The Option B+ Costing Report 2013

Incremental cost implications of adapting Option B+ in Lesotho

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SELEKANE SA BASOTHO LE MA-AMERIKA HO FENYA HIV/AIDS

Acknowledgements

The Ministry of Health wishes to acknowledge the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) for the technical support which they provided during the costing of Option B+ and the United States Agency for International Development (USAID) for their financial support.

Completion of the analysis would not be complete without the inputs of the Government of Lesotho and its HIV program implementing partners. The Ministry would sincerely like to extend their gratitude to WHO, WFP, UNICEF, UNFPA, Baylor College of Medicine, ICAP, Clinton Foundation, EGPAF, MSF, MSH, PIH, LPPA, LENASO, mothers2mothers, NDSO, PSI, and Riders for Health for their support.

Finally, the Ministry acknowledges the wide range of staff members within the Family Health Division, STI/HIV/AIDS Directorate, and Disease Control who were committed to this process.

Photo: A neighbour of horse-rider Potso Seoete watches as he prepares for the journey to the Molika-liko health clinic in the Mokhotlong district, Lesotho, 01 September 2010. Credit: Jon Hrusa/EPA.

Executive Summary

Background

In Lesotho, 320,000 people are living with HIV. Of these, about 5% are HIV-positive pregnant women. In April 2012, the World Health Organization (WHO) released a programmatic update around the benefits of a prevention of mother-to-child HIV transmission (PMTCT) intervention involving lifetime ART among all HIV-positive pregnant women, regardless of their CD4 (Option B+). In line with the WHO programmatic update, in September 2012, Lesotho revised national PMTCT guidelines. In October 2012, at the request of Lesotho's PMTCT technical working group (TWG), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), conducted a cost analysis of direct and indirect costs associated with implementation of Option B+. Direct costs are the costs of providing Option B+ related interventions directly to the targeted population such as pharmaceutical and laboratory interventions. Indirect costs are those costs which contribute to the implementation of Option B+ such as human resource, community-based activities and monitoring and evaluation costs but the benefits to the clients are not directly traceable.

Methodology

The analysis was conducted from the perspective of the MOH. The TWG created a list of undertakings that were required for successful transition from Option A to Option B+. HIV implementing partners provided expenditure data from their programmatic data. This costing focused on clinical interventions that were carried out with respect Option B+ within maternal and neonatal child health (MNCH) during a woman's antenatal and postnatal period. The costs were divided into direct costs and indirect costs. The exchange rate used was one United States dollar to 8.5 Maloti. The key outputs were annual total pharmaceutical costs of initiating and maintaining a mother-baby pair on Option B+ during the first year of switching to Option B+; total cost of switching and initiating the first cohort of pregnant and lactating women and their infants to Option B+; and a comparison of the total costs associated with implementing Option B+ instead of Option A from mid-2013 to 2015. The scope of the analysis did not include long term costs and benefits accrued under Option B+ compared to Option A.

Key findings

The total cost of switching to Option B+ in the transition period came up to US $8.7million (74.5million maloti). Pharmaceutical costs made up at least half of the total cost at US $5million (42.8million maloti). The annual breakdown for pharmaceutical costs per target population is as follows: US $1 (8.57maloti) per exposed infant on NVP per annum and the weighted cost of first line ARV per HIV infected woman per year was US $183 (1,555maloti). The additional cost of moving from Option A to Option B+ from mid-2013 to 2015 was (US $14million) 119.6million maloti switching from Option A to Option B+ will result in substantial increased costs (69.5million maloti) in the first year of implementation. This rise in costs drops by the second year (25.2million maloti) and continues to fall in the third year (25million maloti) but remains higher than the costs estimated for Option A.

Conclusions and recommendations:

This analysis has informed the MOH of expected costs of moving to B+ within the Lesotho context and will be used to advocate for increased funding in certain areas of implementation of B+. It is important

for countries moving to Option B+ to mobilize resources in preparation for a successful rollout of Option B+. Some recommendations stood out from this analysis such as the need for expenditure tracking of PMTCT activities, formulating a sustainability plan for PMTCT and improvement in program documentation.

Continuous expenditure tracking of PMTCT activities from key stakeholders is important to explore the 'real' financial implications of increasing access of ART to HIV-positive pregnant and lactating women. It may also serve as a proxy for baseline costs in the case that other guidelines are adapted in Lesotho.

In order to achieve sustainability of the benefits achieved as new guidelines are adapted; it is recommended that facility and community-level costing of the cascade of services required to successfully implement Option B+ is carried out. Based on the findings, resource mobilization activities and sustainability plans may be better targeted toward districts based on the demographic, human resource capacity or geographic variability among other factors.

To successfully achieve efficient expenditure tracking and to draw up adequate sustainability plans; information on overall programmatic impact on the targeted population should be accurately documented and made readily accessible to decision makers. For example, focusing trends in rates of new infections or repeat pregnancies; effect of chronic treatment on women initiated on ART for life; the eventual effect on healthcare workers of increasing by 12% more people per year to chronic ART clinics; cost of early initiation on pediatric treatment; and shifting to 2nd/3rd line drugs will provide insight into future resource needs and allocation.

