Toolkit 2.0

Expanding and Simplifying Treatment for Pregnant Women Living with HIV:

Managing the Transition to Option B/B+

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World Health Organization

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

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Who we are:
Established in 1998, the Interagency Task Team (IATT) for the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children provides support for the roll-out of normative guidance, progress tracking of Global Plan targets and coordination of technical assistance to countries based on nationally determined needs in PMTCT and pediatrics. It is a partnership of 33 member organizations, including UN agencies, non-governmental organizations (NGOs), donor agencies and networks of people living with HIV. The partnership was reconfigured in 2011 to focus on providing technical support to the Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive1 (Global Plan). Co-convened by UNICEF and the World Health Organization (WHO), the IATT leverages the expertise and resources of its members to coordinate and track the provision of technical assistance primarily to the 22 priority countries, to monitor progress of country-led implementation of the Global Plan, and to develop, update and disseminate operational and normative tools and guidance related to the elimination of mother-to-child HIV transmission (EMTCT). The IATT is the technical partnership supporting the achievement of the goals outlined in the Global Plan and participates in the Global Steering Group of the Global Plan.

IATT Partners
The IATT member organizations are: African Network for the Care of Children Affected by HIV/AIDS (ANECCA), French National Agency for Research on AIDs and Viral Hepatitis (ANRS), Baylor International Pediatric AIDS Foundation (BIPAI), Catholic Medical Mission Board (CMMB), Centers for Disease Control and Prevention, USA (CDC), Clinton Health Access Initiative (CHAI), Department of Foreign Affairs, Trade and Development, Canada (DFATD), Earth Institute, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), EngenderHealth, Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau (ESTHER), FHI360, Global Fund for AIDS, Tuberculosis and Malaria (GFATM), Global Network of People Living with HIV (GNP+), International AIDS Society (IAS), International Center for AIDS Care and Treatment Programmes (ICAP) at Columbia University's Mailman School of Public Health, International Community of Women Living with HIV/AIDS (ICW), International Planned Parenthood Federation (IPPF), IntraHealth, JHPIEGO, Joint United Nations Programme on HIV/AIDS (UNAIDS) Secretariat, Management Sciences for Health (MSH), Mothers2Mothers (M2M), U.S. Office of the Global AIDS Coordinator (OGAC), Population Council, Save the Children, UK Department for International Development (DFID), United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA), United States Agency for International Development (USAID), World Bank (WB), World Health Organization (WHO) and World Vision.

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Toolkit, Expanding and Simplifying Treatment for Pregnant Women Living with HIV: Managing the Transition to Option B/B+

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Acronyms and Abbreviations

3TC	lamivudine
ACT	artemisinin combination therapies
AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
BCC	behavior change communication
BLC	Business Leadership Council
CDC	Centers for Disease Control and Prevention
CEWG	Community Engagement Working Group
CHAI	Clinton Health Access Initiative
CHW	community health worker
CIDA	Canadian International Development Agency
CPD	continuous professional development
CSO	Civil Society Organisations
DBS	dried blood spot
EFV	efavirenz
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	early infant diagnosis
EMTCT	elimination of mother-to-child transmission (of HIV)
EQA	external quality assurance
FBO	faith-based organizations
FDC	fixed dose combination
FEWG	Finance and Economic Working Group
FP	family planning
HCW	health care worker
HEI	HIV-exposed infants
HIV	human immunodeficiency virus
HR	human resource
HRH	Human Resources for Health
HTC	HIV testing & counseling
IATT	Inter Agency Task Team
IEC	information, education and communication
LMIS	logistic management information systems
LTFU	loss-to-follow-up
M&E	monitoring and evaluation
m2m	mothers2mothers
MEWG	Monitoring and Evaluation Working Group
MLP	mid-level provider
MNCH	maternal, newborn and child health
MOH	Ministry of Health
MSH	Management Sciences for Health
MTCT	mother-to-child transmission
MTT	Missing the Target
NCGM	National Center for Global Health and Medicine
NGO	non-governmental organisation
NIMART	nurse initiated management of ART
NVP	nevirapine
OGAC	Office of the U.S. Global AIDS Coordinator
OI	opportunistic infection
PCR	polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PID	patient identifier
PLHIV	person living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
POC	point-of-care
PSCM	procurement and supply chain management
QC	quality control
QI	quality improvement
sdNVP	single-dose nevirapine
SCMS	Supply chain management systems
SMS	short message service
SOW	scope of work
SRH	sexual and reproductive health
TB	Tuberculosis
TDF	tenofovir disoproxil fumarate
TWG	technical working group
U5	under-5
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VL	viral load
WHO	World Health Organization

Introduction

What is the toolkit?

The concept for the toolkit arose as more countries decided to adopt Option B/B+, as outlined in the 2012 WHO 'Programmatic Update on the Use of ARVs for Treating Pregnant Women and Preventing HIV Infection in Infants' and recommended in the 2013 WHO 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection'. The toolkit provides a road map to support the planning and implementation of Option B/B+, and to help countries scale up more effective interventions and programmes to achieve the goals of the Global Plan Towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive (the Global Plan).

The toolkit is a collection of assessment tools and checklists that describe the key considerations to be taken into account when transitioning to Option B/B+. Programme implementers and policymak- ers can use the toolkit in its entirety or select from the 10 sections that address different programme components. As more countries adopt and scale up Option B/B+, there is a need for guidance and tools to assist countries in determining the road map, funding requirements and realistic time-frames required for effective implementation.

The toolkit is not intended to be exhaustive but a critical step in presenting the various political, financial and programmatic factors to consider when implementing Option B/B+. The toolkit is a 'living document', with modules developed in a phased manner and new tools added based on country feedback and assessment of need. As countries gain experience using these tools and implementing Option B/B+, lessons learned will be integrated into these documents. These may include a health facility readiness assessment tool and a checklist to assess laboratory needs.

Why was the toolkit developed?

The potential for prevention of mother-to-child transmission (PMTCT) to have a profound impact on the HIV epidemic and broader maternal and child health agenda has never been clearer and more compel- ling. In response to these tremendous opportunities and also to WHO's 2012 programmatic update and 2013 WHO Consolidated ARV Guidelines, this toolkit is meant primarily to help countries begin the process of thinking through key programmatic issues related to the implementation of Option B/B+. Planning well to address these key issues can hopefully help countries avoid unnecessary bottlenecks in rolling-out Option B/B+. The toolkit focuses on pre-implementation planning at the national level, recognizing that sub-national planning is a part of the process. Designed to provide easily accessible, succinct and user-friendly items (key questions, checklists, etc.), the toolkit can be used by the Ministry of Health (MOH), in particular national PMTCT and other technical working groups, as well as IATT member organizations or other partners as these groups work together to plan for a transition to Option B/B+.

Three reference normative guidance documents informed the development of the toolkit and can be consulted

for further information. These are:

- WHO Programmatic Update on the Use of ARVs for Treating Pregnant Women and Preventing HIV Infection in Infants, April 2012 (http://whqlibdoc.who.int/publications/2011/9789241501941_eng.pdf)
- WHO Technical Update on Treatment Optimization: The Use of Efavirenz in Pregnancy: A Public Health Perspective, July 2012 (http://whqlibdoc.who.int/publications/2012/9789241503792_eng.pdf)
- 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (www.who.int/entity/hiv/pub/guidelines/arv2013/en/)

The second edition of the toolkit is divided into 10 key sections, including:

1. **Option B/B+: Key Considerations for Country Programmes (UNICEF)** is an overarching guidance document that lays out key issues for implementation (April 2013).
2. **Moving Towards Option B/B+: Readiness Assessment Checklist and Discussion Guide (PEPFAR/OGAC)** is a comprehensive checklist for national programmes to review as they plan for implementation of Option B/B+. The checklist covers a large number of key programme areas, from political commitment to early infant diagnosis, posing critical questions to be addressed as well as indicating minimum readiness standards for implementing Option B/B+ (June 2014).
3. **Moving Towards Expanded HIV Services for Children: Readiness Assessment Checklist and Discussion Guide: (Child Survival and Lab Working Groups)** is a step-by-step guide to strengthening and scaling up infant diagnosis and paediatric HIV care, treatment and support programmes. Similar to the national readiness checklist, but focused specifically on children living with HIV, it spans a wide array of programme areas, from political endorsement to sample collection, ARV regimen use and retention in care (June 2014).
4. **HIV Rapid Test Quality Assurance Checklist (Lab Working Group)** is designed to facilitate the process of thinking through key HIV Rapid Test quality assurance (QA) and programmatic issues needed to improve HIV rapid testing in MNCH settings. This document complements the national readiness checklist by offering more detailed recommendations specific to HIV testing activities (June 2014).
5. **Tuberculosis/HIV Checklist (CDC)** is intended to be used to integrate TB/HIV services into the broader continuum of MNCH settings, including community and facility-based sites providing post-partum services, immunizations and other child health interventions (June 2014).
6. **Costing Tool describes the costing (FEWG)** models that can be used to cost operational plans for Option B/B+ implementation, including description of programme inputs and outputs associated with each model (April 2013).

7. **Human Resources for Health (HRH Task Team)** tool outlines key considerations around HR capacity and task shifting as an essential component for successful implementation of Option B/B+ (April 2013).

8. **Procurement and Supply Chain Management (SCMS Task Team)** provides a list of key questions for the MOH to consider as it strengthens and adjusts procurement and supply chain management systems to accommodate transition to Option B/B+, and includes links to resources and tools to assist with forecasting (April 2013).

9. **Enhanced Monitoring and Evaluation Systems (MEWG)** provides an overview of concepts and questions to guide national discussion of M&E issues specific to Option B/B+ implementation, as well as quality assurance methods and a list of potential topics for operational research (April 2013).

10. **Community Engagement (CEWG)**: There are two tools on community engagement. The first consists of recommendations for MOH on involving communities in Option B/B+ on planning and implementation discussions, while the second document is designed for civil society organizations to use in dialogue with the MOH to advocate for the rights of people living with HIV (April 2013).

Why were additional tools added to the toolkit?

True to form, this toolkit has been a living document and work in progress. Additional tools were incorporated into the toolkit in light of the release of the 2013 WHO Consolidated ARV Guidelines and the move towards more integrated HIV and MNCH/SRH service delivery models. The new tools were developed to provide more in-depth information and recommendations on programme areas that merit special attention, and to respond to the evolving needs and concerns expressed by programme implementers and people living with HIV, as countries transitioned to providing lifelong ART to pregnant and breastfeeding women. Although many countries have already made this transition, many have not achieved national scale-up and there is an opportunity to make programmatic adjustments prior to expanding services. In addition, certain issues, such as paediatric HIV treatment and HIV Rapid Test Quality Assurance are persistent challenges across many Global Plan countries. These tools are intended to assist countries in designing and implementing strategies to improve and accelerate progress in these specific programmes areas.

Specifically, four new tools were added to the toolkit and one existing tool was revised:

- **Moving Towards Option B/B+ Readiness Assessment Checklist** was updated to reflect the 2013 WHO Consolidated ARV Guidelines.

- **Moving Towards Expanded HIV Services for Children: Readiness Assessment Checklist and Discussion Guide**, specifically focuses on delivering, scaling up and integrating child survival and paediatric HIV care and treatment services to address the considerable gap between adult and paediatric ART coverage.

- Two tools were developed to delve into programme areas that were briefly touched upon in the overarching Readiness Assessment Checklist: **the HIV Rapid Test Quality Assurance Checklist and the TB/HIV checklist**. Given the anticipated increase in HIV testing and heightened concerns related to quality assurance in the context of providing lifelong treatment,

a checklist on HIV Rapid Test Quality Assurance Checklist was developed. Similarly, high rates of TB/HIV co-infection in many countries and the shift towards providing integrated TB and HIV services in MNCH settings prompted the creation of that checklist.

We expect that as implementation of the 2013 WHO Consolidated ARV guidelines is scaled up, changes in programme strategies, approaches and priorities may contribute to the ongoing development of additional tools to address programme and knowledge gaps.

Who is the toolkit for?

This document is intended primarily for use by the MOH, IATT member organizations, NGOs and other partners and funding agencies to use in providing technical assistance and facilitating discussions with national-level policymakers. While this document may contain helpful advice for any country considering adopting Option B/B+, it especially focuses on potential issues surrounding Option B+ in high and intermediate prevalence countries, drawing 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. Although it is meant primarily to aid the decision-making processes at the country level, other multinational partners in the public and private sector may also find it helpful to better understand the challenges countries may be facing.

How was the toolkit developed?

Given the increasing number of countries that approved the shift to Option B/B+ between 2012 and 2013, the need to provide standard guidance to inform the planning implementation phase was identified. The considerations presented in the toolkit draw on lessons learned from Malawi's experience as the first country to implement Option B/B+.

The initial planning for the toolkit was catalyzed during a two-day meeting was held in October 2012 with eight members of the IATT and hosted by the CDC in Atlanta. The IATT requested that working groups and task teams prepare draft documents on pre-defined themes including: supply chain management, human resources for health, community engagement, and monitoring and evaluation. During this meeting, IATT members reviewed and provided comments on draft versions of the documents prepared by members of the IATT working groups. The toolkit also incorporated inputs from the Global Steering Group of the Global Plan.

How can you make the most of this toolkit?

While exploring the toolkit, it is important to remember that these tools are broad guidelines that should be adapted to the specific context where Option B/B+ is being implemented. The toolkit summarizes the main questions to address when implementing Option B/B+ and includes checklists and guidance related to key components of the health system, which can be viewed together or separately based on the interests or needs of the user.

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Option B/B+:
Key Considerations for Country Programmes

1.1 Introduction

1.1.1 The global context

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

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

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

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

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

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

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

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

Table 1: Three Options for PMTCT[a]

	WOMEN WITH CD4 COUNT ABOVE 350 CELLS/MM³	WOMEN WITH CD4 COUNT BELOW 350 CELLS/MM³	CHILD RECEIVES
OPTION A	During pregnancy: AZT starting as early as 14 weeks of pregnancy At delivery: single-dose NVP and first dose of AZT/3TC After delivery: daily AZT/3TC through 7 days postpartum	Triple ARVs started as soon as diagnosed and continued for life	Daily prophylaxis (NVP) from birth until 1 week after all breastfeeding has finished; or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks
OPTION B	Triple ARVs starting as early as 14 weeks of pregnancy continued through childbirth (if not breastfeeding) or until 1 week after all breastfeeding has finished		Daily prophylaxis (NVP or AZT) from birth through age 4–6 weeks regardless of infant feeding method
OPTION B+	Triple ARVs started as soon as diagnosed and continued for life		

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

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

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]" urging countries to consider what the advantages of Option B/B+ may be in their contexts stating: "Options B and specifically B+ seem to offer important programmatic and operational advantages and thus could accelerate progress towards eliminating new paediatric infections." Along with discussing the potential operational benefits of both options, WHO's programmatic update also emphasizes additional advantages beyond PMTCT associated with Option B+ in particular (See Box 1).

