policy

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PREVENTION OF MOTHER-TO-CHILD TRANSMISSION IN KENYA

COST-EFFECTIVENESS OF OPTION B+

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Introduction

New guidance from the World Health Organization (WHO) and the President's Emergency Plan for AIDS Relief (PEPFAR) supports countries that desire to implement a new strategy for the prevention of mother-to-child transmission of HIV (PMTCT), called Option B+. This strategy recommends that all HIV-positive pregnant women, regardless of CD4 count, receive triple antiretroviral (ARV) therapy for life. The strategy offers several advantages, including a possible reduction in adult infections, especially among sero-discordant couples; extended protection from mother-to-child transmission in current and future pregnancies starting from conception; and regimen simplicity.

While Option B+ requires more resources to implement than other strategies, some stakeholders have suggested that it may lead to long-term savings.

Like many sub-Saharan African countries, Kenya is exploring the adoption of Option B+ as the standard of care in their PMTCT programs. Recently, the government and its partners have been giving increased attention to the elimination of mother-to-child transmission of HIV (eMTCT). The country's eMTCT implementation framework aims to reduce new mother-to-child (vertical) infections to below 5 percent by 2015 and keep mothers alive.

In line with the global MTCT elimination action plan, the Kenya eMTCT plan recommends a comprehensive four-pronged approach, where elimination targets for each prong have been established. These include Prong 1: a 50 percent reduction of HIV incidence among women; Prong 2: a reduction of unmet need for family planning to zero among all women; Prong 3: the reaching of over 90 percent of HIV-positive women with more efficacious ARV-based prophylaxis to reduce the vertical transmission rate to below 5 percent; and Prong 4: a 90 percent reduction of HIV-related maternal deaths up to 12 months postpartum and a 90 percent reduction in HIV-attributable deaths among infants and children below 5 years old. The four pillars of the eMTCT framework are (1) health systems investment and strengthening, (2) political commitment and advocacy, (3) community systems strengthening and forging of effective partnerships, and (4) resource mobilization.

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Since resources are limited, evidence-based decisions are needed to effectively scale up PMTCT service delivery to achieve eMTCT goals. The National AIDS and STI Control Programme (NASCOP), a division within the Ministry of Health, in partnership with Health Policy Project (HPP), have embarked on an exercise to compare the cost-effectiveness of Option B+ to other PMTCT strategies (i.e., Option A). This brief presents the results, examining alternative implementation scenarios in Kenya over the period 2012–2016 and comparing infections averted and total cost.

Since the national PMTCT program began in 2002, more than 5,000 health facilities (>60%) now offer PMTCT services. National-level statistics suggest that in 2011, 80 percent of HIV-positive pregnant women received some form of ARV prophylaxis. Of the HIV-exposed infants, 63 percent received ARV prophylaxis.

ARV Options for PMTCT

Under **Option B+**, all HIV-positive women are initiated on triple ART upon diagnosis and continued for life, without interruption, regardless of CD4 status. In countries where Option B+ is not yet adopted, the protocol can be as follows.

All HIV-positive pregnant women currently eligible for antiretroviral therapy (ART) (WHO-defined clinical stage 3 or 4 or with CD4<350 cells/mm^3) but not on ARVs, should initiate triple ART as soon as possible for HIV treatment and for the purpose of PMTCT.

All HIV-positive pregnant women not eligible for ART at the time of pregnancy, but who need an intervention for PMTCT, should start on ARV prophylaxis. The options are as described in Table 1:

- **Option A**: AZT (300 mg twice daily) initiated from 14 weeks of pregnancy or as soon as possible thereafter, followed by additional ARVs in labor, delivery, and post-delivery.
- **Option B**: In settings with the capacity to initiate and monitor triple ART, HIV-positive pregnant women not otherwise eligible for ART can be started on triple ART at 14 weeks of gestation, and continued until one week after the infant stops breastfeeding.