Contents

1 Introduction

1.1 Background

As of 2012, the Kingdom of Lesotho had a population of approximately two million people and was ranked as a lower/middle income country with a GDP of 1,193USD per capita[1]. Lesotho is also associated with a high HIV prevalence of which 23% of adults were HIV-infected in 2011[2]. In a move to respond to this health crisis among other development goals, Lesotho made a commitment, under the Abuja Declaration, to allocate 15% of the total national budget toward health programs[3]. Part of this budget will go toward subsidizing medical services and drugs at health centres and hospitals. In the most recent national budget dissemination by the Minister of Finance, it was proposed that 12% of the country's 2013/14 budget would be allocated toward health expenditure.[4] This is a great stride toward strengthening the health system, especially in light of the new approach toward eliminating mother- to-child transmission (MTCT) and pediatric HIV.

Elimination of mother-to-child transmission of HIV in Lesotho has made remarkable progress in the last decade. Modifications have been introduced in prevention of mother-to-child transmission (PMTCT) interventions since its introduction into Lesotho in 2003. To date, Lesotho has managed to successfully scale up PMTCT provision to 100% of eligible sites[5]. Incidentally, in 2009/10, expenditure on HIV prevention activities rose to 29% from 9% (in 2007/8)[6]. The *Global Plan towards the Elimination of New HIV Infections among Children By 2015 And Keeping Their Mothers Alive: 2011-2015* was introduced by UNAIDS in 2010[7]. Within a year of this introduction, in December 2011, Lesotho officially launched its costed *National Strategic Plan for Elimination of Mother to Child Transmission of HIV and for Paediatric HIV Care and Treatment 2011/12-2015/16 (EMTCT PLAN)*[8]. The plan was largely based around implementation of the 2010 WHO guidelines and a spectrum of activities related to the four PMTCT prongs which were underscored by WHO's 2010 Option A PMTCT regimen. The total operational cost for implementing this plan was greater than 1billion Maloti[8]. In brief, the 2010 WHO guidelines stipulated that, under Option A:

- An HIV-infected pregnant woman with CD4>350 receives Zidovudine (AZT) starting at 14 weeks and AZT, Lamivudine (3TC), and Nevirapine (NVP) during labor, and that the infant receives Nevirapine suspension until one week post-cessation of breastfeeding; while
- An HIV-infected pregnant woman with a CD4<350 is initiated on antiretroviral therapy (ART) [9].

The key strategic areas of the eMTCT plan were:

Strategic Area 1	Prevention of HIV infections among HIV uninfected women and men of reproductive age
Strategic Area 2	Prevention of unintended pregnancies in women infected with HIV
Strategic Area 3	Prevention of transmission of HIV from women infected with HIV to their children
Strategic Area 4	Increase access to quality treatment, care and support for HIV infected women, their male partners and their families
Strategic Area 5	Promote access to quality paediatric HIV treatment, care and support for all HIV infected infants, children and adolescents
Strategic Area 6	Integration between HIV, MNCH and other related services
Strategic Area 7	Health system strengthening (HSS)
Strategic Area 8	Coordination and collaboration between government and all relevant organisations

Table 1 Strategic Areas of the EMTCT plan

Strategic areas 1-4 are synonymous with the four PMTCT prongs. The remaining strategies relate to demand creation of services, promoting uptake of services, the six pillars of health system strengthening and coordination and collaboration among the government and stakeholders[8].

In April 2012, the WHO released a programmatic update on the *Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants* which recommended lifelong antiretroviral therapy for HIV-infected pregnant women, further putting Lesotho's goal of eliminating new pediatric infections by 2015 in sight[10]. Lesotho shifted from implementing the WHO-recommended Option A regimen to initiating HIV-positive pregnant women on ART for life. In September 2012, Lesotho started updating its national PMTCT guidelines and looking into financial considerations of implementing operational changes necessary to switch from Option A to Option B+ regimen[11].

1.1.1 Option B+

Under Option B+, all HIV-infected pregnant and lactating women are initiated on lifelong triple ARV regimens as soon as they are diagnosed as HIV-positive - initiation is not dependent on CD4 results. The preferred regimen for HIV-infected pregnant women is tenofovir/lamivudine/efavirenz (TDF/3TC/EFV). The infant receives daily Nevirapine (NVP) from birth through to 6 weeks of age, regardless of the feeding method[11].

At first glance, Option B+ seems to be the more costly option of treatment as it involves scaling up treatment to a wider population. However, the long term advantages of Option B+, such as reduced reliance on initial CD4 testing to determine eligibility for treatment which can serve as a bottleneck to access to treatment in resource-limited settings, simplified regimen and easier prescription of a more efficacious regimen to prevent mother-to-child transmission and the benefits of treatment as protection in future serodiscordant relationships, could outweigh the initial increase in costs.

As a first step toward moving to Option B+; an initial costing exercise was conducted to determine the immediate costs that would be incurred in the first phase of implementing Option B+. The subsequent long-term cost and benefit implications of Option B+ will not be explored in this costing but are highly recommended[10].

1.2 Objective

The overall aim of this costing exercise was to investigate the incremental costs that would be incurred as a result of the operational changes necessary to shift from Option A to Option B+ in Lesotho. The objective of this costing exercise was led by the question: *What is the incremental expenditure required to transition from Option A to the implementation of Option B+ in the Kingdom of Lesotho?*

1.3 Approach

The approach was two-fold: i) to estimate the absolute cost incurred for the cohort of HIV-infected pregnant and lactating women and their infants receiving Option B+ who attend ANC and postnatal care during the transitory period from Option A to Option B+; and ii) to review the cost implications on the EMTCT plan for the remaining three years. The transitory period refers to the cohort of all pregnant and lactating women who will be attending antenatal and postnatal care from April 2013 up until the end of

the postnatal period which we align with the time they cease receiving services in MNCH or when the child is 24 months old.