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

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

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

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

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

1.1.3 Purpose of this document

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

1.1.4 More equitable access with a rights-based approach

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

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

1.1.5 Overview of this document

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

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

1.2 Political Commitment & Policy Endorsement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Box 2: Benefits of Option B+ Beyond PMTCT

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

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

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

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

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

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

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

1.3 Financial Considerations

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

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

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

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

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

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

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

1.3.2 Finance: mobilizing adequate resources and strengthening the health system

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

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

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

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

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

1.4 Service Delivery Model

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

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

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

With regard to location, several models are possible including:

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

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

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

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

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

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

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

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

1.4.2 Decentralisation and scale-up

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

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

1. The need for ART to be implemented at sites providing MNCH services – bringing ART to the women and children who need it; and

2. The need for coordinated and comprehensive care and support for ART adherence and retention at the community and facility level

[d] This includes early infant diagnosis, support for breastfeeding and nutrition, cotrimoxazole, nevirapine

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

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

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

1.4.4 Infrastructure: making adequate space for ART within MNCH facilities

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

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

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

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

1.5 Human Resource Capacity

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

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

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

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

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

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

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

1.6 ART Regimen Choice

1.6.1 Reach consensus on a recommendation for the optimal regimen

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

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

Box 3: WHO Technical Guidance

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

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

that optimal drug regimens are becoming more affordable and that further price reductions are possible.[20]

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

1.7 Supply Chain Management

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

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

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

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

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

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

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

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

1.8 Monitoring, Evaluation & Data Use

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

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

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

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

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

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

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

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

1.9 Site Supervision & Quality Management

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

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

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

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

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

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

1.10 HIV Testing & Counseling in PMTCT Settings

1.10.1 Quality assurance for rapid HIV testing in PMTCT programmes

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

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

1.10.2 Couples HIV testing and counseling

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

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

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

1.11 Counseling on ART Initiation & Adherence

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

1.12 Laboratory & Clinical Monitoring

1.12.1 Clinical monitoring

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

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

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

1.12.2 Laboratory systems: quality assurance and expanding virologic testing

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

1.13 Early Infant Diagnosis

1.13.1 "A better test": point of care infant diagnosis and tests for treatment failure

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

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

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

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

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

1.14 Retention in Care & Treatment

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

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

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

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

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

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

1.15 Family Planning

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

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

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

1.16 Community Involvement

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

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

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

Such group medical visits have been increasingly shown to be effective when delivering care for a variety of chronic medical conditions, including HIV.[34] 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.[35]

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

1.16.2 Local communities: owning the future and demanding accountability

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

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

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

1.16.3 Maximizing effectiveness of lay cadres and community health workers

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

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

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

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

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

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

1.16.4 Maximizing effectiveness of lay cadres and community health workers

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

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

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

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

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

1.17 Roll-Out Strategy

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

1.18 Conclusion: Moving Forward Boldly Together

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

References

1 Joint United Nations Program on HIV/AIDS (UNAIDS). *Countdown to zero: global plan for the elimination of new HIV infections among children by 2015 and keeping their mothers alive, 2011–2015.* Geneva, UNAIDS, 2011. http://www.unaids.org/en/media/unaids/contentassets/documents/unaid¬spublication/2011/20110609_JC2137_Global-Plan-Elimination-HIV-, accessed 11 July 2012

2 UNAIDS, *Report on the Global AIDS Epidemic*, 2012, published estimates. http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_en.pdf

3 UNAIDS, *Report on the Global AIDS Epidemic*, 2012, published estimates. http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_en.pdf

4 WHO. *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants.* Recommendations for a public health approach (2010 version). Geneva, WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241599818_eng.pdf, accessed 11 July 2012

5 Government of Malawi Ministry of Health *Quarterly HIV Program Report: HIV Testing and Counseling, Prevention of Mother to Child Transmission, and Antiretroviral Therapy (October – December 2011)* Lilongwe, Government of Malawi, 2012. http://www.hivunitmohmw.org/uploads/Main/Quarterly_HIV_Program_Report_2011_Q4.pdf, accessed 11 July 2012

6 Government of Malawi Ministry of Health. *Quarterly HIV Program Report: HIV Testing and Counseling, Prevention of Mother to Child Transmission, and Antiretroviral Therapy (April – June 2011)* Lilongwe, Government of Malawi, 2011(a) http://www.hivunitmohmw.org/uploads/Main/Quarterly%20HIV%20Programme%20Report%202011%20Q2.pdf, accessed 11 July 2012

7 WHO. *Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: Programmatic update.* WHO, Geneva, 2012. http://www.who.int/hiv/pub/mtct/programmatic_update2012/en/index.html, accessed 11 July 2012

8 Business Leadership Council, UNICEF, and the Clinton Health Access Initiative. *A Business Case for Options B and B+ to Eliminate Mother to Child Transmission of HIV by 2015.* New York. 2012. http://www.unicef.org/aids/files/hiv_BusinesscaseB.pdf

9 Chirwa Z. Integrating ART/PMTCT services into Maternal Neonatal & Child Health (MHCH) services to enhance test and treat for pregnant & lactating women (Option B+) the Malawi Experience at the International Treatment. *2nd International Treatment as Prevention Conference, Vancouver; 22 – 25 April 2012.* (Session no. 1.5, http://www.youtube.com/watch?v=pQVPtcxHWOs; accessed 11 July 2012.)

10 Schouten EJ et al. Prevention of mother-to-child transmission of HIV and the health-related Millennium Development Goals: time for a public health approach. *The Lancet,* 2011, 378:282–284.

11 WHO, UNAIDS, UNFPA, UNICEF (2010) *Guidelines on HIV and infant feeding 2010: Principles and recommendations for infant feeding in the context of HIV and a summary of evidence.* Geneva, WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241599535_eng.pdf, , accessed 11 July 2012

12 Government of Malawi Ministry of Health. *Malawi Integrated Guidelines for Clinical Management of HIV, 2011, First Edition.pdf* Lilongwe, Government of Malawi, 2011(b). http://www.hivunitmohmw.org/uploads/Main/Malawi%20Integrated%20Guidelines%20for%20Clinical%20Management%20of%20HIV%202011%20First%20Edition.pdf, accessed 11 July 2012

13 The Clinton Health Access Initiative (CHAI). *CHAI ARV Ceiling Price List.* CHAI, 2012 http://www.clintonhealthaccess.org/files/CHAI_ARV_Ceiling_Price_List_May_2012.pdf, accessed July 16, 2012

14 Stinson K et al. Initiation of highly active antiretroviral therapy among pregnant women in Cape

Town, South Africa. *Trop Med Intl Health*, 2010, 15(7):825-32.

15 Killam WP, et al. Antiretroviral therapy in antenatal care to increase treatment initiation in HIV-infected pregnant women: a stepped-wedge evaluation. *AIDS*, 2010, 24(1):85-91.

16 Ferguson L, et al. Patient attrition between diagnosis with HIV in pregnancy-related services in Kenya: a retrospective study. *JAIDS*, 2012, 60(3):e90-e97

17 Sanne I, et al. Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRASA): a randomized non-inferiority trial. *Lancet,* 2010, 376:33-40.

18 Callaghan M, et al. A systematic review of task- shifting for HIV treatment and care in Africa. *Hum Resour Health*, 2011.8:8. doi:10.1186/1478-4491-8-8

19 Long L et al. Treatment outcomes and cost-effectiveness of shifting management of stable ART patients to nurses in South Africa: an observation cohort. *PLoS Medicine*, 2011, 8:e1001055.

20 UNAIDS. South Africa's savings in procurement of antiretroviral drugs to increase access to treatment for people living with HIV. http://www.unaids.org/en/resources/presscentre/featurestories/2012/november/20121130zatreatmentprices/. *30 November 2012*. Accessed December 7, 2012.

21 Doherty, T. et al. Improving the coverage of the PMTCT programme through a participatory quality improvement intervention in South Africa. *BMC Public Health* 2009, 9:406. http://www.biomedcentral.com/1471-2458/9/406. Accessed December 24, 2012.

22 Theuring, S et al. Male Involvement in PMTCT Services in Mbeya Region, Tanzania. *AIDS Behav* (2009) 13:S92–S102. http://link.springer.com/content/pdf/10.1007%2Fs10461-009-9543-0, Accessed December 24, 2012.

23 Morfaw, F LI et al. Male participation in prevention programmes of mother to child transmission of HIV: a protocol for a systematic review to identify barriers, facilitators and reported interventions *Systematic Reviews* 2012, 1:13. http://www.systematicreviewsjournal.com/content/1/1/13, Accessed December 24, 2012.

24 Jani I et al. Point-of-care CD4 improves patient retention and time-to-initiation of ART in Mozambique. *18th International AIDS Conference, Vienna, Austria, 18–23 July 2010* (Abstract FRLBE101; http://pag.aids2010.org/Abstracts.aspx?SID=641&AID=17805, accessed July 11, 2012)

25 Mee P, et al (2008). Evaluation of the WHO criteria for antiretroviral treatment failure among adults in South Africa. *AIDS* 22:1971-7.

26 UNITAID. *HIV/AIDS diagnostic technology landscape - 2nd edition*. Geneva, UNITAID, 2012. http://www.unitaid.eu/images/marketdynamics/publications/UNITAID-HIV_Diagnostics_Landscape-2nd_edition.pdf, accessed 11 July 2012

27 UNAIDS, *Report on the Global AIDS Epidemic*, 2012, unpublished estimates.

28 Parpia ZA et al. *p24 antigen rapid test for diagnosis of acute paediatric HIV infection*. J Acquir Immune Defic Synd, 2010, 55(4):413-9.

29 van Deursen P et al. Measuring human immunodeficiency virus type 1 RNA loads in dried blood spot specimens using NucliSENS EasyQ HIV-1 v2.0. *Journal of Clinical Virology*, 2010, 47:120–125.

30 Boender, T, Sonia et al. Barriers to Initiation of Pediatric HIV Treatment in Uganda: A Mixed-Method Study. AIDS Res Treat, 2012; 2012. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3286886/ . Accessed

December 24, 2012.

31 Fatti G, et al. Better Antiretroviral Therapy Outcomes at Primary Healthcare Facilities: An Evaluation of Three Tiers of ART Services in Four South African Provinces. PLoS ONE, 2010, 5(9): e12888. doi:10.1371/journal.pone.0012888

32 IATT on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children. *Preventing HIV and Unintended Pregnancies: Strategic Framework 2011-2015*. New York, 2012.

33 Taylor-Ide D and Taylor CE. Just and Lasting Change. *When Communities Own Their Futures*. Baltimore, MD: The Johns Hopkins University Press. 2002

34 Decroo T et al. Distribution of antiretroviral treatment through self-forming groups of patients in Tete Province, Mozambique. *Journal of Acquired Immune Deficiency Syndromes*, 2011, 56:e39–e44.

35 Jaffar S et al. Rates of virological failure in patients treated in a home-based versus a facility-based HIV-care model in Jinja, southeast Uganda: a cluster-randomised equivalence trial. *Lancet*, 2009, 374:2080–2089.

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

2

Moving Towards ART for All Pregnant and Breastfeeding Women:

Readiness Assessment Checklist Disacussion Guide

2.1 Background Information

The Readiness Assessment Check List is designed to assist countries in planning for implementation of 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (http://www.who.int/hiv/pub/guidelines/arv2013/en/). In order to ensure that all critical program components are addressed, it highlights 16 topic areas with prioritized tasks.

The following topics are covered:

1. Political Commitment and Policy Endorsement
2. Financial Considerations
3. Service Delivery Model
4. Human Resource Capacity
5. ART Regimen Choice
6. Supply Chain Management
7. Monitoring, Evaluation and Data Use
8. Site Supervision and Quality Management
9. HIV Testing and Counseling in PMTCT settings
10. Counseling on ART Initiation and Adherence
11. Laboratory and Clinical Monitoring
12. HIV-Exposed Infant Diagnosis & Pediatric Treatment
13. Retention in Care and Treatment
14. Family Planning
15. Community Involvement
16. Roll-Out Strategy

Recommended timing of tasks

The timing of each task is recommended as either before implementation (yellow), early in implementation (green), or during implementation (blue). Space is provided for assessing how far along the program is in completing the specified task. An example follows:

ART REGIMEN CHOICE	COMPLETED	IN PROCESS	NOT YET STARTED
Simplification & harmonisation of PMTCT and adult treatment regimens			
Plan for alternate regimen for pregnant women not tolerant of 1st line			
Optimisation of 1st line regimen for infants			
Establishment of pharmacovigilance system, where appropriate			

Supplementary discussion guide

The discussion guide is designed as a supplement to the Readiness Assessment Check List. Following the same format as the Check List, it provides standards and additional questions for consideration to guide discussion in each topic area. The relevant section of the Readiness Assessment Check list is included at the bottom of each section of the discussion guide.

For further information

The Readiness Assessment Check List and Discussion Guide are planning tools and do not address every aspect of PMTCT and ART programs. Rather, they are meant to highlight items in the context of a transition to providing ART for all pregnant and breastfeeding women that may not have been considered previously, and are essential for program strengthening. Further information and considerations for topics such as Financial Considerations, Service Delivery Model, Human Resource Capacity, Supply Chain Management, Lab and Clinical Monitoring, HIV-exposed Infant Diagnosis and Pediatric Treatment, and Community Involvement may be found in other tools in this toolkit.

2 Moving Towards ART for All Pregnant and Breastfeeding Women: Readiness Assessment Checklist Discussion Guide

The 2013 consolidated guidelines recommend that all pregnant and breastfeeding (BF) women living with HIV should initiate ART and, based on national programme decisions, that either all women continue ART as lifelong treatment or women not eligible for ART for their own health stop after the MTCT risk period. Countries planning for this transition, and those working to expand and strengthen their programme, may find it useful to refer to this readiness assessment checklist, which addresses a range of issues from national policy to facility readiness. The checklist, as well as an accompanying discussion guide, were developed by United States President's Emergency Plan for AIDS Relief, and are included in the 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (http://www.who.int/hiv/pub/guidelines/arv2013/en/).

Acronyms: ANC=antenatal care, BF=breastfeeding, HR=human resources, MNCH=maternal, neonatal, and child health

Key: Before implementation | Early in implementation | During implementation

POLITICAL COMMITMENT AND POLICY ENDORSEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
Commitment to Global Plan goals (national and subnational)			
Full-time MoH staff responsible for PMTCT (national & possibly subnational)			
Functional technical working group inclusive of stakeholders from MNCH, PMTCT, and HIV treatment, including health care workers and people living with HIV			
National and subnational endorsement of ART for all pregnant and BF women (Option B or B+)			
National guidelines updated to incorporate ART for all pregnant and BF women			
FINANCIAL CONSIDERATIONS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Costing of current PMTCT strategy			
Costing of ART for all pregnant and BF women, both short and long term			
Conduct resource gap analysis			
Increased program funding needs reflected in budget			
Demonstration of national financial commitment			
SERVICE DELIVERY MODEL	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Defining minimum package of services to provide ART to all pregnant and BF women			
Assessment of system capacity (infrastructure, HR, and commodities) to decentralize ART to MNCH settings, including absorbing women with HIV and their families			
Timing and location of transition between PMTCT and long-term treatment services has been determined (including consideration of lifelong ART provision within MNCH)			
Systematic identification of ART clients who become pregnant and linkage to MNCH			
Testing and treating partners and family members within MNCH			
Referral of stable ART clients at current ART facilities to new decentralized ART sites			
HUMAN RESOURCE (HR) CAPACITY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
National endorsement of task shifting/sharing for ART initiation and maintenance			
Assessment of HR capacity (nurse, midwife, pharmacy, lab) to support ART scale-up			
Core competencies in HIV management for each health worker cadre			
Training strategy for ART provision to support rapid scale-up			
Updating of national in-service and pre-service curricula			
Nursing and midwifery scopes of practice support nurse initiated and managed ART			
Strategy for retention, retraining, and continuing professional development of health workers, especially those providing in PMTCT/ART			
ART REGIMEN CHOICE	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Simplification & harmonization of PMTCT and adult treatment regimens			
Plan for alternate regimen for pregnant women not tolerant of 1st line			
Optimization of 1st line regimen for infants			
Establishment of pharmacovigilance system, where appropriate (see discussion guide)			
SUPPLY CHAIN MANAGEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Supply chain gap assessment including quantification, distribution, stock management			
18 month forecast, quantification, and supply plan developed			
Stock management of ART in MNCH settings (training, capacity, security)			
If modifying 1st line regimen, plan for using ARVs already ordered			
Revised supply chain management system (consumption, forecasting, & distribution)			

MONITORING, EVALUATION, AND DATA USE	COMPLETED	IN PROCESS	NOT YET STARTED
ANC/PMTCT register allows for documentation of initiation vs already on ART			
ART register allows for documentation of pregnancy and BF status			
Tools and registers in MNCH allow for cohort monitoring of maternal ART retention and exposed infant retention in care			
Pregnant and BF women initiated on ART in MNCH settings are included in site and national level ART M&E systems			
System to track and measure linkages and transition between MNCH and long-term HIV care & treatment for maternal and infant (for example, mother-infant pair longitudinal register, unique identifiers)			
Program evaluation designed to detect early successes and challenges, and to assess longer term maternal and infant coutcomes, including mother-to-child transmission.			
Routine data quality assurance			
Harmonization of PMTCT and ART M&E systems and data review processes			
Standardized client file or card for HIV+ pregnant and BF women and exposed infants			
SITE SUPERVISION AND QUALITY MANAGEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Routine site supervision and clinical mentoring for quality of care			
Continuous quality improvement process for the PMTCT program			
HIV TESTING AND COUNSELING IN PMTCT SETTINGS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Quality assurance measures for rapid HIV testing in all PMTCT sites			
Policy decision on treatment of discordant couples			
Couples HTC and follow-up of discordant couples incorporated into PMTCT			
Strategy to link or register male partners living with HIV in ART program			
COUNSELING ON ART INITIATION AND ADHERENCE	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Specialized messaging and support services for pregnant and BF women initiating ART			
Structures to expedite preparation for ART initiation			
Alternative protocols developed for women not in need ART for their own health who decline treatment for life			
LABORATORY AND CLINICAL MONITORING	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Treatment monitoring capability for toxicity			
Availability of baseline CD4 (point-of-care or reliable sample transport)			
Algorithm for CD4 and/or viral load monitoring			
HIV-EXPOSED INFANT DIAGNOSIS AND PEDIATRIC TREATMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
EID capacity paralleling PMTCT program scale-up			
Strengthening of "EID cascade" – early diagnosis, rapid results return, active case finding of infants infeceted with HIV, and initiation of treatment			
Retention of HIV exposed infants through end of BF including assuring final diagnosis			
Expand access to pediatric treatment			
RETENTION IN CARE AND TREATMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
System to ensure that ALL pregnant and BF women living with HIV are enrolled in ongoing HIV care and/or treatment			
Models of service delivery that consider harmonized mother-infant pair follow-up			
Facility and community-based services to support adherence and trace defaulters			
Innovative solutions to improving accessibility of ART			
FAMILY PLANNING	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Assessment of family planning service availability and commodities			
Access to and uptake of voluntary family planning services in settings providing ART			
COMMUNITY INVOLVEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Women living with HIV are engaged in the planning, implementation and monitoring at national, subnational an community levels			
Community based activities and services to support PMTCT scale-up and retention			
ROLL-OUT STRATEGY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Roll-out strategy has been planned			
Real-time evaluation of implementation in order to inform further scale-up			

2.2 Political Commitment and Policy Endorsement

National endorsement and commitment demonstrated through MoH staffing, policy changes, and involvement of stakeholders are critical to successful implementation of a program providing ART to all pregnant and breastfeeding women.

