OPTIONS B AND B+:
KEY CONSIDERATIONS FOR COUNTRIES TO IMPLEMENT AN EQUITY-FOCUSED APPROACH

Eliminating New HIV Infections Among Children and Keeping Mothers Living with HIV Alive and Well
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1.0 Introduction

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 deaths by 50%. There is now 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 drugs for prevention of mother to child transmission (PMTCT), a substantial increase from 48% in 2010.

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 pregnant women in need was lower than access among adults in the general population at 34% vs. 47% in 2010, far from the Global Plan target of 90% ART access by 2015. Low access of pregnant women to ART exists despite the fact that coverage of HIV testing is generally much higher in pregnant women than other adult populations. While poor ART access for pregnant women is a pervasive problem for many PMTCT programs, 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, rather than shrinking back in the face of challenges. Reaching the hardest-to-reach women and children with ART will require thinking “outside of the box” to take implementation to a higher level of efficiency and effectiveness. Indeed, limited resources and pressing needs for broader maternal, neonatal and child health (MNCH) require that HIV programs maximize not only cost-effectiveness, but also benefits for other health programs. Clearly, a true “game-changer” is needed: an implementation modality for PMTCT that is at once both simpler and better than the current approaches.

Is this possible? The great news is: yes! A new approach called “Option B+” has already begun to show impressive results in “real world”, resource-constrained settings, dramatically increasing the numbers of pregnant women enrolling on ART. The tide is turning - now is the time to move with the momentum and embrace a bold public health approach to effectively eliminate new paediatric HIV infections.

2. Options B and B+: a simplified approach to integrated PMTCT & ART at the primary care level

What are Options B and B+? 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/mm³: Option A and Option B. 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 ART – beginning in the antenatal period and continuing throughout the duration of breastfeeding. At the end of breastfeeding those women who do not yet require ART for their own health would discontinue the prophylaxis and continue to monitor their CD4 count, eventually re-starting ART when the CD4 falls below 350 cells/mm³. Along with these two options a third approach is now being used, Option B+, in which all pregnant women living with HIV are offered life-long ART, regardless of their CD4 count. Table 1 below, adapted from WHO, summarizes these three different options.
Table 1: Three Options for PMTCT

<table>
<thead>
<tr>
<th>Treatment (for CD4 count &lt; 350 cells/mm³)</th>
<th>Prophylaxis (for CD4 count &gt; 350 cells/mm³)</th>
<th>Infant receives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option A</td>
<td>Triple ARVs starting as soon as diagnosed, <em>continued for life</em></td>
<td>Antepartum: AZT starting as early as 14 weeks gestation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intrapartum: at onset of labour, single-dose NVP and first dose of AZT/3TC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Postpartum: daily AZT/3TC through 7 days postpartum</td>
</tr>
<tr>
<td>Option B</td>
<td>Triple ARVs starting as soon as diagnosed, <em>continued for life</em></td>
<td>Triple ARVs starting as early as 14 weeks gestation and <em>continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding</em></td>
</tr>
<tr>
<td>Option B+</td>
<td>Triple ARVs starting as soon as diagnosed, <em>continued for life</em></td>
<td>Triple ARVs starting as soon as diagnosed, <em>continued for life</em></td>
</tr>
</tbody>
</table>

Option B+ was first conceived and implemented in Malawi where the national ART program 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 simple “one size fits all” approach which would enable women to access ART at high levels even in settings with poor access to CD4 testing. The early experience with Option B+ in Malawi has borne this out, being extraordinarily successful, with a more than five-fold increase in the numbers of pregnant women being enrolled on ART in only the first quarter of full nationwide implementation.\(^5\) \(^6\) Importantly, implementation of Option B+ in Malawi involved much more than a change in antiretroviral regimen. Option B+ was part of a larger strategy in which Malawi’s ART and PMTCT programs fully integrated with one another so that ART could be administered by nurses at primary care facilities where women and children were already accessing MNCH services. Using this equity-focused approach, Malawi has been able to rapidly expand access to ART for pregnant women in hard-to-reach areas throughout the country.

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”\(^7\) in which it urged countries to consider what the advantages of Options B and 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 due to greater simplicity of Option B and B+, WHO’s programmatic update also emphasizes that Option B+ in particular may have significant additional advantages beyond PMTCT. These include providing better protection for maternal health and greater reduction

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1 This table is adapted in a slightly modified form from a Table 1 in WHO’s 2012 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
in the sexual transmission of HIV than other options. While acknowledging the additional cost of Option B+ in terms of drugs, WHO notes that the cost of a simplified first-line once-daily regimen of efavirenz/TDF/3TC has decreased substantially, and that the overall cost-effectiveness of Option B and B+ are likely to be greater than Option A. However, the update also makes it clear that adopting Option B or B+ is “no easy” fix for PMTCT, and that ultimate success of Option B+ in particular will require an increased investment in interventions to improve long-term ART adherence and retention. Intensified support is also needed for other aspects of PMTCT programs beyond ART, including ensuring support for safe breastfeeding for HIV-exposed infants.

Importantly, the WHO update also highlights how options B and B+ fit into larger HIV initiatives and opportunities. Adoption of Option B/B+ could streamline monitoring and evaluation of progress on implementation of the Global Plan and simplify procurement and supply chain management, as most countries move to a single drug regimen for PMTCT and 1st line ART. Additionally, Option B, and especially B+, creates the opportunity to implement on a wide scale WHO/UNAIDS “Treatment 2.0” strategy of the “radical simplification” of HIV treatment¹, through decentralizing ART to the primary care level and task-shifting to nurses and other cadres. Related to this, implementing Options B and B+ provides an excellent opportunity to begin rolling-out of “treatment as prevention”, which can have a significant impact in reducing new HIV infections due to sexual transmission among sero-discordant partners.

But along with great potential of Option B/B+ to impact a wide-range of HIV objectives, it is also critical not to overlook the unprecedented opportunities that implementation of Option B/B+ will provide to strengthen broader MNCH services, including optimal infant feeding practices for HIV free survival of HIV-exposed infants and young children. The provision of life-long ART to women, children, and family members through the very same primary care facilities that provide MNCH services means that over time a very larger fraction of all ART patients will receive treatment at these facilities. ART programs and MNCH programs therefore need to come together like never before so that both can be successful. As part of this new level of collaboration, ART resources, which represent the lion’s share of HIV funding in many countries, should be invested more intensively in strengthening the health systems that support MNCH services. This can lead to a broad and sustainable improvement in health for all women, children, and their family members.

3. Purpose of this document

The potential for PMTCT to have a profound impact on the HIV epidemic and broader maternal and child health has never been clearer and more compelling. In response to these tremendous opportunities and also to WHO’s recent programmatic update, this document is meant primarily to help countries that desire to be ahead of the curve and begin the process of preparing to adopt Option B or B+ now.

The document therefore contains considerations on key policy, programmatic and partnership issues that relate to implementation of Option B or B+. Planning well to address these key issues can hopefully help countries “hit the ground running” and avoid unnecessary bottlenecks in rolling-out Option B or B+.

This document does not provide new formal guidance, but rather discusses technical considerations that are relatively broad in scope, so that different country contexts can adapt the advice to their more specific needs. Additionally, as was suggested in the WHO programmatic update, it is hoped that as countries consider what is a best fit for their context, valuable lessons will be learned that can be shared more broadly and feed into the global revisions of HIV recommendations by WHO in 2013.
While this document may contain helpful advice for any country considering adopting Option B or B+, it especially focuses on the advantages of Option B+ in high and intermediate prevalence countries, urging such countries to consider adopting an implementation model of nurse-initiated ART in MNCH settings. This document draws to some extent on the early experience of Malawi, the first low-income country to successfully begin implementation of Option B+ on a nationwide scale.

4. Target audiences of this document

This document is intended primarily for use by national governments and their partners at the country-level. Although it is meant primarily to aid the decision-making processes at the country-level, other multi-national partners in the public and private sector may also find it helpful to better understand the challenges countries may be facing. In particular, multi-national partners may find the last section of the document useful in envisioning how they might better focus support to countries to help make the most of an investment in Option B+.

5. Overview of this document

In addition to this introductory section, the document contains four other sections:

Section 2, “The Rationale for Option B+: Full integration and Simplification at the Primary Health Care Level”, provides an explanation of how Option B+ can be a critical component of a larger simplified approach of implementation of ART within primary care facilities that provide MNCH services, in line with the principles of WHO/UNAIDS Treatment 2.0 initiative. Through such an equity-focused public health approach, fully integrated PMTCT and ART services can efficiently reach the lowest level of the health system.

Section 3, “Key Considerations for Policies and Processes: Building Consensus at the Country Level”, provides suggestions for processes and criteria that countries can use to help build broad consensus on important issues related to ART for pregnant and lactating women. This includes big-picture issues such as whether to adopt Option B/B+ and with it a simplified approach to ART-PMTCT implementation at the primary care level. More specific technical issues are also discussed for countries to consider in formulating policies related to Option B/B+.

Section 4, “Key Considerations for Program Planning: Bringing ART into MNCH Settings and Bringing Women and Children to the Services”, is meant to inform implementation plans of those countries that ultimately choose to adopt Option B/B+. It emphasizes a model of nurse-administered ART at primary care facilities, outlining important considerations for programs as they seek to bring integrated ART-PMTCT services to the most vulnerable women and children.

Section 5, “Key Considerations for Partnerships: Making the Most of a Tremendous Opportunity to Improve the Health of Women and Children”, discusses how to ensure that an investment in ART for all pregnant women yield returns far beyond PMTCT. To broaden, maximize, and sustain impact, partnerships will be crucially important with other health programs, technological innovators, people living with HIV, and local communities.

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”.
The Rationale for Option B+: Full Integration and Simplification at the Primary Health Care Level

In attempting to attain high-levels of coverage of women and children with ART and other necessary interventions, PMTCT programs have frequently been plagued by what has come to be known as the “PMTCT cascade”. The PMTCT cascade refers to the loss-to-follow-up (LTFU) that occurs throughout the antenatal, intrapartum, and postnatal periods at various points along the continuum of care. Since women and children access HIV services through MNCH platforms, improving retention along the continuum of care will require not only HIV-specific interventions, but also addressing larger structural bottlenecks, including especially the weak linkages between HIV and MNCH services and systems that exist in many settings. Demand-side bottlenecks also need to be addressed, as women are often not well informed of what services they should receive, why these services are important, or where and when they can access them.

While PMTCT services have by necessity been implemented within MNCH settings, ART services have generally not been. Therefore, it is perhaps not surprising that the gulf within the continuum of care between ART services and MNCH services has been particularly glaring in many cases. However, as described below, implementation of Option B+ can provide an opportunity to address some of these structural and demand-side bottlenecks in the continuum of care, by bringing ART, PMTCT, and MNCH services together for fuller integration. As part of these efforts, investing in the MNCH platform will continue to be critical, as MNCH remains the gateway by which women and children access PMTCT and ART services.

Full Integration of PMTCT and ART services and programs is needed

Why has increasing access to ART among pregnant women been so challenging in many settings? One key reason is that PMTCT services and ART services have often operated in largely separate, vertical fashion, being poorly integrated with regard to their location, providers, and timing. With regard to location, ART services are typically not available in all lower-level clinics, whereas in many countries some form of PMTCT services, including ARVs, have scaled up to most, if not all, primary health care centers that provide antenatal and broader MNCH services. With regard to providers, nurses, who are the primary providers of PMTCT services, have not yet begun to initiate ART in many of the primary health care facilities where women come for MNCH services. Low availability of ART at MNCH sites results in particularly poor access to ART for the most vulnerable women and children, as many would have to travel long distances from their homes to access ART at higher-level facilities. Even when women are able to reach these facilities, poor coordination with respect to the timing of service delivery can be a bottleneck to access. While ART in pregnant women should be initiated as soon as possible to minimize the risks of infant infections and maternal mortality, ART clinics are often not organized to give priority to pregnant women. Delays related to scheduling, laboratory testing, or adherence counseling often preclude ART from starting until later in gestation or after birth.