2 Methodology

The costing was carried out in October 2012 from the provider's perspective; the MOH. The MOH PMTCT Technical Working Group (TWG) undertook a series of steps critical to the successful transition from Option A to Option B+, and the costing was ultimately based around these activities, focusing on additional near-term costs necessary to move from Option A to B+. A costing tool was developed by EGPAF-Lesotho. A similar tool was used to assist the MOH in the costing of its recent plan to eliminate mother-to-child transmission. Costs were based on expenditure data from HIV implementing partners. Costs were also collected through literature reviews. A mark-up of 7% was used on all pharmaceutical purchases to allow for suppliers' profit, freight, and tax charges based on recommendations made by pharmaceutical distributors. The cost data were divided into direct drug costs and non-drug direct and indirect costs, such as laboratory, human resource, and community costs. The exchange rate used was one United States dollar to 8.5 Maloti.

The key outputs based on this methodology were:

- Total pharmaceutical costs of initiating and maintaining a mother-baby pair on Option B+ during the first year of switching to Option B+;
- Total cost of switching and initiating the first cohort of pregnant and lactating women and their infants to Option B+; and
- Projection of costs for implementing Option B+ instead of the Option A for the remaining years of the elimination plan.

The scope of the analysis did not include long-term costs of putting women on ART for life nor the aggregated costs of paying for the full set of benefits and costs accrued under Option B+ compared to Option A. To avoid duplication of costing efforts, we endeavored to exclude costing those activities that were systemic and/or budgeted for under the Elimination Plan since the activities were running simultaneously.

2.1.1 Model Structure

The model focuses on: new antenatal care (ANC) HIV-positive clients who are yet to be initiated on any treatment; new ANC clients who were already on treatment and will continue receiving treatment in the maternal, neonatal, and child health (MNCH) setting; lactating clients still attending ANC who were previously initiated on Zidovudine (AZT) as prophylaxis only; and all HIV-exposed infants born to new ANC clients.

2.1.2 Demographic details

For consistency, population estimates were drawn from the EMTCT plan. It is expected that 57,339 pregnant women will attend ANC in 2013. One hundred percent of these ANC attendees will be screened for HIV, and due to the opt-out consent method, approximately 98% of these women will receive their HIV test results. This analysis used the current ANC HIV prevalence rate in Lesotho of 25.8% to calculate the proportion of clients who will present as HIV-positive in the first year of implementing Option B+. According to the EMTCT PLAN targets, 94% of these women will be initiated on ART; this

translates to 12,946 HIV-infected pregnant women on Option B+ in 2013, and includes new clients yet to be initiated and those who are already on treatment. The proportion of lactating women who will need to be initiated on ART for life will be calculated as: *the proportion of lactating mothers who still attend post-natal care ("retention rate") multiplied by the monthly average number of actual women who attended ANC multiplied by the number of months in a year over HIV prevalence in ANC.*

Parameters	*Base*	*Source*
Number of pregnant women	*57,339*	*[8]*
Percentage of pregnant women attending ANC	*95%*	*[8]*
Percentage of pregnant women receiving HIV test results	*98%*	*[8]*
Current ANC HIV prevalence rate	*25.80%*	*[8]*
Percentage clients receiving treatment	*94%*	*[8]*
Seroconversion rate during lactation	*0.10%*	*[12]*
Seroconversion rate at time of delivery	*2.30%*	*[13]*
MTCT rate without intervention	*20%*	*[12]*
Maternal mortality rates	*1.5%*	*[2]*
*Infant mortality rates**	*4.5%*	*[14]*

Table 2 Population parameters

3 Costing

3.1 Pharmaceutical Costing

3.1.1 Population assumptions for pharmaceutical costing

The assumptions which guided the drug costing are as follows: i) all HIV-exposed infants will be initiated on NVP - 12,946 infants will receive NVP for 6 weeks; ii) Cotrimoxazole will be given to adults whose CD4 count is less than 350 (calculated for a 12 month period) and to all HIV-exposed infants from 6 weeks up to twelve months; and iii) the preferred regimen is TDF/3TC/EFV which will be given to at least 50% of the clients. In addition to the preferred regimen, there are 5 alternative regimens: TDF/3TC/NVP, AZT/3TC/EFV, AZT/3TC/NVP, Abacavir/lamivudine/efavirenz (ABC/3TC/EFV), and ABC/3TC/NVP.

Drug regimen	Assumptions	Proportion
TDF/3TC/EFV	*70% of HIV-infected pregnant women will be on a TDF regimen, based on the targets; 75% of these clients will be initiated on the preferred regimen*	**52.5%**
TDF/3TC/NVP	*25% of patients on a TDF-based regimen will be on TDF/3TC/NVP*	**17.5%**
AZT/3TC/EFV	*25% of patients will receive an AZT-based regimen; 10% will be given AZT/3TC/EFV*	**10%**
AZT/3TC/NVP	*15% of these clients will receive AZT/3TC/NVP*	**15%**
ABC/3TC/EFV	*The remaining 5% of the population will be given ABC-based regimens; 60% of this population will be given ABC/3TC/EFV regimen*	**3%**
ABC/3TC/NVP	*2% of this population will be given ABC-based regimens*	**2%**
Total		**100%**

Table 3 First-line drug regimen population assumptions

The distribution of the population across the different regimens is based on national pharmaceutical consumption data. The population includes all HIV infected women who are expected to receive drugs irrespective of when the HIV status was determined and regardless of whether they were initiated on ART previously. We assume that all HIV infected women are initially initiated on the first line regimen but may be 'switched' to second line regimen thereafter if the need arises.