- ☐ Is there commitment at national and subnational levels to the *Global Plan towards Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive?*
- ☐ Is there an eMTCT champion within the Ministry of Health (MoH) to mobilize local and international partners around PMTCT programming?
- ☐ Is there a full-time MoH team dedicated to PMTCT? Does this team sit under the MNCH or HIV program leadership? Has there been consideration of providing this team leadership autonomy to allow for a bridging of MCH and HIV programs?
- ☐ Has a TWG or task team been convened that is inclusive of stakeholders, including health care workers and women living with HIV?
- ☐ Are MNCH, PMTCT, and HIV treatment leadership coordinating around adoption of the 2013 WHO Consolidated Guidelines?
- ☐ Has the country endorsed the WHO recommendation to provide ART to all pregnant and breastfeeding women (Option B or B+)?
- ☐ Have national guidelines been updated torecommend providing treatment for all pregnant and breastfeeding women?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Commitment to Global Plan goals (national and subnational)			
Full-time MoH staff responsible for PMTCT (national & possibly subnational)			
Functional technical working group inclusive of stakeholders from MNCH, PMTCT, and HIV treatment, including health care workers and people living with HIV			
National and subnational endorsement of ART for all pregnant and BF women (Option B or B+)			
National guidelines updated to incorporate ART for all pregnant and BF women			

2.3 Financial Considerations

Short and long term cost projections have been modeled incorporating commodities, human resources, capacity building, and infrastructure needs and are reflected in the national budget.

- ☐ Has the current PMTCT or eMTCT strategy been costed?
- ☐ Have cost projections (short-term and long-term) been conducted for transition to providing ART for all pregnant and breastfeeding women?
  - Is there a costed national plan to scale-up ART?
  - Is this plan used as the basis costing the provision of ART for all pregnant and breastfeeding women?
- ☐ What additional resources are required (e.g. human resources, commodities, and infrastructure) to implement the provision of ART for all pregnant and breastfeeding women?
  - Is there a defined set of criteria that needs to be met for a previously ANC-only site to become a treatment site? Can this be quantified?
- ☐ Are program funding needs for providing ART to all pregnant and breastfeeding women reflected in the budget?
- ☐ What is being covered by national government? Global Fund? PEPFAR? Other donors?
- ☐ Where are the funding gaps?
- ☐ Who currently funds ARVs for treatment? For PMTCT prophylaxis? Who will be responsible for ARV purchasing if all HIV+ pregnant women are offered treatment? Who will be responsible for funding additional HRH, logistics, infrastructure and transport costs?
- ☐ How will the costs of ARVs and service provision be allocated between the treatment and PMTCT programs?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Costing of current PMTCT strategy			
Costing of ART for all pregnant and BF women, both short and long term			
Conduct resource gap analysis			
Increased program funding needs reflected in budget			
Demonstration of national financial commitment			

2.4 Service Delivery Model

The optimal service delivery model will vary by country context but should incorporate initiation of ART, care of the mother-infant pair through breast-feeding, transition to long-term ART (when, where, by whom), and family planning (including repeat pregnancies among women on ART).

- ☐ Has a minimum package of services been determined for PMTCT to standardize implementation of the 2013 WHO consolidated guidelines?
  - Does this package include initiation of antiretroviral treatment (ART), or only ART refills? Is this package harmonized with the national ART package of care?
  - Does the package vary by level of facility? What level of facility will initiate treatment?
  - What percentage of MNCH facilities currently offer this minimum package?
- ☐ In what settings are pregnant women currently receiving ARVs (ANC/MNCH or HIV treatment)?
  - How will HIV+ women at facilities not offering treatment be linked into the system, especially given the generally low rate of successful initiation when relying upon referrals?
  - What is the feasibility of incorporating ART into MNCH service delivery? Or MNCH services into ART settings?
- ☐ Where will the mother-exposed infant pair be followed post-partum? For how long?
- ☐ Where will mothers and any HIV-infected infants be provided with long-term care and treatment services? In order to improve retention of both mothers and HIV-exposed infants, what provisions can be made to ensure that mothers and infant receive care together?
- ☐ What is the capacity of current treatment facilities to absorb newly initiated women living with HIV in the postpartum period?
- ☐ What is needed to develop the capacity of smaller MNCH-focused facilities to provide long-term ART (infrastructure, human resources, commodities, etc)?
  - What is the planned model of ART provision in sites that currently have only 1-2 nursing staff?
  - Is it anticipated that other (non-pregnant) ART clients will seek ART at these decentralized sites?
  - What is the plan for down referral of ART clients from more centralized ART sites to new decentralized ART sites?
- ☐ Where will partners (and family members) be tested and treated? How will they be linked to care and treatment services?

☐ How will the functionality of the chosen service delivery model(s) be evaluated during early implementation to inform further roll-out and program modification in the medium and long term?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Defining minimum package of services to provide ART to all pregnant and BF women			
Assessment of system capacity (infrastructure, HR, and commodities) to decentralize ART to MNCH settings, including absorbing women with HIV and their families			
Timing and location of transition between PMTCT and long-term treatment services has been determined (including consideration of lifelong ART provision within MNCH)			
Systematic identification of ART clients who become pregnant and linkage to MNCH			
Testing and treating partners and family members within MNCH			
Referral of stable ART clients at current ART facilities to new decentralized ART sites			

2.5 Human Resource Capacity

National policy authorizes multiple health care worker cadres to initiate, prescribe, and manage ART.

☐ Does national policy authorize nurses, midwives, and/or clinical officers to initiate, prescribe and manage ART for pregnant women?

- Are these tasks allowable in the scope of practice for these health care workers? If they cannot initiate ART, are they allowed to refill ART prescriptions during follow-up visits?

☐ Are there any national policies or regulations limiting these cadres from providing ART to pregnant women or children that need to be rectified? (A review of national policies/regulations is recommended).

☐ Will all health care workers in the approved cadres be qualified as HIV service providers, or will special certification be required?

Human resource requirements for ART scale-up have been assessed and incorporated into healthcare workforce planning.

☐ Has there been an assessment of the human resource requirement that would be needed to scale-up services (i.e. doctors, nurses, pharmacist, community health care workers, laboratorians) based upon the planned model of ART provision for peripheral facilities?

- If not, what is the plan for the completion of this task? Does this consider the graduated decentralization of ART to rural facilities?

☐ What data are available on the distribution of the different health workforce cadre that can inform training and service-delivery scale-up? This data should consider:

- Numbers and training of current health workers (nurses, physicians, community health workers) at all sites offering MNCH services
- Estimated number of patients initiating/continuing ART at all sites offering ANC

National training and credentialing specifies competencies for ART prescribing, initiation, and management of adults and children.

☐ Have the essential competencies for various health care worker cadres (including lab, pharmacy, community health workers, and peer counselors) needed to operationalize the provision of ART to all pregnant and breastfeeding women been determined?

☐ Are there national pre-service and in-service training plans for equipping health workers with needed competencies? Does this training consider the additional support (job aids, algorithms, HIV patient records, data collection) needed for nurses to have expanded scopes of practice?

☐ Does existing/planned in-service and pre-service training have national standardization and endorsement by MOH and regulatory bodies?

☐ What systems exist or need to be established to ensure that PMTCT and ART management is incorporated into continuous professional development (CPD) programs required for re-licensure?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
National endorsement of task shifting/sharing for ART initiation and maintenance			
Assessment of HR capacity (nurse, midwife, pharmacy, lab) to support ART scale-up			
Core competencies in HIV management for each health worker cadre			
Training strategy for ART provision to support rapid scale-up			
Updating of national in-service and pre-service curricula			
Nursing and midwifery scopes of practice support nurse initiated and managed ART			

2.6 ART Regimen Choice

For simplicity, the first-line ART regimen for PMTCT should be easy for patients to take, have minimal toxicities, and be harmonized with the national treatment regimen for non-pregnant adults.

- ☐ Has regimen simplification been considered (e.g. tenofivir/lamivudine/efavirenz [TDF/3TC/EFV] in a single fixed-dose combination tablet with once daily dosing) for PMTCT?
- ☐ What are the plans for harmonizing the PMTCT regimen with the first-line regimens for non-pregnant adults?
- ☐ If an ART regimen change will be needed, what are the financial implications? How and over what timeframe will the previous first line regimen be transitioned?
- ☐ What types of toxicities would be most expected, and thus what types of clinical and laboratory monitoring may be necessary? (e.g. CD4 would be needed if NVP remains in the regimen)
- ☐ For pregnant women unable to tolerate the first-line regimen (secondary to side effects or toxicity), what alternative will be available? Will this be available at all sites or through referral?
- ☐ What first-line ART is available for HIV-infected infants? Has lopinavir/ritonavir been considered?
- ☐ Will a national surveillance system be established to monitor any potential effects of ART on pregnant women and newborns, or will the program rely on regional birth defect surveillance systems for monitoring?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Simplification and harmonization of PMTCT and adult treatment regimens			
Plan for alternate regimen for pregnant women not tolerant of 1st line			
Optimization of 1st line regimen for infants			
Establishment of pharmacovigilance system, where appropriate (see discussion guide)			

2.7 Supply Chain Management

An inventory management protocol should be in place for rapid test kits, ARVs, early infant diagnosis (EID) and other key commodities that includes forecasting, consumption reporting, and procedures for ordering emergency supplies.

- ☐ Has there been an assessment of the supply chain management reliability and identification of funding or partners to strengthen the supply chain management system?
- ☐ If sites previously providing only PMTCT prophylaxis will now be providing treatment, what are the training, transportation/distribution, and storage capacity needs in order to provide ART at those facilities?
- ☐ Has an 18 month forecast, quantification, and supply plan been completed? Have all key stakeholders been consulted in developing this information?
- ☐ What policies are in place for the storage of ARVs throughout the supply chain? Especially in regards to the cold chain needed if lopinavir/ritonavir will be the regimen of choice for HIV-infected infants.
- ☐ If a new first line regimen will be provided to pregnant and breastfeeding women, how will current ARV stock be quantified, distributed, and managed in order to minimize wastage?
- ☐ Are there separate systems in place for the forecasting and distribution of rapid HIV test kits, ART, infant prophylaxis, cotrimoxazole, and EID? If so, are there plans to integrate these systems at both national and facility level?
- ☐ Has forecasting taken into consideration the need for alternative regimens for patients who experience adverse events or toxicities with the first line regimen?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Supply chain gap assessment including quantification, distribution, stock management			
18 month forecast, quantification, and supply plan developed			
Stock management of ART in MNCH settings (training, capacity, security)			
If modifying first line regimen, plan for using ARVs already ordered			
Revised supply chain management system (consumption, forecasting, & distribution)			

2.8 Monitoring, Evaluation and Data Use

National M&E registers need to accommodate longitudinal monitoring of mothers living with HIV and their HIV-exposed infants in order to track linkages and retention.

- ☐ Are ANC/PMTCT registers and monthly reports capturing women on treatment? Can pregnant women newly initiated vs already on ART be differentiated? If not, what updates are needed?
- ☐ Do ANC/PMTCT registers allow for longitudinal follow up? If not, how is retention of clients tracked?
- ☐ Is it possible to link mother-infant pairs in the current registers or client tracking systems ? If no, what is the feasibility of creating this type of register?
- ☐ Do client cards (ANC & Child Welfare cards) capture maternal and infant HIV status and ARV regimen?
- ☐ Is there a unique identifier that links mother and infants together? Can one be created?
- ☐ What is the feasibility of establishing a routine cohort monitoring system for pregnant women initiating ART focusing on timeliness of ART initiation and retention on treatment?

PMTCT and ART M&E systems need to be harmonized to facilitate follow-up of clients and minimize double counting.

- ☐ How are pregnant and breastfeeding women who are initiated on ART in MNCH settings registered in national ART M&E system?
  - Will ART files be opened in ANC/MNCH for women initiating ART?
  - Are women initiated on ART at ANC/MNCH entered into a site ART register or electronic data base?
  - How will the decentralization of ART clients to new peripheral sites be monitored? Will current ART records be transferred to new sites?
- ☐ How can the PMTCT and ART M&E systems? Will the national ART M&E system be extended to new peripheral sites that will be providing ART for all pregnant and breastfeeding women?
- ☐ Are women already on ART who become pregnant systematically counted in the PMTCT program? Are ART registers designed to facilitate this documentation?

- ☐ Are standard individual medical records in use for both pre-ART and ART patients? How will these be adapted for use for pregnant women? Will they include an exposed infant section? How will they be stored?
- ☐ Are program data reported by PMTCT and ART routinely reviewed and used for feedback to national and sub-national program managers? Specifically, are PMTCT, ART, and MNCH program data that monitor ART initiation and retention as well as key MCH services like immunizations and family planning, summarized and reviewed frequently to inform rollout and ongoing implementation?
- ☐ Can the M&E for the transition to providing ART for all pregnant and brestfeeding women be the impetus for joint data review between MNCH and ART programs?
- ☐ Ministries should plan for systematic evaluation of the roll out of treatment for all pregnant and breastfeeding women, including maternal morbidity and infant HIV-free survival (including final status at the end of breastfeeding).

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
ANC/PMTCT register allows for documentation of initiation vs already on ART			
ART register allows for documentation of pregnancy and BF status			
Tools and registers in MNCH allow for cohort monitoring of maternal ART retention and exposed infant retention in care			
Pregnant and BF women initiated on ART in MNCH settings are included in site and national level ART M&E systems			
System to track and measure linkages and transition between MNCH and long-term HIV care & treatment for maternal and infant (for example, mother-infant pair longitudinal register, unique identifiers)			
Program evaluation designed to detect early successes and challenges, and to assess longer term maternal and infant outcomes, including mother-to-child transmission.			
Routine data quality assurance			
Harmonization of PMTCT and ART M&E systems and data review processes			
Standardized client file or card for HIV+ pregnant and BF women and exposed infants			

2.9 Site Supervision and Quality Management

Implementation of the recommendation to offer treatment to all pregnant and breastfeeding women should be accompanied by routine and intensive site supervision that emphasizes rapid remediation of identified issues.

- ☐ What site supervision systems and strategies are currently in place to ensure quality service provision and data collection?
- ☐ What site supervision tool developments/modifications will be required to expand supportive supervision?
- ☐ What human and financial resources will be available or are needed (e.g., from partners, MOH, etc.) for implementing additional site supervision activities? Is there appropriate supervisory capacity in these groups?
- ☐ What quality improvement policies and procedures are in place at the national, district, and site level for HIV care and treatment services?
- ☐ Have the district health supervisors, implementing partners, and/or facility staff been trained in continuous quality improvement techniques so that they may institute resolutions for noted deficiencies?
- ☐ What type of clinical mentoring support is currently available for site staff? Are district and/or regional consultative services available (via telephone or patient referral)?
- ☐ What site-level reference materials and job aids will be necessary for sites that will be providing treatment for all pregnant and breastfeeding women, and, potentially, their partners and families?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Routine site supervision and clinical mentoring for quality of care			
Continuous quality improvement process for the PMTCT program			

2.10 HIV Testing and Counseling (HTC) in PMTCT Settings

A strong quality assurance process for rapid testing is critical to minimize the risk of incorrect HIV results.

- ☐ What external quality assurance (EQA) measures and programs are being instituted for HIV rapid testing in PMTCT settings (e.g. quality control checks, standardized documentation paralleling the testing algorithm, proficiency testing of health care workers)?
- ☐ Have appropriate resources been allocated at the national and regional level to scale-up and support EQA activities?
- ☐ Is the National Reference Laboratory prepared and able to provide oversight and coordinate supervisory visits?
- ☐ Have strategies for corrective actions been developed as part of the EQA program?

MNCH settings should offer and encourage couples HIV testing and counseling with support for mutual disclosure.

- ☐ What current programs are in place for couples counseling and partner testing?
- ☐ What new counseling messages will be needed in the context of providing all pregnant and breastfeeding women with treatment?
- ☐ Where/when will HIV-positive male partners be evaluated for ART eligibility and/or initiated on ART?
- ☐ Has there been consideration of offering treatment to all HIV-positive men with HIV-negative pregnant or breastfeeding partners in order to prevent horizontal transmission?
- ☐ How are couples defined with regard to social norms? Should alternative approaches to polygamous families and unofficial partners be considered or adopted?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Quality assurance measures for rapid HIV testing in all PMTCT sites			
Policy decision on treatment of discordant couples			
Couples HTC and follow-up of discordant couples incorporated into PMTCT			
Strategy to link or register male partners living with HIV in ART program			

2.11 Counseling on ART Initiation and Adherence

Expedited yet high-quality counseling for ART initiation and adherence is an essential element of implementing treatment for all pregnant and breast-feeding women.