Table 1. ARV prophylaxis Options A and B for HIV-positive pregnant women not eligible for ART [1,2]

Stages	2010 Kenyan Guidelines	WHO Option A (CD4 > 350 cells/mm^3)	WHO Option B (CD4 > 350 cells/mm^3) *
Pregnancy	AZT from 14 weeks	AZT from 14 weeks	Triple ARVs (AZT + 3TC + NVP) from 14 weeks till 1 week after the end of breastfeeding
Labor	sd NVP and then AZT+3TC	sd NVP and then AZT+3TC	
After birth: mother	AZT+3TC daily for 7 days	AZT+3TC daily for 7 days	
After birth: infant (breastfed)	NVP daily until 1 week after the end of breastfeeding	NVP daily until 1 week after the end of breastfeeding	Daily NVP or AZT from birth till age 4–6 weeks
After birth: infant (not breastfed)	NVP daily till age 6 weeks	NVP daily till age 4–6 weeks	

* Option B: If not breastfeeding, then triple ARVs continue until childbirth.
Abbreviations: sd—single dose; 3TC— lamivudine; AZT—zidovudine; NVP—nevirapine. Sources: MOH, 2010, MOH, 2012.

Research Questions

1. What is the total cost per year over 2012–2016 of adopting Option B or Option B+ in Kenya? How do the costs compare to the current strategy of Option A?
2. What are the total number of infant and adult HIV infections averted over 2012–2016 under Option B and Option B+, compared with the current Option A strategy?

Methodology

To answer the above questions, HPP estimated the potential infections averted and costs associated with implementing the Option B+ strategy, while also considering Option B as an alternative.

Cost Data

Only direct costs of service delivery were included. Unit costs of ARV drugs and laboratory commodities

were sourced from the recent Ministry of Health's HIV Forecasting and Quantification report (2012) for Kenya. The cost of antiretrovirals for each HIV-positive mother and exposed infant pair, given the strategy, were based on dosages in Kenyan guidelines or WHO documents. Early infant diagnosis costs were excluded. Labor inputs were based on studies and best practice and were valued at current fully-loaded salary levels (exchange rate: 84KSh/US$) for cadres expected to deliver PMTCT. The total direct unit cost was **$76 for Option A, $466 for Option B** (from the 14th week of pregnancy till the end of breastfeeding—about 12 months as per Kenyan PMTCT guidelines), and **$317 for Option B+** per patient year.

Scenarios

We analyzed five scenarios for PMTCT implementation (see Figure 1).One scenario reflects continuation of the current strategy (**Base**), which aligns with Option A but has a minority being treated under Option B. A portion of HIV-positive pregnant women were started on triple ART prior to their current pregnancy. This portion should grow over time as Kenya's adult ART program matures. Annual proportions for this group are similar across all five scenarios. Some HIV-positive pregnant women with CD4 counts below 350 cells/mm^{3}will start on triple ART in the current pregnancy—about 9 percent of the total in 2012. Percentages for this group will increase if Option B+ is implemented at scale. All values were derived from recent Ministry of Health data.

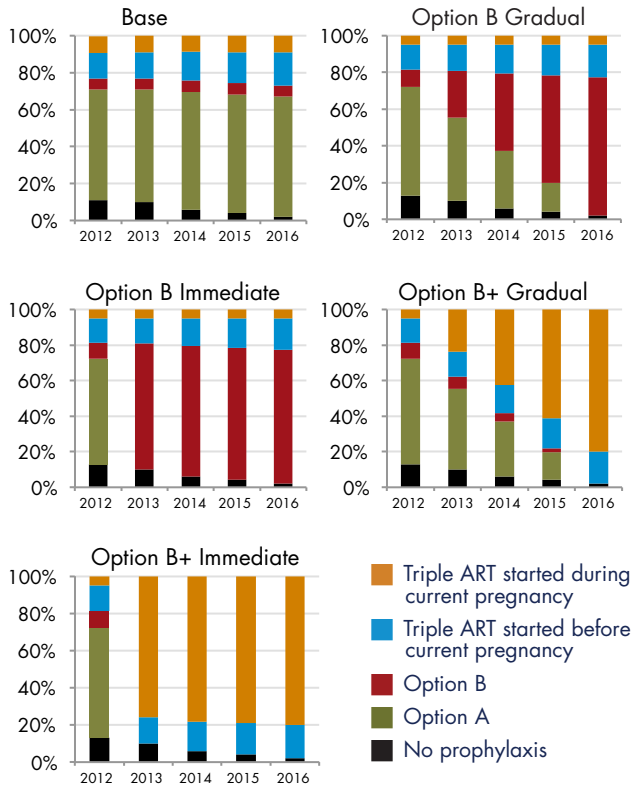
Two scenarios are based on gradually implementing Option B or Option B+ (**Options B and B+ Gradual**) over 2012–2016. With the gradual increase in the share of Option B+, the proportion for "triple ART started during current pregnancy" rises. Another two scenarios are based on Option B or Option B+ implemented all at once from 2012 (**Options B and B+ Immediate**).

