Kenya

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Abstract

Globally, countries have made significant achievements in reducing rates of mother-to-child transmission (MTCT) of HIV. In Kenya, MTCT rates were most recently estimated at 8%, with 220,000 children under 15 years of age living with HIV. In 2013, the World Health Organization recommended highly active antiretroviral therapy (HAART) for all HIV-infected pregnant and lactating women. APHIA*PLUS*KAMILI supported rollout of a county-level, targeted, rapid scale-up of HAART in 152 high-volume facilities in Kenya. A review and comparison of data from these facilities in 2013 and 2014 revealed a significant increase in the proportion of women started on HAART and a reduction in MTCT.

Introduction

Globally, programs targeting the prevention of mother-to-child transmission (PMTCT) of HIV have transitioned from preventing HIV-infection among infants born to pregnant women living with HIV to implementing interventions that not only prevent transmission but also keep the mother alive and healthy. There have been significant reductions in adult and pediatric HIV prevalence in sub-Saharan Africa. From 2008 to 2011, there was a 24% decline in new infections among children. In six countries (Kenya, South Africa, Togo, Burundi, Namibia and Zambia), new infections among children declined by 40–49% (WHO 2013). Kenya, identified as one of 22 priority countries by the Joint United Nations Programme on HIV/AIDS (UNAIDS) (UNAIDS 2014), has an estimated HIV prevalence of 6% and approximately 1.6 million people living with HIV/AIDS, including 79,000 pregnant women in need of PMTCT interventions annually (UNAIDS 2014; NASCOP 2014a). Kenya has made substantial progress since the PMTCT program began in 2002 with the introduction of HIV testing and counseling among pregnant women and provision of antiretroviral (ARV) prophylaxis. In 2007, Kenya adopted an "opt-out" HIV testing policy for antenatal care (Ujiji et al. 2011). Provision of a single dose of the ARV nevirapine (NVP) to HIV-positive mothers at the onset of labour was the basic intervention to reduce MTCT of HIV, which can occur in utero, during delivery or through breastfeeding. A short course of prophylaxis with one or more ARV drugs given around labour and delivery reduces the transmission risk, but the risk of postnatal transmission remains high in settings where prolonged breastfeeding is the norm, as in Kenya (Becquet et al. 2009; NASCOP 2014b). Transmission of HIV from mother-to-child through breastfeeding accounts for 10–15% of the MTCT risks (NASCOP 2014b). Kenya's guidelines recommend six months of exclusive breastfeeding for all women, both HIV-infected and uninfected.

According to the most recent Demographic and Health Survey in Kenya, by six months, over 99.3% of women were still breastfeeding, but only 42% were exclusively breastfeeding, which poses a great risk of postnatal transmission due to mixed feeding (KNBS 2015; NASCOP 2014b).

By 2009, more than 80% of pregnant women accessing antenatal care services in Kenya were being tested and counseled for HIV and 79% of those testing positive received maternal ARV prophylaxis with two drugs, zidovudine (AZT) and NVP; however, the MTCT rate remained high at 27%, largely due to health system challenges related to

obtaining CD4 counts, an indicator of immune suppression and a criteria for determining eligibility for treatment versus prophylaxis. In 2012, one study showed that 83% of women living with HIV in Nyanza Province did not have samples taken for CD4 testing (Dillabaugh et al. 2012). However, by 2012, Kenya had achieved universal HIV testing with more than 90.7% percent of all pregnant women in Kenya tested for HIV (NASCOP 2014b).

After multiple PMTCT guideline adaptations, based on the expanding evidence base and World Health Organization (WHO) recommendations, in 2014, Kenya began scaling up access to lifelong HAART for all HIV-infected pregnant and breastfeeding women. Not only does HAART take into consideration the well-being of the mother (treatment instead of prophylaxis), but it is also more effective in reducing transmission of HIV to her child (NASCOP 2014a). The evolution of guideline recommendations can be found in Table 1.

The 2014 guidelines are better for both the provider and women living with HIV for several reasons, most importantly that the regimens are simpler, drugs prescribed have fewer side effects than those used previously and all women receive the same treatment, eliminating the need for providers to interpret complicated algorithms. Now, pregnant and breastfeeding mothers living with HIV receive a fixed dose combination of tenofovir, lamivudine, and efavirenz given once daily (NASCOP 2014a; WHO 2013).