- ☐ Who will provide pre- and ongoing ART adherence counseling for women in the ANC/MNCH setting?
- ☐ Given the need to expedite ART initiation, how will the adherence counseling sessions be structured differently from the standard adherence counseling provided in treatment centers?
  - How will disclosure be supported?
  - How will simple clear messaging on the benefits and need for ART initiation as a PMTCT intervention be emphasized?
  - How will an opt-out approach be ensured? When is the appropriate time to discuss opting out (at initiation vs near end of breastfeeding)?
  - What risks and/or side effects of ART will be highlighted?
- ☐ Will ART be initiated on the same day as diagnosis, or at a return visit? Consider an developing or adapting an algorithm to determine readiness.
- ☐ What services will be available for women initiating ART for life to support optimal adherence (i.e. community support groups, mentor mothers)?
- ☐ What alternatives will be available to women who do not wish to commit to ART for life (eg CD4 and stopping ART at end of breastfeeding if over threshold for treatment eligibility)?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Specialized messaging and support services for pregnant and BF women initiating ART			
Structures to expedite preparation for ART initiation			
Alternative protocols developed for women not in need ART for their own health who decline treatment for life			

2.12 Laboratory and Clinical Monitoring

There should be defined clinical algorithms for monitoring and investigating medication-related toxicities, with defined referral networks, if applicable.

- ☐ What potential medication-related toxicities and adverse events are associated with the preferred national ART regimen?
  - Does investigation or diagnosis of these toxicities require laboratory monitoring?
  - Has this monitoring been incorporated into the HCW training package?
- ☐ What is the current lab capacity for the necessary test(s) on site at ANC/MNCH sites? By referral?
  - Will an expansion of referral networks (or on-site capability) be required?
  - How will the efficacy of referrals be monitored? Do referred patients/specimens actually reach the referral sites?
- ☐ Is a current adverse event reporting system in place? What types of modifications or expansion may be required?
- ☐ What are the indications for patient referral to higher-level facilities?

Each program should have a clear algorithm for conducting baseline CD4 testing in newly diagnosed pregnant women, particularly in an Option B context.

- ☐ Is a baseline CD4 needed for ART regimen selection (e.g., if using NVP)?
  - If yes, what are the CD4 criteria and what regimens will be used for each?
- ☐ Will a baseline CD4 be collected at the first ANC visit but a universal regimen started?
  - If CD4 not collected at first visit, when is the proposed timing of CD4 collection?
- ☐ If a baseline CD4 is not part of the clinical algorithm, what is the proposed method for monitoring treatment success or failure (alternative immunologic criteria vs viral load)?
- ☐ What percent of current MCH sites have CD4 available on-site? Through referral?
- ☐ Will an expansion of CD4 access be required? If so, what is the role of POC technology vs. expansion of specimen transport networks?

There should be standardized, evidence-based clinical algorithms for routine laboratory monitoring of pregnant women started on ART during ANC.

- ☐ Will any baseline labs be required prior to ART initiation (e.g., hemoglobin for AZT or creatinine for tenofovir)?
- ☐ Will any immunologic monitoring be performed pre- or post-partum?
- ☐ Will viral load monitoring be recommended at any point (e.g., at suspected treatment failure or at postpartum visit to ensure VL is undetectable during breastfeeding)?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Treatment monitoring capability for toxicity			
Availability of baseline CD4 (point-of-care or reliable sample transport)			
Algorithm for CD4 and/or viral load monitoring			

2.13 HIV-Exposed Infant Diagnosis and Pediatric Treatment

Early detection of HIV infection in HIV exposed infants coupled with early ART initiation should be prioritized given the documented survival benefits.

- ☐ What plans have been put in place to expand EID capacity (both in the lab and at the facilities) to handle the scale-up in PMTCT services?
- ☐ Have systems been developed to strengthen the "EID cascade"?
  - What strategies are planned to facilitate EID for HIV-exposed infants at 4-6 weeks of age?
  - What systems are developed to ensure that results for DNA PCR are returned to the clinic AND mother/caregiver within 4 weeks of specimen collection (i.e. SMS/test messaging)?
  - What systems are in place to promote and prioritize active case finding of HIV-infected infants? How can these systems be strengthened?
  - What strategies have been developed to strengthen the linkage between diagnosis and the initiation of treatment?
- ☐ Is there a cohort register to track HIV exposed infants or mother-infant pairs that includes EID testing, return of result to client, cotrimozazole prophylaxis and initiation of ART for infants found to be HIV-positive?
  - Is there a way to link HIV-exposed infants with their mothers?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
EID capacity paralleling PMTCT program scale-up			
Strengthening of "EID cascade" – early diagnosis, rapid results return, active case finding of infants infected with HIV, and initiation of treatment			
Retention of HIV exposed infants through end of BF including assuring final diagnosis			
Expand access to pediatric treatment			

2.14 Retention in Care and Treatment

Proactive interventions to retain pregnant and breastfeeding women initiated on ART, particularly in contexts where lifelong treatment will be initiated, are critical for maternal health and prevention of vertical transmission.

- ☐ What tracking systems have been established to minimize LTFU for women on ART in PMTCT settings?

- ☐ How well established are support services (i.e. support groups, mentor mothers, etc.) for pregnant and breastfeeding women? What systems are in place to facilitate linkage to these support services?
- ☐ What creative solutions can be considered for improving accessibility to refills and follow-up for women during pregnancy and afterward (e.g. dispense at ANC and only visit ART when need monitoring, community distribution of ARVs, mobile units to provide more decentralized services)?
    - For women who will need to be referred to other facilities for ART refills after pregnancy, what systems are in place or can be established to strengthen that linkage?

Service delivery models emphasizing the coordination of services for the mother-infant pair are needed to reduce LTFU and ensure optimal survival outcomes.

- ☐ Are HIV+ mothers and their exposed infants currently followed jointly as a pair?
    - Where do mothers receive ongoing HIV care and/or treatment services?
    - Where do infants receive EID, NVP, and cotrimoxazole prophylaxis?
    - Where are MNCH services such as family planning, infant feeding counseling, and immunizations provided?
- ☐ Are these services or appointments coordinated or linked?
- ☐ What are the options for coordinating mother-infant follow-up services?
- ☐ Are HIV-exposed infants systematically identified in Under-5 or child welfare clinic?
- ☐ What systems are in place to track LTFU and/or support retention of mother-infant pairs (cell phone text messages, community workers sent to home, etc)?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
System to ensure that ALL pregnant and BF women living with HIV are enrolled in ongoing HIV care and/or treatment			
Models of service delivery that consider harmonized mother-infant pair follow-up			
Facility and community-based services to support adherence and trace defaulters			
Innovative solutions to improving accessibility of ART			

2.15 Family Planning

Voluntary family planning services and choices should be offered as a component of comprehensive PMTCT and HIV care and treatment service delivery.

- ☐ What is the proportion of women who have an unmet need for family planning?
- ☐ Has an assessment of current fertility rate, birth spacing, family planning services, contraceptive availability, and unmet need for contraception been conducted?
- ☐ How can contraceptive access and uptake for postpartum women be incorporated into PMTCT and/or ART services?
- ☐ What counseling and services are available for HIV-positive families who desire additional children?
- ☐ Are there any synergies that can be capitalized on for supply chain management of family planning commodities and ART in MNCH settings?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Assessment of family planning service availability and commodities			
Access to and uptake of voluntary family planning services in settings providing ART			

2.16 Community Involvement

It is critical that women living with HIV and the communities they live in are fully engaged throughout the planning, implementation, and monitoring of the adoption of the PMTCT component WHO 2013 Guidelines in order to support the supply and quality of PMTCT services, to increase uptake of PMTCT services, and to create an enabling environment that allows women living with HIV to be partners in their own health care.

- ☐ Are community members (faith or community based organizations, community support groups, networks of women living with HIV, civil society organizations) involved in the planning, implementation, and monitoring of the transition to providing treatment to all pregnant and BF women?
- ☐ Have discussions been held with women living with HIV to discuss how providing treatment to all pregnant and breastfeeding women will affect the care they receive and to understand their concerns and level of acceptance of the new policy?
- ☐ Has a mechanism been developed for community/civil society organizations to provide feedback to government and health care officials on the quality of services delivered to women and their families once the PMTCT component of the WHO 2013 Consolidated ARV Guidelines is implemented?

- ☐ Have treatment literacy and IEC materials been developed to help educate the community of the importance and benefits of offering treatment to all pregnant and breastfeeding women?
- ☐ Has an assessment been made of current community engagement activities to determine best practices that should be replicated to support the expansion of PMTCT services?
- ☐ What strategies are being used to increase the engagement of community members, especially men, in identifying attitudes and practices that impact women's decisions to access PMTCT services?
- ☐ Will the community support services typically in place for ART services be established at new sites that do not currently offer ART?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Women living with HIV are engaged in the planning, implementation and monitoring at national, subnational an community levels			
Community based activities and services to support PMTCT scale-up and retention			
Community structures to support orphans and vulnerable children			

2.17 Roll-Out Strategy

- ☐ What percent of facilities currently offer PMTCT services (including ARVs for prophylaxis)?
- ☐ Will the program be implemented nationally all at once, or phased-in?
    - If phasing-in, will the approach be geographic (by health zone, district, etc), or based on facility volume (or a combination)
    - How will the quality of ART for pregnant women be routinely assessed to ensure similar standards between PMTCT and standard treatment programs?
    - Is the goal to have long-term ART provision within ANC/MCNH?
    - When will the new sites providing ART in ANC/MNCH offer ART to all eligible patients in their catchment area?
- ☐ What evaluation will be put in place to assess the success of and identify implementation challenges in the initial phases of implementation?

TASK	COMPLETED	IN PROCESS	NOT YET STARTED
Roll-out strategy has been planned			
Real-time evaluation of implementation in order to inform further scale-up			

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

3

Moving Towards Expanded HIV Services for Children:

Readiness Assessment Checklist and Discussion Guide

3.1 Background

In 2012, among 65 reporting countries, only 35 per cent of infants born to mothers living with HIV received an HIV test within the first two months of life and only one third of children living with HIV initiated treatment.[1] Compared to adults, paediatric ART coverage is quite low. The 2013 WHO *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection*, which recommends the initiation of lifelong ART for all pregnant and breastfeeding HIV-positive women (Option B+) provides an ideal opportunity to improve retention of the mother-infant pair within care, ensuring that all HIV-exposed infants receive a final definitive diagnosis and HIV-infected infants initiate ART. Given the significant gap between adult and paediatric coverage, this checklist outlines key programmatic considerations and priorities to ensure that children living with HIV are not left behind as efforts to eliminate MTCT of HIV are scaled up. This is particularly important, as improving HIV-free survival and providing universal treatment for children living with HIV are two of the primary targets in the Global Plan.

3.2 Purpose and Intended Use of the Tool

This document accompanies the HIV infant diagnosis and paediatric HIV treatment readiness checklist. It may be used to assess readiness by the health system to improve care and treatment for these children. This document is meant to explain in more detail in each of the following sections: political commitment and policy endorsement/roll-out strategy/financial planning/service delivery model; human resource capacity; monitoring, evaluation and data use; site supervision and quality management; laboratory and clinical monitoring; antiretroviral regimen choice; supply chain management; identification and HIV testing for HIV-exposed infants; counselling on diagnosis, ART initiation and adherence; infant, child and adolescent diagnosis and treatment; retention in care and treatment; and family referrals and community involvement.

3.3 Audience

The checklist is a tool that may be used by national and sub-national policymakers and programmatic leaders to review the steps needed to improve infant diagnosis and increase treatment coverage for HIV-infected infants and children.

3.3 Systems Considerations

Political commitment and policy endorsement/roll-out strategy/ financial planning/service delivery considerations

This section of the checklist includes considerations that should take place at the central level regarding necessary policies and political endorsement to effectively rapidly scale up HIV testing, care and treatment services for children 0–19 years of age as well as financial, service delivery and human resource considerations for readiness. This checklist will be useful to government officials at the central, regional and district levels and highlights critical issues that need to be addressed to close the gap between adult and paediatric ART coverage.

It is recognized that successful programmes usually have one or more paediatric HIV 'champions' that continuously advocate for the goal of increased paediatric ART coverage and ensuring equal access to quality HIV services for children. This would be reflected in organizational structures if countries had full-time staff devoted to the paediatric HIV programme in their respective ministries who can lead active and goal-oriented activities of a nationally representative and diverse Paediatric Technical Working Group.

Human resource capacity

Because many areas where HIV-infection among children is prevalent have challenges in delivering paediatric medical care by paediatricians, an essential component for improving infant diagnosis and increasing paediatric HIV care and treatment coverage is assessing the national legislation and regulation regarding task sharing. Task sharing in this context includes nurse initiation and management of ART (NIMART) for children, pregnant women and adults. Addressing obstacles that limit or restrict expanded scopes of practice for appropriately trained professionals is critical. Absence of official sanctioning by the health ministry regarding task sharing (e.g., NIMART) results in a work environment without legal protections, thereby making the health workforce legally, professionally, ethically vulnerable for the services they provide.

Further assessing HRH capacity involves determining what kind of accurate workforce data is available to assist with program planning. Increasingly, countries are investing in human resources information systems (HRIS), which provide accurate, timely and comprehensive profiles of a country's workforce size, composition, and deployment patterns. When linked to broader health information – such as paediatric HIV disease burden, health services utilization and patient outcomes, HRIS can be a powerful tool for prioritizing health workforce deployment and resource allocation regarding workforce training in order to meet health system goals.

It is essential that core competencies for the regulated health workforce (e.g., nurses, doctors, clinical officers, laboratory technicians, etc.) are revised, updated and consistent with global HIV practices and standards, such as those defined in WHO's 2013 Consolidated ARV guidelines to diagnose, prevent and treat HIV. Planning for scale up of EID and paediatric ART involves outreach to relevant professional regulatory bodies in order to assess and ensure professional standards governing provider practices are consistent with paediatric HIV programme policies and protocols.

At minimum, a national training strategy for ART scale-up would include:

- Prioritization of training resources to sites where scale-up activities are occurring;
- Assessment of provider training requirements so that in-service content appropriately targets need;
- Coordination of PEPFAR-implementing partners' training resources (including content, training venues, etc.) in order to avoid duplication of offerings and minimize gaps in coverage; and
- Evaluation of training experiences so as to ensure that the offerings are sufficient and adequately support sites providing scaled-up paediatric HIV services.

Significant investments have been made regarding in-service and pre-service training. In many instances, there has been little oversight or coordination regarding the nature of these investments. Review of these training curricula and ensuring consistency between in-service and pre-service offerings with the national HIV programme/policies is essential for maximizing and sustaining paediatric HIV scale-up efforts.

Ensuring that newly trained HIV providers remain engaged in paediatric HIV service delivery requires anticipatory planning to offset clinical practice challenges. As an example, as mid-level providers become increasingly engaged with initiating and managing paediatric HIV care, establishing appropriate referral systems and provider support networks offers a supportive environment for the newly trained mid-level clinician who may feel overwhelmed in assuming new responsibilities in patient care.

Most recently, a number countries have developed (or are developing) continuing professional development programmes (CPD), which are increasingly becoming a prerequisite for professional re-licensure. For example, Kenya's medical practitioners are required to renew their medical license annually and document specific CPD credits they have earned in a given year. Ensuring that CPD offerings contain updated information regarding paediatric HIV care is an effective strategy that enables practitioners to be apprised and updated in latest protocol recommendations.

3.5 Implementation Considerations

Monitoring, evaluation, data use and databases

To support infant diagnosis and paediatric HIV care and treatment services, the national HIV Monitoring and evaluation (M&E) framework tools should include information on children and routinely collect agreed upon indicators. The paediatric M&E priorities should include, for example: 1) strengthening routine paediatric programme monitoring; 2) ensuring high data quality; 3) supporting data use for evidence-based programme planning; 4) conducting programme evaluation and operational research; and 5) building M&E capacity.