The second-line regimen population assumptions are drawn based on the national pharmaceutical consumption estimate of 2%. The time at which the switch to second-line regimen would occur was not modeled into the costing exercise but an estimate of the same length of time as the first-line regimen was used to avoid under-costing.

Drug regimen	Assumption	Proportion
AZT/3TC/LPV/r	*Based on Lesotho pharmaceutical consumption estimates*	**0.5%**
AZT/3TC/ATV/r	*Based on Lesotho pharmaceutical consumption estimates*	**0.0005**
TDF//3TC/ATV/r	*Based on Lesotho pharmaceutical consumption estimates*	**0.0005**
TDF/3TC/LPV/r	*Based on Lesotho pharmaceutical consumption estimates*	**1.4%**
AZT/TDF/3TC/LPV/r	*Included in previously outlined amounts*	
Total		**2%**

Table 4 Second-line drug population assumptions

3.1.2 Pharmaceutical Costs

The total cost of ARVs is estimated at US$5million. The amount includes:

- The cost of cotrimoxazole for adults and exposed infants;

- NVP for HIV-exposed infants;
- ART for HIV-infected pregnant and lactating women; and
- Additional cost of purchasing single 3TC and NVP, in order to make use of the AZT that was previously purchased for prophylactic use.

Abbreviation	Unit cost (Maloti) excl. VAT	Population	Cost/Year/Patient (Maloti)	Cost/ Patient/Year/ (US$)
Nevirapine (infants)	3.40	12946	8.57	1.00
Cotrimoxazole				
Adults	178.22	4967	65	8
Children (suspension)	92.92	1165	116	13.80
Children (tablet)	3.65	11781	46	5.40
TDF/3TC/EFV	137.94	6797	1683	198
TDF/3TC/NVP	80.61	2266	1332	157
AZT/3TC/EFV	123.76	1295	1510	178
AZT/3TC/NVP	93.91	1942	1146	135
ABC/3TC/EFV	198.61	388	2423	285
ABC/3TC/NVP	176.99	259	2159	254
AZT/3TC/LPV/r	367.98	65	4489	528
AZT/3TC/ATV/r	473.48	6	5776	680
TDF//3TC/ATV/r	451.95	6	5514	649
TDF/3TC/LPV/r	346.45	181	4227	497

Table 5 Drug cost per patient per annum

The weighted cost of CTX per exposed infant is US$6. The weighted cost of first-line ART per HIV infected woman is US$183, while the weighted cost of second-line regimen cost per HIV-infected woman per year is US$510.

3.2 Laboratory Costing

The type and frequency of laboratory testing required per person were stipulated in the new WHO guidelines. As a result, there are seven laboratory tests central to the successful implementation of Option B+. The laboratory tests include those which allow HIV-positive women to be detected and entered into the PMTCT cascade; recommended baseline tests for uninfected and HIV-positive pregnant women and monitoring tests exclusively for those women on treatment. HIV test kits are included in this costing exercise, even though they are not necessary for monitoring patients. However, HIV testing is important because it serves as an entry point for accessing Option B+, so it is important to include HIV testing for pregnant women entering ANC and their children. The assumptions guiding the frequency of testing are as follows:

Test	Method of testing	Assumptions
HIV testing	Determine test	All clients will be tested at their initial visit, all clients who test HIV-negative will be re-tested twice more prior to and/or during delivery and two times during lactation. All infants will be tested at 9 and 18 months.
	Double Check Gold test	All pregnant women who test HIV-positive with the *Determine* test will have a second confirmatory test with the *Double Check* test (1)*. All infants will be tested at 9 and 18 months of age (2)*.
CD4 cell count	CD4 testing	CD4 counts will be carried out for each HIV-infected pregnant woman every 6

Test	Method of testing	Assumptions
		months: at the first visit as a baseline at 14 weeks), at 38 weeks, and four times during the postpartum period (6)*.
Hemoglobin levels	Hb testing	All pregnant women will have hemoglobin tested at their initial visit. HIV-positive women on AZT-based regimens will be monitored more regularly at monthly intervals during antenatal and postpartum periods (24)*.
Renal function tests	Creatinine tests	Creatinine tests will be carried out at baseline, 2 months, and 6 months for clients who are receiving TDF-based regimens (3)*.
Liver function tests (LFTs)	Alanine Aminotransferase (ALT)	LFTs will be carried out for all HIV-positive pregnant women, plus all clients on NVP-based regimens in the first, second, and sixth months after initiation on treatment, and every 6 months thereafter (6)*.
HIV testing in children	DNA PCR	The test will be carried out on all HIV-exposed infants at 6 weeks. If positive, a confirmatory test will be done immediately. However, if first DNA PCR is negative, it is repeated at 3 weeks (3)*.
Full blood count	All	At least one full blood count will be carried out per HIV-infected pregnant woman (1)*.

Table 6 Laboratory testing assumptions

Laboratory testing was estimated at US$2,844,749. Costs per test are shown in Table 6 below.

