IATT
THE INTERAGENCY TASK TEAM
The Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children

6 Costing Tool:

Considerations in Costing a Transition to Option B/B+

6.1 Introduction

Using costing models for informed decision-making

New data about the effectiveness of ART in halting transmission to uninfected partners, and the recognition that putting all HIV-positive mothers on ART might be more logistically feasible than managing a complex PMTCT protocol has led to increased interest in WHO Option B/B+. While Option B+ offers many programmatic benefits, the cost of providing lifelong ART to all HIV-infected pregnant women is a concern for many policymakers. Projections indicate that Option B+ is more expensive than implementing Option A, and marginally more expensive than Option B, however the exact price difference between Option A, B, and B+ varies considerably from country to country based on the nature of the national epidemic and the coverage rates achieved by the national programme. For this reason, it is essential that policymakers use country-specific data when evaluating the potential costs and benefits of a transition to a new PMTCT strategy. Costing models can help programme managers make an informed decision about whether Option B+ is an appropriate and affordable public health strategy given their country's unique programmatic context.

In order to maximize the benefit of cost modeling, it is crucial that policymakers understand the scope and limitations of modeling, as well as key inputs needed to ensure accurate cost outputs. The aim of this document is to provide high-level guidance for MOH staff, policymakers, and programme managers at the national level who are considering a transition from the current PMTCT strategy to a new regimen, including Option B+. It consists of three sections: 1) an overview of modeling considerations and factors to consider when evaluating the cost of Option B+; 2) an overview of four costing models that have been made available through the IATT FEWG, as well as key inputs required for the models; and 3) outputs provided by the models. The document concludes with contact information for members of the IATT FEWG who are available to assist with costing analyses.

6.2 Modeling Considerations

Models are useful planning tools and can provide excellent directional guidance. However, several limitations of models should be kept in mind. Models are not meant to provide exact costs, nor can they perfectly predict the future. Rather, they provide an estimate that can assist decision-makers and programme planners. Decision-makers should use other tools and knowledge to understand and "reality-check" the outputs of the model. While a model can indicate an estimate of the costs required to implement a programme, decision-makers will ultimately need to determine how money should be spent based not only on cost but feasibility, political will, existing resource gaps, and other factors.

Model scope: operational considerations

The first question policymakers should ask when considering the cost of a transition to a new PMTCT regimen is, "what operational costs would be incurred by such a transition?" A number of operational considerations must be made in planning a robust national EMTCT programme, and these factors are essential to consider early in the costing process. From training to supply chain management, these operational components are critical to generating relevant cost outputs. Here are just a few of the operational components that policymakers should consider when evaluating the cost of a new regimen:

- **Health systems strengthening** – New or additional staff will likely need in-depth PMTCT training, and refresher trainings may be needed for those already trained in PMTCT and the most recent guidelines. For countries anticipating a switch from Option A to Option B/B+, there are training costs to consider when revising national guidelines.
- **Infrastructure** – Costs including new building costs, maintenance, and refurbishment should be estimated as part of the planning process. New and existing laboratory infrastructure for CD4 testing (including point-of-care technology) is a key component of the capital costs for PMTCT, including yearly maintenance costs for CD4 machines. Additional capital expenditures may include exam beds, desks, chairs, computers, and other similar items.
- **Quality monitoring and evaluation** – M&E is essential to track progress towards EMTCT goals and is another key building block for a strong health system. Costs for M&E-specific equipment, personnel, and technology should be accounted for, as well as costs for technical support and supervision visits, surveys, and evaluation studies.
- **Retention** – Retention in and linkage to care have increasingly played an important role in the effectiveness of PMTCT; costs for tracking and following up with patients (mobile phones, transport stipends, peer-to-peer tracking etc.) should be included.
- **Transport** – Transport related costs including capital, maintenance, and fuel factor into a strong costing analysis. Transport costs for EID and CD4 samples should also be included. Supply chain strengthening is an additional area to calculate PMTCT costs. PMTCT-related supply chain activities might include pharmaceutical mentoring and supervision visits for stock management.