The number of tools for routine monitoring should be kept as simple as possible. These tools can be either of an electronic or paper-based format, depending on the national resources. Some of these tools include:

- Mother and child pair longitudinal register: to collect information on infants' HIV exposure, DBS collection date, HIV test results and HIV final diagnosis, as well as information on linkages to clinical and non-clinical HIV services.
- Care and treatment register: to document cotrimoxazole prophylaxis administration, TB screening, ART initiation, ongoing ARVs provision and regimen, and information on linkages to other paediatric HIV clinical and non-clinical services
    - Child health card includes information on HIV exposure status, testing, and infection status and PMTCT ARV exposure, and similar card is provided to caregiver
    - Maternal health card includes information on HIV status and PMTCT ARV exposure
    - HIV-exposed and HIV-infected infant/child patient charts and registers link to maternal ART records and vice versa
    - A system for programme evaluation to detect early successes and challenges and to assess long-term paediatric outcomes allows for mid-course adjustments to better meet needs of children, their families, and the providers who serve them. The programme should aim to improve data quality, which can be accomplished through routine data quality assurance. At the end of the reporting period, collected information on key indicators should be aggregated, analysed, interpreted, summarized and widely distributed to stakeholders. The results should be used at each level from site (health facility, community) to national level to strengthen the national paediatric programme, including EID, assist in HIV commodities forecasting and planning strategies for scaling up national HIV paediatrics towards the Millennium Development Goals Monitoring, evaluation, data use and databases

Site supervision and quality management

Routine site supervision should be part of national management structures and should lead to actionable items for regular quality improvement (QI) and enable routine QI by sites. Malawi's routine site supervision system includes ministry, donor and implementing partner representatives and has been discussed widely for its completeness and value in reinforcing programme goals. Clinical mentoring could be provided within such a site supervision system, or could be performed outside it. Clinical mentoring is particularly valuable in early phases of decentralization or roll-out of new activities, to reinforce training and programme goals, and to provide support for decision-making by clinicians. Since infant diagnosis and paediatric HIV care and treatment may be perceived to require extra skills or knowledge, clinical mentoring may be particularly valuable in these early phases.

Laboratory and clinical monitoring

HIV-infected children require routine clinical and laboratory monitoring. At baseline, CD4 determinations are needed to determine treatment eligibility in clinically well children older than 5 years of age. Once on ART, children need to be monitored on a regular basis for two principal reasons: 1) to detect signs of drug toxicities related to ARV or other drugs that may be subclinical; and 2) to detect early treatment failures. In most paediatric HIV programmes, the use of second-line ART regimens is very limited and probably reflects the difficulties in identifying treatment failure by the use of clinical and immunologic parameters. Viral load is becoming, albeit slowly, increasingly available and should be used by clinicians to monitor children on ART. While data on how often and when to perform VL testing may not yet be available, algorithms for VL testing routinely after a period of time following treatment initiation or in the event of a clinical or immunological change can be considered.

Antiretroviral (ART) regimen choice

Paediatric antiretroviral drug preparations have increased in number, with further drug formulations expected to meet the unique dosing and acceptability needs of children. However, paediatric drug formulation availability is often negatively affected by small orders compared with adult drugs. Therefore, there is often a need for national HIV treatment programmes to rationalize drug formularies to ensure adequate supply and simplify treatment options. ART regimen choice must consider effectiveness, side-effect profile, availability, ease of administration, cost, and storage and distribution issues. Additionally, optimal regimen choices vary across age groups. Preferred ART regimens have been outlined in the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (please refer to <www.who.int/hiv/pub/guidelines/arv2013/download/en/> for more information).

Supply chain management

Supply chain management is critical to ensure that necessary commodities are available at the point of care to identify HIV-exposed and infected infants, and translate into life-saving paediatric HIV care and treatment interventions. This is increasingly important as services expand and ART regimens change with new guidelines. Personnel responsible for supply chain management are recommended to conduct the checklist items below, and also be familiar with paediatric HIV commodities, including testing supplies and reagents, and drug formulations in order to ensure a smoothly operating paediatric HIV care and treatment programme. HIV programme supervisors should be regularly updated on commodity forecasts, supply chain challenges, and strategies.

Identification and testing of HIV-exposed infants and young children

Early diagnosis of HIV infection is essential for ensuring timely initiation of ART and reducing the high morbidity and mortality that occurs among HIV-infected children who do not receive treatment. In 2010, in response to emerging data showing dramatic survival benefits of early ART initiation among HIV-infected infants and children, WHO issued the revised 'Recommendations on the Diagnosis of HIV infection in Infants and Children' (<www.who.int/hiv/pub/paediatric/diagnosis/en/>). Key elements include:

- HIV virological testing to be used to diagnose HIV infection in infants and children below 18 months of age.
- All HIV-exposed infants to have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter.
- Infants with an initial positive virological test result to start ART without delay, and, at the same time, a second specimen to be collected to confirm the initial positive virological test result.
- Infants with signs and symptoms suggestive of HIV infection to undergo screening with HIV serological testing and, if positive, follow with virologic testing to confirm infection.
- HIV-exposed infants to undergo HIV serological testing at around 9 months of age (or at the time of the last immunization visit). Infants with reactive serological assays at 9 months should receive a virological test to identify HIV-infected infants who need ART.
- Children 18 months or older, with suspected HIV infection or HIV exposure, to have HIV serological testing performed according to the standard diagnostic HIV serological testing algorithm used in adults.

In 2012, among 65 reporting countries, only 35 per cent of infants born to mothers living with HIV received an HIV test within the first two months of life.[2] Initiation of lifelong ART to all

pregnant and breastfeeding HIV-positive women (Option B+) provides an ideal opportunity to improve retention of the mother-infant pair within care, ensuring that all HIV-exposed infants receive a final definitive diagnosis and HIV-infected infants initiate ART.

HIV-exposed or infected children who aren't engaged in care during PMTCT have few opportunities for diagnosis and treatment; therefore testing and counselling in high-risk settings (provider-initiated testing and counselling [PITC] in in-patient facilities, malnutrition treatment clinics, tuberculosis clinics, children of adults on ART or TB treatment) remains one of the most common ways to identify HIV-infected children. Often these children are old enough (if older than 18 months) to undergo a rapid test, making quality assurance of and proficiency in use of rapid tests important. Using prevalence of positivity data from a variety of settings where children are universally tested, even for a short period, and diagnosed with HIV can prove very valuable in determining where additional testing would identify more children in need of treatment. Linkage to and retention in care has been a major challenge facing infant diagnosis and all PMTCT programmes, with numerous reports consistently demonstrating high rates of loss to follow-up along the PMTCT cascade. Therefore, assuring linkage from the testing settings to treatment settings is critical. This process can be facilitated if members of the same family are tested together and referred together.

Counselling on infant diagnosis, ART initiation and adherence/HIV testing and counselling of all child-at-risk settings

When HIV-infected children are identified early, during the PMTCT cascade, they may not appear ill, therefore careful counselling on the benefits and possible side effects of initiating ART is useful for caregivers and will affect adherence. Factors that influence caregiver decisions regarding whether children initiate and continue with treatment include transportation costs, food availability, time constraints, perception that the child is healthy, perceived stigma, religious beliefs, and male partner support. Therefore, these issues should be addressed during counselling, nutritional needs assessed for those affected by HIV, and appropriate referrals made. In addition, as treatment is initiated (regardless of CD4 count among children aged less than 5 years who may not have benefited from PMTCT programs), disclosure among family members may need to be addressed prior to disclosure to children. Family disclosure is a noted and strong factor in family adherence; adherence is critical to the individual's health (maintaining an adequately suppressed viral load), but also for public health, since poor adherence may lead to resistance, use of second- and third-line regimens, and added costs.

Sample collection transport and return of results

Timely delivery of test results – including DBS for early infant diagnosis, rapid test results for confirmation of diagnosis and viral load monitoring – is critical for initiation of treatment. Delays in the turnaround time of results are common in many settings and contribute to loss to follow-up, whereby HIV-positive infants are not enrolled in treatment until they are sick. Developing a national strategy for establishing an efficient transport system for the country is an important step in addressing this challenge. The communication channels between testing laboratories, which may only be at the central or regional level and facilities where DBS samples are collected, should be fully defined and functional. Procedures for following up on discordant results, rejected DBS samples and missing results should be outlined, and both medical and laboratory staff oriented on these procedures. To facilitate this, many countries have increased the use of SMS technology such as printers and/or cell phones to facilitate the more rapid return of results to health facilities and caregivers. Quality assurance of paediatric HIV testing is important and refresher trainings should be considered for sites that consistently submit poor-quality DBS samples.

Facility capacity to monitor the infant HIV testing cascade to identify where significant drop-offs occur can improve programme performance and result in the timely recuperation of children at risk of not returning for results, confirmatory diagnosis and treatment and children already lost to follow-up. Expanding access to ART where PMTCT services are provided will reinforce linkages between diagnosis and treatment, as children are more likely to disengage from care if MNCH services, testing and treatment are offered at different facilities.

Infant, child and adolescent HIV diagnosis and treatment

Principles for increasing treatment coverage include: 1) active case-finding for infected infants, children and adolescents; 2) implementing the new WHO guidelines for treatment of HIV in children; 3) linkage and retention of infants, children and adolescents into clinical care and treatment; and 4) enhanced training of health-care providers to build capacity for paediatric HIV testing, care and treatment and to monitor impact of training through quality improvement, supervision and mentoring support.

Active case-finding includes testing at appropriate ages until a final infection status is determined for HIV-exposed infants, PITC in high-risk settings, such as in-patient wards, malnutrition treatment clinics, tuberculosis clinics, and among children of adults on ART. Testing targets are recommended, especially in districts where PITC is not systematically applied.

Implementation of the 2013 WHO Consolidated ARV Guidelines includes:

- Ensuring implementation of universal ART initiation for all HIV-infected children under 5 years, regardless of CD4 count or percentage;
- Ensuring that treatment guidelines for older HIV-infected children and adolescents (age 5

years and older) are aligned with adult treatment eligibility criteria;

- Setting aggressive numeric age-disaggregated treatment targets;
- Ensuring that paediatric HIV services are decentralized along with adult HIV services and made available at the lowest-level possible with skilled health-care providers;

  and

- Ensuring consistent supply of efficacious, easy-to-use regimens with optimal paediatric formulations.

Updated ART eligibility criteria expands paediatric HIV treatment eligibility, while simplifying programmatic implementation by no longer requiring CD4 testing for ART initiation in children under the age of 5. The revised guidelines also align CD4 count thresholds for treatment in children 5 years and older with those for adults.

Retention and linkage of infants, children and adolescents in lifelong care and treatment is enhanced with the following activities:

- Collecting and analysing data with age disaggregation whenever possible to improve programme planning and identification of gaps in programme services; and
- Ensuring quality-improvement activities that address the challenges of following mother-infant pairs and loss to follow-up of children and adolescents.

Enhanced training of health-care providers to build capacity for paediatric HIV testing, care and treatment and to monitor impact of training through quality improvement, supervision and mentoring support improves programme quality and outcomes for HIV-exposed and HIV-infected children. Supporting national programmes to strengthen policy and regulatory mechanisms to build human-resource capacity for paediatric HIV services through task sharing is critical to increasing treatment access to districts without multi-level health-care infrastructure.

Retention in care and treatment

Health-care providers and systems play a critical role in retention. Patient or caregiver satisfaction with health workers and health facilities can be a quality-improvement measure to increase retention. Providing training and redistributing the workload of providers will address lack of skills and reduce heavy workloads, which undermine relationships with patients. In addition, stigma and negative perceptions towards HIV-positive parents and children have reduced the numbers of mothers bringing their children in for diagnosis, care and treatment. Multiple site-level issues that influence retention of infected children in care and treatment programmes should also be addressed: clinic waiting times, understaffing, and inadequate clinical/laboratory services. Services that are bundled can address many of these issues, because cross-training can reduce workload and reduce stigma among health workers, and the 'one-stop shop' can reduce

transportation costs and loss of time from work.

Family referrals/community involvement

The combination of various services needed to reduce paediatric HIV-infection morbidity and mortality may be provided by different partners through a continuum of service networks and through effective linkages between health facility, community and household. The overall goal of this linkage is to increase uptake of paediatric HIV testing, care and treatment services and improve long-term survival and retention of HIV-exposed/infected children in care and treatment in order to thrive in adulthood.

At the family level: Family plays a fundamental role in the continuum of paediatric HIV care and treatment. Some of those roles include: connection to health facilities to access HIV testing, ARVs and other medications, adherence support, reporting side effects, ongoing engagement in health care for HIV-infected children and available services for children (e.g., visit to health facilities, services providing services for children affected by AIDS (OVC), nutrition, and immunization services).

At the community level: Community involvement will provide additional non-clinical services to families living with HIV-exposed/-infected or -affected children. Community organizations can support and guide families in need of HIV services for diagnosis, promote HIV de-stigmatization, and promote adherence to care and treatment to reduce lost to follow-up and family withdrawal from attending health facilities. Such organizations can also link families to additional services in the community (e.g., group and/or peer support services, social and economic assistance for children affected by AIDS, nutrition education, counselling services), and assist social workers to track families of children lost to follow-up or who self-withdraw from services. Community systems strengthening will ultimately increase the uptake of paediatric HIV services and significantly improve adherence and long-term retention.

3 Paediatric HIV Treatment Readiness Assessment Checklist: Moving Towards Expanded HIV Services for Children

The WHO 2013 Consolidated ARV guidelines recommend that all HIV-positive children younger than 5 years old should initiate ART, and that children aged 5–19 should initiate ART if they meet clinical criteria or have a CD4 cell count of ≤500. Countries working to expand and strengthen their EID and paediatric HIV treatment programmes, including decentralization efforts or expansion of ART eligibility to any age, may find it useful to refer to this 'readiness assessment checklist', which addresses a range of issues, from national policy to facility readiness. The checklist and an accompanying discussion guide were developed by PEPFAR.

Key: Before implementation | Early in implementation | During implementation

SYSTEMS CONSIDERATIONS			
POLITICAL COMMITMENT AND POLICY ENDORSEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Commitment to expand paediatric HIV services reflected in overall HIV/AIDS goals (national and sub-national) with inclusion of paediatric HIV advocacy messages and package of interventions (described below)			
Full-time Ministry of Health staff responsible for paediatric HIV care and treatment (optimally in collaboration with MNCH or Child Survival Units and HCT and Nutrition teams in the MoH) at central, regional and district levels			
Functional paediatric HIV care and treatment technical working group (TWG) includes stakeholders from MNCH, laboratory services and other relevant areas within the MoH, the private sector, international donors and non-governmental organizations (NGOs), representative of various health-care worker (HCW) cadres, and organizations of people living with HIV/AIDS (i.e., mothers and adolescents)			
National and sub-national endorsement of ART for all children <5 years irrespective of CD4 cell count, and 5–19 years if CD4 ≤500, or other criteria based on national guidelines			
Updated National Paediatric HIV Care and Treatment Guidelines that reflect most recent WHO guidelines (all children <5 years and those 5–19 years if CD4+ ≤500) or that reflect national discussions on capacity and need to catch up to adult coverage			
Treatment coverage targets for children 0–14 years of age are included in national, regional, provincial and district plans			
Updated paediatric HIV testing guidance and training materials accompanied by a strategic plan to rapidly scale up the implementation of systematic PITC for children aged 0–14 years through the use of lay counsellors, nurses and other health-care providers in postnatal care services, inpatient and outpatient services, nutritional programmes and EPI			
National PMTCT guidelines address the importance of integrated and coordinated care of mother-infant pair and includes latest WHO recommendations for infant and young child HIV testing			
National testing algorithm for HIV-exposed infants and young children addresses the following: • Collection of DBS from 4–6 weeks of age for PCR testing • How to manage an infant with positive PCR test indicating HIV infection • Further testing of an infant with an initial negative PCR test to determine final HIV status • Screening and testing of HIV-exposed infants initially identified at a later age – e.g., at 6 or 12 months of age • Routine HIV testing for final diagnosis >18 months and 6 weeks after cessation of breastfeeding • Testing with presumptive treatment of clinically suspicious infants and children			
National endorsement of task sharing for collection of DBS and rapid testing of infants and children			
National guidelines and policy allow non-clinicians to initiate paediatric ART and provide paediatric ART refills			
ROLL-OUT STRATEGY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Documented national roll-out or scale-up strategy shared with implementing partners (IPs), stakeholders; regions develop strategies based on the national strategy			
Protocols for real-time evaluation of implementation to inform further scale-up complete			
FINANCIAL PLANNING	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Costing of routine testing of all children in high-risk settings, routine EID and reaching final diagnosis for all HIV exposed infants (HEI)[a], and care and treatment strategy			
Costing of ART for all children <5 years, 5–15 years if CD4 ≤500, based on selected drug regimens or other national plan			
Conduct resource gap analysis including recommendation on how to address the existing gaps			
Increased programme funding needs reflected in budget			
Demonstration of national and international financial commitment			

[a] According to WHO, infants and children born to mothers living with HIV until HIV infection in the infant or child is reliably excluded and the infant or child is no longer exposed through breastfeeding. For those <18 months of age, HIV infection is diagnosed by a positive virological test (HIV DNA or HIV RNA) six weeks after complete cessation of all breastfeeding. For a HIV-exposed children >18 months of age, HIV infection can be excluded by negative HIV antibody testing at least six weeks after complete cessation of all breastfeeding.