ARV	Test	Cost per test (Maloti)	Cost per test (US$)
All	HIV test		
	Adults - Determine Tests	12.43	1.46
	Double Check Gold	14.84	1.74
	Infants – Determine	12.43	1.46
	Double Check Gold	14.84	1.74
	Infants- DNA PCR	18	2.12
	CD4 test	46	5.41
	FBC	55.36	6.51
AZT-based	Hb test	19.79	2.33
NVP-based	Liver Function Test	213	25
TDF-based	Creatinine Test	45.22	5.32

Table 7 Cost per laboratory test (excl. VAT)

The most expensive laboratory test is the LFT at US$25 per test. Hb monitoring would be carried out more frequently (at least 20 times during antenatal and postnatal periods). The cost of Hb monitoring was inclusive of replacement analyzer meters required as a result of depletion, but excluded the cost of maintaining those that were already in the system.

At US$2.33 per test per person, Hb testing is one of the least expensive methods of monitoring while LFTs were a high cost method of monitoring. The overall population requiring LFTs is significantly lower (34%), since it is geared more toward HIV-positive pregnant women on NVP-based regimens. LFTs are estimated at US$1,000,000 due to the high unit cost of US$25 per test.

Creatinine tests were targeted toward 72.8% of the population and would be conducted at least nine times, yet the overall cost was less than US$500,000. This cost was indicative of costing at the central laboratory instead of using point-of-care (POC) testing, as POC was not available in-country at the time

of this exercise. DNA PCR unit costs are considering the cost of DBS kits only and exclude costs of labor or capital costs. We assume that DNA PCR testing will also be done at the Lesotho Central Laboratory.

The total cost per laboratory test is shown in Table 7. Health systems strengthening efforts, such as human resources, procurement and maintenance of capital and equipment, administration, and transportation costs, could not be wholly attributed to the introduction of Option B+ alone. Therefore, an assumption was made that these costs would be absorbed into the budget of the Department of Laboratory Services and other implementing partners. Further analyses in the future could show the actual proportion that would be assigned to Option B+ roll out.

	Type of test	Total cost (in Maloti)	Total Cost (US$)
Entry	HIV testing adults	3,383,873	398,103
Monitoring	Hb monitoring	2,112,325	248,509
	CD4 testing	3,573,192	420,375
	Creatinine tests	3,764,633	442,898
	LFTs	8,542,163	1,004,960
Baseline	FBCs	716,675	84,314
Infants	HIV rapid testing infants	529,726	62,321
	DNA PCR	628,194	73,905
	Total	**23,250,780**	**2,735,384**

Table 8 Total costs for each laboratory test

HIV testing for pregnant women is US $398,103 and HIV testing for exposed infants cost more than 50% of adult costs. Table 7 shows that the cost for monitoring HIV infected women only is US $2,201,056 which is 80% of the laboratory costs.

3.3 Indirect costs

The indirect non-drug costs are costs which are not directly linked to care of individual patients but are essential to successful implementation of Option B+. These costs refer to the cost incurred for community sensitization, monitoring and evaluation (M&E), supportive supervision, and training.

3.3.1 Community Engagement

Community sensitization plays an essential role in the success of Option B+. Although, not exhaustive, the community component designed at this stage was expected to addresses issues surrounding demand creation, dissemination of information and retention of clients in care. These community activities were designed to inform and educate the community of Lesotho on the shift toward Option B+ in order to encourage the community to inquire about and access Option B+ services. The TWG discussed the main strategies which they would need to engage and educate the community, and there were several community approaches proposed, including some innovative approaches for Option B+ implementation which were unlike those in the existing EMTCT plan. The role of the media was strongly recognized and necessitated a sensitization workshop on the new treatment guidelines to inform their future reporting. The community component also included an aspect of new hires for the m2m model to become functional.

Activity	Description	Cost (in Maloti)
Conduct community preparedness and mobilization sessions for new PMTCT guidelines (pitsos)	This involves health workers conducting meetings and information sessions for five days/district. Each meeting would require materials, snacks, lunch and transport.	408,500
Train journalists on how to report on maternal health, PMTCT, and child survival	This training would be conducted as a day workshop at the central level. Information packs, guidelines, newsletter and other training materials will be provided.	12,050
Produce and disseminate multimedia messages for radio, TV, newspaper, billboards, and music on maternal health, PMTCT, and child survival	This includes a radio spot, a newspaper advert, pay slip, water statements, and bulk messaging.	73,980
Develop harmonized education materials for key community actors	This involved pocket message guide for local government councilors, community health workers, brochure, recipe book, poster	28,070
Conduct training of trainers (TOT) for key community actors (local counselors, community health workers, youth organizations) on social mobilization for maternal health, PMTCT, and child survival	Trainers would need to train community actors for a week per health center. Training materials, accommodation and logistics were costs that were considered here.	1,008,473
Conduct performance review meetings with key community actors	Follow up meetings with the community actors would be conducted after the trainings would have been conducted at district level	171,000
m2m expanded model*	As a strategy to monitor adherence, it was proposed that a system similar to that of mentor mothers be expanded to all health facilities within the country.	2,214,000

Table 9 Cost per community component

*see M2m expanded model[15].

3.3.2 Health System Strengthening- Monitoring and Evaluation (M&E)

M&E costs were mainly associated with the revision of registers, summary forms, tally sheets, and SOPs. The TWG recommended that a consultant would be needed to oversee development of new indicators and ensure they were uploaded into the national health management information system (HMIS). The full financial commitment required under M&E was not calculated as the extent to which changes would occur could not be easily distinguishable from those already implied in the elimination plan. M&E totaled about 47,000 Maloti (6% of the total cost). Generally, trainings and mentorship visits incorporated M&E components. However, at the time of this costing, it was not possible to deduce the exact proportion of costs that would be spent on M&E training, supportive supervision and mentorship.

