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THE INTERAGENCY TASK TEAM

The Interagency Task Team on the Prevention and Treatment  
of HIV Infection in Pregnant Women, Mothers and Children



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# Option B/B+:

Key Considerations for Country Programmes

## 1.1 Introduction

### 1.1.1 The global context

The Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive is well underway, with ambitious goals of reducing the number of new HIV infections in children by 90% and HIV-related maternal and child deaths by 50%.<sup>1</sup> Now, there is unprecedented collaboration and political will to accomplish these goals, and many countries have made exceptional progress. According to UNAIDS estimates, in 2011, 57% of pregnant women living with HIV in low and middle-income countries received effective antiretroviral (ARV) drugs for PMTCT, an increase from 48% in 2010.<sup>2</sup>

Nonetheless, many implementation challenges remain, and chief among them is ensuring that high proportions of women and children in need of antiretroviral therapy (ART) can access it. Global access to ART among HIV positive pregnant women in need was lower than access among adults in the general population at 30% vs. 54% in 2011.<sup>3</sup> Low access of pregnant women to ART persists despite the fact that HIV testing is generally much higher in pregnant women than other adult populations. While poor ART access for pregnant women is pervasive, it disproportionately affects women and children living in areas far from ART sites or in settings with weak health systems.

An AIDS-free generation is within reach. But to achieve this goal, all partners will need to redouble their efforts and boldly move forward in the face of challenges. Reaching the majority of women attending antenatal care (ANC) at lower levels of care will require thinking “outside of the box” to take implementation to a higher level of efficiency and effectiveness. Indeed, with ever more limited resources, the move to Option B/B+ underscores the need to strengthen the broader maternal, newborn and child health (MNCH) platform and maximize synergies with other sectors, for example nutrition and social protection, care and support programmes to ensure long term retention and adherence.

### 1.1.2 Option B/B+: potential for more effective PMTCT and ART implementation

In considering which approaches to PMTCT implementation may be most effective to reach the goal of an AIDS-free generation, it is important to recognize that ARV regimen choice for HIV positive pregnant women is likely to be one key determinant of success. Under WHO’s 2010 PMTCT ARV guidance, countries had the option to choose between two prophylaxis regimens for pregnant women living with HIV with CD4 greater than 350 cells/mm.<sup>3,4</sup>

Under Option A, women receive antenatal and intrapartum antiretroviral prophylaxis along with an antiretroviral postpartum “tail” regimen to reduce risk of drug resistance, while

infants receive postpartum antiretroviral prophylaxis throughout the duration of breastfeeding. Option B, on the other hand, has a simpler clinical flow in which all pregnant and lactating women with HIV initially are offered a triple combination of ARV drugs – beginning in the antenatal period and continuing throughout the duration of breastfeeding. At the end of breastfeeding, women who do not require ART for their own health discontinue the prophylaxis, re-starting ART when the CD4 count falls below 350 cells/mm.<sup>3</sup> Along with these two options, a third approach is now being used, Option B+, whereby all pregnant women living with HIV are offered lifelong ART, regardless of their CD4 count. Table 1 below, adapted from WHO, summarizes these three different options.

Option B+ was first conceived and implemented in Malawi where the national ART programme had already been functioning well using a public health approach which did not depend heavily on CD4 testing to determine who should initiate treatment. Malawi envisioned that Option B+ would be easier to implement due to its simplified approach which would enable women to access ART at high levels even in settings with poor access to CD4 testing. Early experience with Option B+ in Malawi has borne this out with a more than five-fold increase in the numbers of pregnant women being enrolled on ART in the first quarter of nationwide implementation<sup>5,6</sup> (see Malawi MOH website at <http://www.hivunitmohmw.org> for updated quarterly data on

**Table 1:** Three Options for PMTCT<sup>a</sup>

	WOMEN WITH CD4 COUNT ABOVE 350 CELLS/MM <sup>3</sup>	WOMEN WITH CD4 COUNT BELOW 350 CELLS/MM <sup>3</sup>	CHILD RECEIVES
OPTION A	<p>During pregnancy: AZT starting as early as 14 weeks of pregnancy</p> <p>At delivery: single-dose NVP and first dose of AZT/3TC</p> <p>After delivery: daily AZT/3TC through 7 days postpartum</p>	<p>Triple ARVs started as soon as diagnosed and continued for life</p>	<p>Daily prophylaxis (NVP) from birth until 1 week after all breastfeeding has finished; or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks</p>
OPTION B	<p>Triple ARVs starting as early as 14 weeks of pregnancy continued through childbirth (if not breastfeeding) or until 1 week after all breastfeeding has finished</p>		<p>Daily prophylaxis (NVP or AZT) from birth through age 4–6 weeks regardless of infant feeding method</p>
OPTION B+	<p>Triple ARVs started as soon as diagnosed and continued for life</p>		

<sup>a</sup> This table is adapted in a slightly modified form from Table 1 in WHO's 2012 Programmatic Update: "Programmatic Update Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants", available at [http://whqlibdoc.who.int/hq/2012/WHO\\_HIV\\_2012.6\\_eng.pdf](http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.6_eng.pdf)



ART initiation among pregnant women living with HIV). More importantly, implementation of Option B+ in Malawi involved much more than a change in ARV regimen. Option B+ was part of a larger strategy which rested on the full integration of Malawi's ART and PMTCT programmes so that ART could be administered by nurses at primary care facilities where women and children were already accessing MNCH services. By decentralizing ART services, Malawi has been able to rapidly expand access to ART for pregnant women in hard-to-reach areas throughout the country. While the early experience in Malawi has demonstrated the potential of the Option B+ approach, long-term success will depend on ensuring that women who initiate ART are retained in care over the long-term. (For more information on Malawi's experience implementing Option B+, please see the Report from the Malawi MOH: [http://www.hivunitmohmw.org/uploads/Main/Quarterly\\_HIV\\_Programme\\_Report\\_2012\\_Q3.pdf](http://www.hivunitmohmw.org/uploads/Main/Quarterly_HIV_Programme_Report_2012_Q3.pdf)).

In April 2012, in response to Malawi's early success and other strategic and technical developments, WHO released an important programmatic update on the "Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants,"<sup>7</sup> urging countries to consider what the advantages of Option B/B+ may be in their contexts stating: "Options B and specifically B+ seem to offer important programmatic and operational advantages and thus could accelerate progress towards eliminating new paediatric infections." Along with discussing the potential operational benefits of both options, WHO's programmatic update also emphasizes additional advantages beyond PMTCT associated with Option B+ in particular (See Box 1).

While acknowledging the additional cost of Option B+ in terms of drugs, WHO notes that the cost of the fixed dose once-daily regimen of tenofovir/lamivudine/efavirenz

(TDF/3TC/EFV) recommended for first line has decreased substantially, and that the overall cost-effectiveness of Option B/B+ is likely to be greater than Option A. However, the update also makes it clear that adopting Option B/B+ is "no easy" fix for PMTCT, and that the ultimate success of Option B+ will require an increased investment in interventions to improve long-term ART adherence and retention, including community and family based interventions to support families on treatment.

While implementation of Option B/B+ provides important opportunities, it also presents new challenges and unknowns. To be a successful public health strategy, the universal offer of ART to all pregnant women living with HIV will require an additional investment in health systems, and ARV drugs and commodities, while ensuring the rights

**Box 1:** WHO Programmatic Update Highlights Potential Advantages of Option B+

- Better protection for maternal health
- Greater reduction in the sexual transmission of HIV than other options
- Streamline monitoring and evaluation of progress towards Global Plan
- Simplification of procurement supply chain management
- Wide scale implementation of Treatment 2.0 initiative
- Treatment as prevention
- Strengthen MNCH platform
- Optimal infant feeding practices for HIV free survival



of women are protected and that women and their partners are able to make informed choices about their treatment options. It will be important for national authorities in consultation with community based organisations representing women living with HIV to weigh the advantages and disadvantages of Options A, B, and B+ in relation to their own contexts, resources, and national health objectives. This includes the opportunity costs of an increased investment in Option B/B+, compared with investing in other pressing health needs.

### 1.1.3 Purpose of this document

This document provides a broad overview of the programmatic issues and decisions that countries may face as they transition to Option B/B+. It does not provide formal technical guidance or tools related to specific technical issues; however, references are made throughout this document to relevant tools where these exist and to the complementary sections of the toolkit. The Key Considerations document ties together the more specific checklists and assessment tools and intends to help countries facilitate more nuanced programmatic discussions at the country level. It is also hoped that as countries move to the implementation phase, valuable lessons may be learned that can be shared more broadly and help to enrich this document.

### 1.1.4 More equitable access with a rights-based approach

Two guiding ethical principles underline the considerations outlined in this document. Firstly, achieving the Global Plan targets will require an **equity-focused approach**, meaning that programmes seek to bring quality PMTCT services to lower levels of care where the majority of women access ANC and delivery services, and to ensure women and children presently disadvantaged and excluded from treatment programmes receive quality and affordable treatment and are retained in care. Too often, HIV services have been rolled-out first to well-functioning, higher-level sites. If programmes only focus on sites already implementing ART or where external partners are providing technical support, progress will be slow, and lessons learned from these settings may not be applicable to primary care facilities where most women and children access MNCH services.