In addition to the operational considerations listed above, community engagement is increasingly recognized as a key component necessary for the success of EMTCT programmes, particularly for retention in and linkage to care. Many costs related to community engagement fall into the broad operational cost categories described above (e.g. training, transport, salary, meetings, and communication); however, it is critical to think through these costs as they relate to the key components to consider in costing EMTCT community engagement strategies. These costs include: establishing and strengthening community-based support services; training community workers to deliver comprehensive prevention of vertical services; community-based support for linkages to and

retention in facility-based services; community education, awareness and demand creation for behavioural campaigns; and establishing mechanisms to review progress for community activities.

Sustainability and mitigating cost factors

Financial sustainability and long-term costs are important factors for countries considering a transition to Option B+. Recent modeling indicates that the up-front costs of moving to Option B+ are relatively substantial; however, over the medium and long term, the incremental cost of Option B+ is reduced by the fact that many HIV-positive pregnant women would likely become eligible to initiate treatment for their own health in a reasonably short period of time. Recent studies indicate that approximately half of all HIV-infected pregnant women are eligible for ART.[b] In addition, other studies found that 20% of HIV-infected pregnant women with CD4 counts 350-500 had a CD4+ decline to <350 threshold within 12 months of delivery, and almost half of this group met the ART threshold by 24 months postpartum – although this progression was slower for women with CD4 counts >500.[c] This evidence suggests that regardless of PMTCT regimen, a substantial portion of HIV infected pregnant women could be eligible for lifelong ART within 2-3 years of giving birth.

Modeling suggests that this timeframe for disease progression, coupled with the increasing number of pregnant women already on ART, results in the incremental cost of Option B+ growing less rapidly after 3-4 years. Other factors also influence the cost and cost-effectiveness of Option B+, including reduced paediatric infections and horizontal transmission through increased access to ART. Countries with high fertility rates, short birth intervals, and long breastfeeding periods will often find that these factors lower the incremental cost of Option B+. While Option B+ remains more expensive and may not be appropriate for all countries, under the right circumstances it may well be sustainable for resource-constrained countries in the medium to long term. Countries will need to consider their own epidemic, service coverage rates, and funding resources before deciding whether Option B+ is an affordable and appropriate strategy.

Costing vs. budgeting: an interactive process

While costing and budgeting are closely related, there is an important difference between the two activities. Costing can help examine the impact of increasing resource allocation in key areas and allows for understanding the resources required at a given level of service uptake needed to achieve programmatic goals. When faced with trade-offs as to where to allocate resources, a combination of impact and cost modeling helps inform

[b] Carter et al. J Acquir Immune Defic Syndr 2010;55:404–410.

[c] Ekouevi et al. Maternal CD4+ Cell Count Decline after Interruption of Antiretroviral Prophylaxis for the Prevention of Mother-to-Child Transmission of HIV. PLoS ONE 2012: 7(8): e43750.

the return on investment of different decisions (such as implementing Option A vs. B vs. B+). Budgets, in turn, are based on costing analyses. Once the financial costs of running a programme are established, a budget can be used to plan for the funds available to pay for the cost of the programme. Cost estimates can be linked to budgets for each prong, activities and programme areas, which allows for the identification of under and over-funded service areas.

6.3 Key Inputs Required for PMTCT Costing

Impact models offer a mathematical representation of the real-world; therefore, model outputs are only as accurate as model inputs. If poor quality data are used in cost modeling, the model's outputs are likely to be inaccurate. For this reason, it is important to use accurate, country-specific inputs wherever possible, and to understand that inaccurate inputs can have a large impact on the final output produced by models.

This section provides an overview of four costing models that can be used to project the costs associated with a national EMTCT plan or a transition to a new PMTCT regimen: the CHAI PMTCT and Peds Impact and Costing Model; the National Center for Global Health and Medicine (NCGM)[d] Costing tool for Elimination Initiative; the PEPFAR PMTCT Costing Model; and the Futures Institute Spectrum Model. All four models are open source, operate from a public health or programme perspective, and are designed to assist policymakers in decisions surrounding PMTCT programmes and national EMTCT plans. Spectrum is a PC based application that includes cost, impact, family planning, and demographic projections, while the CHAI, NCGM, and PEPFAR models are excel based spreadsheets that focus primarily on cost and impact. Each model employs slightly different assumptions, methodologies, and inputs – factors that policymakers may wish to consider when choosing a model. In practice, however, validation exercises have shown that the outputs produced by the four models are directionally similar. A full comparison of the inputs and capabilities of these four models can be found in the table on the following page.