PMTCT services in Kenya are implemented as part of focused antenatal care (ANC) provided within maternal child heath settings

Table 1. Kenya national guideline changes from initiation of the PMTCT program to present

Year	Recommended interventions for prevention of mother-to-child transmission of HIV	
	Mother	Infant
2002	Single dose NVP at onset of labour	
2005	AZT from 28 weeks gestation; single dose NVP at onset of labour	
	HAART (AZT/3TC/NVP) for pregnant women with CD4 count <200 or WHO clinical stage 3 or 4	
2006	AZT from 28 weeks gestation; single dose of NVP + AZT/3TC at onset of labour; AZT + 3TC for 7 days	Single dose NVP + AZT for 7 days
	HAART (AZT/3TC/NVP) for all pregnant women WHO clinical stage 4	
	HAART (AZT/3TC/NVP) for pregnant women with CD4 count <350 *and* WHO clinical stage 3	
	HAART (AZT/3TC/NVP) for pregnant women with CD4 count <200 *and* WHO clinical stage 1 or 2	
2010	AZT from 14 weeks gestation; single dose NVP at onset of labour; AZT + 3TC for 7 days	Single dose NVP + 3TC 7 days + AZT for 6 weeks
	HAART (AZT/3TC/NVP) for pregnant women with immunosuppression (CD4 <350 or WHO clinical stage 3 or 4)	
2011	HAART (AZT/3TC/NVP) for pregnant women with immunosuppression (CD4 <350 or WHO clinical stage 3 or 4)	NVP for 6 weeks
	AZT from 14 weeks gestation; single dose NVP at onset of labour; AZT + 3TC for 7 days	NVP until 1 week after cessation of breastfeeding
2012	Option A: AZT from 14 weeks gestation; single dose NVP at onset of labour; AZT + 3TC for 7 days	NVP until 1 week after cessation of breastfeeding
	Option B+: HAART (TDF/3TC/EFV) for all pregnant and breastfeeding women living with HIV	NVP for 6 weeks
2014	HAART (TDF/3TC/EFV) for all pregnant and breastfeeding women living with HIV	NVP for 12 weeks

NVP=nevirapine; AZT=zidovudine; 3TC=lamivudine; TDF=tenofovir; EFV=efavirenz; (NASCOP 2014a; WHO 2013)

and include: provision of HIV testing and counseling for women, their partners and other family members; nutritional counseling and psychosocial support; initiation and monitoring of women on HAART; and follow-up of HIV-exposed infants. Integration of HIV into ANC has improved the follow-up and health outcomes of mother-baby pairs (Turan et al. 2012). This case study looks at whether a rapid scale-up of implementation of HAART guidelines in project-supported facilities was effective in increasing HIV testing for pregnant women, initiating HIV-infected women on HAART and providing ARV prophylaxis to HIV-exposed infants.

Intervention

The APHIA*PLUS*KAMILI project, led by Jhpiego, is implementing comprehensive HIV services in Eastern and Central regions of Kenya, covering 480 health facilities in nine counties. The project is funded by the United States Agency for International Development (USAID) and works closely with the Ministry of Health to strengthen health services and build the capacity of healthcare workers to provide comprehensive HIV/AIDS services, including PMTCT. Several of APHIA*PLUS*KAMILI project's staff are members of the national PMTCT/antiretroviral therapy (ART) guideline committee, which developed the government plan outlining the path to elimination of MTCT of HIV. Project planning to scale up the uptake of HAART among HIV-infected pregnant women began in late 2013, before the release of the new guidelines in June 2014 (NASCOP 2014a). As a first step, county managers, sub-county health managers and more than 3,000 PMTCT service providers were sensitized on the new guidelines.

Due to frequent revisions of the national HIV guidelines, there was a need to update service providers with the latest national HIV guidelines and ART recommendations to build their skills and competence in implementing the current guidelines. Continuous medical education, monthly supportive supervision and clinical systems mentorship were used as cost-effective ways to transfer skills. Laboratory networks were strengthened to ensure that all HIV-exposed infants receive a polymerase chain reaction (PCR) test to establish if they were infected in utero, and that all mothers living with HIV have access to viral load testing, an essential component of HIV clinical care. To enhance social support and improve retention in care, the project introduced the government-endorsed "Mentor Mothers" program, where mothers living with HIV provide support and guidance to pregnant women newly diagnosed with HIV. The program aimed to increase the number of women newly tested and initiated on HAART, transition pregnant and breastfeeding women previously started on ARV prophylaxis onto HAART and engage women known to be living with HIV but not on HAART to start treatment and adhere to it. Quality improvement initiatives included administration of a site-integrated management system—an assessment tool that looks at the quality of care offered to people living with HIV, chart reviews and an HIV-exposed infant cohort analysis.