Secondly, a **rights-based approach** is emphasized, in which women are empowered to make an individual informed choice about HIV testing and treatment. Just as HIV testing is now universally offered to pregnant women in many countries, under Option B/B+, ART is universally offered to pregnant women living with HIV, with the right to opt-out. As part of the universal offer of ART to pregnant women living with HIV, it is essential that the rights of women be protected and that efforts to combat stigma and discrimination are intensified on all levels.





### 1.1.5 Overview of this document

The documents are organized by programme category and aligned with the PEPFAR Country Readiness Assessment Tools (Section 1 of the toolkit).

For more specific discussion of the relative technical and business merits of Options A, B and B+, readers should see the aforementioned WHO's April 2012 Programmatic Update on Option B/B+ as well as UNICEF/Business Leadership Council's "A Business Case for Options B and B+: to Eliminate Mother to Child Transmission of HIV by 2015."<sup>8</sup>

## 1.2 Political Commitment & Policy Endorsement

The following section outlines the key policy issues that may need to be addressed once the decision is made to move to Option B/B+. Additional tools are available in this toolkit to complement the considerations highlighted in this overarching document, optimizing systems that can be used for many years to come.

### 1.2.1 Aligning national structures responsible for coordination of PMTCT, ART, and other health programmes

Cultivating a collaborative and inclusive environment is important to achieving consensus at the country level on adoption of Option B/B+ guidelines and how best to implement them. Effective transition to Option B/B+ will require countries to assess the skills, competencies and resources needed to oversee and manage implementation and policy development on PMTCT and ART, facilitate this shift and ensure collaboration and agreement across different sectors. In most countries structures exist that provide technical guidance and oversight for PMTCT and ART implementation, often called technical working groups (TWGs). While PMTCT and ART technical structures are often somewhat separate from one another, for countries to move forward effectively for full integration of PMTCT and ART, it is critical that these two technical structures collaborate very closely, if not merge into a single group. In the case of Malawi, the ART and PMTCT TWGs effectively merged and continued to operate as one unit in planning for the roll-out of the implementation of ART in all facilities providing MNCH services.<sup>9</sup> Such high-level integration of the technical leadership and management functions of PMTCT and ART programmes is likely a prerequisite to seeing the full integration of these services at the primary health care level.

The ART-PMTCT technical structures should also be as inclusive as possible with regard to bringing other stakeholders into their deliberations. This includes health care workers (HCWs) with hands-on implementation experience at the facility level, technical advisors from international agencies, women living with HIV, and experts from other health



programme areas, such as MNCH, family planning, infant feeding and nutrition, and child health.

In most countries, different levels of cooperation exist between HIV and other health programmes, such as MNCH and family planning. In light of this reality, other stakeholders beyond the HIV programme should be consulted and engaged in the planning process, recognizing that HIV programmes have mutual interests with MNCH programme. HIV treatment of all pregnant women and their infected infants in MNCH clinics would mean a large proportion of patients starting ART would be doing so in MNCH settings. In addition, many of these patients would also be followed-up at the primary health care level and through community based and family support programmes. The ART programme therefore needs the MNCH clinics to function well. Recognizing this, HIV, MNCH, and family planning (FP) programmes should come together to brainstorm about how to use this opportunity to collaborate more effectively.

## 1.2.2 Rapidly assess PMTCT progress, focusing on ART access for pregnant women and their children

As a first step to inform the discussion on how to manage the transition to Option B/B+, countries will need to evaluate their current PMTCT progress. An in-depth and time-consuming review of the national programme may not be necessary, and would not be advisable in most cases, as this could lead to unnecessary delays. Analyzing select core indicators, including quality improvement (QI) indicators, to take stock of performance should be prioritized in order to identify areas that need strengthening or to recommend additional activities for effective implementation of Option B/B+.

In conducting a rapid assessment of PMTCT program progress, the two most critical areas to examine are: a) the proportion of HIV positive pregnant women in a given country, state, region/province, district, and facility accessing ARV regimens for PMTCT<sup>b</sup> and; b) ART coverage among HIV infected infants and children. Facility level performance data is a good barometer for how well the PMTCT programme is doing at the different levels of care. Data should be readily available at this level (though unfortunately in many cases it may not be – which in and of itself, would be a strong indication that change is urgently needed.)

ART access for pregnant women and children should be evaluated at the *sub-national level* to determine both the numbers and proportions of pregnant women and children accessing ART, as well as the types and locations of facilities that are providing ART for pregnant women and children, and whether access is a function of income or education levels. If ART services predominantly remain at higher level facilities, urban areas, and “centers of excellence” supported by external partners, this should be weighed against population in need.

<sup>b</sup> The number of pregnant women in need of ARV regimens can be roughly estimated in a given area (i.e. district, facility) by multiplying the estimated antenatal HIV prevalence applicable to that local area X the number of pregnancies per year X 40%, which is roughly the proportion of pregnant women living with HIV that qualify for treatment with a CD4 cut-off of 350.



In addition to looking at quantitative data, programmes may want to incorporate qualitative feedback from health workers and the users of health services. This information may be readily available from site visits that have been conducted as part of regular supervision or programme reviews, or could be rapidly obtained via a survey of health workers or women living with HIV using mobile phones or other technology. Health workers and women living with HIV can be asked simple questions focused on what is working and what is not working with regard to ART access for pregnant women and children and what practical measures could be introduced to ensure sustained access to services.

Results from a rapid assessment should be used to inform MOH decision-making on the most appropriate implementation model for Option B/B+ and to determine the policy and programme changes that will facilitate a smooth transition to a more simplified and integrated approach.

A single mode of implementation for reaching mothers and children will probably not be a good fit for every facility in a given country. However, it may be helpful for each country to come to consensus about the *predominant* mode of implementation it will use to reach all pregnant women in need of ART and to provide care and treatment for HIV-exposed and infected children. Overall, to facilitate decentralized care and maximize effectiveness, it is strongly recommended that countries with intermediate and high HIV prevalence consider an approach that emphasizes nurse-administered ART and paediatric care in primary health care facilities that provide MNCH services.<sup>c</sup>

### 1.2.3 Come to agreement on the choice of PMTCT Option B/B+

Many countries may be specifically interested in differentiating between Option B/B+, considering the comparative advantages and disadvantages of each. With this in mind, Table 2 on the following page provides a list, though not exhaustive, of some potential advantages and disadvantages of Option B+ relative to Option B.

<sup>c</sup> Provision of ART within such facilities may not be practical in some contexts, particularly low prevalence settings where very small proportions of women are HIV-positive. If ART is not provided in the same clinics or facilities where women test positive, active, and timely referrals need to be implemented to ensure that pregnant women start ART as soon as possible after diagnosis.



**Table 2:** Potential Advantages & Disadvantages of Option B+ compared to Option B

POTENTIAL ADVANTAGES OF OPTION B+ <sup>10</sup>	EXPLANATION
Initiating treatment is not dependent on CD4 testing	Ensures that lack of access to CD4 testing does not prohibit women from receiving needed treatment
Streamlines implementation with a “one-size-fits-all” approach at the service delivery level	This may be easier for patients & providers to understand and more suitable for nurse-administered ART at primary health care centers
Avoids the “stop-start” approach of Option B for women with CD4 > 350	Under Option B women who might have more than one pregnancy may need to start and stop treatment more than once. The risk of resistance associated with starting and stopping treatment has not been well-studied. This may be particularly important in high fertility settings
Decentralization of ART services provides an opportunity to provide ART in primary health care centers and increase ART access to more disadvantaged groups and rural populations	A positive HIV test is the only lab test needed to initiate ART with Option B+. However, with Option B one could also start triple ARV, and decide at a later point, with CD4, whether this is lifelong prophylaxis  A fixed dose regimen of one pill once a day makes it possible for lower cadres to deliver
Provides a clear message to all in the community that ART, once started, needs to be adhered to for life	With Option B, there could be a “spillover” effect on adherence if some in the community think it is OK to stop and start ART
Longitudinal monitoring of mother-infant pairs can provide important information on the quality of the PMTCT program from 1st ANC visit until confirmation of HIV diagnosis at 18 months or at the end of breastfeeding	Monitoring transfers out after breastfeeding and back into the ART programme is a particular complicated issue that needs to be addressed with Option B, but not B+
Integrated ART-PMTCT programme management	Option B+ may provide the opportunity to more fully integrate ART and PMTCT at the service-delivery level as well as with regard to the higher-level programme functions
Health benefits to women living with HIV	Reduced risk of tuberculosis and other opportunistic infections
Prevention of sexual transmission to an uninfected partner	Starting treatment early more likely to reduce viral load and thereby decrease risk of transmission to uninfected partner
POTENTIAL DISADVANTAGES OF OPTION B+	DESCRIPTION
Greater medication costs	Women with CD4 > 350 stop ART after breastfeeding with Option B so fewer ARVs need to be purchased
Potential for more drug toxicity and increased drug resistance	Some women are exposed to ARVs for a shorter time with Option B and may therefore experience fewer side effects. Increased risk of drug resistance if poor adherence or retention
Other additional costs of service delivery	With more women on treatment, there will be additional staff, space, & other infrastructure needed to support this
Potential re-direction of scarce resources away from non-pregnant PLHIV with CD4 ≤ 350	Pregnant women obtain relatively more health benefit from treatment than non-pregnant women with CD4 > 350 after they have ceased breastfeeding



## 1.2.4 What do women want? Exploring the acceptability of Option B/B+

A critical component for how well a transition to Option B/B+ will work is how acceptable it is to women living with HIV. In choosing ARV regimens for PMTCT, the efficacy of a regimen has typically been a much more important criterion than its acceptability, given that it has been justifiably assumed that women will want to use the most effective regimen. However, in cases where two options may have similar efficacy for an individual woman, understanding the relative acceptability of the options becomes especially critical from a human rights perspective. Therefore, when comparing options, it is important to hear from women living with HIV themselves regarding their preferences and whether they would like to have the opportunity to choose between the two options. Option B and especially Option B+ may have health benefits for women with higher CD4 counts (see Box 2 for further discussion of this). Nevertheless, the health benefits of Option B+ may not be dramatic compared to Option B for women with CD4 greater than 350, and some women with CD4 >350 may prefer to stop ART after the cessation of breastfeeding and only re-start again when it is clearly necessary for their own health.