3.3.3 Health System Strengthening- Human Resources

Part of the success of implementing new guidelines comes from having effective and efficient staff on the ground. Staff not only need to be sensitized on the changes in national policy, but they also have to be well-trained and adequately supervised. Two rounds of training would be carried out. The first round of trainings would be the regional, followed by district-level trainings. In between trainings; supportive supervision and mentorship would be carried out at the site level. The regional trainings were aimed at 230 participants, while the district ones target 230 additional participants (including nurses, medical doctors, and pharmacy and laboratory staff). Supportive supervisory and mentorship visits will be carried out quarterly by staff from the central level for a period of at least three days at a time.

Activity	Total cost (Maloti)	Total Cost (US$)
District trainings	2,770,330	325,921
Regional trainings	2,412,930	283,874
Quarterly supportive supervision and mentoring per district	1,187,600	139,717

Table 10 Cost per human resource component

In the initial Option B+ costing, only the regional trainings and supportive supervision and mentorship were included. The cost of the initial regional training and support supervision totaled approximately 3.6 million maloti. An additional 2.7 million Maloti would be required to provide the district trainings. Human resources costing did not include employment of new hires.

4 Synthesis of Costs

Based on the above calculations, it will cost US$262 per annum to diagnose, treat and monitor an HIV-positive pregnant woman. It takes an additional US$19 per year to provide prophylaxis and monitor the HIV status of an exposed infant under the Option B+ guidelines. Based on the *eMTCT Plan*, the Option A mother-baby package was less than US$200 per annum[8].

Pharmaceutical costs for the first year of implementing Option B+ are estimated at US$5million (42million Maloti) and US$195 (1,657 Maloti) per mother-baby pair. Laboratory costs amounted to US$2.8million (24milion Maloti), while community activities, capacitating human resources, and M&E were US$423,592 (3.6million Maloti), US$460,715 (3.9 million Maloti), and US$5,642 (47,960 Maloti), respectively.

Activity	Cost (Maloti)	Cost (US$)
Trainings	3,600,530	423,592
Pharmaceuticals	42,849,695	5,041,141
Laboratory	24,180,369	2,844,749
M&E	47,960	5,642
Community	3,916,074	460,715
Total	**74,594,628**	**8,775,839**

Table 11 Total near-term cost of Option B+ implementation in Lesotho

The highest cost area is the pharmaceuticals required for Option B+. Initially, this cost will fall slightly, then begin to rise again as the ANC prevalence becomes flat. Laboratory costs will increase with the introduction of Option B+, as there are different and more expensive tests required for monitoring of clients on the TDF regimen. Since mentorship and supportive supervision would be intensified, expenditure on trainings was not expected to be very high. Most supervisory and mentorship activities were preempted and costed under the EMTCT plan.

4.1 Cost implications on the EMTCT plan

Option B+ translates to an initially higher burden of cost on the health system. Over the remaining three year period of the *Elimination Plan*, the changes which are necessary for the implementation of Option B+ will cost a total of US$14million (119.6milllion maloti). Naturally, the costs are higher in the first year of implementation and amount to US$ 8.77 million (74.5million Maloti). However, the total incremental costs from Option A to Option B+ for the first year of implementation were US$8.17million (69.5million Maloti), which included drugs, non-drug costs and indirect costs. The additional costs for the subsequent years of the plan are US$2.96 million (25.1 million Maloti) and US$2.95million (25million Maloti), which were attributed to the procurement of ART.

There are also some cost implications with respect to the NSP. Since Option B+ is being introduced in the third year of the elimination plan, the changes enter the EMTCT plan from the third year up to the fifth year. The additional costs of Option B+ are directed toward *Strategic Area 3 of the* EMTCT plan- for trainings, supportive supervision and pharmaceuticals. Changes in community activities are absorbed in *Strategic Area 4*, while laboratory and community are assigned to the health system strengthening *Strategic Area 7*. The revised costs per strategic area for the remaining three years are shown in the figure below.