SERVICE DELIVERY CONSIDERATIONS	COMPLETED	IN PROCESS	NOT YET STARTED
Minimum package of services to provide to HIV-exposed, HIV-infected children and adolescents is defined for each different level of the health-care system			
System capacity (infrastructure, human resources, commodities) assessed and micro-planned for scaling up of paediatric HIV testing (including EID) and decentralizing paediatric ART to MNCH settings			
Timing and location of transition between MNCH and long-term treatment services determined (including consideration of lifelong ART provision within MNCH)			
Procedures for transfer of care during paediatric ART decentralization determined – i.e., categorization of patients requiring more specialized vs. routine care			
Procedures for determining HIV status of hospitalized children, malnourished children, children with TB, and children of ART clients (family testing) and linkage to MNCH complete			
Procedures for treating partners and family members within MNCH			
Referral of stable ART clients at current ART facilities to new, decentralized ART sites			
HUMAN RESOURCE CAPACITY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
National endorsement of task sharing for paediatric HIV testing, ART initiation and maintenance on treatment			
Assessment of human resource capacity (nurse, midwife, pharmacy, lab) to: • Support ART scale-up among children • Scale-up infant and young child HIV testing, as well as routine PITC to mothers during breastfeeding			
Core competencies defined for each HCW in HIV management			
Implementation of training strategy for paediatric HIV provider-initiated testing and counselling (PITC) and ART to support rapid scale-up of these services for children			
Updating of national in-service and pre-service curricula in PMTCT and ART for paediatric HIV testing, care and treatment, and disclosure			
Strategy for retention, in-service supervision, retraining and continuing professional development of health workers, especially for those providing paediatric HIV testing and ART			
ART REGIMEN CHOICE	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Optimization and rationalization of first-line regimen for infants, children and adolescents			
Plan for availability of lopinavir/ritonavir (Lop/r) for children <3 years old			
Plan for availability of efavirenz (EFV) for children >3 years old			
Simplification and harmonization of adult, adolescent and child (>3 years old) treatment regimens			
Plan for availability of a second-line regimen for all children that follows WHO guidance and best practices			
Establishment of pharmacovigilance system, where appropriate (see discussion guide)			
SUPPLY-CHAIN MANAGEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Supply-chain gap assessment, including quantification, distribution and stock management, for testing supplies and ARV drugs at sites and reagents at laboratories (consider bulk procurement depending on demand, pooled procurement mechanisms)			
Systematic and consistent flow of data from the site and laboratory level to national level that informs accurate commodity forecasting			
18-month forecast, quantification and supply plan developed			
Stock management of ART in MNCH settings (training, capacity, security) • Sites and laboratories maintain appropriate buffer stock • Knowledge of product specifications for EID, optimized sample collection materials (such as DBS bundles), product limitations (such as the short shelf life of EID reagents), appropriate delivery cycles			
If modifying first-line regimen to lopinavir/ritonavir, plan for using ARVs which have already been procured[b]			
Revised supply-chain management system (consumption, forecasting and distribution) based on early evaluation			
IMPLEMENTATION CONSIDERATIONS			
M&E AND DATA USE	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Implementation of simplified medical records and registers for all mother-infant pairs, HIV-exposed infants and for HIV-infected children in pre-ART and/or ART, including updated tools to collect longitudinal data on paediatric HIV testing, paediatric pre-ART and paediatric ART			
Implementation of HIV-exposed maternal-infant card and child health card, both identifying the time of weaning from breastfeeding to identify ongoing exposure			

[b] For more information, please refer to the Updated Paediatric ARV Formulary List at http://www.emtct-iatt.org/wp-content/uploads/2014/04/IATT-Sept-2013-Updated-Paediatric-ART-Formulary-Report3.pdf

M&E AND DATA USE	COMPLETED	IN PROCESS	NOT YET STARTED
MCH register allows for documentation of key paediatric HIV testing and treatment indicators – e.g., infants receiving an HIV test initiation and already on ART for children			
ART register allows for documentation of key paediatric HIV care indicators – i.e., cotrimoxazole prophylaxis, TB screening and INH prophylaxis			
Tools/registers in MNCH and ART clinics allow for cohort monitoring of maternal ART retention, HIV-exposed infant retention, and outcomes in care			
Children initiated on ART in MNCH settings are included in site and national-level ART M&E systems			
A system/protocol includes paediatric ART initiation in MNCH in district and national ART M&E systems			
System to track and measure linkages/transition between MNCH , exposure period and long-term HIV care and treatment for HIV-exposed and HIV-infected infants and children (linkages tracked, with unique identifier)			
Standardized appointment registers are used to strengthen identification of defaulting mother-infant pairs			
Programme evaluation designed to detect early successes and challenges, and to assess long-term infant and child outcomes			
Routine data quality assurance conducted			
Harmonization of MNCH and ART data-review processes			
National standardized laboratory requisition form for PCR testing of DBS, which includes: • Maternal and infant ARV exposure and infant feeding status included in forms • Patient identifier to allow linkage, at the laboratory and at the site, of multiple samples from same infant			
DATABASES	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Laboratory-based PCR testing data in each PCR laboratory, including clinical and demographic data from the laboratory requisition form, are stored in electronic database for ease of analysis			
Laboratories evaluate their PCR testing data at regular intervals for programme monitoring and planning purposes			
Databases from multiple national PCR testing laboratories can be merged to create a national database on PCR testing that is used to produce regular reports on national EID programme, as well as for national programme monitoring and planning purposes			
National infant HIV testing coverage can be calculated from site-based HIV-exposed infant registers or testing logbooks and laboratory-based electronic data			
Systems in place to link infants and mothers across multiple databases at site, laboratory, sub-national and national level			
SITE SUPERVISION AND QUALITY MANAGEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Routine site supervision and clinical mentoring for quality of care			
Continuous quality improvement process for paediatric PITC and ART in MNCH programme			
LABORATORY AND CLINICAL MONITORING	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Current geographical distribution of laboratories meets current and projected programme needs, with maximum efficiency of testing, and avoids redundancy of human resources or machine capacity			
Capacity to provide early infant diagnosis using DBS (with reliable sample transport and result distribution) or point-of-care test in MNCH and ART clinics			
Capacity to monitor for common ART-related toxicities			
Availability of baseline CD4 (point of care, or reliable sample transport with result distribution)			
Innovative solutions to scale-up of infant HIV testing, including point of care early infant diagnosis (EID) technologies (as these become available and are pre-qualified by WHO)			
Capacity to monitor response to treatment using viral load			
Evaluation of laboratory human resources, PCR testing capacity and platforms for concurrent scale-up of VL monitoring and infant HIV testing			
Capacity to screen for or diagnose common paediatric opportunistic infections (e.g., malaria, tuberculosis, cryptococcus, etc.)			
LABORATORY QUALITY ASSURANCE MEASUREMENTS FOR PCR TESTING OF DBS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Routine monitoring of DBS sample quality			
Routine running of quality controls while conducting PCR testing			
Implementation of policy for re-testing the following sample PCR results in the laboratory as part of internal laboratory measurements: positive PCR, equivocal PCR, negative PCR			
Systems in place to prevent cross-contamination of PCR testing of DBS and VL DBS at testing laboratories where both are tested			

LABORATORY QUALITY ASSURANCE MEASUREMENTS FOR PCR TESTING OF DBS	COMPLETED	IN PROCESS	NOT YET STARTED
Participation in an in-country or an international external quality assurance (EQA) programme			
Implementation of SOPs for equipment maintenance and calibration			
Adherence to biosafety policies			
PCR results are reviewed and signed by supervisor/laboratory director before being reported			
IDENTIFICATION AND SCREENING FOR HIV-EXPOSED INFANTS AND YOUNG CHILDREN	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Infants and young children are routinely screened for HIV exposure and HIV infection at: • Immunization clinic (EPI) • Under 5 clinic • At risk child consultation • MNCH clinics • OPD • TB clinics • Malnutrition clinics • HIV/ART clinic • In-patient wards			
Integration of infant and young child HIV testing into all MNCH services			
Implementation of routine provider-initiated HIV testing and counselling (PITC) of mothers post-partum			
COUNSELLING ON INFANT TESTING, ART INITIATION AND ADHERENCE	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Enhanced counselling at ANC regarding importance of repeat HIV testing of infants and young children until six weeks after cessation of breastfeeding			
Specialized messaging and support services for caregivers of infants and children initiating ART			
Structures to expedite preparation for ART initiation for infants and children			
Developmental approach to child-focused HIV counselling incorporated in ART counselling services (testing, disclosure and adherence support)			
Alternative protocols developed for children whose caregivers decline HIV testing or treatment initiation			
Protocols developed for disclosure, and incorporated into routine-care algorithm			
HIV TESTING AND COUNSELLING IN ALL CHILD-AT-RISK SETTINGS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Quality assurance measures for rapid paediatric HIV testing in all inpatient and outpatient settings			
Rational policy for rapid testing in outpatient settings depending on prevalence (see toolkit discussion)			
Strategy to link or register other HIV-infected family members into HIV care and treatment services			
CHILD AND ADOLESCENT HIV DIAGNOSIS AND LINKAGES TO TREATMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Strategy to implement case finding of infected children: testing and linkages in high-risk settings; testing and linkages for children of adults on ART			
Adolescent-friendly treatment services available (see <pepfar.net>), including need for prevention, family planning and adherence counselling			
Child-friendly corners or services established where feasible			
SAMPLE COLLECTION, TRANSPORT AND RETURN OF RESULTS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
National strategy for sample transport (DBS for EID and VL, as well as other samples) and return of results that ensures a standardized system throughout the country			
Time taken from sample collection to return of result to site does not exceed four weeks			
Established communication channels between testing laboratories and DBS collection sites to allow follow-up on discordant results, rejected DBS, missing results			
Positive PCR results are fast-tracked back to the caregiver and family for prompt initiation of ART			
System in place for provision of training/refresher training to sites that submit poor-quality DBS			
Innovative solutions to return of results, including SMS technology linking to printers and/or cell phones			
DBS sample collection for paediatric HIV PCR testing, and results return capacity paralleling PMTCT programme scale-up			
Monitoring of positive results returned to caregiver and infant initiation of ART			
Identification of infant HIV testing cascade weaknesses and plans for improvements (diagnosis, results returned, active case finding of HIV-infected infants, and initiation of treatment)			
Expand access to paediatric treatment in all ART and PMTCT settings			

RETENTION IN CARE AND TREATMENT	COMPLETED	IN PROCESS	NOT YET STARTED
Strategies to improve retention of HIV-exposed and HIV-infected infants include community outreach, peer support groups, escorted referrals, family clinics, integrated services and coordinated appointments with mother and infant			
Retention of HIV-exposed infants through end of breastfeeding, including ascertainment of final diagnosis			
System to ensure that all HIV-infected children are enrolled in ongoing HIV care and, if eligible, treatment			
Strategy and implementation plan for nutritional assessment, counselling, and support			
Models of service delivery that consider harmonized/bundled follow-up and co-appointments for infected mothers and their children (post-partum, immunization, TB screening, well-child clinic and nutrition services, etc.)			
Facility and community-based services to track defaulting mother-infant pairs throughout breastfeeding period, children receiving treatment and to support adherence			
FAMILY REFERRALS	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Linkage between all services providing infant and young child HIV testing and paediatric ART services using systems such as triplicate referral forms, patient escorts, use of unique patient ID numbers recorded at referring and receiving service, appointment registers, designated staff to follow up on all HIV-infected infants and children			
Strategy, implementation and evaluation plan to provide HIV infected women, their children and families with economic and social protection services			
Refer infected women and all of their children to social services and community-based support			
COMMUNITY INVOLVEMENT	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Families living with HIV are engaged in the planning, implementation and monitoring at national, sub-national and community levels			
National communication strategy for 2013 WHO Consolidated ARV Guidelines includes infant and young child HIV testing messages			
Community-based activities and services support HIV treatment scale-up and retention for children			

Resources

1 World Health Organization, *Global Update on HIV Treatment 2013: Results, impact and opportunities*, WHO, Geneva, 2013.

2 Joint United Nations Programme on HIV/AIDS, *A Progress Report on the Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive*, UNAIDS, Geneva, 2012.

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4 HIV Rapid Test Quality Assurance Checklist

4.1 Background

The past decade has seen a rapid global scale-up of HIV testing and counselling (HTC), the vast majority using HIV rapid tests (HIV RT). The relative simplicity of HIV RTs has expanded the accessibility of HIV testing in areas with limited laboratory facilities and no formal laboratory trained staff, thereby significantly increasing the number of persons who learn their HIV status. As the provision of antiretroviral therapy (ART) for all pregnant and breastfeeding women and for all children <5 years of age is scaled-up, there is an increased need to ensure the quality of HIV rapid testing and address common service delivery issues regarding HIV testing in maternal, newborn and child health (MNCH) clinics.

4.2 Purpose and Intended Use of the Tool

The purpose of this checklist is to facilitate the process of thinking through key HIV RT quality assurance (QA)[1] and programmatic issues needed to improve HIV rapid testing in MNCH settings. This document expands upon the Option B/B+ Readiness Assessment Checklist and offers more detailed recommendations on specific HIV testing activities.

4.3 Audience

This checklist will be useful for public health authorities, programme managers and laboratory technicians at the central, regional and district levels when planning for and establishing minimum standards and requirements for the quality assurance of HIV rapid testing in MNCH programmes.

4.4 Introduction

The World Health Organization *2013 Consolidated Guidelines on the Use of Antiretrovirals for the Treatment and Prevention of HIV Infection* recommended the provision of ART for all HIV-positive children <5 years of age and for pregnant and breastfeeding women living with HIV. Consequently, ART initiation is based solely on the result of the HIV RT for pregnant and breastfeeding women and for children 18 months – 5 years of age (children <18 months have PCR as their diagnostic HIV test). Misclassification (false positive or false negative) of HIV RTs can occur due to inherent limitations of the HIV RT, use of expired test kits, deviation from the national testing algorithm, (including a screening test, confirmatory test and tiebreaker), or any deviation from the HIV RT standard operating procedure. Responsible programming demands the implementation of QA systems to ensure the accuracy of HIV test results. In particular, it is important that HIV-negative women and children are not mistakenly initiated on lifelong ART, and that women and children living with HIV do not miss PMTCT and ART treatment opportunities due to misdiagnosis.

The following areas need to be addressed to assure the quality of HIV RTs: 1) a national policy for HIV RT QA; 2) standardized HIV RT training and national certification programme for testers;[2] 3) the regular use and review of a standardized HIV RT QA logbook;[3] 4) the implementation of a national HIV RT proficiency testing programme;[4, 5] and 5) the routine use of quality control (QC) samples. It is critical that all MNCH sites adopt these policy and QA activities to ensure the accuracy of HIV test results.

HIV Rapid Test Quality Assurance Checklist for MNCH Settings

Key: Before implementation | Early in implementation | During implementation

POLICY ENGAGEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
National guidelines for laboratory quality assurance in HIV rapid testing (including proficiency testing and the use of a standardized HIV RT QA logbook)			
Costing and budget allocation for QA activities			
National technical working group (TWG) inclusive of stakeholders from MNCH, PMTCT, HIV treatment and laboratory to review HIV testing strategies and ensure the national HIV testing algorithm follows WHO guidance			
Implement mechanisms to address rapid test kit stock-outs, expired test kits and recalls			
Policy decision on the treatment of discordant couples			
Include RT QA monitoring in all site supervision visits			
TRAINING AND CERTIFICATION	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
National policy requiring training, periodic re-training and certification of HIV testing personnel			
HIV testing training curricula incorporated into all pre-service and in-service ART and PMTCT trainings and including the use and analysis of standardized QA logbooks and proficiency testing			
USE OF STANDARDIZED LOG BOOK	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Standardized HIV logbook or register used to capture key HIV testing data (e.g., kit names, lot #, expiration dates, and result of each test in the algorithm)[a]			
HIV testing logbooks or registers harmonized *across* programmes and used at all sites (e.g., HTC, PMTCT, inpatient, etc.)			
Ensure that clinical site staff and site supervisors review standardized logbook data and perform corrective actions as needed			
PROFICIENCY TESTING AND QUALITY CONTROL	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Proficiency testing (PT) and quality control (QC) programme is in place to monitor the competency of all testing personnel and sites with dried tube specimens (DTS) or plasma			
PT programme data are used to provide timely feedback and corrective actions to the testing sites			
SERVICE DELIVERY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Strategy for repeat testing during pregnancy/labour and delivery and during the breastfeeding period developed and implemented			
Strategy for HIV testing for older children of HIV-positive pregnant and breastfeeding women developed and implemented			
Partner testing and disclosure assistance services available for all pregnant and breastfeeding women			
Strategy to provide ART to HIV-positive male partners developed and implemented			
Implementing universal HIV screening at immunization clinics in high-burden settings			

[a] Revision of existing registers to include key HIV RT QA elements is an acceptable alternative.

Resources

1 Parekh, Bharat S., et al., 'Scaling Up HIV Rapid Testing in Developing Countries: Comprehensive approach for implementing quality assurance', *American Journal of Clinical Patholology*, vol. 134, no. 4, October 2010, pp. 573–584.

2 World Health Organization, 'Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a quality system approach', WHO, Geneva, 2005, available at <http://whqlibdoc.who.int/publications/2005/9241593563_eng.pdf?ua=1>.