### Box 2: Benefits of Option B+ Beyond PMTCT

- **Reducing the sexual transmission of HIV:** Randomized clinical trials have demonstrated that “treatment as prevention” is highly effective in preventing sexual transmission of HIV, with a greater than 95% risk.
- **Reducing the incidence of tuberculosis:** Starting treatment in women with CD4 counts higher than 350 dramatically reduces incidence of active tuberculosis<sup>1</sup>.
- **Reducing maternal mortality:** Observational data supports the contention that there may be a benefit of HIV treatment in reducing HIV-associated maternal mortality, even in women with CD4 above 350<sup>1</sup>.
- **Increasing uptake of ART and retention in ART programmes:** By requiring that ART services be decentralized to all facilities providing MNCH services, the Option B+ approach has the potential to improve ART access for pregnant women and children in remote areas and avoids mixed messages being sent to communities about the need for everyone who starts ART to adhere to it for life.
- **Benefits for other MNCH and family planning services:** Enrolling all women living with HIV in one pathway of follow-up at facilities can also help make the routine offer of family planning services to HIV-positive women more straightforward to implement.
- **Increasing child survival and reducing stunting:** For exposed infants, maternal ART during breastfeeding (Option B/B+) provides both high levels of protection from HIV infection and the many benefits of exclusive breastfeeding may reduce child mortality related to diarrhea and chronic malnutrition such as stunting linked with not breastfeeding.



With this in mind, countries will need to engage closely with national stakeholder groups and community based organisations representing women living with HIV to understand women's perceptions, attitudes, and preferences with regards to treatment options. These consultations can also identify critical barriers to treatment access and adherence, for example, the cost of accessing treatment, nutritional needs and stigma and discrimination, which can be used to inform policy decisions as well as future implementation plans at the national and district level. In this regard, some countries may want to invest more time and resources to conduct more in-depth qualitative "formative research," which can inform future behaviour change communication (BCC) messages to increase ART uptake, retention, and adherence (see more on this topic in the section on Community Involvement). Countries may also want to explore the community and individual-level acceptability of ARV regimens in relation to infant feeding practices, particularly breastfeeding.

Regardless of the national policy chosen, respect for individual choice and human rights requires that the risks, benefits, and alternatives to a recommended course of treatment be communicated to patients to realize true informed consent. To balance individual choices and rights with operational effectiveness, countries may learn from prior HIV policy changes that have been successfully implemented, most notably the adoption of "opt-out" HIV testing or the WHO 2010 infant and young child feeding recommendations.<sup>11</sup> In each of these cases, women are given clear recommendations, but also given the right to make a different choice. Based on these models, countries adopting Option B+ should strongly consider an approach where all pregnant women living with HIV are recommended to continue on ART, where women with CD4 > 350 receive specific counseling on the potential benefits, risks, and alternatives to ART, so they maintain the choice to stop treatment after the cessation of breastfeeding, if they so desire.

### 1.2.5 Clarify policies and procedures necessary to adopt Option B/B+

There are a number of inter-related policy decisions that countries will need to make that might be best addressed through a comprehensive revision of national HIV prevention, care, and treatment guidelines. Performing such a comprehensive revision in the case of Malawi resulted in fully integrated national guidelines on HIV for all populations to set the stage for the transition to Option B+ (for reference Malawi's integrated guidelines are publicly available on the internet).<sup>12</sup> The revised WHO guidelines on ART, due for release in 2013, can also inform decisions on country specific policies.



## 1.2.6 Garner high-level endorsement of Option B/B+ and associated policies

Having conducted the various analyses and consensus-building activities, the ART-PMTCT technical structure should be well-prepared to present the case for change to the highest levels of the government body with authority to make policies. Showing that recommended changes are not only technically sound, but also cost-effective, broadly supported by many partners, and aimed at addressing HIV-related problems, and improving broader maternal and child health will increase chances for successful implementation. A summary of the key process and policy considerations related to adopting Option B/B+ is outlined in the PEPFAR Country Readiness Assessment Tool.

# 1.3 Financial Considerations

## 1.3.1 Estimate the cost and cost-effectiveness of providing ART for all women in PMTCT

Estimating both the cost and incremental cost-effectiveness of implementing each option is critical to inform implementation decisions and to develop a roll-out strategy. Costing and determining cost-effectiveness requires specialized expertise which may not be present among ART and PMTCT programme managers or policymakers. Various partners, namely Clinton Health Access Initiative (CHAI), PEPFAR and the Futures Institute have developed models to estimate costs for the different options. In addition, UNICEF, CHAI and the Business Leadership Council (BLC) have produced “A Business Case for Options B and B+: to Eliminate Mother to Child Transmission of HIV by 2015,”<sup>8</sup> which describes a model that projects impact and cost over time.

Option B+ is more expensive relative to A or B due to the cost of ARV drugs. Relatively straightforward to estimate, the current annual cost for a TDF/3TC/EFV regimen is on average \$159 per patient year,<sup>13</sup> but this estimate is likely to continue to decline. However, it is also crucial to include additional operational costs that may be incurred in implementing Option B/B+, such as additional nursing time required to administer ART, as well as financial support for community structures to expand treatment adherence and other ancillary support services. Additional costs for training, supervision, and revising monitoring and evaluation systems should also be included. Assessing the fully cost implications of implementing Option B/B+ also means taking into consideration the financial resources required to support a fair share of the human resources (HR) at primary health facilities implementing MNCH services that will now be responsible for administering ART to a potentially greater number of pregnant women living with HIV. Similarly, operational costs such as electricity, maintenance, security, etc. should be included in costing estimates.

Short-term and long-term costs should be differentiated from each other as well as initial outlays and recurring costs. With regard to short and long-term costs for individual



patients, it should be recognized the women with higher CD4 levels under Option B who would stop ART, need to start ART again in a few years. There is only a small proportional difference in the absolute life-time cost of ART in a young individual who will be on treatment for decades when comparing costs between Option B+ and B.

Comparing the incremental cost-effectiveness of various treatment options by using their estimated “real world” public health effectiveness in a given country context, rather than simply using efficacy estimates based upon clinical trial results is essential. As part of a feasibility analysis, PMTCT-ART technical structures may have derived ranges of how effective Option B/B+ will be in their country context and these estimates can be used for the incremental cost-effectiveness calculations. Estimation of cost-effectiveness should also include other benefits of earlier treatment, most notably reduction of sexual transmission and incident tuberculosis cases. The costs of failure should also be included in the overall analysis, given that an option that has less public health effectiveness creates additional costs based on the need for paediatric treatment (and adult treatment if the benefits of earlier treatment for prevention of sexual transmission are taken into account). Countries may also want to analyze how cost-effectiveness is sensitive to the price of ARVs, as ARV prices continue to decline and may become much less expensive to manufacture in the future. Accounting for such possibilities in costing estimates may encourage stakeholders to see that Option B/B+, despite high investments at the outset, will become more cost-effective and potentially cost-saving in the future.

For more on cost and cost-effectiveness related to Option B/B+ see the costing tool in Section 3 of the toolkit and “A Business Case for Options B and B+: to Eliminate Mother to Child Transmission of HIV by 2015.”

### 1.3.2 Finance: mobilizing adequate resources and strengthening the health system

Mobilizing adequate resources for implementation of Option B/B+ is challenging, since it often takes a year or more to successfully apply for new funding, either from internal and/or external sources. Given that adopting Option B/B+ involves providing ART to all PMTCT women, one alternative may be reprogramming funding that is already budgeted for ART to facilitate implementation. Although the two programmes have increasingly overlapped in recent years, many country budgets and donors separate ART and PMTCT activities, and ART is generally better resourced than PMTCT. In adopting Option B+, Malawi used this approach, reprogramming resources from an existing Global Fund grant. However, using such reprogrammed funds to support initial implementation without a clear commitment for longer-term funding carries some risks.