In addition to the need for better integration of services, there is also a pressing need for full integration of the larger PMTCT and ART programs. This includes management and supervision, financing, laboratory systems, supply chain management, and monitoring and evaluation. Although ART programs have typically had much greater funding than PMTCT programs, they have rarely focused on reaching pregnant women as a core objective, leaving most of the responsibility for addressing this critical gap to PMTCT programs. PMTCT programs, on the other hand, have struggled to develop effective referral systems to ART sites, establish lab transport networks, and extend a reliable supply chain of antiretroviral drugs to the very large number of primary care MNCH facilities that they must support. These difficulties have been compounded by the fact that PMTCT
and ART monitoring systems are usually separate and poorly linked, resulting in widespread difficulties measuring and reporting on the number of pregnant women initiating ART – an indicator that is fundamental for measuring progress. Training and supervision of PMTCT and ART providers is also often uncoordinated, and the overall management of the two programs is sometimes not fully unified, with ART tending to have a higher political profile and stronger leadership.

The poor integration of PMTCT and ART programs and services cannot be accepted as the status quo, as it leads to very inefficient use of resources and highly inequitable access to services for the most vulnerable women and children. ART and PMTCT services need to be co-located and administered by nurses and midwives at the primary care level where women and children are already accessing other MNCH services. And ART and PMTCT programs need to join together to strengthen the health system so that it can efficiently serve the hardest-to-reach women and children.

2. Simplification of ART and PMTCT interventions is also critically important

However, full integration of ART and PMTCT will not be sufficient alone to bring implementation to a higher level of efficiency and effectiveness. Further simplification of the PMTCT and ART interventions themselves is also a critically enabling factor to enable fully integrated PMTCT and ART services to be provided at the primary level of care.

First, the antiretroviral regimen in general and the antiretroviral drug prophylaxis regimen for PMTCT in particular need to be simplified. As outlined earlier, of the two choices in WHO’s 2010 PMTCT recommendations, Option A is clearly more complicated than Option B, in requiring maternal antenatal and intrapartum antiretroviral prophylaxis, a different antiretroviral postpartum “tail” to reduce risk of drug resistance, and postpartum antiretroviral prophylaxis to infants throughout the duration of breastfeeding. Furthermore, under Option A those mothers who do require treatment for their own health begin lifelong antiretroviral therapy with a different drug regimen. In contrast, under Option B, a single preferred antiretroviral regimen can be used for all women. Therefore, while both Option A and Option B have comparable and very high individual level efficacy, resulting in <5% vertical transmission rates in clinical trials conducted in relatively well-resourced and controlled environments, the “real world” operational public health effectiveness for Option A and Option B may be quite different from one another due to the greater simplicity of Option B, especially in the context of a weak health system. While in its 2010 guidance WHO noted the potential advantage of Option B’s simplicity in administration, at the time the guidance was issued there was little real world country data yet to compare the effectiveness of the two options, since the clinical trials had only recently been completed. Therefore, the great majority of high-burden countries made decisions to adopt Option A, given the lower costs of drug regimen per pregnant woman treated. However, as implementation has progressed and the enrollment of pregnant women on ART has continued to lag, it has become apparent that the complexity of implementing Option A is a key bottleneck that is contributing to slower progress than desired.

However, while Option B is clearly simpler than Option A with respect to the drug regimen, the laboratory and timing requirements of both options complicate implementation. Both require CD4 testing to identify who needs life-long treatment, and this has been a major barrier to access in many settings, especially in hard-to-reach areas, but even to a surprising degree in higher-level health facilities. Additionally, although all women start out with the same regimen under Option B, those who do not yet require ART for their own health must stop it for a period of time after the cessation of breastfeeding. This complicates implementation, requiring a system to confirm breastfeeding has stopped, transfer out a fraction of women from the ART program, keep these women in follow-up, and then re-start them on ART at some point in the future. Furthermore, especially given the high
fertility rates that exist in many countries with high HIV prevalence, option B would effectively require that some women start and stop ART multiple times over the course of several pregnancies.

Equity requires that we seek to reach the hardest-to-reach women, children, and families first. While, well-resourced higher-level facilities and “centers of excellence” may have had some degree of success in implementing Option A or Option B, even these facilities have typically had extreme difficulty obtaining the 90% ART coverage target among pregnant women living with HIV in need of treatment recommended in the Global Plan. To reach all women and children in need, and especially the most vulnerable, the currently complex PMTCT and ART interventions need to be greatly simplified, effectively merging into a single intervention for pregnant women.

3. **Option B+**: full integration and simplification at the primary health care level

The good news is that a fully integrated and simplified approach to PMTCT and ART has now begun to be implemented successfully on a large scale. As mentioned earlier, “Option B+” provides a potentially better alternative to Option A or Option B through which all pregnant women living with HIV can initiate ART for life regardless of CD4 count. After an in-country consultation to assess the feasibility of Option A and Option B, Malawi concluded that neither would be best for its country context, choosing instead Option B+, for reasons which have been outlined in detail elsewhere. From a health systems standpoint, Option B+ streamlines PMTCT by enabling simplification of the supply chain, monitoring systems, and program management. At the service delivery level, Option B+ also streamlines implementation with a “one-size-fits-all” approach that is easy for patients and providers to understand. Through making a positive HIV test the only condition necessary to initiate ART, Option B+ makes it feasible to implement the most effective PMTCT interventions for mother and child at the smallest and most remote health centers, thereby ensuring that lack of access to CD4 testing does not prohibit women from receiving needed treatment. Additionally, Option B+ also provides a straightforward approach to postnatal follow-up that can be integrated with efforts to help women safely breastfeed their infants. And, by avoiding the “start-stop-start” approach that would be required with option B for many women who might have more than one pregnancy, Option B+ makes it easy to convey clear public health message to all people in the community that ART, once started, needs to be adhered to for life. Furthermore, Option B+ offers additional potential health benefits, including reduction in sexual transmission of HIV and improved maternal health.

It is important to recognize that Malawi’s decision to adopt Option B+ involved embracing much more than a change in an antiretroviral drug regimen. Rather, Malawi rightly saw that what was called for was simplification and integration of PMTCT and ART programs, services, and interventions on every level. The leadership of the two programs therefore joined together, revising the national guidelines, supply chain, monitoring and evaluation, and human resources strategies and plans for both PMTCT and ART. Full integration also occurred at the service delivery level, as Malawi utilized an equity-focused approach of nurse-administered ART in all facilities providing MNCH services, thereby making the services available to women and children close to where they live and without requiring referral out to other facilities. Malawi also capitalized on the opportunity to integrate HIV interventions with other services in MNCH facilities, for example by integrating the routine offer of family planning into the standard package of ART follow-up for all women initiating Option B+. 
As mentioned earlier, the initial experience with implementation of Option B+ in Malawi, which began nationwide in late 2011, has been very positive, with a more than 5-fold increase in the quarterly number of pregnant women initiating ART as compared to before Option B+ was implemented (7,218 in Q 4 2011 vs. 1,257 Q2 2011)\(^1\). In the first full quarter of implementation of Option B+ at all MNCH facilities, pregnant or lactating women represented ~40% of all new patients initiating ART (14,017 out of 34,669)\(^1\). As a result, the total numbers of all patients initiating ART in the national program increased by an astounding 88% after implementation of Option B+ for only one quarter. While these dramatic proportions are expected to decrease somewhat in future quarters after an initial backlog of women have all enrolled on Option B+, it is still predicted that almost 25% of all people newly initiating ART in Malawi will be pregnant once the system reaches steady state.

As countries respond to the recent WHO programmatic update and consider whether to adopt Option B or B+, they can be encouraged by Malawi’s initial success. While each country context will be different, Malawi’s experience provides a public health “proof-of-concept”, demonstrating the dramatic benefits that can come about in part through adopting one simplified regimen for all women in PMTCT. A simpler regimen can open up a new world of possibility in terms of how and where ART can be implemented, making it much more feasible to implement ART at the lowest level of the health system. However, it would be misguided to conclude from this success that a change in regimen alone will be the panacea for the problems of PMTCT. Malawi’s early success has been the result of a number of synergistic factors coming together, including strong leadership, a fully integrated approach to ART and PMTCT, and an equity-focused strategy of nurse-initiated ART within primary care facilities. Nevertheless, while Option B/B+ is not a PMTCT panacea, it is likely

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**Figure 1**

Malawi’s Early Success: More than a ARV Regimen

**Radical Simplification of ART–PMTCT Interventions**
Lifelong ART for all pregnant women living with HIV (Option B+)

**Full Integration of ART-PMTCT Services**
Nurse initiated ART in all MNCH settings

**Full Integration of ART-PMTCT Programmes**
Management, M&E, Supply Chain, Human Resources, Lab

**Equity, Effectiveness, and Broader Health Impact**
High ART access for pregnant women on the primary care level
“Treatment 2.0” and Treatment as Prevention
Strengthened health systems and MNCH services
one essential component of a highly efficient and simplified modality of PMTCT-ART implementation at the primary care level. However, it is also important to recognize that long-term success with Option B+ for Malawi and other countries will not only depend on the ability to initiate high numbers of pregnant women on ART, but also to retain them on life-long ART.
3.0 Key Considerations for Processes and Policies: Building Consensus at the Country Level

Since the beginning of widespread implementation of PMTCT in low and middle-income countries about a decade ago, there have been multiple changes in recommended prophylaxis regimens, beginning with short course AZT and single-dose nevirapine, followed by the 2006 WHO guidelines which recommended more effective regimens for prophylaxis and ART for the pregnant women with CD4 less than 200, and then the 2010 guidelines recommending Option A or Option B for prophylaxis and a CD4 cut off of less than 350 for life-long ART. With each change in guidelines, substantial transaction costs have occurred, including revising guidelines, retraining of providers, adapting monitoring and evaluation systems, and developing new plans for procurement and supply chain management. It is understandable that countries may be weary of the many changes, and perhaps even hesitant to consider making further policy changes in response to the 2012 WHO programmatic update.

However, on the positive side, those countries that begin the discussion now about transitioning to Option B+ can be energized by the realization that once Option B+ is adopted the basic approach of treating all pregnant women living with HIV is not likely to change again soon. If countries plan well for this transition, they can move forward focusing on how to continuously improve their PMTCT and ART programs, rather than being preoccupied by which antiretroviral regimen to use. This includes focusing on optimal infant feeding practices and improving routine postnatal follow-up for both mothers and infants. Seen in this light, Option B+ offers a great opportunity to focus on implementation with a long-term view, optimizing systems that can be used for many years to come. With this in mind, the following section outlines key processes that countries may find helpful in coming to consensus about whether to adopt Option B or B+, and also outlining some key policy issues that may need to be addressed if the decision is made to move from Option A to Option B or B+.

1. Foster collaboration of PMTCT, ART, and other health programs

Cultivating a collaborative and inclusive environment is important throughout the process of coming to consensus at the country level about whether and how to adopt Option B/B+. In most countries structures exist which provide technical guidance and oversight for PMTCT and ART implementation, often called technical working groups (TWGs), though the nomenclature differs from country to country. While PMTCT and ART technical structures are often somewhat separate from one another, in order 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 with one another in order to conduct a feasibility assessment of different PMTCT regimen options. After the decision to adopt B+ as a regimen, these groups continued to operate as one unit in planning for the roll-out of the implementation of ART in all facilities providing MNCH services. Such high-level integration of the technical leadership and management functions of PMTCT and ART programs is likely a prerequisite to seeing subsequent 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 with “real world” implementation experience at the facility level, technical advisors from international agencies, women, including mothers, living with HIV, and experts from other health program areas, such as MNH, family planning, infant feeding and nutrition, and child health.
In most countries different levels of cooperation exist between HIV and other health programs, such as MNCH and family planning. However, in some cases there may be a history of competition for limited resources or even some tension between different program areas. In light of this reality, other stakeholders beyond the HIV program may approach the possibility of providing antiretroviral therapy for all women in PMTCT with some skepticism or even opposition. A reflex reaction may be to oppose such a policy based upon fears that it will further drain human and financial resources away from under-supported MNCH and FP programs.