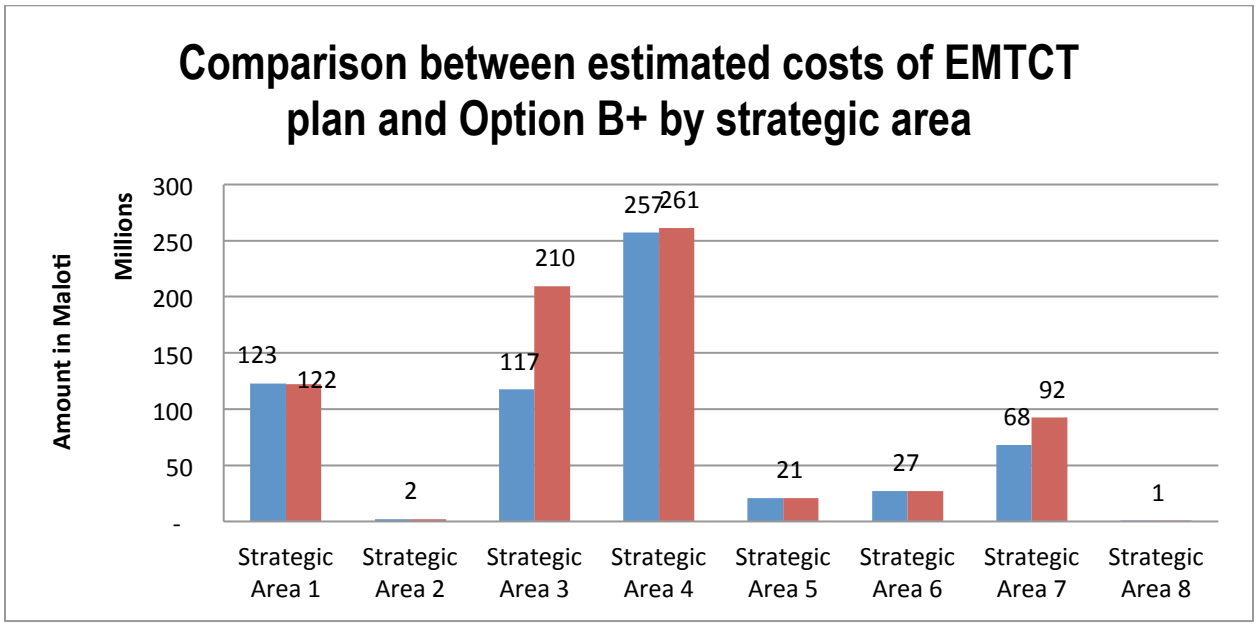

Figure 1: Comparison between estimated costs of EMTCT plan and Option B+ by strategic area

The strategic areas that are seemingly untouched are strategic areas 2, 5, 6, and 8, which are related to: prevention of unintended pregnancies in women infected with HIV; promoting access to quality paediatric HIV treatment, care and support for all HIV-infected infants, children and adolescents; integration between HIV, MNCH, and related services; and coordination and collaboration between Government and all relevant stakeholders.

The changes in annual estimated costs are shown Figure 2. Costs begin to change in year 3 of the plan as Option B+ is introduced, and the costs increase in the last three years. The total costs for implementing Option B+ were calculated as 74.5million Maloti for the first year. The total incremental costs from Option A to Option B+ for the first year of implementation were 69.5million Maloti, which included drugs, non-drug, and indirect costs. The additional costs for the subsequent years of the plan are 25.2 million Maloti and 25 million Maloti, which were attributed to the procurement of ART.

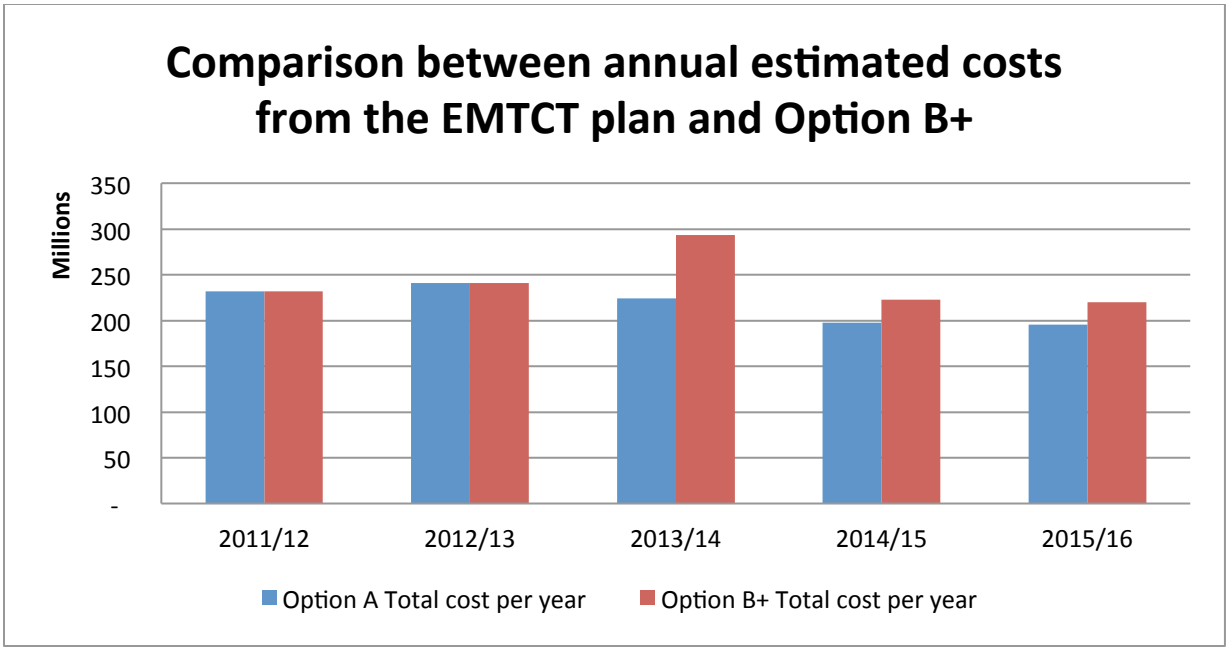

Figure 2: Comparison between annual estimated costs from the EMTCT plan and Option B+

5 Discussion

The burden of costs will increase during the first phase of introduction of Option B+ due to the initial programmatic recurring costs of increasing pharmaceutical supplies to capture the back-log of initiating lactating mothers and transitioning to a new triple regimen for a significantly larger population; intensified laboratory monitoring of HIV-positive women on ART and early infant diagnoses costs. This drop in costs is reinforced by the comparison between Option B+ and Option A cost outcome which shows a spike in costs in 2013/14, a slight fall in the latter year and a gradual decrease thereafter.