While each model requires slightly different inputs, the 20 parameters listed below are key requirements for the CHAI, NCGM, PEPFAR and Spectrum models, and have a strong influence on the outputs produced. This list is not intended to be comprehensive: each model requires additional inputs and may use slight variations of what is provided in this document. In general, however, these are the most critical inputs, and variations in their values will have the strongest bearing on outputs. Consequently, policymakers considering a costing analysis should ensure that valid, country-specific data are available for the following parameters in Table 1:

[d] NCGM is a research institute based in Japan that promotes basic research into the pathogenesis of infectious diseases as well as translational and clinical research aimed at the development of innovative diagnostic and treatment modalities.

Table 1

POPULATION PROFILE	PROGRAMMATIC COVERAGE	OPERATIONAL COSTS
Number of HIV positive pregnant women, or the number of total live births and HIV prevalence among pregnant women	Coverage of PMTCT services, defined as the percent of HIV+ pregnant women receiving ARVs for PMTCT. Requires ANC attendance (%) and percent of ANC-attending women who receive an HIV test	Regimen distribution for HIV positive pregnant women and local price paid for ARVs, per year
CD4 distribution of HIV positive pregnant women (including percent of pregnant women with CD4 < 350)	Coverage of adult and paediatric ART services, including coverage of co-trimoxazole for children.	Unit cost of HIV tests, CD4 tests, PCR, and other lab costs
Mortality rate for women with CD4 < 350 on treatment, CD4 < 350 without treatment, and CD4 > 350	Percent of HIV+ pregnant women receiving each PMTCT option (A / B / B+) over the next five years	Annual cost of pre-ART services, including co-trimoxazole prophylaxis
Percent of HIV positive mothers who breastfeed, and average breastfeeding duration	Coverage of CD4 testing within PMTCT	Other non-drug costs, including health worker salaries, training costs, infrastructure and maintenance plans, lab and facility capital investments, monitoring and evaluation, etc.
Average time until women with CD4 > 350 become eligible for treatment based on clinical staging or decline in CD4 count	Percent of HIV positive pregnant women receiving ART prior to start of pregnancy	Programmatic and overhead costs, including supply chain management
Contraceptive prevalence and/ or percent unmet need for family planning (Spectrum)	Monthly or yearly retention rates	Annual unit cost of providing a family planning method for one woman, per family planning method (Spectrum)
	Average time until women with CD4 < 350 are identified & initiated on ART	
	Family planning method mix	

Finally, in addition to inputs provided by the country team or policymakers, models operate on certain key assumptions that may not always be true in the real world. Often these assumptions are built into the models. Policymakers should be aware of the assumptions being made in the model, and should take them into consideration when interpreting the model outputs.