3 World Health Organization, 'A Handbook for Assuring and Improving HIV Testing and Counselling Services: Field-test version', WHO, Geneva, 2010, available at <http://whqlibdoc.who.int/publications/2010/9789241500463_eng.pdf?ua=1>.

4 Parekh, Bharat S., et al., 'Dried Tube Specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings', Journal of Virological Methods, February 2010, vol. 163, no. 2, pp. 295–300.

5 Benzaken, Adele Schwartz, et al., 'External Quality Assurance with Dried Tube Specimens (DTS) for Point-of-Care Syphilis and HIV Tests: Experience in an indigenous populations screening programme in the Brazilian Amazon', Sexually Transmitted Infections, vol. 90, no. 1, February 2014, pp. 14–18.

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5 Tuberculosis/HIV Checklist

5.1 Background

In sub-Saharan Africa, tuberculosis (TB) is the leading cause of death among people living with HIV (PLHIV), and parental deaths due to TB have resulted in almost 10 million orphan children worldwide by 2009 [1-2]. As the number of women living with HIV has increased, TB incidence among women in their childbearing years has also increased, leading to an increased risk of TB- and HIV-related morbidity and mortality for mothers and their children [3-4]. In high HIV prevalence settings, such as sub-Saharan Africa, TB is reported to cause up to 15% of all maternal mortality [5]. Maternal TB presents a risk not only to the pregnant woman, but also to her newborn and young children. HIV-infected pregnant women with TB disease are at increased risk of transmitting *both* TB and HIV to their infants [3-4]. Focusing efforts on prevention, identification, and treatment of TB disease in HIV-infected pregnant women has the potential to improve health outcomes not just for women, but for their children as well.

5.2 Purpose and Intended Use of the Tool

In countries implementing lifelong antiretroviral treatment (ART) for pregnant and breast-feeding women (commonly referred to as "Option B+"), prevention of mother-to-child HIV transmission (PMTCT) sites will effectively function as HIV care and treatment centers for women and, often, for their children and families as well. As national PMTCT programs are revising guidelines, training curricula, and recording and reporting tools for Option B+, this is a unique opportunity to incorporate TB/HIV activities into program planning efforts. TB/HIV services should also be integrated into the broader continuum of maternal, newborn, and child (MNCH) settings, including community and facility-based sites providing postpartum services, immunizations, and other child health interventions.

In order to reduce the impact of TB among mothers and children, it is essential that PMTCT and MNCH programs adopt the World Health Organization (WHO) recommendations for TB/HIV, including implementing TB intensified case finding (e.g. screening of all PLHIV and systematic evaluation of contacts of people with potentially infectious TB), infection control measures, and isoniazid preventive therapy (IPT) [6-8].

5.3 Audience

The checklist below is intended to assist national program managers, clinic administrators, and other public health officials as they work towards integration of TB/HIV services in PMTCT and MNCH programs.

Readiness Assessment: Integration of TB/HIV Activities in PMTCT Sites

Key: Before implementation | Early in implementation | During implementation

POLITICAL COMMITMENT & POLICY ENDORSEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
National-Level Activities			
PMTCT/MNCH, pediatric HIV, and TB stakeholders are included in national TB/HIV committee membership			
National PMTCT guidelines emphasize the impact of TB on women and their children and the importance of implementing TB/HIV activities including intensified TB case finding, infection control measures and IPT at ANC/PMTCT sites			
National TB/HIV guidelines specifically address the needs of pregnant and breastfeeding women and children			
National policies support use of IPT in HIV-infected pregnant and breastfeeding women in accordance with WHO recommendations			
National TB and HIV guidelines specifically recommend contact tracing for children less than 5 years old and all PLHIV who are exposed to a sputum smear-positive TB case			
Site-Level Activities			
Site-level policies are developed to promote linkage between PMTCT/MNCH and TB clinical services			

TRAINING	COMPLETED	IN PROCESS	NOT YET STARTED
National-Level Activities			
National PMTCT/MNCH training curriculum is revised to include principles of TB intensified case finding, infection control, and IPT			
National TB/HIV training curriculum is revised to emphasize the needs of pregnant and breastfeeding women and their children			
Site-Level Activities			
Each PMTCT/MNCH site designates one staff person to attend training on TB/HIV (either as part of PMTCT training or through separate TB/HIV training program)			

INFECTION CONTROL	COMPLETED	IN PROCESS	NOT YET STARTED
Site-Level Activities			
Site-level infection control focal person or committee is identified			
Site-level infection control policy is developed, including plans for regular review and updating			
Site-level infection control policy and plans are implemented and monitored by the designated focal person			
Triage policies are implemented to rapidly identify patients suspected of having TB (e.g. coughing patients) and separate them from other patients for rapid evaluation			
Patient waiting areas and medical examination rooms are well-ventilated, e.g. with open windows/doors and fans			
Healthcare workers are trained to use personal protective measures when examining patients with presumptive TB or when overseeing sputum production			
Healthcare workers are offered regular TB screening and those identified with TB are followed to ensure they receive appropriate TB treatment			
Patient educational materials about TB signs and symptoms and cough etiquette are visibly displayed in the clinic			

INTENSIFIED CASE FINDING	COMPLETED	IN PROCESS	NOT YET STARTED
Site-Level Activities			
Referral mechanisms for evaluation of women and children who are suspected of having TB are established			
A standardized TB symptom screening tool[a] for PLHIV is available and is used to screen pregnant and breastfeeding women at every clinical visit			
All infants or children living with HIV who are seen in MNCH services are screened for TB disease using a standardized symptom screening tool[b]			
Women and children with presumptive TB are actively followed to ensure that they are appropriately evaluated, including access to Xpert MTB/RIF as the initial diagnostic test for PLHIV			

INTENSIFIED CASE FINDING	COMPLETED	IN PROCESS	NOT YET STARTED
Site-Level Activities			
Women and children confirmed to have TB disease are followed to ensure that they are initiated on TB treatment as soon as possible			
Women and children identified with TB disease are encouraged to bring other household members to the clinic for TB screening and evaluation			
Infants born to mothers with known TB disease (or with other known household TB contact) are fully evaluated for TB disease and receive treatment or prophylaxis in accordance with national guidelines			
ISONIAZID PREVENTIVE THERAPY	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
Site-Level Activities			
HIV-infected pregnant and breastfeeding women in whom active TB disease is excluded[c] are offered IPT			
HIV-infected children (age 1 year and older) in whom active TB disease is excluded[c] are offered IPT, regardless of TB contact history			
HIV-infected infants (age < 1 year) who have known contact with a TB case and in whom active TB disease[c] is excluded are offered IPT			
MONITORING AND EVALUATION (M&E)	**COMPLETED**	**IN PROCESS**	**NOT YET STARTED**
National- and Site-Level Activities			
Mechanism for communication between TB and PMTCT M&E systems is established			
PMTCT M&E tools are updated to capture data on TB screening, TB diagnosis, TB treatment, TB treatment outcomes, IPT initiation and IPT completion			
TB suspect registers are available to enhance follow-up women (or children) who need evaluation for TB disease			
IPT registers or other M & E tools are available to track adherence and outcomes of women (or children) initiated on IPT			
TB infection control measures and healthcare worker surveillance for TB are routinely documented			

[a] WHO recommends the use of an evidence-based 4-symtpom screen among all adults living with HIV, including pregnant women: current cough, fever, night sweats, or weight loss. An individual with one or more of these symptoms should be considered to have presumptive TB and referred for evaluation [6].

[b] WHO recommends that children living with HIV be screened for TB by asking about fever, current cough, contact history with a TB case, or poor weight gain [defined as reported weight loss, or very low weight (weight-for-age less than –3 z-score), or underweight (weight-for-age less than –2 z-score), or confirmed weight loss (>5%) since the last visit, or growth curve flattening].

[c] Active TB disease can be reliably excluded in people living with HIV who screen negative (i.e. answer no to all questions) by the WHO evidence-based TB screening tool. Patients should continue to be closely followed during the IPT course to assess for new TB symptoms.

Resources

1 World Health Organization. Global Tuberculosis Control: WHO Report 2013. Geneva, Switzerland: World Health Organization, 2013. Available at http://www.who.int/tb/publications/global_report/en/.

2 STOP TB Symposium 2011: Meeting the Unmet Needs of Women and Children for TB Prevention, Diagnosis and Care: Expanding Our Horizons. Available at http://www.stoptb.org/wg/dots_expansion/childhoodtb/new.asp.

3 Gupta A, Bhosale R, Kinikar A, et. al. Maternal Tuberculosis: A Risk Factor for Mother-to-Child Transmission of Human Immunodeficiency Virus. The Journal of Infectious Diseases. 2011; 203:358-363.

4 Gupta A, Nayak U, Ram M, et. al. Postpartum Tuberculosis Incidence and Mortality among HIV-infected Women and Their Infants in Pune, India, 2002-2005. Clinical Infectious Diseases. 2007; 45:241-249.

5 Getahun H, Sculier D, Sismanidis C, Grzemska M, Raviglione M. Prevention, Diagnosis, and Treatment of Tuberculosis in Children and Mothers: Evidence for Action for Maternal, Neonatal, and Child Health Services. The Journal of Infectious Diseases, 2012; 205 (supplement 2):S216-S227.

6 World Health Organization. Guidelines for Intensified TB Case-finding and Isoniazid Preventive Therapy for People Living with HIV in Resource-Constrained Settings. Geneva, Switzerland: World Health Organization, 2011. Available at http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf.

7 World Health Organization. Recommendations for Investigating Contacts of Persons with Infectious Tuberculosis in Low- and Middle-Income Countries. Geneva, Switzerland: World Health Organization, 2012. Available at http://apps.who.int/iris/bitstream/10665/77741/1/9789241504492_eng.pdf.

8 World Health Organization. WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households. Geneva, Switzerland: World Health Organization, 2009. Available at: http://www.who.int/tb/publications/2009/9789241598323/en/

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6 Costing Tool:

Considerations in Costing a Transition to Option B/B+

6.1 Introduction

Using costing models for informed decision-making

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

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

6.2 Modeling Considerations

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

Model scope: operational considerations

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

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

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

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

Sustainability and mitigating cost factors

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

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

Costing vs. budgeting: an interactive process

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

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

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

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

6.3 Key Inputs Required for PMTCT Costing

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

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

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

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

Table 1

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

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

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

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

6.4 Outputs

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

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

6.5 Choosing a Model & Contact Information

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

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

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

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

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

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

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

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

7 Human Resources for Health

7.1 Background Information

This guide is intended to support Ministries of Health dialogue on Human Resources for Health with national and international stakeholders in the training, recruitment, and deployment of health workers and updating/reviewing relevant regulatory frameworks for defining health workers scope of practice, within the context of Option B/B+ roll-out.

- Why should Ministries of Health consider dialogue with stakeholders around HRH in the context of Option B/B+ roll-out?
    - The goal to eliminate new HIV infections among children by 2015 and keep mothers alive demands responsive and efficient HRH to support and sustain swift country response.
    - In the majority of the Global Plan priority countries, shortage of health workers, inadequate mix, mal-distribution of existing workforce, and low morale are major challenges in meeting the EMTCT goal. Within the last decade, countries used several approaches and strategies to address HRH for expanding access to HIV testing, care and treatment services. It is important that countries build on lessons learned, and continue scaling up what works. It is also essential that programmes foster innovation and ongoing programme learning in the context of scaling up option B/B+.
- What should Ministries of Health consider as key HRH discussion and talking points in the context of scaling up Option B/B+? A number of factors countries may consider, in addressing the quantity and quality of their HRH base are listed below. It is anticipated that these factors would be considered in the context of a broader HRH assessment, to develop short-term as well as long-term solutions.

7.2 Policy & Needs Assessment for HRH

Understand HRH needs in the context of Option B/B+ roll-out.

- Assess HRH needs in the context of Option B/B+ scale up.
    - Identify what types of cadres of health workers are needed at various levels of the health system, including facilities in rural settings and other marginalized communities.
    - Prioritize gaps in cadres, the distribution of health workers, and training and support required to roll-out Option B/B+.
    - Assess the capacity of programme managers at various level of the health care delivery system to plan, coordinate, implement and monitor Option B/B+ roll-out.

- Assess the number and distribution of HR managers who are deployed across the health systems and their role in implementing identified solutions.

Determine if HRH policies, regulatory frameworks and programme environments impede Option B/B+ roll-out.

- **Assess HRH policies regarding mid-level provider (MLP) initiation of ART (i.e. clinical officers, nurse practitioners, and midwives).**[b] Determine if official policies (MOH, regulatory boards/councils) impede PMTCT roll-out or if they are sufficiently harmonized regarding ART initiation and updated health workers "scopes of practice."
- **Work with health professional associations, national credentialing authorities, MOH chief officers (e.g., Chief Nursing Officer, Chief Clinical Officer, etc.), health workers, academic representatives, and networks of PLHIV** in your country, with respect to task shifting. A holistic approach to operationalizing PMTCT services requires communication with these stakeholders as well as their involvement in facilitating HRH/clinic readiness for implementing national protocols.
- **Consider critical HRH issues in responding to both acute and chronic care.** Recognize that HIV care and treatment is a lifelong intervention for the woman who is living with HIV. Ensuring continuity of care or retention, patient education and counselling, linkage to community resources are some of the essential aspects of chronic care.
- **Collect and show evidence where task-shifting has worked.** This includes nurse initiated management of ART (NIMART) in Lesotho, South Africa, and many other countries.
- Ensure supportive programme environment framework for delivery of ART at primary health facilities where most women and children access services. In some settings, policies may not allow ARV drugs to be dispensed at primary care health centers.

[b] Countries may have various cadres of health workers who are mid-level providers, but the list often includes clinical officers, nurse practitioners, midwives, and others.

Identify key stakeholders and build partnership around HRH for Option B/B+ roll-out.

- **Disseminate HRH information to strategic partners and build partnership around HRH.** Raise HRH challenges with strategic partners and find solutions. Many organisations can collaborate in this area. Work with partners especially the MOH Department of HRH, international organisations such as WHO, UNICEF, UNAIDS, and UNFPA, as well as partners such as Management Sciences for Health (MSH), EGPAF, and IntraHealth, and other IATT partners to identify solutions and decide how to best transition your regimens. Identify strong HRH partners, including those in the private sector.
- **Foster collaboration across different national programmes** (e.g. among HIV, sexual and reproductive health (SRH), Tuberculosis (TB)). Such collaboration could focus on shared priority areas such as health workers training and supportive supervision, drug procurement and supply management, programme monitoring and evaluation, and community involvement. The lack of programme collaboration may increase service providers' workload, for instance, by the requirement to fill out multiple registers, aggregate and report data to parallel multiple programmes and partners, or health workers may be pulled out to attend multiple uncoordinated trainings. This is a particularly pressing issue in rural facilities, which are often poorly staffed.
- **Encourage provider dialogue on maximizing the role of "lay" health personnel in PMTCT services.** This discussion can be enhanced through shared examples of community impact, discussion points, talking notes, and clear facts about the effectiveness of engaging community members as client advocates. Collaborate with relevant leadership to ensure this information is also included in provider training.
- **Support and facilitate opportunities for health workers feedback and experience to inform policy dialogue.** Continued programme learning through healthcare providers' feedback, evaluation and best practice documentation can facilitate policy dialogue.

Include HRH needs in the national Option B/B+ roll-out plan.

- **Identify an HRH focal point** in the national HIV/AIDS commission/programme to oversee and support HR in the implementation of Option B/B+. Develop the Scope of Work (SOW) for the HRH focal point.
- **Embed HRH in the national EMTCT roll-out plan,** and incorporate short and long-term strategies to address key priority issues related to human resources in the context of Option B/B+ roll-out.
- **Consider expanding the human resource base for Option B/B+ roll-out.** Studies and programme experience indicate that community support is an essential component of HIV care and treatment.

- Strengthen community systems and linkages with facility level services to support access, retention, and treatment adherence.
- Expand community HRH workforce, and also prepare existing health workers who play role in the training, supervision and mentoring of community workers.
- Link services with initiatives that could help pregnant women when they are most vulnerable, immediately after a positive HIV test result and the need for lifelong treatment, such as mothers2mothers (m2m) or local networks of PLHIV.
- Highlight the importance of community support in lifelong treatment and retention in HIV care, and treatment adherence.[c]

- **Remain alert to inequities as macro data hide important differences** and urban-rural imbalances. Many women and their families in rural locations may face difficulties in accessing health services, if they have to travel long distances to receive ART as this adds transport cost. One consideration, particularly in high burden settings, is to decentralize HIV care and treatment to peripheral facilities that are close to their home. However in most settings, health workers tend to concentrate in urban locations and rural facilities often face limited staffing. In such settings, where feasible, the existing limited health staff can particularly be supported by community workers and community level interventions.

[c] In 2012, UNAIDS published a literature review examining the role of communities in HRH and EMTCT, and especially their psychosocial role. The study developed a conceptual framework that focuses on communities and how they can be engaged more effectively in service delivery. The report is in a special issue of the Journal of the International AIDS Society: http://www.jiasociety.org/jias/index.php/jias/article/view/17390.