Rather than ignoring such concerns or moving into a competitive mode, the HIV program would be wise to respond in a spirit of true collaboration, recognizing that HIV programs now have clearer shared interests with MNCH programs than ever before. HIV treatment of all pregnant women would mean a very large fraction of patients starting ART will be initiating services within MNCH clinics and will be followed-up at the primary health care level. The ART program therefore needs the MNCH clinics to function well. Recognizing this reality HIV, MNCH, and family planning programs can come together to brainstorm about how to use this opportunity to collaborate more intentionally. (See Section 5.1 for more on this subject)

2. Rapidly assess PMTCT progress, focusing on ART access and equity

As a first step to inform the discussion about whether to adopt Option B or B+, countries may find it helpful to rapidly assess their current PMTCT progress. An in-depth and time-consuming review of national program may not be necessary, and indeed would not be advisable in most cases, as this could lead to unnecessary delays. Rather than muddle the picture by looking at too many details, program should hone in on a few core indicators to honestly take stock of performance.

In making such a rapid assessment, arguably the most critical criteria to examine is what proportion of pregnant women in need of ART in a given country, state, region/province, district, or facility are accessing ART.\(^2\) This is a clear and simple barometer of how well the PMTCT program is doing, and data should be readily available for this indicator (though unfortunately in many cases it may not be - which in and of itself would be a strong indication that change is urgently needed!) Importantly, countries should evaluate ART access for pregnant women on a sub-national level through an equity-lens, seeking to determine whether the hardest-to-reach women are accessing ART, or whether, as is often the case, the pregnant women who are accessing ART disproportionately hail from certain areas of the country or facilities with better access to resources. Programs should examine both the numbers and proportions of pregnant women accessing ART, as well as the types and locations of facilities that are providing ART for pregnant women. If ART services are predominantly relegated to higher level facilities, urban areas, and “centers of excellence” supported by external partners, this should be a sign that change is needed. As part of the process of analyzing access of pregnant women to ART, programs are also highly encouraged to examine ART access for infants and children.

In addition to looking at quantitative data, programs may want to incorporate qualitative feedback from health workers and end-users if possible. This information may be readily available from recent site visits that have been conducted as part of regular supervision or program reviews, or perhaps could be rapidly obtained via a survey of a few health workers using mobile phones or other means. 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. They can also be queried about whether they believe it is realistic to expect to reach the MTCT initiative

\(^2\) The number of pregnant women in need of ART 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.
target of 90% of pregnant women in need receiving ART using their current ARV prophylaxis regimen (i.e. Option A or B) and approaches to implementation.

After completing such a rapid assessment, countries will likely fall mainly into two categories. A few countries which are implementing Option A may find that they are on track with respect to their PMTCT and ART goals and targets. As WHO noted in its April 2012 programmatic update, such countries do not necessarily need to prioritize switching from Option A to Option B or B+, at least in the short term. On the other hand, many countries will likely find their current progress is far off track with respect to reaching pregnant women with ART. For these countries, major changes should be considered, including adopting Option B or B+.

3. Come to consensus on optimal modalities of PMTCT-ART service delivery

Before proceeding to decide on a specific drug regimen (i.e. A, B, B+), it is advisable to come to consensus on what mode of implementation of ART is best fit to the particular goals and context of a country. The mode of implementation includes where ART for pregnant women will be implemented (location), who will initiate it (providers), and when ART will be offered to women (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”15 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 physicians only or ART-initiated by other cadres as well, including nurses/midwives and clinical officers. And with respect to timing, possible models include timing of the ART visit being coordinated with ANC and MNCH visits in the postnatal period versus relatively uncoordinated (i.e. ART is only offered at certain days or times that does not necessarily overlap with ANC or other MNCH visits).

Evidence supports what common sense would also seem to indicate - that implementation of ART for pregnant women within MNCH clinics can result in much higher levels of uptake than when women are referred out to other sites, such as for example ART clinics at 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.16 Other programmatic experience also strongly supports the contention that providing ART within MNCH can increase ART uptake compared to referring out to other sites. Indeed, even when pregnant women are referred out from MNCH clinics to separate ART clinics within the same facility, such as often occurs in large hospital settings, these referrals can be associated with high rates of LTFU.17 Therefore, it is advisable, at least in most high HIV prevalence settings, to aim to initiate ART for pregnant women in the same facilities that provide MNCH services, and in the same clinical space whenever possible.

While co-location of PMTCT-ART services for pregnant women is important, it is generally not sufficient for optimizing ART-PMTCT uptake. For example, in one observational study, there was little difference between uptake among three clinics using a full-integrated, partially integrated, and un-integrated location of ART-PMTCT services.18 In this case, though the clinic had an integrated location, different providers were providing ART and PMTCT services (physicians vs. nurses) and at different scheduled times. This underlines the importance of integrating all three aspects of services - location, providers, and timing – to maximize the likelihood of pregnant women initiating ART. Indeed, arguably the most critical ingredient of the Malawi’s early success with Option B+ is that Malawi chose 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 are carefully transitioned at some point after delivery, to another clinical space where lifelong ART can continue to be provided, preferably, though not necessarily, in the same facility. The optimal timing and location of transition from PMTCT to a separate long-term ART program 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.

Along with 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 core responsibility of ensuring HIV-exposed and infected infants receive the necessary interventions in the postnatal period. This includes early infant diagnosis, support for breastfeeding and nutrition, cotrimoxazole, nevirapine or zidovudine prophylaxis for the first 4-6 weeks after birth, and, for those infants who are infected, timely ART. Given the number of different interventions that HIV-exposed and infected infants require, it is important that there is a “home” at the facility where the needed care and longitudinal follow-up is coordinated. A family-centered approach in which mothers and infants have the same “home” for care has been implemented successfully in many contexts, and this model also offers the potential to bring male partners in for testing and treatment.

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 the needed services for HIV-exposed and infected children. Overall, in order to maximize equity, population-based coverage, and 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. It is important to allow for the fact that 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. However, if ART is not provided in the same clinics or facilities where women test positive, active, timely referrals need to be implemented to ensure that pregnant women start ART as soon as possible after diagnosis and are not LTFU. An active referral means that the referring site takes responsibility for ensuring the referral is accomplished, for example by accompanying the pregnant women to the ART clinic and systematically verifying that ART was initiated.

4. Compare the operational effectiveness of Options A, B and B+

Once consensus has been reached about what the main mode of implementation should be for a country’s goals and context, the next step is to come to agreement on what the form of PMTCT-ART protocol (Option A, B, or B+) is a best fit for this mode of implementation. “Operational effectiveness” is a broad term that encompasses both the feasibility of implementation in “real world” clinical environments as well as broader health system issues that relate to the scalability of an intervention to achieve high population-based coverage. WHO’s recent programmatic update has already stated that Options B and especially Option B+ are likely to have greater operational effectiveness due to greater simplicity than Option A. With this helpful guidance, countries can move forward to validate whether Option B or B+ is likely to be operationally superior in their context.

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5 Indeed, it is clear that adopting Option B/B+ in settings where ART is not provided on at the same site where HIV testing occurs could be highly problematic without such active referral systems in place. In such cases, if women are referred out to an ART clinic, but not given any antiretroviral prophylaxis, Option B/B+ could have unintended negative consequences in reducing access to prophylaxis for PMTCT.
Now that countries have been implementing Option A or Option B for some time, they have the advantage of having data to better inform a comparison between Option A, B, and B+. However, since a country is typically implementing only one of these three options, the evaluation of how well other options that are not actually being implemented might function will have to depend to a large extent on expert opinion, estimates, and educated judgments. Countries may not need to do an in-depth assessment that would involve gathering new data, but in most cases may be able to estimate what the comparative effectiveness of implementing the three regimens (A, B, and B+) might be in their context based upon existing data and experience. Estimating a range of what proportion of pregnant women would be able to access ART using either option A, B, or B+ may be helpful, and can also be useful in later comparison of incremental cost-effectiveness (see Section 3.7 below).

Malawi’s experience shows that such consultative processes, though they are less definite in some ways than a formal evaluation, observational study, or comparative clinical trial, can nevertheless be extremely useful. In comparing the projected feasibility of implementing different PMTCT regimens in its context, Malawi conducted a consultation, using information from its current programs to identify key bottlenecks that it saw with regard to Options A and B. For Option A, Malawi had already found that implementing a combination PMTCT regimen in the antenatal and intra-partum periods was challenging. Many health providers and patients both had difficulty understanding the complexity of the different drug regimens, including which drugs should be taken and when. And in considering Option B, Malawi noted that lack of wide availability of quality assured CD4 testing was a major bottleneck to women accessing ART. Furthermore, for both Option A and Option B, Malawi’s consultation noted that telling some women to stop ART after breastfeeding could lead to confusion in the community about the need for life-long adherence to ART. In light of these considerations and others, strong consensus was reached that option B+ was best for Malawi. A similar process may be helpful in enabling other countries to come to broad agreement about which regimen to use. Table 2 below outlines some inter-related elements that countries might consider in comparing the operational effectiveness of the three options.

<table>
<thead>
<tr>
<th>Key Element</th>
<th>Questions to Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory requirements</td>
<td>Is the regimen dependent on high access to CD4 testing to function effectively?</td>
</tr>
<tr>
<td>Simplicity for providers</td>
<td>Is the regimen easy for nurses and other providers to understand and implement?</td>
</tr>
<tr>
<td>Equity</td>
<td>Can the regimen be effectively provided in hard-to-reach areas, with marginalized communities, and at the lowest level of the health system?</td>
</tr>
<tr>
<td>Timing-dependence</td>
<td>Is implementation of the regimen dependent on timing, including starting and stopping drugs at different times and/or specific timing of labs?</td>
</tr>
<tr>
<td>Follow-up pathway(s)</td>
<td>How will mothers and children be followed on the different regimens? Is a single, streamlined follow-up pathway possible?</td>
</tr>
<tr>
<td>Dependence on breastfeeding duration</td>
<td>Does implementation of the regimen cease at the cessation of breastfeeding? If so how will it be verified that women have stopped breastfeeding?</td>
</tr>
<tr>
<td>Supply chain</td>
<td>How complicated are the supply chain requirements for the regimen? Can the supply chain easily be integrated with the ART supply chain?</td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>How straightforward is it to monitor and evaluate receipt of the regimen? Can M&amp;E systems for the regimen be integrated with those for the ART program?</td>
</tr>
<tr>
<td>Adherence messages</td>
<td>What adherence messages and support need to be provided with the regimen? Are these consistent with those of the national ART program?</td>
</tr>
<tr>
<td>Integration Suitability</td>
<td>How easy will it be to integrate the regimen within MNCH, ART, and family planning platforms and services?</td>
</tr>
<tr>
<td>Community Engagement</td>
<td>What are the structures in place in health facilities and community systems (e.g. church, traditional, networks of people living with HIV) for demand creation and service delivery support?</td>
</tr>
</tbody>
</table>
5. What do women want? Exploring the acceptability of Options A, B, and B+

A critical component for how well an intervention will work is how acceptable it is to its recipients. In choosing antiretroviral 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, in comparing Options A, B, and B+ it is important to hear from women living with HIV themselves regarding which option they would prefer, and also 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 section 3.6 below 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 fraction of 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.

With this in mind, countries may want to use qualitative methods such as surveys or focus groups to understand in their own local cultural context women’s perceptions, attitudes, and preferences with regards to Options A, B, and B+. Countries can use the information they glean to inform their policy decisions as well as their future implementation plans. In this regard, some countries may want to invest to conduct more in-depth qualitative studies, sometimes called “formative research”, which can inform future behavior change communication messages to increase ART uptake, retention, and adherence (see more on this topic in section 4.3.1). As part of this process, countries may want to explore broader issues related to cultural or community acceptability of the interventions, such as whether it is a preferred norm for all women to receive the same intervention or whether people think there could be a “spillover” effect in reducing adherence in the larger national ART program if large numbers of women in the community were known to be stopping and starting ART under option B. Countries may also explore the community and individual-level acceptability of Options A, B, and B+ in relation to infant feeding practices, particularly breastfeeding.

Regardless of whether Option B or B+ is the national policy chosen, a respect for autonomy and human rights requires that the risks, benefits, and alternatives or a recommended course of treatment be communicated to patients in order to have true informed consent. Option B+ may have clear advantages in terms of operational feasibility, and these benefits should have an important role in informing a country’s decision about what policy to recommend. To balance individual autonomy vs. operational effectiveness countries may glean lessons from prior HIV policy changes that have led to implementation successes. These include: 1) the adoption of “opt-out” HIV testing, in which pregnant women are routinely offered HIV testing; and 2) the WHO 2010 infant and young child feeding recommendations, under which national or sub-national authorities make a directive recommendation about an optimal infant feeding practice for a given context. In each of these cases women are provided with a clear recommendation, but also given the right to “opt out”. Based upon these models, countries adopting Option B+ may want to consider an approach, where all women are recommended to continue on ART, but in which women with CD4 > 350 are given specific counseling on the potential benefits, risk, and alternatives to ART, so that they may “opt-out” after the cessation of breastfeeding for a time if they so desire.