	TOOL NAME		PMTCT AND PEDS IMPACT AND COSTING MODEL V 2.1	COSTING TOOL FOR ELIMINATION INITIATIVE	
TOOL INFORMATION	Organisation		CHAI	NCGM	
	Tool description		Spreadsheet-based deterministic model of MTCT and cost of PMTCT programme and paediatric treatment programme	Spreadsheet-based interactive tool for elimination of new paediatric HIV infections and congenital syphilis	
	Scenarios and timeframe for analysis		Includes MTCT impact and costs resulting from 1-5 years of pregnant women receiving Option A, B, or B+. Model is structured for side-by-side comparison of up to 5 scenarios or 5 years	Includes MTCT and costs for women over user defined period; able to run analysis up to 5 scenarios at the same time. Includes all regimens of 2010 guidelines	
PROGRAMME INPUTS	CD4 distribution		✓ (<200, 200-350, 350-500, >500)	✓ (<200, 200-350, >350)	
	Breastfeeding	Rates	✓	✓	
		Duration	✓	✓	
	ANC attendance		✓	✓	
	Unmet need for family planning		✓	✓	
	HIV testing coverage		✓	✓	
	CD4 test coverage		✓	Assumes 100% coverage	
	ARV prophylaxis/ART coverage		✓	✓	
	% of women on ART before pregnancy		✓	✓	
	Timing of start of PMTCT		User defined	14 weeks of pregnancy	
	Multiple ART regimens		✓	✓	
	Duration of maternal ARVs included in costs		Through cessation of breastfeeding (A/B)	User defined	
COST INPUTS	HIV, CD4, & other tests		✓	✓	
	ART for eligible women		✓	✓	
	ARV prophylaxis for women		✓	✓	
	ART for infected children		✓	✓	
	Non-Drug costs		Bottom-up population- and task-based approach to HR and lab costs; determines total cost based on unit costs. Activity-based approach to operational costs	Bottom-up population- and task-based approach to HR and lab costs; determines total cost based on unit costs. Activity-based approach to operational costs	
	Overhead costs		Included user-defined operational costs	Not included	
OUTPUTS	Transmission rates		Perinatal (0-6 weeks), Postnatal (through end of BF), and Final MTCT	Final (pregnancy through end of breastfeeding) MTCT rate	
	Number of children infected through MTCT		Perinatal, Postnatal & Final # infections	Final # infections	
	Infections averted		✓	✓	
	Drug costs		Prophylaxis and treatment for both mothers and infants	Maternal prophylaxis and treatment, and infant prophylaxis	
	Total programme (financial and/or economic) costs		Total PMTCT and child treatment costs	Drugs, HR, lab commodities and shipping	

PEPFAR PMTCT COSTING MODEL	SPECTRUM	TOOL NAME		
PEPFAR	Futures Institute	**Organisation**		TOOL INFORMATION
Spreadsheet-based model for costing PMTCT programmes and treatment for women initiated on ART through PMTCT	PC based application containing a suite of easy to use policy models to assess impact and aggregate cost of PMTCT services	**Tool description**		
Includes PMTCT and treatment costs over a period of up to 5 years; compares costs of current option alongside Options A, B, B+, and a proposed scenario (i.e. a transition from A or B to B+)	Includes MTCT impact and aggregate cost for women over user-defined period; able to run multiple scenarios. Includes SdNVP, Option A, Option B and HAART (for mother's health and Option B+)	**Scenarios and timeframe for analysis**		
✓ (<350, >350)	✓ (<200, 200-350, >350)	**CD4 distribution**		PROGRAMME INPUTS
	✓	**Rates**	**Breastfeeding**	
✓	✓	**Duration**		
✓		**ANC attendance**		
	✓	**Unmet need for family planning**		
✓		**HIV testing coverage**		
✓	✓	**CD4 test coverage**		
✓	✓	**ARV prophylaxis/ART coverage**		
✓	✓	**% of women on ART before pregnancy**		
14 weeks of pregnancy	14 weeks of pregnancy	**Timing of start of PMTCT**		
✓	✓	**Multiple ART regimens**		
User defined	User defined	**Duration of maternal ARVs included in costs**		
✓	✓	**HIV, CD4, & other tests**		COST INPUTS
✓	✓	**ART for eligible women**		
✓	✓	**ARV prophylaxis for women**		
Costed separately	✓	**ART for infected children**		
Uses per person average for non-drug costs based on literature & research; includes recurrent costs (HRH, lab, clinical visits, etc) and investments (equipment, training, etc)	Unit cost for counseling (pre- and post-test), Service delivery (aggregates clinical visits, lab visits costs etc.) and cost of formula for child	**Non-Drug costs**		
User-defined markup for programmatic and overhead costs	If available as unit cost can be aggregated with service delivery cost	**Overhead costs**		
Final (pregnancy through end of breastfeeding) MTCT rate	Perinatal (0-6 weeks) and Postnatal (through end of breastfeeding)	**Transmission rates**		OUTPUTS
Final # infections	Final # infections	**Number of children infected through MTCT**		
✓	✓	**Infections averted**		
Maternal prophylaxis and treatment, and infant prophylaxis	Included in total cost	**Drug costs**		
Total PMTCT and maternal treatment costs	Total PMTCT and child treatment costs	**Total programme (financial and/or economic) costs**		