Whatever the case, long-term commitments of additional resources will be necessary to fund the increased cost of Option B/B+, particularly the ARV drug costs. At minimum, this will require additional internal resources that countries make available through domestic public sectors funds, and in most cases this will also require additional external





resources. Countries that develop costed elimination of mother-to-child transmission (EMTCT) plans and commit a substantial amount of their own internal resources will have a stronger case when requesting external funding. Illustrating the cost savings associated with Option B+ in the longer term due to the larger number of paediatric infections averted, as well as the decline in ARV drug prices driven by larger patient volumes is important.

Utilizing resources effectively to strengthen the health system is another key challenge when rolling-out Option B/B+. Scale up of ART in all MNCH facilities demands a significant investment in human resources (health and community-based), supply chain management, monitoring and evaluation, and physical infrastructure. Given the move toward integration, MNCH and ART programmes should find ways to pool resources and to jointly strengthen the systems that are essential for the provision of all health services at the primary care level. Budgets for both PMTCT and ART should reflect increased funding needs for implementation of national EMTCT plans. However, more effective PMTCT programs that further reduce the number of new pediatric HIV infections will likely reduce the need for spending on pediatric ARV drugs.

For a more detailed list of typical costing inputs see the tool on Costing in Section 3 of the toolkit.

## 1.4 Service Delivery Model

### 1.4.1 Come to consensus on optimal modalities of PMTCT-ART service delivery

Reaching consensus on the mode of ART implementation best suited to the particular goals and context of a country is a critical step in the planning phase for transitioning to Option B/B+. Given the costing and human resource implications associated with decentralisation, it is vital that service delivery models and decentralisation are evaluated during the initial planning phase. Key questions to consider when choosing the most appropriate mode of implementation include:

- *where* ART for pregnant women and children will be implemented (location)
- *who* will initiate it (providers) and;
- *when* ART will be offered to women and children (timing).

With regard to location, several models are possible including:

- location of ART services within the same MNCH clinic that provides PMTCT (“fully integrated” location);
- ART services located in a separate building or section within the same overall health care facility as PMTCT; (so-called “proximal partially integrated<sup>14</sup>” location); or



- ART services in a separate health facility than the PMTCT services (“not integrated” location).

With respect to providers, options include ART initiated by medical doctors only or ART initiated by other cadres as well, including nurses/midwives and clinical officers. With respect to timing, possible models include coordinating ART consultations with ANC and MNCH visits in the antenatal and postnatal period versus relatively uncoordinated visits (i.e. ART is only offered at certain days or times that do not overlap with ANC or other MNCH visits).

Evidence indicates that implementation of ART for pregnant women and children within MNCH clinics can result in much higher levels of uptake than when clients are referred out to higher level facilities, which tend to be more distant from where women live. A cluster-randomized trial in Zambia showed that the provision of ART in MNCH facilities approximately doubled the uptake of ART by pregnant women compared to when ART was provided by out-referral.<sup>15</sup> Although referring pregnant women and infected infants from MNCH clinics to separate ART clinics within the same facility, which often occurs in large hospital settings, is preferable to referring patients to distant facilities, co-location can be associated with high rates of loss to follow up.<sup>16</sup> Therefore, it is more desirable, at least in most high HIV prevalence settings, to initiate ART for pregnant women and infants in MNCH settings whenever possible. Yet, in doing so, it is important to bear in mind that offering ART to HIV positive pregnant women in primary health care facilities may create demand for services for partners, post-partum HIV positive women and children as well as other ART patients living in the catchment area. Therefore, plans to initiate ART in ANC at lower level health facilities, should be well aligned and linked to decentralisation plans for the adult ART programme and viewed as an opportunity to strengthen family-centered approaches to HIV care. In the same vein, clinical standards for ART provision within MNCH settings should be comparable to national standards for the adult programme and equally robust systems used to monitor the quality of care provided to pregnant women living with HIV.

While co-location of PMTCT-ART services for pregnant women is important, it is generally not sufficient for optimizing ART-PMTCT uptake. In one observational study, there was little difference between uptake among three clinics using a full-integrated, partially integrated, and un-integrated approach to delivering ART-PMTCT services.<sup>14</sup> Although services were co-located at the clinic, different providers were providing ART and PMTCT services and at different scheduled times. This underscores the importance of integrating all three aspects of services - location, providers, and timing – to maximize the likelihood of women and children initiating ART. Arguably, the most critical ingredient of the Malawi’s early success with Option B+ was the decision to implement ART in all sites providing MNCH services, with nurses initiating ART in a coordinated fashion with ANC visits.

Given that space and staffing in MNCH is often limited, hybrid models can also be considered in which ART is initiated by nurses in MNCH, but women and children are carefully transitioned at some point after delivery, to another clinical space where lifelong ART can be provided. The optimal timing and location of transition from PMTCT to a separate



long-term ART programme will vary somewhat based upon the specific characteristics of sites within a country, though in most cases it will likely be preferable to transition after weaning.

In addition to coming to consensus about the preferred modality of ART initiation and follow-up of pregnant mothers, it is also important to agree on the recommended mode of follow-up of HIV-exposed and infected infants and young children. In countries where ART will be initiated in primary care facilities that provide MNCH services, it is logical for the same health care workers and clinics providing ART for the mother to be given the primary responsibility of ensuring HIV-exposed and infected infants receive the necessary interventions in the postnatal period.<sup>d</sup> A family-centered approach whereby mothers and infants have the same “home” for care has been implemented successfully in many contexts, and also offers the potential to bring male partners in for testing and treatment. Testing and treating partners and family members is vital to optimizing the benefits of treatment as prevention and to providing psychosocial support for pregnant women initiating HIV at the time of diagnosis.

## 1.4.2 Decentralisation and scale-up

Systems will need to be revised and strengthened for ART to be reliably delivered in primary care facilities providing MNCH services. Provision of ART to women and children involves new responsibilities, and it is important to ensure that health systems are adequately equipped to optimize treatment outcomes. For example, measures must be taken to minimize stock-outs of ART and to establish a system for patient monitoring and retention. In some cases, countries may want to consider a phased approach to roll-out of Option B/B+, which focuses on learning by doing, while maintaining a mindset of urgency. In this regard, countries may want to learn from Malawi’s example, which prioritized certain districts to implement B+, followed by implementation in all districts nationwide within less than a year. This approach allows rapid learning from a variety of sites within a district, including primary care centres, while optimizing higher-level health systems functions at the district level. Furthermore, it is necessary to take into account the workload implications of decentralizing HIV services from ART sites or higher level health facilities to primary care facilities based on all ART patients in a given district or catchment area.

For high and intermediate prevalence settings, two challenges must be overcome to provide more equitable access to ART for pregnant women living with HIV:

1. The need for ART to be implemented at sites providing MNCH services – bringing ART to the women and children who need it; and
2. The need for coordinated and comprehensive care and support for ART adherence and retention at the community and facility level

<sup>d</sup> This includes early infant diagnosis, support for breastfeeding and nutrition, cotrimoxazole, nevirapine



### 1.4.3 Bringing ART services to women and children: preparing the health system to support ART within all primary health care clinics offering MNCH services

Health system bottlenecks vary from country to country and across different regions within the same country. Therefore, it may be helpful for national programmes to work closely with district health teams to conduct health system bottleneck assessments to better understand where they need to focus their local resources to enable facilities that provide MNCH and PMTCT services to also provide high quality ART services.

In addressing supply-side and demand-side bottlenecks to accessing services, it is important to look not only at individual health system components, but also to keep in mind the continuum of care for women and children. Loss-to-follow-up occurs at multiple points in the antenatal and postnatal periods, with missed opportunities existing both with regard to MNCH and HIV services. For HIV goals to be met, women and children first need to access general MNCH services at high levels. Further investments in the broader MNCH platform are required to address barriers to HIV and MNCH service integration and to strengthen linkages where these are weak.

### 1.4.4 Infrastructure: making adequate space for ART within MNCH facilities

Perhaps one of the more straightforward health systems issues to consider in transitioning to Option B/B+ is the physical infrastructure required to administer ART in MNCH settings. A health center that has adequate space to provide ART may not necessarily need renovations to switch to Option B/B+. However, the longer duration of adherence counseling prior to ART initiation and the potentially more frequent visits over a longer period of time may put a strain on available space.

The amount of space required and whether or not renovations are needed will differ from site to site, depending on the patient volume anticipated, other services in operation at the facility, and existing condition of and space available at the facility. Improving patient flow or the organisation of services within the clinic by scheduling ART consultations at times when the facility is less busy (often the afternoons for facilities that provide MNCH services) may minimize the need for extensive renovations in many cases.

Adequate and secure storage space for ARVs is another factor to take into account when initiating ART at primary care clinics. Assessing space and renovation needs should be done by district teams as part of the planning process, and preferably done in a way that maximizes the security of all commodities used at the health facility, including ARVs and other drugs.



To assess their readiness to provide ART for all pregnant women living with HIV, countries may find it helpful to utilize the Country Readiness Assessment Tool developed by PEPFAR in Section 2 of the toolkit.