6. Consider other benefits of option B/B+ beyond PMTCT

In deciding which regimen and associated mode of implementation is optimal for its context, each country may also want to consider other criteria beyond safety, individual-level efficacy, equity, effectiveness, operational effectiveness, and acceptability. Some specific elements that stand out as possible additional benefits of adopting Option B/B+ include the following:
Randomized clinical trials have demonstrated that "treatment as prevention" is highly effective in preventing sexual transmission of HIV, with a greater than 95% risk reduction observed in transmission between discordant couples. Adoption of Option B and especially B+ should therefore have a significant effect in reducing new HIV infections at the population level.

Reducing the incidence of tuberculosis: Starting treatment in women with CD4 counts higher than 350 dramatically reduces incidence of active tuberculosis. 

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. While it is very difficult to conduct a randomized trial to prove this, given that very large numbers of people that would need to be studied and ethical considerations, the biologic plausibility for such a benefit is high. 

Increasing uptake of ART and retention in ART programs: By requiring that ART services be decentralized to all facilities providing MNCH services, the Option B+ approach has the potential to improve ART access not only for pregnant women, but also for other populations of patients needing ART in remote areas, including children. As compared to Option B, Option B+ also has a potential advantage of avoiding 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: Implementation of ART in primary care facilities will present the opportunity and obligation to strengthen MNCH services and the health systems that support them. 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: Breastfeeding for women living with HIV may be safer under ART. For exposed infants, ART may reduce child mortality related to diarrhea and chronic malnutrition such as stunting linked with not breastfeeding.

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

Before committing to adopting Option B or B+ and associated policies that can make it work, it is important to estimate both the cost and incremental cost-effectiveness of implementing each option in comparison to one another (A, B, B+). Estimating cost and cost-effectiveness requires specialized expertise which may not be present among ART and PMTCT technical experts. Therefore, it is advisable to engage others with the requisite experience. A methodology for assessing cost and cost-effectiveness of the different options has been developed by UNICEF, Clinton Health Access Initiative CHAI and the Business Leaders Council (BLC), that can be can be quickly adapted to a particular country context to enable local estimates to be made without “reinventing the wheel”. Other methodologies may also be available and useful.

Most of the ongoing additional expenses of Option B relative to A or Option B+ relative to B is the cost of ARVs. This is relatively straightforward to estimate, and for an efavirenz/TDF/3TC regimen the current annual cost is $159 per patient year. However, it is also especially important to include additional staff costs that may be incurred in implementing Option B or B+, such as additional nursing time required to administer ART, as well as financial support to community structures to expand treatment adherence and other ancillary support services. The additional cost for training, supervision, and revising monitoring and evaluation systems should also be included. In addition to being necessary to assess the fully-loaded costs, this information is important for the HIV program to be able to financially support a fair share of the human resources at primary health clinics implementing MNCH services that will now be taking on the additional responsibility of ART. In a similar way, other costs for running such sites (electricity, maintenance, security, etc.) should be included. Short-term and long-term costs should be differentiated from each other as well as one-
time costs and recurring costs. With regard to short and long-term costs for individual patients, it should be recognized that women with higher CD4 levels who under Option B would stop ART will on average need to start ART again in a few years. Given that a young person who initiates ART should expect to remain on it for life, the absolute life-time cost of ART in an individual is not much different in a patient on Option B+ vs. B (or B/B+ vs. A either).

With regard to cost-effectiveness, it is essential to compare the incremental cost-effectiveness of Option A, B, and B+ 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. This difference between efficacy and effectiveness is indeed fundamental to the whole process of comparing the different options. As part of the analysis of feasibility and effectiveness, PMTCT-ART technical structures may have derived ranges of how effective they think Option A, B, and 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 important benefits of earlier treatment, most notably reduction of sexual transmission and incident tuberculosis cases. Importantly, the costs of failure should also be included in the overall analysis, given that a less effective option creates additional costs in terms of the need for paediatric treatment (and also adult treatment if the benefits of earlier treatment for prevention of sexual transmission are taken into account). Countries may also want to include a sensitivity analysis to understand how the cost-effectiveness is sensitive to the price of ARVs, as ARV prices continue to decline, and much less expensive to manufacture possibilities may be available in the future. Including such possibilities in the estimate may help encourage stakeholders that Option B or B+, while perhaps requiring an increased investment now, will become increasingly cost-effective, and perhaps also cost-saving in the future. (For more on cost and cost-effectiveness related to B/B+ see a “Business Case for Options B and B+ to Eliminate Mother to Child Transmission of HIV by 2015”).

8. Reach consensus on a recommendation for the optimal regimen

Having deliberated on the technical issues above as well as others that may arise, the PMTCT and ART technical structures can then seek to come to a consensus about which mode of implementation of ART (i.e. nurse-administered in MNCH vs. other) and also which protocol (A, B, B+) they think is technically optimal in their country context. Based upon this the group may want to draft a brief note, outlining their decision-making process and rationale to share with other stakeholders.

9. Clarify policies and procedures necessary to adopt Option B/B+

Along with the overall decision to adopt Option B or B+, there are a number of associated policy issues that countries will need to make clear decisions on in order to successfully move forward. Some key policy issues that countries may need to address are listed below. These are mostly inter-related and in some cases might be addressed best together through a comprehensive revision of national HIV prevention, care, and treatment guidelines. Performing such a comprehensive revision may be the most efficient way to address these issues, and this is what was done by Malawi in adopting Option B+ (for reference Malawi’s integrated guidelines are publicly available on the internet). 29

- **Antiretroviral therapy regimen:** Countries will need to decide what drug regimen to use for all pregnant women initiating ART, and also whether this will be the same regimen as all other patients initiating ART in the national program. In order to limit the risk of nevirapine-associated hepatoxicity in women with higher CD4 counts and to simplify implementation to 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 or B+. This is in line with WHO’s preferred 1st line drug regimen as identified in its
2011 Treatment 2.0 publication “Short Term Priorities for ARV Drug Optimization”. Recent data has been reassuring about the long-term safety\textsuperscript{26} of efavirenz in pregnancy, and the cost of an efavirenz/TDF/3TC regimen at $159 per patient year is much less than a protease-inhibitor based regimen. 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 program. However, in some cases funding constraints may necessitate 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.

- **Informed consent and the right to “opt out” of ART under Option B+:** Countries that adopt Option B+ will need to consider issues of how to ensure that the autonomy of women is respected. Recommended procedures should be clear about how sites should support and follow-up women with higher CD4 counts who may “opt-out” of lifelong ART after breastfeeding. (See Section 3.5 for more discussion of this issue)

- **Human resources issues:** Nurse-initiated ART is critical for success of Option B or B+. Therefore policies should be clear that trained nurses and clinical officers can initiate ART, and not only continue patients on ART who were already started on ART by physicians. Policies should also be clear that trained nurses can initiate ART in children. Evidence strongly supports having nurses-initiate ART is safe and effective\textsuperscript{27,28,29}. Clear task-sharing and task-shifting policies should also be in place outlining how lower-level cadres can support nurses in different tasks involved in providing care to ART patients (For more on this see section 4).

- **Indications for referrals of ART patients:** While nurse initiated-ART should be the core of many programs, there will be certain clinically complicated cases that should be referred. Guidelines therefore need to clearly spell out what indications are for referrals to physicians and/or higher-level facilities. The vast majority of women starting ART in PMTCT settings are clinically well in WHO stage I or II disease, and therefore only a very small fraction of patients will likely need to be referred.

- **Laboratory testing:** Laboratory monitoring policies and procedures for ART of pregnant and lactating women and children should be harmonized as much as possible with those of the national ART programs. Routine viral load monitoring for treatment failure should ideally be included in national guidelines as per WHO recommendations. Policies and procedures should also be clear about how CD4 testing should be used in monitoring of patients and determining who is eligible for lifelong ART. In particular, for countries that adopt Option B, rather than B+, clear guidance is needed about what should be done in cases where pregnant women do not access CD4 in a timely fashion. To ensure timely ART access, it may be advisable in such circumstances for women to be started on ART under Option B without a CD4 count. However, if this is the case, the default for these women should be that they should stay on ART for life, since there is no baseline CD4 prior to ART initiation that can provide a reference point to determine whether it would be safe to stop ART at the cessation of breastfeeding. For laboratory monitoring for toxicity, countries using a TDF-based regimen should have a clear policy for whether or not routine monitoring of renal function is recommended, and how to manage patients with suspected renal toxicity, whether it is detected clinically or through lab tests. Clear standard operating procedures, policies, and systems also need to be in place to ensure the quality of HIV-testing, particularly under Option B+ where a false-positive test could lead to an HIV-negative woman receiving lifelong ART (Please see Section 4.2.4 for more discussion of this).

- **Adherence counseling and other support:** Adherence counseling is a critical component of ART initiation and policies should state how much adherence counseling should be required before ART initiation and after starting ART. They should also be clear regarding which cadres of workers should be able to provide different types of counseling and what
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 be provided, policies should also make it clear 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 particularly unacceptable.

- **Location of ART services and timing of transition:** Procedures should outline the preferred location(s) for ART services and follow-up of HIV-exposed infants, as well as the preferred timing of any transitions between locations and services, although there will undoubtedly be the need for flexibility depending on the specific characteristics of individual sites. (Please see Section 3.3 for a detailed discussion of this issue)

- **Paediatric ART policies:** As countries revise policies and procedures for Option B/B+, it is highly recommended to take the opportunity to revise paediatric care and treatment polices if needed as well. Indeed, much of the same rationale that supports the Option B+ approach could be used to support a strategy of universally offering ART to all children living with HIV. Among children living with HIV who are under 5 years old, the vast majority already qualify for treatment. While WHO recommends that all children living with HIV under 2 years old initiate treatment\(^{30}\), requirements for CD4 testing to determine who is eligible for treatment in the 2 to 5 year age range often delay or prohibit access to children. The somewhat complicated clinical staging procedures for children can also be difficult for providers in primary care facilities to operationalize. In light these facts, a universal “test and treat” strategy for both women in PMTCT programs and for all children living with HIV, or alternatively all children under 5, merits strong future consideration. Discussions about Option B+ may provide a good forum to begin to consider this possibility. Such an approach could still allow the small fraction of children who receive CD4 testing and do not yet require treatment to “opt out” of it for a time.

- **Testing and treatment of partners:** 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 and B+. Since ART is highly effective in reducing sexual transmission within discordant couples, and because acute HIV infection of pregnant and lactating women is associated with higher risk of MTCT, testing male partners and treating those who are infected is an especially important component of PMTCT programs. WHO published guidelines in 2012 on Couples Testing and Counselling, including recommendations for treating all people living with HIV, regardless of CD4 count, in serodiscordant relationships.

- **Routine offer of family planning to women on ART:** A model where all HIV-positive pregnant women enter one common follow-up pathway provides an excellent opportunity to integrate the routine offer of family planning into ART programs.

- **Infant feeding counseling and support for breastfeeding:** National policies infant feeding in the context of HIV should be made clear and implemented across the board. Breastfeeding for women living with HIV should be recommended under the Option B+ since the use of ART by the mother would make breast milk the optimal feeding practice.