Analysis

Vertical infections averted: Estimation of mother-to-child transmission under each of the five scenarios was conducted using the AIDS Impact Model (AIM), a part of the Spectrum System of Policy Models.

AIM uses the calculated efficacy of different PMTCT strategies in the peripartum stage (closely before and after birth) and during breastfeeding. This draws on transmission probabilities (see Table 2) and the likelihood of breastfeeding at different ages based on the last Kenyan Demographic and Health Survey.[3]

Figure 1. Scenarios for PMTCT Strategies, 2012–2016



Vertical axis represents proportions of HIV-positive pregnant women. Source: authors' assumptions.

Adult infections averted: Placing additional HIV-positive women on ART reduces the risk of HIV transmission to their HIV-negative partners. We used a model to gauge the effect of adult ART, which tracks HIV-positive adults by CD4 count and estimates new adult infections given the risk of transmission at different stages of infection. The model assumes that relative infectiousness is 9.2 during the primary stage, 1.0 in the chronic stage, and 7.3 in the late stage when the CD4 count drops below 200 cells/mm^3. For adults on ART, the value was 0.04 based on HIV Prevention Trials Network (HPTN) 052.[4]

Allocation of costs: For HIV-positive women with CD4 < 350 cells/mm^3 that start triple ART in the current pregnancy (any scenario), two years of drug costs were included. After two years, costs transfer to the adult ART program. For women with CD4 > 350 cells/mm^3 who start triple ART in the current pregnancy under Option B+, five years of drug costs were included. Three of these years reflect an estimate of the time it would take for their CD4 count to drop to 350 cells/mm^3.

Table 2. Mother-to-child HIV transmission probabilities by PMTCT strategy and stage[5]

Strategy	Perinatal	Breastfeeding (per month)	
		CD4 < 350	CD4 ≥ 350
No prophylaxis			
Existing infections			
CD4 < 200	37%	1.57%	N/A
CD4 200–350	27%	1.57%	N/A
CD4 > 350	15%	N/A	0.51%
Incident infections	30%	28%*	28%*
Option A	2%	N/A**	0.2%
Option B	2%	N/A**	0.2%
Triple ART started before pregnancy	0.5%	0.16%	N/A
Triple ART started during pregnancy	2%	0.2%	N/A

* Total transmission probability, not by month. ** Not applicable, as these women are eligible to get triple ART.

Results

Cost-effectiveness analysis helps to identify the most efficient strategies for averting HIV infections. Based on AIM, 85,710 HIV-positive pregnant women needed PMTCT in 2012, declining to 82,164 by 2016. The cost of implementing the Base scenario over 2012–2016 is US$45.5 million, and 39,546 infant infections are projected to occur. When compared with the Base scenario, implementing the Option B scenarios will not avert infant or adult infections. However, implementing the two Option B+ scenarios will avert infant and adult infections (see Table 3)—but at a significant additional cost.

The average costs per infection averted compared with the base scenario are shown in Table 3. Kenya should compare these values with other HIV prevention interventions to assess whether Option B+ is affordable given the available resources. Cost-effectiveness is not the only reason a country may wish to implement Option B+. The strategy could help streamline program implementation or improve the retention of women in care.

Table 3. Costs and impacts by scenario, 2012–2016

Compared to Base scenario:	Option B		Option B+	
	Gradual	Immediate	Gradual	Immediate
Infant infections averted	0	0	3,554	5,788
Adult infections averted	0	0	8,285	10,552
Incremental cost (US$ mill.)	$61.5	$90.9	$224.6	$347
Cost per infection averted (US$)	-	-	$18,967	$21,234

Limitations

A threshold for a strategy being cost-effective is when the cost per unit of a measure such as Disability Adjusted Life Years (DALYs) is below three times the gross domestic product per capita. However, we did not estimate DALYs. Additional study on the advantages of Option B+ is warranted, especially on other purported health benefits of Option B+, such as reduced resistance to ARVs and reduced incidence of postnatal opportunistic infections.

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