## 1.5 Human Resource Capacity

### 1.5.1 Human resources: implementing nurse-initiated ART and task-shifting

Initiation of ART by nurses and clinical officers in MNCH settings may be necessary in most contexts for successful implementation of Option B/B+ and to improve ART access for infants and children. Evidence strongly supports that nurse-initiated ART is safe and effective.<sup>17,18,19</sup> Clear task-sharing and task-shifting policies should also be in place outlining how peer educators and community based care workers can support nurses in different tasks involved in providing care to ART patients. Consideration needs to be given to how these cadres can be appropriately remunerated and supported (For more on this, see the Community Involvement section). National policies and guidelines must be revised to enable nurses to initiate ART, and should clearly spell out the indications for patients to be referred to medical doctors or higher-level facilities. The majority of women starting ART in PMTCT settings are in WHO stage I or II disease, and therefore only a small number of patients will likely need to be referred. Policies should also be clear that trained nurses can initiate ART in children.

The in-service and pre-service training curricula also need to be updated for nurses and other cadres to reflect any new responsibilities related to ART management. Better training in paediatric diagnosis and treatment is especially important for nurses and clinical officers in MNCH settings

Along with these clear guidelines and curricula, there need to be adequate numbers of nurses at MNCH clinics to provide ART without detracting from their existing patient duties. District teams, in coordination with provincial and central managers, should conduct an analysis to ensure each MNCH facility slated to initiate ART has adequate nursing staff. Although Option B/B+ is actually simpler to administer from a provider perspective, it may be reasonable to assume that nurses already providing PMTCT prophylaxis could switch to providing ART without additional human resources. However, nurses initiating pregnant women on ART may need more time to provide adherence counseling which is lengthier for patients starting ART compared to PMTCT. Defining retention strategies to minimize the loss of health care professionals and community care workers due to burn out as well as providing continuous professional development opportunities for these cadres is necessary, as they assume more responsibilities.

Nurses will also need to be trained as ART providers, as well as other relevant members





of the teams at health facilities that will be involved in providing ART (i.e. clinical officers, pharmacists, data clerks, support staff, etc.). In the case of Malawi's Option B+ roll-out, teams were trained together in the new national guidelines which included integrated PMTCT, adult and paediatric ART, and other related topics such as infant diagnosis and the routine offer of family planning for HIV-positive women. Given the expense of off-site training, it may be more effective and a better investment of resources to train teams of providers on-site using a comprehensive approach.

Please consult the checklist on Human Resources for Health in Section 4 for more details on this topic.

## 1.6 ART Regimen Choice

### 1.6.1 Reach consensus on a recommendation for the optimal regimen

Deciding which regimen class to recommend for PMTCT and whether this will be the same regimen as all other patients initiating ART in the national programme lays the foundation for many subsequent activities. To the greatest extent possible, this decision should take into account the advantages of harmonizing PMTCT, adult and paediatric ART regimens to simplify forecasting and quantification and reduce fragmentation of commodity markets. Aligning these regimens has the added benefit of simplifying administration of ARVs for health providers.

To limit the risk of nevirapine-associated hepatotoxicity in women with higher CD4 counts and to simplify implementation of a once-daily regimen, WHO's programmatic update recommends an efavirenz and tenofovir disoproxil fumarate (TDF) containing regimen for pregnant women initiating ART under Option B/B+, which is aligned with WHO's preferred 1st line drug regimen for adults. Despite previous caveats about the use of efavirenz in the first trimester of pregnancy, recent data has been reassuring about the long-term safety of efavirenz in pregnancy. The cost of an efavirenz/TDF/3TC regimen at \$159 per patient year is much less than a protease-inhibitor based regimen and increasingly more cost-effective. Recent developments with the MOH in South Africa announcing a new tender in November 2012 for even lower prices per patient per year (approximately \$120 USD) for fixed dose combinations (FDC's) indicate

#### Box 3: WHO Technical Guidance

For more information on WHO recommended adult ART regimens, see the 2011 Treatment 2.0 publication "Short Term Priorities for ARV Drug Optimization." ([http://whqlibdoc.who.int/publications/2011/9789241501941\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241501941_eng.pdf))

For more information on the safety of using EFV in pregnancy, including pharmacovigilance, please refer to see WHO's document: "Technical update on treatment optimization: use of efavirenz during pregnancy in a public health perspective," published in July 2012. ([http://whqlibdoc.who.int/publications/2012/9789241503792\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241503792_eng.pdf))



that optimal drug regimens are becoming more affordable and that further price reductions are possible.<sup>20</sup>

For simplification of supply chain, monitoring and evaluation, and service provision, the ideal approach would be to use the same initial regimen for all patients in the national ART programme. However, in some cases funding constraints may require that different types of patients are initiated on different regimens. Countries where resources are insufficient to provide the same first-line regimen for other ART patients outside of PMTCT may consider a phased approach with the long-term goal of harmonizing to one regimen. National guidelines should also clearly indicate alternate 1st line regimens for pregnant women who experience adverse drug reactions to the approved 1st line regimen.

## 1.7 Supply Chain Management

### 1.7.1 Procurement and supply chain: ensuring ART supply in all MNCH facilities

Moving to Option B/B+ provides some advantages with respect to procurement and supply chain management, but also presents new challenges. With regard to *procurement*, quantification of ARVs becomes simpler because there is only one rather than multiple regimens. However, the absolute cost of procuring ARVs may be greater with Option B/B+, compared with currently available ARV regimens. In transitioning to Option B/B+, countries will need to consider interrelated issues of mobilizing resources for the additional costs of drugs, forecasting and quantification, deciding what procurement mechanisms to use, and coordinating procurement lead times based on both funding availability and the implementation schedule of rolling out Option B/B+.

Regarding procurement mechanisms, coordinated central procurement approaches are supported by major donors such as the Global Fund and PEPFAR, who often finance a large fraction of ARVs. Where applicable, countries can work closely with these donors and the procurement mechanisms they support to reduce the costs of drugs or procurement lead times.

Greater investment in strengthening the supply chain system is required to deliver ART reliably to all sites providing PMTCT services, rather than only to a smaller number of higher-level ART centers. Stock-outs of PMTCT commodities at lower level MNCH facilities have been commonplace in some countries. Once MNCH sites have initiated ART services, such stock-outs would be even more harmful, as they would increase rates of vertical transmission, and put mothers and children at increased risk for developing resistance. Equally important, stock outs are a reflection of the quality of care and have implications for retention rates, as pregnant women may be less likely to return to a health facility with frequent stock-outs. As demand for testing and treatment increases, it is imperative to ensure that forecasting takes into account the needs of both public and



private sectors and places equal emphasis on test kits and ARV drugs.

With this in mind, it is critical that a clear plan and system for managing the supply of ARVs to all facilities is developed. Standardized tools for forecasting and consumption reporting are one important component. Planning should not be done in a top-down fashion, but should include micro-planning at the district level. Given the relative predictability in the numbers of HIV positive pregnant women and infants identified each quarter it may be reasonable to use either a “push” or a “pull” system depending on the country needs. Wherever feasible, programmes should seek to fully integrate the ARVs into the supply chain system that serves primary care facilities providing MNCH services, rather than using a separate vertical system for HIV commodities. Ensuring a reliable supply of other MNCH commodities is a critical element in the continuum of care for mothers and children. In places where essential MNCH commodities are lacking, women may be less likely to attend ANC, which can translate into low uptake of HIV testing, PMTCT, and ART. Training of mid-level pharmacists is necessary to ensure there is sufficient human resource capacity to accommodate the increase in demand for ARV drugs and commodities and for more effective integration of the supply chain management system. Setting up a pharmacovigilance system to collect and manage information on adverse drug reactions and drug utilisation may be considered.

Measures to ensure commodity security are also critical, given the risk that leakage will increase as the supply chain expands to many lower-level primary health care sites. These should be integrated with other commodity security systems at MNCH facilities where other valuable commodities such as artemisinin combination therapies (ACTs) are also widely used. Installing or scaling up the use of logistic management information systems (LMIS), at the national, provincial/regional and district levels may help improve the accuracy of forecasting and facilitate monthly pipeline reporting.

Please refer to the checklist on supply chain management for more detail on the specific elements to consider when preparing the SCMS to accommodate Option B/B+.

## 1.8 Monitoring, Evaluation & Data Use

### 1.8.1 Monitoring and Evaluation (M&E): clear targets, integrating PMTCT and ART systems, and utilizing data

Adopting Option B/B+ can simplify monitoring and evaluation of plans for elimination of mother to child transmission and help all stakeholders have a clearer understanding of progress towards elimination goals. Instead of multiple regimens to track for different categories of women and different drugs used during the antenatal, intrapartum and post-natal periods, Option B/B+ offers one regimen for all women at all times.

To begin with, developing and communicating clear targets for pregnant women on ART



can help promote accountability at all levels. Clear targets are especially critical for the: 1) number of pregnant women initiated on ART and; 2) the numbers of women retained on ART at different time points. Targets should be set at the facility, district, and national levels through a participatory upward process rather than a top-down one.

Secondly, integration and linkages between ART and PMTCT monitoring systems is critical. One major potential advantage of Option B/B+ is the opportunity to link PMTCT monitoring and evaluation with ART M&E. Monitoring and reporting is further simplified by providing ART in primary care facilities where women access MNCH services rather than by referring women out to other facilities.