- **Community engagement – in the design and planning of services, in demand creation activities and in provision of support services, including but not limited to adherence support.**
10. 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 related to the highest levels of the government body with authority to make policies. The chances for success should be increased by showing that the recommended changes are not only technically sound, but also cost-effective, broadly supported by many partners, and aimed not only at addressing HIV-related problems but also improving broader maternal and child health. Table 3 on the next page provides a summary of the key process and policy considerations related to adopting Option B/B+. 
<table>
<thead>
<tr>
<th>Key Issue</th>
<th>Suggestions for Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaboration of PMTCT, ART, and other health areas</td>
<td>PMTCT and ART technical structures should collaborate very closely, if not merge into a single group. Be as inclusive as possible with regard to stakeholders from other health program areas, such as family planning, nutrition, and child health.</td>
</tr>
<tr>
<td>Rapid assessment of PMTCT-ART progress</td>
<td>Evaluate ART access for pregnant women on a sub-national level, seeking to determine whether the hardest-to-reach populations have equitable access. Examine 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.</td>
</tr>
<tr>
<td>Modes of PMTCT-ART service delivery</td>
<td>Come to consensus about the preferred modality of ART initiation and follow-up of pregnant mothers and HIV-exposed and infected infants and children. Countries with intermediate and high HIV prevalence should strongly consider an approach emphasizing nurse-administered ART and paediatric care in primary health care facilities that provide MNCH services.</td>
</tr>
<tr>
<td>Operational effectiveness of Option A, B, B+, &amp;B+</td>
<td>Estimate what the comparative effectiveness of implementing the three regimens (A, B, and B+) might be in a country context based upon existing data, experience, and expert opinion. Reach agreement about what would be the most effective regimen for the country context.</td>
</tr>
<tr>
<td>Acceptability of Options B and B+</td>
<td>Use qualitative methods such as surveys or focus groups to understand women’s perceptions, attitudes, and preferences with regards to Options, A, B, and B+.</td>
</tr>
<tr>
<td>Other benefits of option B/B+</td>
<td>Consider other potential benefits of Option B/B+ including: reduction in sexual transmission of HIV, reducing incidence of tuberculosis, reduction in maternal mortality, increased uptake of ART, and benefits for other MNCH and family planning programs</td>
</tr>
<tr>
<td>Cost and cost-effectiveness</td>
<td>Estimate cost and cost-effectiveness of Options A, B, B+, using their estimated “real world” public health effectiveness in a country context. Include long-term costs and costs of failure.</td>
</tr>
<tr>
<td>Address policy &amp; procedural issues</td>
<td>Provide guidance on specific technical issuer related to Option B/B+. Many PMTCT policy issues are inter-related with larger HIV policies. In some cases a comprehensive revision of national HIV guidelines might be the most efficient way to address these inter-related issues</td>
</tr>
<tr>
<td>ART regimen</td>
<td>Decide on an ART regimen for all pregnant women initiating ART (efavirenz, TDF, and 3TC or FTC is recommended) and whether this will be the same regimen as all other patients initiating ART in the national program. Seek to have the same regimen if resources allow.</td>
</tr>
<tr>
<td>Informed consent &amp; right to &quot;opt out&quot;</td>
<td>Ensure policies and procedures protect the autonomy of women and are clear about how sites should support and follow-up women with higher CD4 counts who may “opt-out” of lifelong ART for a time after cessation of breastfeeding.</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Provide clear guidance on quality assurance for rapid testing and indications for virologic, CD4, and toxicity testing. For countries that adopt Option B clear guidance is needed about what should be done in cases where pregnant women do not access CD4 in a timely fashion.</td>
</tr>
<tr>
<td>Human Resources</td>
<td>Ensure that trained nurses and clinical officers can initiate ART and explain how lower-level cadres can support nurses in ART-related tasks.</td>
</tr>
<tr>
<td>Service location &amp; transition</td>
<td>Outline the preferred location(s) for ART services and follow-up of HIV-exposed infants, as well as the preferred timing of any transitions between locations and services.</td>
</tr>
<tr>
<td>Indications for Referrals</td>
<td>Guidelines need to clearly spell out what indications are for referrals from nurses at the primary care level to physicians and/or higher-level facilities.</td>
</tr>
<tr>
<td>Adherence counseling &amp; other support</td>
<td>Clarify how much adherence counseling should be required before ART initiation and after starting ART, as well as which cadres of workers should be able to provide different types of counseling. Ensure ART initiation among pregnant women is considered to be urgent.</td>
</tr>
<tr>
<td>Paediatric ART</td>
<td>Coordinate revisions of paediatric care and treatment policies and procedures (if needed) with changes related to Option B/B+. Consider ‘test and treat’ approach for children as well.</td>
</tr>
<tr>
<td>Male partners</td>
<td>Clarify policies and procedures for male partners, including treatment eligibility criteria.</td>
</tr>
<tr>
<td>Family planning</td>
<td>Ensure the routine offer of family planning to all women on ART.</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>Clarify the infant feeding recommendations for women living with HIV. Ensure consistent and broad implementation of the recommendation</td>
</tr>
<tr>
<td>High-level policy endorsement</td>
<td>Present the comprehensive case for change related to Option B/B+ to the highest levels of the government body with authority to approve policies.</td>
</tr>
</tbody>
</table>
4.0 Key Considerations for Program Planning: Bringing ART into MNCH Settings and Bringing Women and Children to the Services

Many countries have already developed national plans aimed at effectively eliminating MTCT by 2015. This involved an in-depth process that in some cases was only recently completed, and some elements of the plans may not need to change dramatically solely because of the decision to move from Option A to Option B or B+. For efficiency, it is important not to be unnecessarily slowed down by duplication of prior planning processes.

Nevertheless, the decision to move to Option B or B+ will in many, if not most, cases involve a significant shift in certain approaches to implementation. For example where the implementation mode is changing toward provision of ART within MNCH clinics, there will need to be major changes in the plans for training, supervision, supply chain management and other areas. In all cases, new, simplified targets will be needed that reflect greater numbers of pregnant women being initiated and being retained on ART. Budgets will also have to be revised to reflect the increased costs of ARV drugs and other needed health system investments to bring ART services to the primary care level. And, as part of this planning process, countries will also need to decide on what overall strategy they will take to rolling-out Option B/B+.

1. An equity-focused approach to rolling-out Option B/B+

Countries should approach rolling-out Option B/B+ with urgency, at least for the substantial majority that are not making adequate progress using Option A to reach pregnant women with ART. If a justification given for slow, gradual roll-out of Option B/B+ is that ART services are not ready to be provided to pregnant women on such a widespread scale, it should be recognized that high access to ART is in reality a requirement for Option A as well. Challenges in providing ART for a high proportion of women should not be used as an excuse to maintain a status quo that is not working in countries implementing Option A. Rather these may be a clarion call to consider transitioning to a new mode of implementation as quickly as possible.

At the same time, the reality of the situation in many contexts is that systems will need to be revised and strengthened in order 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 start out on the “right foot”, preparing the health system for success and avoiding putting women’s long-term treatment options at risk. For example, measures need to be taken to ensure stock-outs of ART will not occur and that a system is in place to enable monitoring and retention of women on life-long ART. With this in mind 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.

However, if such a phased roll-out approach is adopted it should be equity-focused. Too often services have been rolled-out first to well-functioning, higher-level sites, with the eventual plan to reach harder-to-reach facilities or populations. If programs focus initially only at sites already implementing ART or where external partners are already providing extensive technical support, progress in reaching the most vulnerable women and children will be unacceptably slow. Furthermore, the lessons learned and good practices developed from such pilot implementation may not be applicable to primary care facilities where most women and children access MNCH services.

In this regard, countries may want to glean a lesson from Malawi, which took an equity-focused approach to phased implementation and learning. In this case certain districts were the first to
implement the B+ approach, followed by implementation in all districts nationwide within less than a year after the earlier pilot districts. This approach allows rapid learning from a variety of sites within a district, including primary care centres in remote areas. It also provides the opportunity to optimize higher-level health systems functions at the district level including management and supervision, M&E, and supply chain.

As was noted earlier in Section 3, there are many items that countries need to consider in making a change in regimen to Option B or B+. However, it is also helpful to think broadly about the key strategic thrusts of implementation needed for success. In this regard two challenges stand out for an equity-focused approach in most high and intermediate prevalence settings:

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

The following two sub-sections address some key issues for countries to consider as they plan to meet these two challenges.

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

Different countries and different sub-national areas within countries will have different health system bottlenecks that need to be addressed in order to roll-out ART within all MNCH facilities. Thus, it may be helpful for national programs 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 the facilities that provide MNCH and PMTCT services to also provide high quality ART services. Countries may also consider conducting such bottleneck assessments focused on the supply side in tandem with other activities to better understand barriers on the demand side (see discussion of formative research in 4.3.1 below).

In addressing supply-side and demand-side bottlenecks to women and children accessing services, it is important to look not only at individual health system components, but also to keep in mind the larger concept of 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. Therefore, programs need to invest in the broader MNCH platform, seeking to address structural bottlenecks to HIV and MNCH service integration and to strengthen linkages where these are weak.

With this in mind outlined below are specific ways in which key inter-related elements of the health system may need to be supported in order to implement ART effectively in all facilities providing MNCH services and to retain women and children in the continuum of care. Elements that countries should include in their bottleneck assessments and subsequent planning include: 1) human resources, including with the health and community systems; 2) procurement and supply chain management; 3) monitoring and evaluation; 4) laboratory systems; 5) infrastructure; and 6) health finance.

2.1 Human resources: implementing nurse-initiated ART and task-sharing

Initiation of ART by nurses and clinical officers in MNCH settings is arguably implicit in Option B+, and also necessary for most contexts for successful implementation of option B. As mentioned
earlier, 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 physicians or higher-level facilities. 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.

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 should conduct an analysis to ensure each MNCH facility slated to initiate ART has adequate nursing staff. Since Option B or B+ is actually simpler in most respects than Option A, it may be a reasonable assumption that many sites where nurses are already providing PMTCT prophylaxis could switch to providing ART without additional human resources. However, because the initial adherence counseling of patients starting ART may be lengthier than that for PMTCT, there may be a need to free up some additional time in the nurses’ schedule to enable them to initiate ART. Nurses working at MNCH clinics that do not use individually scheduled appointments for antenatal care and well child visits are often very busy in the morning, but tend to be less busy in the afternoon, so in such settings it may be feasible to schedule some ART clinics in the afternoon.

Nurses will also need to be *trained as ART providers*, as well as other relevant members of the team 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 comprehensive 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. Especially given the expense of off-site training, it may more effective and a better investment of resources to train teams of providers using such a comprehensive approach.

Initiating ART is a substantial new responsibility. Therefore, following training, nurses and other staff need to be *supported from above and supported from below*. Nurses and other staff can be *supported from above* with supportive supervision and mentoring. With regard to supportive supervision, it is recommended a system be in place at the district level by which sites are visited on at least a quarterly basis, and more frequently if possible during the immediate period after they have begun providing ART for all women in PMTCT. Supervision should be integrated, involving both PMTCT and ART services, and should be coordinated and/or combined with supervision visits by other MNCH program areas where feasible to minimize cost and foster collaboration between different program areas. A mechanism should be put in place that ensures rapid monitoring and assessment, with an immediate correction component and follow up. Key focuses of supervision should be 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 stocks of drugs and test kits are adequate, and identifying specific problems that sites are facing. Technology can be explored as a tool to strengthen the supervisory process, for example through the using of smart phones to increase objectivity and provide a score for a future visit. Mentoring refers to a more in-depth on-site coaching through which providers with more clinical experience in ART support providers at sites with less experience to make specific changes to improve the quality of services. On-site mentoring was used by Malawi in rolling-out Option B+, with more than 350 mentors employed to support sites throughout the country.\(^{31}\)

Along with support from above, nurses and other staff should be *supported from below* with task-sharing and task-shifting via other cadres of health workers where appropriate. See section 4.2.2 below for more discussion of how lay cadres and community health workers can be employed to help with the added responsibility of providing ART at the primary care level.
2.2 Procurement and supply chain: ensuring ART supply in all MNCH facilities

Moving from Option A to Option B or 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 in that there is only one regimen rather than multiple regimens. However, the absolute costs of procuring ARVs will be greater with option B/B+, at least in the near future with currently available ARV regimens. In planning the transition to B/B+, countries will need to consider interrelated issues of mobilizing resources for the additional costs of drugs, what procurement mechanisms to use, forecasting and quantification, and coordinating procurement lead times with both funding availability and the implementation schedule of rolling out Option B/B+.

For discussion on mobilizing resources for additional ARV costs, see the “health finance” section below. 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, and where applicable countries can work closely with these donors and the procurement mechanisms they support to see whether these would be helpful in helping reduce the costs of drugs or procurement lead times.

With regard to supply chain management the need to deliver ART reliably to all sites providing PMTCT services, rather than only to a smaller number of higher-level ART centers, may require greater investment in strengthening the supply chain system. Stock-outs of PMTCT commodities at low-level MNCH facilities have been commonplace in some countries in the past. Once MNCH sites have initiated ART services such stock-outs would be even more harmful, as they would not only increase new paediatric HIV infections but now also put mothers at increased risk for resistance.