In the long run, we can anticipate that the outcome of Option B+ will translate to a reduction in the burden of HIV disease among infants as vertical transmission rates during pregnancy and lactating periods subside. According to the Kesho Bora study, the mother-to-child transmission rate is likely to fall to 1.7% under Option B+ from 2.7% under Option A[16]. Therefore cost savings will be achieved under Option B+ in the long run as less infants will be infected and require ART treatment for life. Due to this decrease of mother-to-child transmission of HIV, Lesotho will save a total of approximately US$7.5 million per infections averted among infants per year based on a discounted lifetime cost of US$3197 per HIV-infected infant on ART as determined in Malawi[17]. Since these guidelines also encourage early initiation of HIV-infected infants under five years old onto treatment; there will be further increase in overall ART costs. However, early initiation generally results in a lesser cost burden to the Lesotho health system (e.g. less frequent hospital visits and admissions) than late initiation on treatment. The cost savings are not limited to mother-to-child transmission because Option B+ will also facilitate reduction in transmission among serodiscordant couples. Furthermore, based on recent trends, prices of first-line ARV regimens have fallen by an average of 19% between 2009 and 2012[18,19]. As the pharmaceutical market continues to become more competitive, it is expected that the price will fall

even further. Countries should consider these falling prices as they adopt the new PMTCT recommendations.

The success of these new guidelines does not only rest upon securing sufficient financing for the above cost elements but investment and improvement in other health system areas. Prior to 2013, Lesotho's health system was plagued with less than satisfactory service delivery due to human resource shortages as a result of staff attrition, regular staff rotation and migration of health workers[20]. Fortunately, Lesotho made a bid to circumvent such issues by launching the Retention Strategy in April 2013, supported by health development partners, to provide retention allowances to health workers in hard-to-reach areas[21]. As a result, at least 235 health workers have being deployed in hard-to-reach rural areas under the scheme[21]. In addition, to avoid constant rotation of staff among facilities, deployment of permanent staff in all health facilities began in 2012[21]. This will improve stability of the workforce and strengthen health service delivery at facility level. New and old recruits who will be trained on Option B+ will be able to implement their duties without interruption. With continued mentorship and supportive supervision from in-country technical assistance from the MOH and their supporting partners, district program mentors and multidisciplinary mentorship teams from central level, correct implementation of the guidelines will be reinforced.

Option B+ guidelines place emphasis on retesting and initiating lactating women on treatment and continual HIV testing of HIV-exposed infants during the period they are in MNCH. We need intensified community linkages and psychosocial support to achieve 100% testing rates, adherence and retention of women and infants in care throughout their antenatal and postnatal care. At the moment, health workers are implementing methods to follow-up clients using a system that links the 'Appointment Books' for appointment setting and identifying 'missed appointments'; district community coordinators and village health workers (VHWs) commit to tracking these clients among their many other roles in demand creation and peer-to-peer support. Lay counselors are available for HIV testing and counseling in all MCH clinics[8].

Option B+ also calls for a review of M&E tools to capture and disseminate 'new' information as it pertains to the needs of Option B+, such as SOPs to guide implementation and monitoring tools to document interventions along the PMTCT cascade. Aside from the specific programmatic tools that will be budgeted under Option B+, there is also a need for a harmonized national health management information system to include longitudinal data for HIV-positive pregnant women who are attending MCH as they will be on 'ART for life'. Option B+ also requires further investment of resources toward ensuring effective patient adherence and resistance monitoring through laboratory technologies as indicated in the costing.

With respect to the limitations of the costing, it is apparent that the costing was based on a near-term model, which captured only short-term responses that the MOH of Lesotho were expected to successfully avail Option B+ to the first cohort of women in April 2013 and to successfully out to all facilities in Lesotho within the first year. Therefore, it did not explore the long run operational, capital costs and societal cost savings achieved in the long run. It also did not explore all other systemic components that would indirectly facilitate improvement in Option B+ uptake and coverage such as the

MOH initiated retention strategy targeted toward healthcare worker. It would not have been accurate and likely result in an overestimation of costs if the burden of fundamental health system improvement costs were included in the Option B+ costing exercise. Activities emanating from further improvements required on community adherence or retention strategies for clients on treatment were not available at the time of costing and were not included as a result.

5.1.1 Recommendations

Expenditure Tracking. It is important to perform an expenditure tracking survey of PMTCT costs vis-à-vis overall health system costs since the launch of Option B+ to explore the 'real' financial implications of increasing access of ART to HIV-positive pregnant and lactating women. It may also serve as a proxy for baseline costs in the case that other guidelines are adapted in Lesotho.

Sustainability. Will domestic financing of the PMTCT program as it stands be feasible in the near future? Although, high level costing has been done, it is still important to measure the facility-level costs of implementing the cascade of services required to successfully implement Option B+ and observe their variability across districts and level of service delivery. Based on the findings, resource mobilization activities and sustainability plans may be better targeted toward districts based on the demographic, human resource capacity or geographic variability among other factors.

Documentation. Overall trends in rates of new infections or repeat pregnancies; implications of graduating at least 12% more women to chronic ART clinics and early initiation on pediatric treatment; effect of chronic treatment and shifting to 2^{nd}/3^{rd} line drugs; transformations in human resources and supply chain management and other programmatic impact should be explored and documented with respect to the Option B+ experience in preparation for future changes in guidelines that may be introduced into Lesotho. Paying attention to this detail will provide insight into future resource needs and resource allocationfor Lesotho and other countries that will be embarking on transformations of their PMTCT guidelines.

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