Nevertheless, other changes may need to be made to enable such integration of PMTCT and ART M&E systems. Firstly, ART registers can be revised to enable 1) longitudinal monitoring of mother infant pairs from first ANC to at least 18 months post-partum and 2) recording of CD4 counts. Adding a space for family planning on ART registers may be needed to better integrate the routine offer of family planning into the ART programme. Furthermore, if option B, rather than B+, is used, how to deal with transfers out of the ART programme for women with CD4 >350 (and the subsequent transfers back-in at some later point in time) is a challenging problem that needs to be clearly addressed.

In many cases ANC, maternity, and infant follow-up registers also need to be revised to reflect the new Option B/B+ regimen. It is critical that programmes have a national register in place for follow-up of HIV-exposed infants and children, which includes necessary interventions in the postnatal period, such as early infant diagnosis, infant feeding, co-trimoxazole, and postnatal zidovudine or nevirapine prophylaxis from birth through ages 4-6 weeks (with Option B/B+). A unique patient identifier for pregnant women that follows them through ART and is linked to Under 5 registers is recommended to enable monitoring of pregnant women across services and help ensure more robust follow up of mother infant pairs. Patient health cards are also a critically important tool that will need to be updated. For example in Malawi, four different health cards were revised as part of the integrated PMTCT-ART programme: adult formulations, paediatric ARV formulations, an exposed infant card, and a pre-ART card for children. Revising the various M&E registers and tools is a difficult task, but fundamentally important to the entire programme.

For examples of patient registers and M&E tools for Option B+, please see the Malawi MOH website for more specific guidance on enhancing M&E systems ([http://www.hivunitmohmw.org/uploads/Main/Quarterly\\_HIV\\_Programme\\_Report\\_2012\\_Q3.pdf](http://www.hivunitmohmw.org/uploads/Main/Quarterly_HIV_Programme_Report_2012_Q3.pdf)) and see Section 6 in the toolkit.

## 1.9 Site Supervision & Quality Management

While revising various registers and M&E tools is important, systems for data quality assurance are also of critical importance. Health care workers need to be trained in



how to use the revised tools and encouraged to use the data to improve programmes at the district and primary levels of care. Clear targets for the number of pregnant women initiating ART and for ART retention will provide a strong foundation for district managers and health facilities to continuously improve services and measure progress. Quality assurance and improvement tools to assess standards of care will have to be updated. To ensure data quality, adequate human and financial resources must be allocated to conduct data quality assessments and perform supportive supervision at the facility, district and national levels. Drawing from Malawi's experience, it is important to balance data collection with data use and analysis to ensure that data collected is streamlined and informs programme decisions while also minimizing the burden on health staff. Countries also may consider introducing or expanding existing electronic systems, where feasible to collect longitudinal data on mothers and infants receiving PMTCT services.

Under Option B+, quality improvement interventions will be more important than ever for assessing short term results and long-term benefits of PMTCT scale-up. By regularly reviewing programme data at the district level, identifying bottlenecks and setting quarterly targets, PMTCT program managers can monitor and document incremental changes which contribute to longer-term improvements in standard PMTCT indicators.<sup>21</sup>

Initiating ART is a substantial new responsibility for various cadres, which demands regular and structured supervision. Supportive supervision is most effective when a system is in place at the district level where sites are visited on a quarterly basis, and more frequently during the first six months following the provision of ART for all women enrolled in PMTCT.

Mentoring and on-site coaching provided by health workers with more clinical experience in ART to providers at sites with less experience is a potential strategy for accelerating the expansion of PMTCT services to lower level health facilities. On-site mentoring was used by Malawi in rolling-out Option B+, with more than 350 mentors employed to support sites throughout the country.<sup>9</sup>

Supervision should be integrated, involving both PMTCT and ART services, and coordinated and/or combined with supervision visits by other MNCH programme areas where feasible to minimize cost and foster collaboration between different programme areas. A mechanism should be put in place that ensures rapid monitoring and assessment, with an immediate correction component and follow up. Site supervision is an ideal platform to use QI to monitor performance. Supervision should focus on verifying data, analyzing this data with the staff at the site, and collecting it as needed for further analyses at the district or national level. Other important items to be addressed during supervision include assessing whether the standards of services are being met, ensuring adequate stocks of drugs and test kits are available, and identifying specific challenges that sites are facing. Technology can strengthen the supervisory process. One example is the use of smart phones to increase objectivity and provide a score for comparison at a future visit.





## 1.10 HIV Testing & Counseling in PMTCT Settings

### 1.10.1 Quality assurance for rapid HIV testing in PMTCT programmes

As HIV testing & counseling (HTC) services offered in ANC are further decentralized with the scale-up of PMTCT under Option B+, there will be a need to ensure the quality of HIV rapid testing is not compromised and that HIV-negative women in particular are not mistakenly initiated on lifelong ART. Quality assurance systems need to be in place to monitor that testing is done properly and that the correct results are recorded and conveyed to women. Standard operating procedures for HIV testing should therefore be clear at the level of primary care facilities. Linked to this, a system is needed that will enable a sample of tests from all primary care facilities providing PMTCT to be sent back to a central lab for verification of the accuracy of the site-level results.

Such a strategy centers on training and supervision of nurses and lower cadres of HCWs (where relevant) who perform tests and updating testing algorithms and guidelines on quality control. Integrating quality assurance into HTC is critical with task-shifting and the decentralisation of PMTCT services. Results of quality control (QC) testing should be viewed during supervision and used to provide feedback on quality of PMTCT programmes. Costs for conducting quality control on specimens must be considered and integrated into the overall transport network for lower level health facilities that send samples to a referral laboratory.

### 1.10.2 Couples HIV testing and counseling

National policies and procedures for testing and treatment of male partners of pregnant and lactating women should also be clarified as part of the process of considering Option B/B+. Since ART is highly effective in reducing sexual transmission within discordant couples, and because acute HIV infection of pregnant and lactating women is likely associated with higher risk of mother-to-child transmission (MTCT), testing male partners and treating those who are infected is an especially important component of PMTCT programmes. WHO published guidelines in 2012 on Couples Testing and Counselling, including recommendations for treating all people living with HIV (PLHIV), regardless of CD4 count, in serodiscordant relationships.

ANC and PMTCT settings are an ideal entry point to offer HIV counseling and testing for partners and family members of pregnant women living with HIV. Inviting male partners to get tested for HIV can influence the uptake of PMTCT services by promoting communication and disclosure of HIV status. Couples HTC also provides a gateway for preventing transmission in discordant couples, helping HIV-negative couples to remain negative and improving support for follow-up care for HIV-positive pregnant women and



HIV-exposed infants.<sup>22,23</sup> Establishing specific guidelines and job aids on couples HTC and training health care workers, including lay cadres, in their use is crucial to ensuring that male involvement becomes an integral and routine part of the PMTCT programme. Strengthening linkages to the ART programme to ensure that male partners who test positive in PMTCT settings are promptly registered and initiate treatment, if eligible is imperative and facilitates a family-centred approach to HIV care.

## 1.11 Counseling on ART Initiation & Adherence

Adherence counseling is a critical component of ART initiation and policies should state extent to which adherence counseling should be required before ART initiation and after starting ART. Policies should also be clear on which cadres of workers should be able to provide different types of counseling and which adherence strategies works best for that locality. Malawi required pregnant women starting ART under Option B+ to receive the same amount of adherence counseling as other ART patients. While it is important that such structured adherence counseling is provided, policies should clarify that the timing of initiation of ART among pregnant women is a matter of urgency, and that delays in providing or scheduling adherence counseling for women in PMTCT are unacceptable.

## 1.12 Laboratory & Clinical Monitoring

### 1.12.1 Clinical monitoring

One of the advantages of adopting Option B+ is that treatment initiation is not dependent on availability of CD4 testing, which is limited in many contexts. However, Option B+ still requires regular clinical monitoring of patients. To this end, proxies for renal and liver functioning, notably hemoglobin tests, a urine dipstick for protein and bilirubin, and tuberculosis screening may be appropriate prior to starting a pregnant woman on lifelong ART. In addition, CD4, syphilis, biochemistry and EID tests should be available – either on site or through referral – for patient monitoring purposes.

A country's decision to adopt Option B+ prioritizes access to ART for all pregnant women in need over ensuring every woman in PMTCT has a CD4 test before starting treatment. But nevertheless, eliminating CD4 testing as an absolute requirement before starting ART does not mean that countries should not make efforts to provide access to CD4 testing to women before and after they start treatment. When CD4 testing is not available at a PMTCT site that provides ART, women should be offered a clear means of accessing a CD4 test, preferably through the establishment of a network to transport samples to a lab, or perhaps by referral to a higher-level site specifically for CD4 testing (though the women would in such cases continue on ART at the lower-level site where they initiated



it). Countries should also continue to expand use of point-of-care (POC) CD4 testing machines to lower level facilities, as these machines have shown promise in improving access to CD4 testing.<sup>24</sup> Laboratory monitoring will need to be enhanced to determine the efficacy of the regimen and drug toxicities. With more pregnant women starting ART under Option B+, a larger number of tests will need to be performed and laboratory services will need to be improved to make this possible.