With this in mind, it is critical that a clear plan and system for managing the supply of ARVs to all facilities be developed. Standardized tools for forecasting and consumption reporting are one important component. Planning should not be done in a top-down only fashion, but should include micro-planning at the district level. Because HIV prevalence does not vary seasonally, the number of HIV positive pregnant women at each site may be relatively predictable in a given quarter, which should help with quantification of ARV needs by site. Given this predictability, it may be reasonable to use either a “push” or a “pull” system depending on the country needs. Wherever feasible, programs should seek to fully integrate the ARVs into the supply chain system that serves primary care facilities that provide MNCH services, rather than using a separate vertical system for HIV commodities. Indeed, ensuring a reliable supply of other MNCH commodities is critical as part of the continuum of care for mothers and children. 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.

Measures to ensure commodity security are also critical, given that ARVs are quite valuable commodities and the risk of 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.

2.3 M&E: clear targets, integrating PMTCT and ART systems, and utilizing data

Adopting Option B or B+ can greatly simplify monitoring and evaluation of a plan for elimination of mother to child transmission and help all stakeholders have a clearer understanding of whether progress is on schedule. Rather than having multiple regimens to track for different categories of women, there is now only one.
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. These targets could be followed on a sort “dashboard” at each level of implementation, being used to energize the roll-out of option B or B+.

Secondly, integration and linkages between ART and PMTCT monitoring systems is critical. One major potential advantage of Option B/B+ is simplified and streamlined monitoring and evaluation. Monitoring and reporting is simplified by the adoption of one regimen for all pregnant and lactating women rather than multiple regimens, and also by providing ART in primary care facilities where women access MNCH services rather than by referring women out to other facilities. Additionally, a critical area of weakness for many PMTCT programs has been developing robust monitoring and evaluation systems to follow women and children longitudinally over time. Because by necessity ART programs already have such cohort monitoring systems in place, Option B/B+ provides an excellent opportunity to address this weakness because the women in the PMTCT program can be naturally integrated into the ART monitoring system.

Nevertheless, there will likely still be changes that may need to be made to enable such integration of PMTCT and ART M&E systems. Firstly, if ART registers are be used to track the progress of the PMTCT program they have to be revised so that information on pregnant and lactating women is included in a manner that is useful for monitoring, if this is not already the case. Adding in a space for family planning on ART registers may be needed to integrate the routine offer of family planning into the ART program. Furthermore, if option B, rather than B+, is used, how to deal with transfers out of the ART program 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 may also need to be revised to reflect the new Option B/B+ regimen. In particular it is critical that programs have a national register in place for follow-up of HIV-exposed infants and children, which includes the necessary interventions in the postnatal period, such as early infant diagnosis, infant feeding, cotrimoxazole, and postnatal zidovudine or nevirapine prophylaxis from birth through ages 4-6 weeks (with Options B or B+). Patient mastercards are also a critically important tool that will need to be updated. For example in Malawi, four different mastercards were revised as part of the integrated PMTCT-ART program: 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 it is fundamentally important to the entire program.

Of course, revising the various registers and M&E tools is only the beginning. Systems for data quality assurance also remain critical. Health care workers need to be trained in how to use the revised tools and encouraged to use the data to improve programs at the district and primary levels of care. Clear targets for the number of pregnant women initiating ART and for ART retention should provide a strong foundation for district managers and health facilities to continuously improve services and measure progress.

### 2.4 Laboratory systems: quality assurance of rapid tests and expanding virologic testing

HIV testing is the entry-point into PMTCT programs, and it is essential that quality-assurance systems be in place to monitor that testing is done properly and that the correct results are recorded and conveyed to women. As PMTCT services have decentralized to primary care facilities in many countries, it has become apparent in some cases that the quality-assurance of rapid testing is a
weak link. As programs consider moving toward Option B+ at primary care facilities it is more critical than ever that rapid testing be accurate so that HIV-negative women in particular are not mistakenly initiated on life-long ART. 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 fraction 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.

In addition to quality assurance for rapid 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)\textsuperscript{32}. Virologic testing should be conducted first at or around 6 months after ART initiation to determine whether treatment has been effective, and then at regular intervals to screen for treatment failure. 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 approaches 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. 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 Section 5.2.2 for more discussion of this topic).

A country’s decision to adopt Option B+ reflects, among other things, a prioritization of ensuring access to ART for all pregnant women in need over ensuring every woman in PMTCT has a CD4 test before starting treatment. At the same time, 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 it, preferably by 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 can also continue to expand use of point of care CD4 testing machines to lower level facilities, as these machines have shown promise in improving access to CD4 testing.\textsuperscript{33}

2.5 Infrastructure: making adequate space for ART within MNCH facilities

Perhaps one of the more straightforward health systems issues to consider in adopting Option B or B+ is the physical infrastructure required to administer ART in primary health care clinics that also provide MNCH services. Because Option B or B+ is inherently less complex than Option A in some ways, a clinic that has had adequate space to provide Option A may not necessarily need renovations to switch to Option B or B+. However, the additional length of adherence counseling needed for ART and the potentially more frequent visits over a longer period of time with ART may in some cases put a strain on available space. More space may also be required if the ultimate vision is to also have other patients who are not from the PMTCT program come to the facility for ART services (which is recommended). 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. It may be possible to minimize the need for extensive renovations in many cases by better organization of patient flow or services within the clinic and/or by scheduling ART clinics at times when the facility is less busy, which is often the afternoons for facilities that provide MNCH services.

Adequate and secure storage space for ARVs is another must to initiate ART at primary care clinics. This should be assessed by district teams as part of planning for implementation and needed renovations should preferably be done in a way that maximizes the security of all commodities used at the health facility, including ARVs and other drugs.

2.6 Finance: mobilizing adequate resources and strengthening the health system

Mobilizing adequate resources for implementation of Option B/B+ can be among the most challenging aspects of adopting Option B/B+, particularly in the short-term, since it often takes a year or more to successfully apply for new funding, either from internally budgeted sources and/or external sources. Since adopting an Option B/B+ approach involves providing ART to all PMTCT women, one source of resources for implementation may be reprogramming funding that is already budgeted for ART. Although the two program areas have increasingly overlapped in recent years, in many country budgets and among many donors ART and PMTCT remain separate line items, with ART having a much greater amount of resources than PMTCT. Thus, in the short-term at least, reprogramming resources may be one way to kick-start implementation. In adopting Option B+, Malawi used this approach, reprogramming resources from an existing Global Fund grant. However, using such reprogrammed monies to support initial implementation without a clear commitment for longer-term funding can be a risky approach.

Whatever the case, long-term commitments of additional resources will be necessary to fund the increased cost of Option B or B+, particularly the ARV drug costs. At a minimum this will require additional internal resources that countries themselves make available, and in most cases this will also require additional external resources as well. In making the case for additional external funding, countries are most likely to be successful if they demonstrate not only that they have planned well, but also that they have committed a substantial amount of their own internal resources. Additionally, by making it clear that Option B/B+ is cost-effective in their context now, and also will likely be cost-saving given the larger number of paediatric infections avoided that do not need to be treated as well as declining prices of drug regimens in coming future years.

Utilizing resources effectively to strengthen the health system is another key challenge that needs to be met for successful roll-out of Option B/B+. As outlined in the sub-sections above, for ART to be widely implemented in all MNCH facilities will require investment in human resources (including health and community-based human resources), supply chain management, monitoring and evaluation, and physical infrastructure. As they take on the challenge of more widely providing ART at the primary care level, ART programs should collaborate with and support MNCH, family planning, malaria and other programs areas, finding ways to jointly program resources to strengthen the systems that are essential for the provision of all health services at the primary care level (for more on this topic, please see section 5.1).

3.0 Bringing women and children to services: lay cadres and targeted behavior change communication to support adherence and retention

To eliminate MTCT and keep mothers alive, ART services not only need to be available at the primary care level, but women and children also need to continue to utilize them over time. Clearly, “antiretroviral drugs in the cupboard are not enough”. 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
behavior, 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 be lost-to-follow-up, particularly if the appropriate systems are not put in place. Therefore, along with strengthening the health system to bring services to women at the primary care level, it is important to utilize evidence–based interventions to help bring the women and children to the services. Given that ART requires excellent adherence for the rest of ones’ life, it is essential to invest in interventions that create and sustain demand for services, in addition to investing in the services themselves.

With the adoption of Option B+ in particular, 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 providing ART within MNCH should help improve retention in care, as evidence indicates that rates of LTFU are lower at primary care facilities providing ART than at higher level facilities. Additionally, having the same regimen for all women may increase ART uptake, adherence, and retention somewhat, as this can simplify messages provided to patients, providers, and communities about the necessity to adhere to ART for life once started. Further, having one standardized follow-up pathway may improve retention, especially if the pathway does not necessitate some women being referred out to different sites or services than others.

Notwithstanding these natural advantages of Option B+, the decision to implement this approach also means that both ART and PMTCT will need to move to a higher level of intensity in terms of the focus on interventions to improve uptake, client education for treatment literacy, adherence and retention across the continuum of care. In particular, more attention needs to be given to optimizing the contributions of existing community-based platforms, including linking these platforms more intentionally to facilities providing ART services. A strategy for improving adherence and retention that remains almost lopsidedly focused only on what happens at the facility-level is likely to be ineffective. With this in mind, at least 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 behavior change communication in both clinical and community-based arenas. But in order to maximize the effectiveness of such approaches, it is first useful to conduct formative research.

### 3.1 Formative research and targeted message design

A common gap in messages provided to patients regarding adherence and retention is that they are not usually designed based upon formative research that seeks to understand what people are thinking and feeling in a given local context and the reasons why they might not adhere to medication or be retained in care. Effective interventions for behavior change need to go beyond dispensing information, and should aim at attaining specific behavioral objectives by speaking to people’s hearts and minds. Good formative research is therefore standard practice for developing appropriately targeted messages to bring about effective behaviour change. Countries should therefore strongly consider engaging the technical expertise to conduct such research and use it to design appropriately targeted messages and interventions for their local cultural context.

### 3.2 Maximizing effectiveness of lay cadres and community support groups, with leadership by PLHIV

Lay cadres, on the clinic and community level, have played an essential role in both ART and PMTCT programs. They exist in manifold forms in different countries and settings, with PLHIV often being employed in some fashion either 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 actions on the community level. These cadres already play a critical role in reducing LTFU among PMTCT and ART patients, by supporting patients at the community-level, for example through disseminating messages on adherence or tracking patients who have defaulted from care. They can also support nurses with critical duties on the facility level 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 to be more effective. Related to this, it is highly recommended that sites develop a system to track patients who are LTFU, and that lay cadres are given a prominent role in this.

Equipping the lay cadres with appropriate training and tools is another important step to maximize their effectiveness. This includes ensuring that lay cadres have been trained to disseminate the targeted messages designed through formative research, and also trained in adherence counseling, if indicated. Lay cadres should also 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 with patients who default in a timely fashion. As these lay cadres are the glue that can help to link clinical and community-based platforms, programs should also consider using mobile technology to facilitate communication between the lay cadres and facilities.

Motivating the lay cadres is also an important approach to enhance their effectiveness. Many of these workers, even if they are “volunteers”, often have no other job. Poor renumeration can encourage poor performance. While it may not be necessary or appropriate to pay lay cadres in all contexts, countries should seek to standardize the renumeration that these workers receive to the degree that it is possible. Furthermore, although funding efforts to reduce LTFU has generally not been given a high priority in the past, given the increased need to focus on retention and adherence, national governments and donors should prioritize more funding to support lay cadres.

Along with one-on-one interventions to support patients, support groups are also vital for improving retention and adherence. With the adoption of Option B/B+ there will be a need to have these groups take on an even more prominence, in some cases moving from providing mainly psychosocial support and education toward becoming structured settings in which other important follow-up care can be provided. Lay cadres are already playing an important role in interacting with or leading such support groups at health facilities or in communities, and can be a critical bridge to enable the integration of clinical tasks within such support groups. Given the increased volume of patients on ART with Option B/B+, countries may need to think “outside of the box” to develop new ways to utilize support groups as a forum for follow-up group medical visits (see Section 4.3.1 for more on this).