6.4 Outputs

Although each model is capable of producing slightly different outputs, any costing exercise undertaken with the CHAI, NCGM, PEPFAR and Spectrum models will provide policymakers with the following outputs to consider when evaluating the costs and benefits of a transition to a new PMTCT regimen:

- **Total Cost** – The models provide the annual total cost of the national PMTCT/EMTCT programme, including service delivery costs, drug costs, and other operational costs (for a full discussion of the costs included in this category, see section 6.2). The total annual cost of the proposed national strategy can be projected for up to five years, and includes any costs associated with a programmatic scale-up of services.
- **Additional Cost (Incremental Cost)** – In evaluating a proposed strategy, it is important that policymakers consider not only total cost, but also additional (or incremental) cost. This output is defined as the difference between what the current national strategy would cost and what the proposed national strategy would cost over a given timeframe. For policymakers considering a transition to Option B/B+, this output is particularly useful as it provides a measure of the additional resources that would be required under the new strategy. In addition, this output takes into account any scale-up of service provision that would have occurred under the current strategy.
- **Cost by Service Area** – Each model is capable of breaking down the total and additional costs by service area in order to provide policymakers with an understanding of the major cost drivers associated with a transition to a new strategy. By examining the costs attributable to each service area (ARV costs, lab costs, other service delivery costs, etc), policymakers can plan for a transition accordingly.
- **Additional Patient-Years of ART and Costs by Patient Status** – Particularly when considering a transition to Option B+, it is valuable to consider the breakdown of additional patient years of ART by the status of the pregnant woman. In many countries, a substantial percentage of the additional patients initiated on lifelong treatment under Option B+ may in fact have CD4 counts *below 350 cells/mm^3,* however they would not have been initiated on treatment under Option A due to low treatment coverage or insufficient access to CD4 testing in PMTCT. When evaluating the additional cost of B+, it is important to bear in mind that many of these costs will derive from improved coverage for women eligible for lifelong treatment under any PMTCT regimen.
- **Infant Infections Averted** – All four of the models are capable of modeling the infant HIV infections averted through both the current and proposed national strategies.

6.5 Choosing a Model & Contact Information

While no two models will produce identical cost projections, validation exercises have shown that the CHAI, NCGM, PEPFAR and Spectrum models produce directionally similar results. In addition, it is important to note that these four organisations are not the only resources for costing exercises: a number of other groups have also produced reliable costing models. For this reason, it is recommended that policymakers and programme staff use the model from whichever organisation has the greatest presence in country, or with which they already have a strong working relationship. During the modeling process, one of the most difficult steps is deciding on a set of inputs and reviewing the model's assumptions with the modelers. This process typically moves more smoothly and more quickly if the modeler has knowledge of the country's programme and if lines of communication are already open between the modeling organisation and the policymakers requesting the analysis.

Policymakers, program managers, or other parties interested in undertaking a costing study or in finding out more about the models discussed in this section can contact the following members of the IATT Finance and Economics Work Group:

CHAI Model – Elizabeth McCarthy, Clinton Health Access Initiative (emccarthy@clintonhealthaccess.org)

NCGM Model – Naoko Ishikawa, National Center for Global Health and Medicine (Japan) (n-ishikawa@it.ncgm.go.jp)

PEPFAR Model – Benjamin Johnson, Office of the Global AIDS Coordinator (JohnsonBC@state.gov), and Nalinee Sangrujee, Centers for Disease Control and Prevention (nks9@cdc.gov)

Spectrum Model – Adebiyi Adesina, Futures Institute (aadesina@futuresinstitute.org), and Lori Bollinger (lbollinger@futuresinstitute.org)

Please also refer to the contacts for the IATT FEWG on the website at www.emtct-iatt.org.