### 1.12.2 Laboratory systems: quality assurance and expanding virologic testing

Increasing access to virologic testing should be given high priority. This includes continuing to scale up early infant diagnosis via dried blood-spot (DBS) testing to all sites providing PMTCT services, as well as expanding access to quantitative methods to detect treatment failure. Virologic testing is extremely sensitive for screening for treatment failure at an early stage, which is an important indication for laboratory testing among women initiating ART in PMTCT, the vast majority of whom are clinically well. (CD4 testing on the other hand is very insensitive for detecting early treatment failure).<sup>25</sup> Access to virologic testing can occur either through on-site testing, sample transport systems or via referrals to other sites. Many quantitative virologic assays need to be transported on ice and performed within a short time of when a sample was collected, in which case women would need to travel to higher-level sites to provide plasma for virologic testing, with these samples then rapidly linked into a transportation network. However, some machines can now use DBS samples to do quantitative virologic testing, and countries may want to consider such an approach due to its greater logistic feasibility in many settings. Furthermore, new technologies for point-of-care virologic testing hold great promise for improving access and several such quantitative tests may begin to become available by 2013.<sup>26</sup> Especially given the complexity of establishing transport and referral networks to enable widespread access to currently available virologic testing platforms, countries may want to consider investing in these new technologies. (See new WHO guidelines, expected for release mid-2013, for updated guidance on viral load and CD4 monitoring.)

## 1.13 Early Infant Diagnosis

### 1.13.1 “A better test”: point of care infant diagnosis and tests for treatment failure

Early infant diagnosis is an important barometer for assessing the effectiveness of PMTCT programs, determining the impact of providing lifelong treatment to pregnant women living with HIV on vertical transmission rates and providing timely initiation of ART for HIV infected infants. Although scale-up of PCR testing has occurred in many countries, in



2011 only 35% of HIV exposed infants were EID tested within 2 months of age in the 22 priority countries.<sup>27</sup> In resource-limited settings, many challenges remain in scaling up PCR testing, including difficulties transporting samples from sites, returning the results to facilities, and ensuring that infants testing positive receive their results and initiate ART in a timely fashion. The obstacles facing EID exist at all levels of facilities, but are more prominent in rural primary health care facilities far from laboratories.

An inexpensive and simple point-of-care test would be invaluable, as children could be tested at the clinics where they are already presenting for primary health care, receive same-day results, and initiate ART as soon as possible at the same site. Such a simplified early infant diagnosis (EID) test, together with a “better pill” for paediatric treatment, could help streamline a “test and treat” strategy for infants and young children at the primary care level. It also can provide sites real-time feedback on the effectiveness of their interventions. Several point of care EID polymerase chain reaction (PCR) tests are being piloted and some have shown high degrees of sensitivity and specificity based on preliminary data. These tests are expected to be available in 1-2 years and have the potential to significantly increase the number of HIV positive children identified and starting treatment.<sup>26, 28</sup>

A different approach would likely be needed for simpler assays to detect treatment failure, rather than attempting to do testing at many lower-level facilities. Currently, virologic testing for treatment failure is primarily done in centralized labs. This makes it difficult to extend virologic testing to primary care facilities, although the potential use of dried blood spots for quantitative virologic testing may help somewhat in this regard.<sup>29</sup> Point-of-care devices for quantitative or semi-quantitative virologic testing machines, while likely too expensive to place at all primary care facilities, would have potential to greatly increase access to virologic testing in one of the following ways: 1) either they could be placed at intermediate level facilities so that women could periodically be referred up to those centers for testing, or 2) mobile labs could periodically be scheduled to visit primary health centers to offer such testing to patients on ART. A large number of such devices are now in development, and at least 3 or 4 may become available by 2013.

Improved technology will go a long way to improving EID; however, even with current diagnostic methods, it is equally important to ensure rapid turnaround times for delivery of results from the laboratory to the health facility and from the health facility to the caregiver. Increasingly, health facilities use text messages (i.e. short message service [SMS]) to communicate test results to health facilities thereby reducing delays in diagnosis and ART initiation. Active case finding of sick and/or HIV exposed infants, through community health workers (CHWs) should be expanded to complement EID performed at the health facility as many HIV exposed infants are lost to follow up or present late despite being tested and identified HIV positive.<sup>30</sup> Reinforcing the linkages between ANC, EID and ART services, including aligning follow up care for HIV exposed infants with immunisation may help to increase the proportion of HIV exposed infants initiating ART and retained in care.



## 1.14 Retention in Care & Treatment

To eliminate MTCT and keep mothers alive, ART services not only need to be available at the primary care level, but women and children need to continue to utilize them over time. Even a highly effective, tolerable, and simple regimen will not make a difference if women cannot or do not access it. Low rates of care-seeking behaviour, poor adherence, and high rates of loss-to-follow-up (LTFU) are systematic problems for both PMTCT and ART that need attention regardless of which regimen is implemented. While the benefit of Option B/B+ is that many more pregnant and lactating women are rapidly enrolled on ART, the corresponding risk is that many more women will not adhere to treatment or will be lost-to-follow-up, particularly if the appropriate systems are not put in place. Given that ART requires adherence for life, it is essential to invest in evidence-based interventions that create and sustain demand for services, in addition to investing in the services themselves.

With the adoption of Option B+, some improvements in ART and PMTCT retention may naturally follow as the two services integrate with one another. Firstly, decentralizing services to the primary care level through provision of ART within MNCH should help improve retention in care, as evidence indicates that rates of LTFU are lower at primary care facilities providing ART compared to higher level facilities.<sup>31</sup> Additionally, having the same regimen for all women may increase ART uptake, adherence, and retention, as this can simplify messages provided to patients, providers, and communities about the necessity to adhere to ART for life once started. Further, if PMTCT and ART services are integrated, this reduces the number of women being referred out to different sites or services, which can improve retention.

The decision to implement Option B+ will require increased focus on interventions to improve uptake, client education for treatment literacy, adherence and retention across the continuum of care. In particular, optimizing the contributions of community-based platforms and linking these platforms more intentionally to facilities providing ART services is critical to improving the retention of mother-infant pairs in care and providing testing, treatment and psychosocial support to family members.

Poverty hinders access and adherence to treatment. WHO emphasizes the role of reforming health financing systems to reduce financial barriers to access and achieving universal health care coverage. Greater efforts are needed to replace out of pocket payments at clinics with more efficient and equitable financing mechanisms to ensure ART is provided free of charge at the point of delivery. This can be achieved by more equitable health insurance schemes. In addition, measures are needed to reduce cost of transport – for example through transport allowances, free bus passes for chronic care patients or cash transfers for poorest households on treatment.

A strategy for improving adherence and retention that focuses only on what happens at the facility-level is likely to be ineffective. With this in mind, two inter-related types of interventions should be areas of increased focus for improving adherence and retention:



1) more efficient use of lay cadres and support groups and 2) use of targeted behaviour change communication in both clinical and community-based arenas.

## 1.15 Family Planning

Transitioning to Option B/B+ provides a unique opportunity to better address the second prong of the Global Plan – preventing unintended pregnancies and facilitating the integration of family planning and HIV services, with ANC as a primary entry point for HIV positive pregnant women. The importance of family planning integrated within HIV services is paramount to a successful transition to Option B+ given that the global unintended pregnancy rate is 38%, with even higher rates (51–90%) among women living with HIV in some settings.<sup>32</sup> Not only do unintended pregnancies contribute to maternal morbidity and mortality, but reducing maternal mortality is closely linked to improving a child's survival. Fewer unintended pregnancies among women living with HIV will also reduce the potential number of new paediatric infections.<sup>32</sup>

Pregnant women living with HIV on ART during breastfeeding or for life will need to make informed choices on contraceptive use and receive adequate family planning counseling within MNCH settings where the majority of pregnant women and lactating mothers living with HIV receive care and treatment settings under Option B/B+. Implementation of Option B/B+ provides an opportunity to more effectively integrate FP and HIV services, as ART will be provided in the majority of MNCH settings. To facilitate integration, governments first can create an enabling environment by developing a national strategic framework or policies to formally endorse the integration of MNCH, including family planning, HIV and other health services. Assessing family planning commodity needs beyond male and female condoms to ensure a wide range of choice of contraceptive methods and procuring them is a vital component to ensuring that women receiving ART can effectively act on their choice to have, prevent or delay subsequent pregnancies. Integrating family planning, MNCH and ART commodities will become even more important as demands for FP services increase over time with integration at the service delivery level and increased investments in primary prevention and prevention of unintended pregnancies (Prong 1 and Prong 2). Training providers in family planning for HIV positive pregnant women, adapting family planning messages, and revising protocols should accompany the change in ARV regimen for PMTCT.

Concerns regarding the interaction of hormonal contraception and ART have recently been investigated and debated. However, the WHO continues to recommend that there are no restrictions on the use of any hormonal contraceptive method for women living with HIV or at high risk of HIV. The shift to Option B/B+ will require more robust pharmacovigilance to monitor and gather more evidence on the effect of ART use during pregnancy and breastfeeding and among women living with HIV who are trying to conceive.