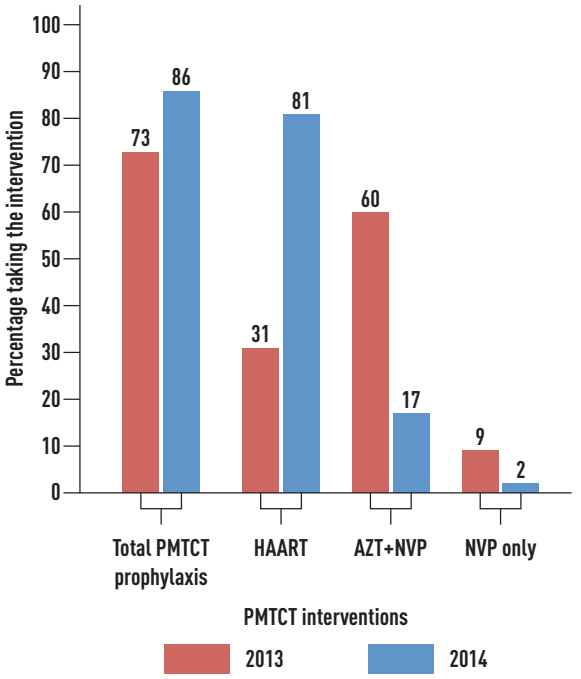
Methodology

Routine data from project-supported health facilities were collected using the Ministry of Health's official PMTCT data reporting tool; data reports were entered in the project's database for analysis. Indicators were collected along the PMTCT cascade from initial diagnosis of the mother until establishment of HIV status of exposed infants at 0–9 months of age. Data obtained in 2013 were used as the baseline and were compared to 2014 data, representing the period of intervention, to see if there was significant change between the two periods. Pre- and post-cohort analysis was conducted using Stata 10. The level of statistical significance was set at $p \leq 0.05$.

Results

In 2013, 84,688 women were newly counseled and tested in ANC and in maternity wards, while in 2014, 91,542 were counseled and tested, an increase of 8% in the number of women tested. HIV prevalence among pregnant women tested for HIV did not differ significantly from baseline to endline, 3.1% and 2.9%, respectively. In 2014, the majority of pregnant women living with HIV accessing services at APHIA*PLUS*KAMILI sites received HAART (81% compared to 31% in 2013). Figure 1 shows the changes in the types of PMTCT interventions provided between 2013 and 2014. Similarly, there was a significant increase in the percentage of HIV-exposed infants who received ARV prophylaxis in 2014 (2,265 or 84.7%) compared to 2013 (1,919 or 71.6%).

Figure 1. Comparison of the uptake of PMTCT interventions by women living with HIV between 2013 and 2014



NVP=nevirapine; AZT=zidovudine

Significant reductions in mother-to-child positivity rates were reported in the two Eastern and Central project regions during the intervention period, compared to the period before the intervention. Table 2 provides information regarding the HIV test results of HIV-exposed infants, as determined by PCR. Nearly 10% of PCR tests conducted were positive in 2013, compared to 6.5% in 2014.

Discussion/Conclusion

Pregnant and breastfeeding women living with HIV should receive HAART for best outcomes for both themselves and their children. The change in the national guidelines and project support to Ministry of Health facilities in Kenya led to a 2.5-fold increase in maternal access to HAART, which likely contributed to the decrease in the percentage of infants who tested positive for HIV by PCR. The use of single-dose NVP, an intervention that is no longer recommended by WHO (WHO 2013), has almost been eliminated in the project sites; only 2% of women received this intervention.

Adherence to treatment is an essential component of successful PMTCT programs. APHIA*PLUS*KAMILI promotes retention of mothers in care by deploying Mentor Mothers to give one-on-one counseling to other women living with HIV. Formation and support of psychosocial support groups also contributes to improving maternal and infant outcomes.

Table 2: Infant prophylaxis and early infant diagnostic testing outcomes in 2013 and 2014

	2013	2014
Infant prophylaxis		
HIV-exposed infants who received nevirapine prophylaxis	1,910	2,265
Percentage of total HIV-exposed infants who received nevirapine prophylaxis	71.6	84.7
Early infant diagnostic testing		
PCR tests conducted	1,814	1,929
Positive PCR results (%)	168 (9.5)	123 (6.5)

There is a tendency for slow adoption of national guidelines and recommendations in resource-limited settings due to gaps in the health-care delivery system (Paintsil and Andiman 2009). Efforts by the APHIA*PLUS*KAMILI project, a rapid results initiative aimed at addressing the gaps, have resulted in faster implementation of guidelines and earlier achievement of improved outcomes. (Rapid results initiatives use a series of accelerated activities to increase achievement of specific health indicators.) The rapid rollout of HAART guidelines resulted in a 49% increase in the proportion of women initiated on HAART. These findings agree with a study of a 2012 rapid results initiative in Nyanza, in western Kenya, which focused on the implementation of the 2010 Kenya ART guidelines and scale-up of universal access to maternal HAART and infant prophylaxis; this initiative produced a 40% increase in HAART uptake and was sustained during the post-initiative period (Dillabaugh et al. 2012). The results of our case study also concur with other rapid results initiatives in PMTCT, such as the 2014 initiative, also in Nyanza, in which male partner participation increased from 7% to 54% (Akama et al. 2014).

Universal maternal HAART has the capacity to reduce MTCT rates and keep mothers and their HIV-exposed infants alive and healthy, as shown in the results of clinical trials that have been done to assess the efficacy of HAART on PMTCT in resource-limited settings, where significant reductions have been observed when maternal HAART was introduced. For example, in a study in Botswana, pregnant women living with HIV who were started on various combinations of HAART in pregnancy, which continued to six months postpartum, had marked reductions in MTCT rates to 1.1% (Shapiro et al. 2010)

Development and dissemination of clinical care guidelines are an important component of any public health program; however, translating recommendations into rapid action is challenging in settings with limited resources. Comprehensive care for women living with HIV, including access to maternal HAART and peer support, is the most effective way of achieving elimination of MTCT of HIV.

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