On 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. As part of this process, one issue to consider is whether there will be a continued need to promote PMTCT-specific support groups, or whether support for the special needs of pregnant and lactating women living with HIV can be integrated into other existing support groups where women on ART will be attending. Especially since with Option B+ women will now be continuing on ART for life after the cessation of
breastfeeding, continuity of care may be best served in some settings by having one PMTCT-ART support group.

PLHIV should have the leadership role both in implementation of these approaches to support adherence and retention, as well as in developing and refining approaches by which lay cadres and support groups can be used more effectively (see Section 5.3.1 for more discussion of this).

3.3 Behavior change: targeted messages in clinical and community arenas

Behavior change communication (BCC) 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 behavior change interventions aimed at increasing ART adherence and retention among pregnant women and ART patients more broadly is an area of programming that has arguably 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. Furthermore, 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 a great opportunity for ART and PMTCT programs, as well as broader HIV prevention programs to come together and commit 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 utilization. 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. The suboptimal retention rates that are currently seen in many national ART and PMTCT programs might be improved if more attention was paid to implementing such state-of-the-art BCC approaches.
<table>
<thead>
<tr>
<th>Key Issue</th>
<th>Suggestions for Countries</th>
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<tbody>
<tr>
<td><strong>Equity-Focused Roll-out Strategy</strong></td>
<td>Approach roll-out with urgency&lt;br&gt;A phased approach, focused on learning by doing, may be necessary in some contexts&lt;br&gt;If a phased roll-out is used, implement initially in a variety of sites within a district, including primary care centers in remote areas. Consider district-wide phased implementation in select districts to optimize higher-level health systems functions (i.e. M&amp;E, SCM, etc.)</td>
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<tr>
<td><strong>Prepare the health system for ART in MNCH settings</strong></td>
<td>Conduct sub-national health system bottleneck assessments to better understand where to focus local resources to enable MNCH facilities to also provide high quality ART services. Assess HR, PSM, M&amp;E, lab, financial, and physical supply-side bottlenecks</td>
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<tr>
<td><strong>Human Resources</strong></td>
<td>Update in-service and pre-service training curricula&lt;br&gt;Assess whether adequate numbers of nurses exist at MNCH clinics to provide ART&lt;br&gt;Train nurses and clinical officers to initiate ART. Train other HCWs at sites to support them&lt;br&gt;Support nurses from above with supervision &amp; mentoring, and from below with task-shifting&lt;br&gt;Train community-based workers for demand creation and service delivery support.&lt;br&gt;Support community-based workers with supervision and mentoring.</td>
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<tr>
<td><strong>Procurement and Supply Chain Management</strong></td>
<td>Consider issues of mobilizing resources for the additional drug costs, procurement mechanisms, forecasting and quantification, and coordinating procurement lead times with funding availability and the implementation schedule of Option B/B+.&lt;br&gt;Develop clear plans and systems for managing the supply of ARVs to all facilities providing MNCH services. Standardized tools for forecasting and consumption reporting and commodity security are important.</td>
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<tr>
<td><strong>Monitoring and Evaluation</strong></td>
<td>Develop and communicate clear targets for pregnant women on ART on all levels&lt;br&gt;Integrate and link ART and PMTCT monitoring systems&lt;br&gt;Update registers, mastercards, and other tools for ART, infant follow-up, ANC, and maternity&lt;br&gt;Train HCWs in the use of the revised tools and encourage use of data to improve programs&lt;br&gt;Strengthen systems for data quality assurance</td>
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<tr>
<td><strong>Laboratory</strong></td>
<td>Implement clear standard operating procedures and a quality assurance system for HIV testing at the level of primary care facilities.&lt;br&gt;Give high priority to increasing access to virologic testing through optimal approaches for a local context, including, sample transport or referrals systems, dried-blood spot testing, and/or emerging point-of-care technologies&lt;br&gt;Provide a clear means for women to access CD4 testing on site or via referral</td>
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<tr>
<td><strong>Health finance</strong></td>
<td>Mobilize sufficient short-and long-term resources from internal and external sources&lt;br&gt;Explore reprogramming ART resources for PMTCT if needed&lt;br&gt;Strategically use ART and PMTCT funds to strengthen systems that support MNCH</td>
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<tr>
<td><strong>Infrastructure</strong></td>
<td>Provide adequate space for ART services and ARV storage at MNCH facilities</td>
</tr>
<tr>
<td><strong>Increasing ART Adherence and Retention</strong></td>
<td>Conduct formative research that seeks to understand what people are thinking and feeling in a given local context and the reasons for poor adherence and retention</td>
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<tr>
<td><strong>Lay Cadres and Support Groups</strong></td>
<td>Formalize the roles and tasks of lay cadres and support groups, including what they will precisely do for PMTCT and ART and how it will be measured&lt;br&gt;Equip the lay cadres with training and tools (i.e. M&amp;E tools, targeted messages, cell phones)&lt;br&gt;Innovate in use of support groups as structured settings to provide follow-up ART care</td>
</tr>
<tr>
<td><strong>Behavior change communication</strong></td>
<td>Develop targeted, reinforcing messages focused on the need for adherence and retention&lt;br&gt;Use clinical and other non-clinical arenas, including community-based groups, peer-to-peer interpersonal communications, and mass media. Link messages to other issues related to prevention, including “treatment as prevention”, partner reduction, and condom utilization</td>
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5.0 Key Considerations for Partnerships: Making the Most of a Tremendous Opportunity to Improve the Health of Women and Children

Adopting and implementing a strategy of universal ART for all women in PMTCT programs is a bold decision with potential to produce tremendous results for women and children. However, to make the most of this opportunity for women and children, buy-in and active engagement from a wide array partners will be essential. In this regard, it is critical to have a common long-term vision for the future that clearly communicates that ART for all pregnant women at the primary care level is not primarily about a change in an antiretroviral prophylaxis regimen or even solely about PMTCT. Rather, when portrayed in the correct long-term light, it becomes clear that the Option B/B+ approach provides an unprecedented opportunity to marry PMTCT with not only ART, but also with broader HIV and MNCH programs.

To unleash the full potential for women and children of an investment in Option B/B+, partnerships are needed that can broaden, maximize, and sustain the impact. To broaden the impact, partnerships between PMTCT, HIV and other health program areas should be intentionally fostered with a shared view of how HIV resources can be used to strengthen the health system and improve the health of all women and children, not just those living with HIV. To maximize the impact, partnerships with the private sector are crucial to expedite the availability of technological innovations that can make implementation simpler, better, and more cost-effective. And to sustain the impact, strong and meaningful partnerships will be needed with people living with HIV and local communities who are the rightful owners of their future.

1.0 Beyond PMTCT: partnering with other HIV and MNCH programs to broaden impact

For PMTCT programs the dream that all pregnant women in the world living with HIV can access ART would likely have seemed impossible to many people a decade ago. Today, given the high rates of HIV testing among pregnant women that have been achieved in many countries, provision of a simplified ART regimen to all pregnant women within MNCH can effectively eliminate MTCT. This is a remarkable opportunity and responsibility which must be met.

However, it would be narrow to focus only on the benefits of the Option B+ approach for PMTCT programs alone. Offering ART within all primary care facilities that provide MNCH services means a paradigm shift for ART programs, as a very large proportion of their patients will now be treated in these facilities. Widespread ART within primary health care clinics serving women can also set the stage for future implementation of effective approaches that use antiretroviral agents to prevent sexual prevention of HIV, including “treatment as prevention”, microbicides, and oral pre-exposure prophylaxis (PrEP). And beyond HIV programs, the Option B+ approach also provides an unprecedented opportunity to bring HIV and maternal, neonatal, child health, and nutrition programs together. As HIV resources are strategically invested in the health systems that support primary care facilities that provide maternal and child health services, a broad and sustainable impact for the health of all women and children can be realized.
1.1 A paradigm shift for ART programs: MNCH as the gateway to Universal Access

Firstly, for ART programs, a universal ART strategy for all women in PMTCT dramatically changes the landscape, creating some challenges, but with these even greater opportunities. The ART program can no longer view the PMTCT program as a minor part of its efforts. With Option B+ increasingly over time the majority of women in the ART program will enter it through PMTCT. For evidence of the dramatic changes that can occur, one need only to look at the early experience in Malawi following adoption of Option B+. In the first full quarter of implementation of Option B+ at all MNCH facilities, pregnant and lactating women represented about 40% of all new patients initiating ART, and the total numbers of all patients initiating ART in the national program increased by an astounding 88%.36 In years to come, the proportion of women starting treatment through antenatal care (ANC) as the entry point may increase further, since many women living with HIV who are starting ART at a late point in programs today would in the future have already started treatment in ANC.

Adopting a strategy of implementation of ART within MNCH facilities therefore can make MNCH services the gateway to Universal Access to HIV treatment for women, children, and other family members. UNAID’s Treatment 2.0 initiative calls for the “radical simplification” of HIV treatment, and advocates decentralizing services to the primary care level as well as reducing costs through several approaches, including task-shifting to nurses and lower-cadres. Option B+ provides a ready-made opportunity to begin to implement these strategies now on a large scale.

Importantly, as countries move to expand Option B+, it is critical to expand paediatric HIV testing and treatment in concert with maternal testing and treatment. Access to paediatric treatment remains much lower than adult treatment access in many high prevalence countries, and children face similar obstacles to their mothers in receiving the care they need, which is often only provided at higher-level facilities, far from where they access primary care. Indeed, the operational barriers that children face in accessing ART are similar if not more extreme. Therefore, as countries consider moving toward Option B+, countries may also want to consider the potential merits of a universal “test and treat” approach for pregnant women and children (see section 3.9 for further discussion of this issue). At a minimum, countries need to ensure that implementation of Option B/B+ integrates paediatric treatment as a key component at every level, including for example training and supervision of providers, supply chain management, monitoring and evaluation. Although Malawi did not adopt a universal treatment strategy for all children, it did use an approach to rolling-out Option B+ that integrated paediatric treatment. This has resulted in significant increases in children enrolled on ART, albeit much less dramatic than the increases in pregnant women initiating ART.

Along with mothers and children, it is important to make the most of opportunities that decentralization of ART services to the primary health care level presents to bring male partners and other adults in for testing and HIV treatment. While reaching male partners can be challenging, Rwanda37 is one example of a country that has had success on a large scale in expanding couples counseling in the context of PMTCT. Overall, it is wise to invest in a manner so that primary health care facilities become hubs for HIV treatment for all people, not just women in PMTCT programs.

1.2 MNCH settings: a new anchor for efforts to prevent the sexual transmission

As facilities providing MNCH services increasingly become centers of HIV treatment, tremendous opportunities also exist to transform these facilities into effective hubs for interventions to prevent the sexual transmission of HIV. “Prong 1” of PMTCT, which is primary prevention of new HIV infections in women of child-bearing age, is essential to meeting the goals of the elimination initiative.
Achieving a population-level reduction in adult HIV incidence in young women will clearly require “combination prevention” in multiple clinical and community-based arenas beyond just MNCH facilities. However, what is sometimes overlooked is how interventions to prevent sexual transmission among women in MNCH settings can potentially be a critical component of the overall effort of reducing infections on the general population level. In the past, efforts to prevent sexual transmission in PMTCT settings were largely limited to counseling for behavior change, condom promotion, and attempting to reach male partners with HIV testing, all of which remain important but also face significant challenges. Now, a new era of HIV prevention is dawning in which a variety of effective biomedical prevention interventions can be implemented through MNCH facilities, adding to the armamentarium of prior interventions to create a much greater potential impact on reducing sexual transmission.

In this regard, implementation of Option B+ with MNCH provides a clear base to begin to implement “treatment as prevention (TasP)” on a large scale. As has been pointed out, TasP faces “a tough road to wide impact”36, with specific implementation challenges that include obtaining high coverage of HIV testing and counseling and also ensuring retention of people on long-term ART. Because HIV testing is readily available in most ANC settings in many countries, and given that most women typically visit ANC multiple times in their lifetime, PMTCT provides perhaps the most feasible entry-point to provide ART to a high proportion of women living with HIV and also to establish a strong follow-up system whereby women can be retained on ART for the long-term.