## 1.16 Community Involvement

### 1.16.1 People living with HIV: driving the implementation of the response

Just and lasting change occurs when “communities own their future.”<sup>33</sup> At its core, health is fundamentally about people. As people living with HIV plan, implement, and monitor programmes intended for them, deep and sustainable impact can occur. In addition, networks of PLHIV can also help refer disadvantaged households to other nutrition and social protection programmes (e.g. transport allowances and cash grants) to reduce some of the persistent barriers to care – most notably, high transport costs.

**PLHIV should play a leadership role** both in implementing approaches to support adherence and retention, as well as in refining approaches to more effectively involve lay cadres and support groups. While there are many ways in which PLHIV will be involved in the effort to simplify ART delivery, combining both clinical services and psychosocial support through self-selecting PLHIV support groups is a promising practice. Networks of PLHIV have played a critical role in providing direct support to men, women and children on treatment – for example, linking those on treatment to health facilities to refill medications and providing adherence counseling.

Such group medical visits have been increasingly shown to be effective when delivering care for a variety of chronic medical conditions, including HIV.<sup>34</sup> Indeed, patients often have better outcomes and express greater satisfaction in such environments, as they are able to help one another solve clinical problems based upon their own experiences. Along with group medical visits, home based ART is another innovative service-delivery approach that has shown excellent results, and can be led by PLHIV.<sup>35</sup>

As part of this process, the integration of pregnant and lactating women living with HIV into other existing support groups is an important consideration. Women continuing on ART for life after the cessation of breast-feeding, may be best served in some settings by having one PMTCT-ART support group.

### 1.16.2 Local communities: owning the future and demanding accountability

Along with PLHIV, communities affected by HIV and AIDS are actively involved in efforts to eliminate new HIV infections among children and keep their mothers alive. There is still the need for simple behaviour change communication messages to raise awareness of



treatment availability. As ART for all pregnant women is implemented at the primary care level, communities can join with PLHIV to lead the way in driving services even closer to where women and children live, developing better ways to provide HIV care and treatment that are more efficient and responsive to peoples' needs.

In addition to taking on an increasing role in planning and implementation, communities and their leaders will need to actively hold their own governments and other partners accountable for progress towards an AIDS-free generation. Simple and clear targets for the number of women initiating ART and the proportions retained in treatment should be developed and communicated at all levels. Communities should be involved in working with their local health facilities and district health managers to set these targets and benchmarks. Simplified targets will not only help motivate facilities, districts, and countries to perform, but also enable local communities to exercise greater ownership over the effort to eliminate new paediatric HIV infections. Community health committees can also check whether treatment is being delivered according to national guidelines and guard against unofficial payments being charged by health workers. By monitoring progress with respect to these simple targets, local communities can demand accountability for results.

### 1.16.3 Maximizing effectiveness of lay cadres and community health workers

Lay cadres, at the clinic and community level, have played an essential role in both ART and PMTCT programmes. Existing in many forms in different countries and settings, PLHIV are often employed as expert patients, support group leaders, or mentor mothers. Many varieties of community-health workers and other ancillary health workers also play an important part in supporting PMTCT, often in an integrated way with other essential health and nutrition activities at the community level. These cadres already play a critical role in reducing loss to follow up among PMTCT and ART patients, by disseminating messages on adherence or tracking patients who have defaulted from care. They can also support nurses with critical duties related to ART and PMTCT, including adherence counseling, HIV testing, and infant feeding support.

Given the increased needs to promote ART adherence and retention, particularly with option B+, there will be a corresponding need for more investment in these lay cadres. Formalizing the roles and tasks with respect to PMTCT and ART may be an important first step in optimizing their impact. In many cases lay cadres are heavily involved in supporting PMTCT, but their scope of work is not always clearly defined, including what they will precisely do for PMTCT and ART and how it will be measured. Clarifying the role of these workers can help them feel fully a part of the health care team and be more effective.

Equipping the lay cadres with appropriate training and tools for their work is another important step to maximize their effectiveness. This includes ensuring that lay cadres



have been trained to disseminate targeted messages and provide adherence counseling. Lay cadres should be equipped with simple and useful M&E tools that can help them and their supervisors at health facilities to measure retention of the patients they are supporting and to follow-up in a timely manner with patients who default. As these lay cadres help link clinical and community-based platforms, programmes should also consider using mobile technology to facilitate communication between the lay cadres and facilities.

Motivating and appropriately remunerating lay cadres is also an important approach to enhance their effectiveness and retention as care workers. Many of these workers, even if they are “volunteers”, often have no other job and in some cases even pay out of their own pockets to serve families in need. Poor remuneration may demotivate lay cadres, lead to burn out and hinder retention of a skilled cadre of community care-givers. While it may not be possible to pay lay cadres in all contexts, countries should seek to standardize the remuneration that these workers receive to the extent possible. Given the increased need to focus on retention and adherence, national governments and donors should prioritize more funding to support community care workers and devise policies that promote continuing education and professional development of highly motivated community care workers.

At the national level, countries may also find it helpful to develop a framework that clearly describes the vision for how lay cadres and support groups can contribute to implementation of Option B/B+, including the lifelong follow-up of mothers initiated on ART.

#### 1.16.4 Maximizing effectiveness of lay cadres and community health workers

Messages provided to patients regarding adherence and retention do not always draw from formative research that seeks to understand beneficiaries concerns and the reasons why they might not adhere to medication or be retained in care. Engaging the technical expertise to conduct such research and using it to design appropriately targeted messages to bring about effective behaviour change in a specific cultural context should be standard practice for developing appropriately targeted messages. In particular, such formative research should ascertain the views of men and women in the community and prevailing gender norms that may prevent disclosure of HIV status within families. Gender disparities are often powerful unseen barriers to HIV testing, disclosure, and accepting/adhering to treatment.

Behaviour change communication interventions have potential to increase the proportion of women accessing ANC and HIV testing, and can also play an important role in improving adherence to ART and retention in ART. However, the use of behaviour change interventions aimed at increasing ART adherence and retention among pregnant women and male and female ART patients more broadly is an area of programming that has been neglected in many settings. Most programmatic support for BCC related to adherence and retention has been heavily facility-based, focusing on messages from providers



in clinical arenas. Adherence counseling in ART and PMTCT in many settings largely involves the providers giving directions and information to patients, rather than using patient-centered techniques such as motivational interviewing to help patients develop their own strategies to overcome obstacles to adherence.

Adopting Option B, and especially Option B+, provides an opportunity for ART and PMTCT programmes, as well as broader HIV prevention programmes to implement integrated BCC interventions on multiple levels with targeted messages that reinforce one another. The messages should focus on need for adherence and retention, but can also be harmonized and linked to other issues related to sexual prevention of HIV, including “treatment as prevention”, partner reduction, and condom utilisation. While adherence support in clinical arenas remains important, these efforts would be most effective if the messages were implemented in concert with a larger campaign that included linked messages provided through multiple channels in other non-clinical arenas, including community-based groups, peer-to-peer interpersonal communications, and mass media. Suboptimal retention rates currently seen in many national ART and PMTCT programmes might be improved if more attention was paid to implementing such state-of-the-art BCC approaches.

Please refer to the tool on Community Involvement which contains a checklist to guide Ministries of Health on how to best engage with communities as they roll-out Option B/B+ as well as guidance for how civil society organisations can raise the concerns of communities and people living with HIV in national level discussions on regimen choice.

## 1.17 Roll-Out Strategy

Managing the transition to Option B+ will require a detailed roll-out plan with realistic timelines and clear roles and responsibilities to ensure the shift to a new regimen is seamless. This includes identifying existing structures and partners to support implementation, assist in training health care workers on new guidelines and monitor programme results and health outcomes. A core element of a roll-out strategy is communicating the change to agencies and partners involved in implementation as well as the general public. Defining key messages on the transition to Option B+, taking into account biomedical and psychosocial perspectives and with the support of clinical experts, community members and women living with HIV will be important to enlisting the support needed for successful implementation. Although the Malawi experience can serve as an example, it is essential for each country to establish mechanisms for real-time monitoring and evaluation of implementation on a quarterly basis to add to the evidence base, monitor clinical and programmatic implications of HIV positive pregnant women starting lifelong treatment and make adjustments to their programme approach based on effectiveness.



## 1.18 Conclusion: Moving Forward Boldly Together

As governments look toward achieving the elimination of mother to child transmission, simplifying testing and treatment offers a unique opportunity to reach the greatest number of HIV positive pregnant women and children in need. As with any large-scale change, transitioning to a new ARV regimen and implementation for PMTCT requires significant planning that engages stakeholders at all tiers of the health system and the development of strategies that are owned by PLHIV and local communities, implemented at the both the facility and community levels. The universal offer of ART to pregnant women living with HIV through Option B/B+ provides a tremendous opportunity for strengthening maternal and child health, and must be met with an approach that is efficient, ensures equitable access, and seeks the input and protects the rights of people living with HIV. With more countries approving Option B/B+, it is our hope that this toolkit can serve as a guide for decisions on implementation approaches. Documenting and sharing country specific experiences will add to the evidence on the long-term effectiveness and sustainability of Option B/B+, as we move forward boldly toward an AIDS-free generation by 2015.



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