But treating women living with HIV is only part of the potential that exists for implementing new strategies involving ARVs for prevention within MNCH settings. Helping women who test HIV-negative to stay uninfected is a critical need, and treating the HIV-positive male partners of pregnant women who do not yet have HIV is an important application of TasP to protect both mothers and children. While involving male partners in PMTCT remains challenging, countries should continue to invest in interventions to increase testing and treatment of partners. Importantly, female-controlled methods of using ARVs to protect against HIV infection are on the horizon, including microbicides and oral pre-exposure prophylaxis. As these hopefully become available in the coming years, there is true promise that MNCH settings can become even better hubs for HIV-prevention, providing women a range of effective options that can help them to stay HIV-negative.

1.3 An unprecedented opportunity for integration of HIV and MNCH programs

Just as it would be too narrow to view Option B+ only through the lens of PMTCT and miss the broader potential for HIV programs, it would also be shortsighted not to see the unprecedented opportunity that Option B/B+ provides to bring HIV and maternal, neonatal, and child health programs together for fuller integration. For decades HIV and MNCH programs have made efforts to integrate with one another, and while there has been much progress, the goal of full integration has often remained elusive, particularly with regard to clinical services. Despite the best of intentions at times, HIV and MNCH programs have often remained in their separate spheres. ART in particular has typically not been tied closely to most MNCH clinics.

However, with Option B/B+, implementation of ART on a large scale at sites providing MNCH services significantly changes the equation for how HIV and MNCH programs must relate to one another. It now becomes more essential than ever before for HIV programs to invest in strengthening MNCH services and the health systems that support them. And while PMTCT resources have been significant, at roughly 5-10% of many country HIV budgets, ART resources are typically much greater, sometimes amounting to more than half of all HIV resources in a country. Considering that financial resources for HIV often dwarf those available for broader maternal and child health, it is critical that HIV programs bear the full share of any additional costs incurred from providing ART in primary care facilities. And beyond this, given the disparity in funding between HIV
and MNCH, ART programs should make intentional efforts to find opportunities to use available resources to strengthen the health of all women and children attending primary care sites.

In this way Option B/B+ can energize renewed discussions between HIV, MNCH, family planning, and nutrition programs about how they can collaborate. How can HIV and MNCH programs collaborate to make supervision, monitoring and evaluation, and supply chain management more efficient? How can community level activities and platforms be joined together, such as through integration of BCC activities related to PMTCT and infant feeding and young child feeding? How can having one common pathway of ART for all women create new opportunities for effective integration of family planning, HIV prevention services such as male circumcision and condom provision and HIV testing and treatment? These are the types of questions that programs can ask together to find “win-wins”.

As countries develop local plans to use HIV and MNCH resources together, partners that help to fund the HIV response can facilitate such collaboration in a number of ways. Firstly donors should continue to move toward supporting direct implementation through national systems wherever feasible, and away from channeling most resources through external partners. Secondly, donors should allow flexibility in using HIV funds to strengthen MNCH programs, while still ensuring accountability for HIV results. A possibly useful approach in this regard is results-based financing, in which districts or health facilities can receive incentives for their performance with regard to specific, measurable HIV service delivery outputs. These incentives can then be programmed to meet other local maternal and child health needs that district management teams or facilities have prioritized. Countries such as Rwanda have already used results based financing effectively, with associated improvements in PMTCT and subsequent freedom to use the incentive funding obtained for other health areas. Particularly because the MTCT elimination initiative has a clear, verifiable target to focus on – the number of pregnant women initiated on ART – it is a good fit for such results-based financing approaches.

2.0 Technology: partnering with the private sector to maximize impact

Technology is a key enabling factor that will enable ART to be provided to all pregnant and lactating women and children in need more efficiently and effectively. While the possible applications of technological innovations are manifold with regard to PMTCT and ART, two categories of innovations are highlighted below that could make a large potential impact: 1) better antiretroviral drugs for pregnant women and children and 2) better virologic tests for infant diagnosis and early detection of treatment failure.

2.1 “A better pill”: new ARV combinations for pregnant women and children

One of the foundational pillars of WHO/UNAIDS’ “Treatment 2.0” strategy is a “better pill” – an antiretroviral regimen that is highly tolerable and effective, simple to implement, more durable with respect to resistance, and much less expensive to manufacture than current first-line options. A better pill is important not only to dramatically reduce costs over the long-term, but also to reduce the risk of resistance among patients who may be temporarily lost-to-follow-up.

Incrementally even better pills are indeed possible in the foreseeable future. A 2010 WHO consultation on priorities for antiretroviral drug optimization identified an adult regimen of dolutegravir (a new integrase inhibitor currently in clinical trials) plus TDF and 3TC as a potentially preferred regimen in the medium-term, due in part to its expected lower cost of production, and potentially more robust barrier to resistance than an efavirenz/TDF/3TC regimen. Dolutegravir was also highlighted as a potentially preferred component for paediatric treatment regimens in this consultation, and could be a major improvement in allowing all children living with HIV to be initiated...
on the same first-line regimen, regardless of whether they have been exposed to nevirapine in PMTCT. Furthermore, dolutegravir may have a major advantage for treatment of pregnant women in that, as an integrase inhibitor, it drives down viral load to undetectable levels much more rapidly than other classes of agents. This may be particularly beneficial for women starting ART late in gestation, helping minimize the residual risk of MTCT and perhaps reducing transmission rates to even lower levels than are currently observed in the best programs.

But for a better pill to have maximum impact for women and children a few important bottlenecks need to be overcome. Firstly, pregnant and women and children need to be prioritized in the planning of clinical trials for new drugs, rather than falling to “the bottom of the barrel” as has often occurred in past drug development efforts. While expediting development may be particularly challenging for pregnant and lactating women due to the need to ensure safety for both mother and child, it is essential to be as proactive as possible in the testing of “better pills” in this critically important sub-population. Without such efforts, a situation is likely to arise where a better ARV combination becomes available for other populations of adults many years in advance of when it has been adequately tested for safety in women of child-bearing potential.

Along with expediting clinical trials in pregnant women and children, companies will most likely need to intentionally collaborate with one another toward the common goal of developing the optimal combinations for pregnant women. Exciting possibilities also exist for better ARVs to be used primary prevention, including for example vaginal rings that release microbicides or injectable pre-exposure prophylaxis formulations, both of which may provide adequate drug levels to prevent HIV for a month after a single application. Countries should be encouraged by all of these possibilities that better ARVs are indeed on the horizon, both for treatment and prevention, and that the cost of drugs can be reduced dramatically, especially if innovator companies will work together toward this goal. Countries should therefore add their voices to the calls of multi-national stakeholders to encourage such collaboration, while also doing their part to expedite in-country registration of new ARVs as these become available.

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

Along with a “better pill”, better virologic tests are urgently needed - simplified, inexpensive, point of care (POC) tests for infant diagnosis and also for the purposes of detecting virologic treatment failure early. There are many exciting possibilities in the pipeline for better virologic tests, and these have been extensively reviewed recently elsewhere. It is important to recognize that a single improved technology may not be an ideal fit for both early infant diagnosis and treatment monitoring, and also that centralized laboratory testing systems will likely continue to play an important role in virologic testing even after the advent of these new point of care diagnostics. With this in mind, a few illustrative possibilities are highlighted below for how POC virologic tests could make a big difference for enrolling the most vulnerable children on ART and preventing development of extensive multi-drug resistance.

Firstly with regard to early infant diagnosis (EID), while much progress has been made in scaling-up access to dried blood spot testing, many challenges remain, including difficulties transporting sample from sites, returning the results to facilities, and ensuring that infants that test positive receive their results and initiate ART in a timely fashion. The obstacles facing EID exist at all levels of facilities, but are particularly prominent in rural primary health care facilities far from laboratories. To reach these hardest-to-reach areas an inexpensive and simple to use point of care test would be invaluable, as children could be tested at the clinics where they are already coming for primary health care, receive same-day results, and initiate ART as soon as possible at the same site. Such a simplified EID test, in concert with a “better pill” for paediatric treatment discussed above, could help streamline a “test and treat” strategy for children at the primary care level. It also can provide
sites important feedback in real-time on how effective their interventions are. The excellent news is that several possibilities are on the horizon for an improved EID PCO assay, including an ultrasensitive p24 assay from the Northwestern Global Health Foundation that began field testing in 2011 and may be available as early as 2013. In early testing the assay was 95% sensitive and 99% specific, with projected costs of $7-$15 per test.

With regard to simpler assays for detection of treatment failure, a different approach would likely be needed 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. 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 by at least two approaches. Either they could be placed at intermediate level facilities so that women could periodically be referred up to those centers for testing, or 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 including: the EOSCAPE HIV assay (Wave 80 Biosciences), the Liat Analyser (Iquum), the NAT system (Alere), and the SAMBA Assay (Diagnostics for the Real World).

The challenge for all partners will be to expedite the availability of such tests in resource-constrained settings, while at the same time working hard to learn how best to deploy them in concert with the already existing lab networks that support EID and quantitative virological tests. Whatever the case, different country and local contexts will have different needs that will dictate how best these tests can be used. Therefore, individual countries should take an active role in conducting operational research to understand how to optimize the use of the tests in their local contexts. They should also work to decrease regulatory barriers to the introduction of these promising new technologies.

3.0 “Just and lasting change”: partnering with PLHIV and communities

“Just and lasting change” occurs when “communities own their future”. Technology will play a critical role in making implementation more efficient, and integration of HIV and other health areas will broaden the impact of an investment in Option B/B+. But at its core health is fundamentally about people. As local people plan, implement, and monitor programs intended for them, deep and sustainable impact can occur.

In attempting to increase community ownership and participation, PMTCT programs have often faced an uphill battle, in part because of the complexity of the interventions themselves. Confusion has been commonplace among patients, providers, and communities with regard to the complex drug regimens for PMTCT and also with respect to recommend infant and young child feeding (IYCF) practices for HIV-exposed infants. The WHO 2010 guidance on IYCF was a huge step forward in eliminating much of this confusion through recommending that national or sub-national authorities make a specific recommendation about what IYCF practice is best for a local context. Now Options B and, especially, B+ can clear up the other major potential area of confusion by making it clear that there is now only one simplified regimen for all women. In this way, Option B+ can demystify the once confusing world of PMTCT, making it so simple that each person can easily comprehend her or his role in the effort to reach an AIDS-free generation.

3.1 People living with HIV: driving the implementation of the response

To roll-out Option B/B+ on a widespread scale and reach an AIDS-free generation, PLHIV will continue to play the key role in driving implementation to make it better and more responsive to the
needs of people. An approach of universal ART for pregnant women living with HIV means that the modalities of implementing services will have to change somewhat to accommodate many more people on ART. However, while many more people will be on ART under option B/B+, they will also start treatment when they are healthy. The use of one pill, once-daily regimen for all women should further simplify implementation. A new and simplified form of ART is now indeed feasible which can be increasingly implemented by PLHIV at the grassroots level. As “Treatment 2.0” begins first on a widespread scale within PMTCT settings, women living with HIV should be in the driver’s seat, developing and refining new and more effective modes of delivering ART.

While there are many ways in which PLHIV will be involved in the effort to simplify ART delivery, one important possibility is through transforming PLHIV support groups into settings where ART clinical services can be provided. Through linking these support groups with nurses and lay cadres, it may be realistic to refill medications and provide adherence counseling in such settings. Such group medical visits have been increasingly shown to be an effective modality of delivering care for a variety of chronic medical conditions, including HIV. 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.

In addition to leading the way to develop better approaches to implementation, PLHIV will continue to play a key role in monitoring programs, holding all partners accountable for respecting human rights. As more and more women learn their HIV status and are offered ART, it will be more important that ever to intensify efforts to combat stigma and discrimination on all levels.

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

Along with PLHIV, larger local communities affected by HIV and AIDS must also own the future efforts to eliminate new HIV infections among children and keep their mothers alive. The simple message must get out to everyone that a straightforward intervention is now available that can dramatically reduce maternal and paediatric deaths from AIDS. 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 implementing ART, 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 in the effort to eliminate new paediatric HIV infections. By monitoring progress with respect to these simple targets, local communities can demand accountability for results.

As all partners look toward the future, there is reason for great hope in the face of many challenges. A simpler and better approach to PMTCT is now available that can be understood by all, owned by local communities, and implemented at the grassroots level. The tide is turning. Now is the time to move forward boldly - reaching the hardest-to-reach women, children, and families first – on the way to an AIDS-free generation by 2015.

2 UNAIDS 2011 data


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