7.3 Training

Ensure health workers receive training in preparation for Option B/ B+ roll-out plan.

- **Ensure providers training (in-service and pre-service) incorporates the latest PMTCT guidance and provides sufficient clinical oversight regarding the introduction of new procedures.** Tailoring generic training to specific disciplines elevates awareness of expected professional competencies regarding ART/PMTCT. Additionally, collaboration with professional regulatory boards facilitates the inclusion of ART/PMTCT questions on credentialing examinations for newly trained graduates. This collaboration can also impact current providers by introducing ART/PMTCT training as a requirement for re-licensure.
- Involve key stakeholders for HRH and HIV & SRH/MNCH programmes in the development of the national roll-out plan and health workers training.
- Incorporate resources required for training, mentoring, and supervising or orienting health workers (i.e. both programme managers and service providers) in the national roll-out plan.
- Have a nationally standardized competency-based training on HIV care and ART, PMTCT for nurses and midwives. Use innovative approaches to ensure continued education of health workers e.g., use of computer or internet based trainings, distance learning approaches, mobile technologies, etc. to minimize service interruption due to health workers participating in training.
- When necessary, have standard operating procedures for health workers at facility levels. This would support health workers in the initial roll-out phase while building their experience.
- Have a more detailed plan for rapid roll-out of targeted training for health workers at national/subnational/facility levels. Match health workers training roll-out with expansion of services.
- **Plan for standardisation and predictability of the Option B+ landscape.** HRH personnel in the clinic will need to interact seamlessly with other staff in the pharmacy, those in the lab, those in the supply chain and those in the psychosocial support teams, among others. This will require respect for procedure in order to have smooth and dependable systems.

Resources

1 WHO, PEPFAR, UNAIDS. 2008. Task shifting: Global recommendations and guidelines. Available at: http://www.who.int/healthsystems/TTR-TaskShifting.pdf

2 WHO and GHWFA. 2011. Global experience of community health workers for delivery of millennium development goals: A Systematic Review, Country Case Studies, and Recommendations for Integration into National Health Systems. Available at: http://www.who.int/workforcealliance/knowledge/publications/CHW_FullReport_2010.pdf

3 WHO. 2012. Programmatic update: Use of Antiretroviral Therapy for treating pregnant women and preventing HIV infection in infants. Available at: http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.6_eng.pdf

4 MSH. 2005. Human Resource Management Rapid Assessment Tool for Public and Private Sector Health Organizations. Available at: http://erc.msh.org/newpages/english/toolkit/hrd.pdf

5 CDC. Strengthening the African Health Workforce. Available at: http://www.cdc.gov/globalaids/success-stories/arc.html

6 USAID, Capacity Plus. HRH: Global Resource center. Accessible at: http://www.hrhresourcecenter.org/

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8

Procurement & Supply Chain Management

8.1 Introduction

In many respects, a switch to Option B/B+ represents a move to greater efficiency and simplification in the supply chain:

> "[In Option B/B+] the ability to use the same regimen for PMTCT and for first-line ART considerably simplifies drug forecasting, procurement, supply to facilities, and drug stock monitoring. The first-line regimen of tenofovir/lamivudine/efavirenz (TDF/3TC/EFV) is available as a single-pill fixed-dose combination and has been recommended recently as the optimized regimen for first-line adult treatment, including for pregnant women.[b]"

Option B+ provides even further advantages in terms of streamlining and simplifying the supply chain, as it does not require CD4 testing to determine ART eligibility (as in Option A) or whether ART should be stopped or continued after risk of MTCT has ceased (as in Option B). As early evidence in Malawi has demonstrated – with a nearly fivefold increase in the numbers of pregnant women enrolled on ART in the first quarter of nationwide implementation – there are many benefits to the one-size-fits-all, integrated approach of Option B+. Likewise, as demonstrated in Malawi, roll-out of Option B+ has meant rapid scale-up and a major change from the previous service delivery model, which has created both opportunities and challenges.

Maintaining ongoing commodity security for women and their children is of utmost importance as this transition is made. Despite the many ways in which implementing Option B+ can radically simplify and harmonize supply chains, it is nonetheless a major change that does require some additional considerations. Not least of which is the additional funding required to purchase the increased volume of ARVs, particularly as countries integrate the ART and PMTCT systems in country, as part of the move to Option B+.

This tool provides some key questions to consider and resources for national decision-makers, program managers, consultants and implementing partners involved in logistics and supply chain to use when planning the implementation of Option B+.

[b] "WHO Programmatic Update: Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants", April 2012, http://www.who.int/hiv/PMTCT_update.pdf

8.2 Key PSCM questions to ask when planning the implementation of Option B+:

Once Option B+ is adopted as national policy, it is recommended that HIV positive pregnant women are treated as part of the general ART programme and stock levels of ART for pregnant women living with HIV monitored as part of the national procurement and supply management (PSCM) system. Currently and increasingly, as countries transition to Option B+, the provision of ART for HIV positive pregnant women occurs in MNCH settings, underscoring the need to strengthen PSCM for MNCH commodities and promote integration of the national MNCH and ART programme, where feasible.

Once Option B+ is adopted as policy, the quantification of ARV needs should include all pregnant women as part of the larger population eligible for ART. Pregnancy actually becomes a criteria for ART eligibility and should not be a cost outside of the ART programme. Partners wishing to contribute to support Option B+ can join the national basket fund and the planning group. For more information on costing ARV drugs for EMTCT the costing tool is useful if EMTCT has a starting point and an ending point. In the case of Option B+, ART use in pregnant women becomes a recurrent cost.

Funding

- Has a costing exercise been completed so that the additional costs of Option B+ are fully quantified and understood?
- Are sufficient funding sources currently available to provide for the additional costs of B+ implementation?
- Who are the partners and what is their role in financing PMTCT and MNCH commodities?

Quantification

- Questions to consider while gathering the inputs for the quantification:
    - How will alternative regimens be incorporated into the quantification?
    - What is the refill strategy at the facility level (monthly, quarterly)?
    - What assumptions are being made as regards to scale-up and speed of switch over to Option B+?

- Are national forecasts conducted for all EMTCT commodities, and if so, how frequently? An annual quantification and forecast is recommended with quarterly review to take account of actual consumption and to enable adjustment of upcoming orders as necessary.
- Are health facilities submitting complete and reliable commodity consumption and service delivery data on a timely basis? If not, what proxy data can be used in quantification and forecasting?
- Is consumption or distribution data used for forecasting and ordering of EMTCT commodities?
- Is the current EMTCT forecasting process a part of the general ART forecasting process in the country? If not, what are the plans to integrate these processes?
- Which tool is currently used for EMTCT commodity forecasting?

Procurement and supply concerns

- In order to prevent excess wastage, what is the plan to use up current existing commodities that will no longer be needed when Option B+ is rolled out?
- Have there been stock-outs of EMTCT commodities in the past 6-12 months?
- Have there been any issues with suppliers in terms of delayed delivery (e.g., with NVP syrup)?
- How does the country currently tender for and procure EMTCT commodities? Is there a plan to integrate this process with general ART procurement and tendering in the country?
- If you have experienced in-country customs clearance process delays, can you order further in advance or use other strategies to mitigate this risk?
- If new commodities or increased quantities of currently stocked commodities are required does the project plan to introduce Option B+ allow sufficient time for the full realistic procurement and delivery cycle of new orders?

Distribution

- Do all sites that provide commodities for PMTCT also provide ART initiation and ART refills? If not, how many facilities provide solely PMTCT? In moving to Option B+, are there plans to expand ART initiation and/or refill services to all sites currently providing only PMTCT commodities?

- Are there currently separate systems for distribution of ART and EMTCT commodities? What are your plans to extend the availability of commodities at the point of service, and limit too many upstream referrals for refills?
- What efforts are being made at the "last mile" of the distribution system, to ensure that commodities make it out to facilities efficiently?
- Are there opportunities to integrate procurement and distribution of EMTCT commodities with that of other systems, including contraceptives, immunisations, etc.? What coordination is happening between the various groups?
- Do systems exist to identify excess stock at sub-distribution point and at facility level to enable products to be reallocated and moved to areas with higher demand? Redistribution mitigates the risk of localized stock outs and wastage at points of lower than expected demand.

Monitoring

- Do PSCM managers at a health facility level monitor consumption and stock levels and number of patients on EMTCT on monthly basis? A monitoring tool can be found at the link here: http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/index.html
- What are the plans for integrating the existing EMTCT M&E systems with those for ART?
- Are strong systems in place to support adherence and retention, during pregnancy and postpartum? This becomes particularly critical with Option B+.

8.3 High-Level Red Flags

Stock-Outs

If you have experienced stock-outs of any EMTCT commodities in the past 12 months, you must investigate the cause of the problem – was it an inaccurate quantification? Poor ordering and reporting from sites? Inefficiencies with distribution at the site level? Unexpectedly rapid scale-up (which is very likely during roll-out of Option B+)? And address the problem accordingly.

Supplier delivery delays

For products for which you experience delivery delays, particularly those that are single-sourced, consider increasing the size of your buffer stock for that product during your next quantification and order cycle, in order to prevent future stock-outs.

Prioritizing pregnant women for ART

It is necessary to conduct sensitisation and advocacy activities to ensure that pregnant women that do not meet the treatment eligibility criteria for the general adult population are still prioritized for ART.

Conclusion

In Option B+, the quantification, PSCM, distribution and monitoring of ARV and other required specific commodities should be integrated in the national ART programme. Health professionals working in PMTCT and MNCH should be represented in the various ART technical working groups to ensure that the specific needs of pregnant women are well addressed. In case the country has a parallel EMTCT system, the above questions raised under quantification, PSCM, distribution, and M&E highlight red flags and a plan for integrating the national ART programme should be urgently implemented to prevent a vertical process which may lead to inefficiency and not be sustainable in the longer term. When integrating the national ART and PMTCT programme, it is important to ensure that all the issues raised above are functioning well in the national PSCM system to ensure an effective supply chain management for all HIV positive pregnant women and individuals eligible for ART.

8.4 Pre-Implementation Checklist

Guidelines

- ☐ Updated PMTCT guidelines, training materials and job aids
- ☐ Guidelines for the management of the new supplies, including stock management, requesting and reporting tools

Checklists

- ☐ Checklists for accreditation of health facilities for the implementation of the revised PMTCT guidelines, including minimum standards of the management of the new supplies (in terms of availability of appropriate human resources, storage quality, capacity and security)
- ☐ Supervision checklists for the pharmaceutical and other health staff, and trainers for the pilot on the new guidelines and of trainers for the pilot

Training

- ☐ Training plans for the health care providers and pharmacy personnel at all levels of the health system, including training of trainers
- ☐ Determine the minimum number of trainers and supervisors required for the training of health workers for the piloting and roll-out of the new guidelines.
- ☐ Training on monitoring and evaluation
- ☐ Task shifting plan to ensure that ARV drugs for treatment can be dispensed in facilities where PMTCT activities are carried out

Piloting and roll-out

- ☐ Identification of health facilities for piloting the new guidelines
- ☐ A plan for phased roll-out of the new guidelines, including data on targeted populations by region or health facility

Quantification and forecasting and procurement (for the first 5 years)

- ☐ National quantification and forecasting of the commodities, including pharmaceuticals and diagnostic laboratory commodities, if possible disaggregated by region, level of care or health facility
- ☐ Procurement plan and budget for the first year, and the first 3-5 years
- ☐ Availability of funds and funding sources

List of key PMTCT commodities for Option B+

- ☐ Laboratory reagents and supplies:
  - Rapid tests
  - CD4
  - EID
- ☐ ARVs:
  - Mothers*:* fixed-dose combination of the preferred regimen (e.g., TDF/3TC/EFV) and the alternative regimens (e.g., AZT/3TC+EFV) for ART
  - Babies: NVP syrup or NVP dispersible
- ☐ Opportunistic infections (OIs):
  - Co-trimoxazole prophylaxis for mothers and babies
- ☐ Maternal Health commodities:
  - Standard list of micronutrients for ANC attendants
  - Diagnostic kits and laboratory reagents required for routine monitoring in ANC

Distribution plans

- ☐ Initial distribution plans by facility
- ☐ Maximum and minimum stock levels agreed for each facility and distribution point
- ☐ Re-supply distribution plans, depending on whether pull or push system is planned
- ☐ An appropriate distribution system for the commodities, if necessary, identification of potential agencies for out sourcing

8.5 Key Resources: Links to Tools

General procurement and supply chain management tools

- PSM Toolbox: www.psmtoolbox.org

WHO early warning indicators to prevent stock-outs

- http://whqlibdoc.who.int/publications/2011/9789241500814_eng.pdf

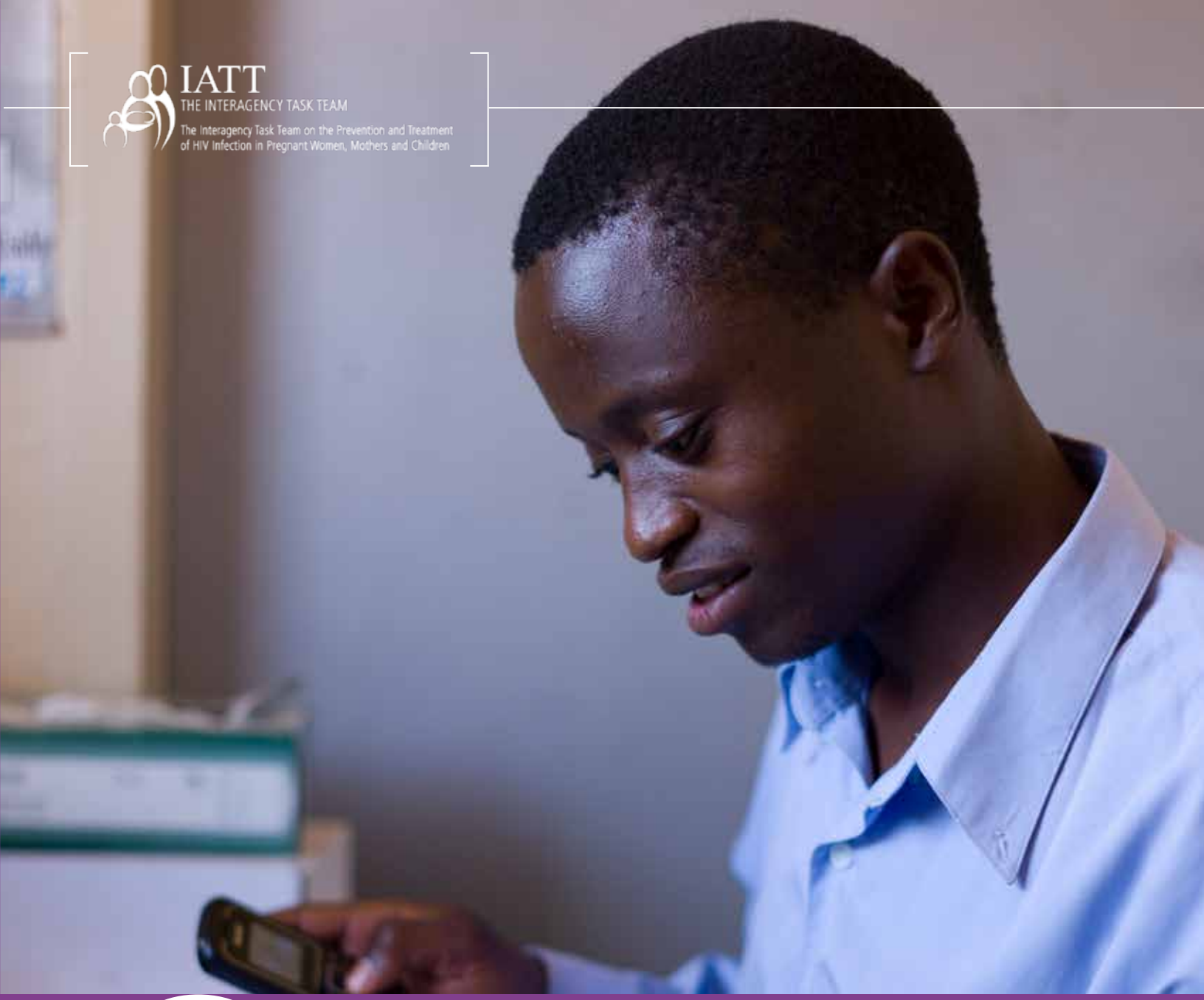
ARV forecasting & quantification (these tools may need to be adapted somewhat for Option B+)

- CHAI ARV Procurement Forecasting Tool: http://www.psmtoolbox.org/en/tool-details%7CQuantification%7CCHAI-ARV-Procurement-Forecasting-Tool%7C74
- Quantimed: http://www.msh.org/projects/sps/Resources/Software-Tools/Quantimed.cfm
- Other tools: To be uploaded as and when they become available

Tools available to support facility-level commodity monitoring

Most countries have tools for monitoring the consumption, quantities issued and overall stock levels of ARVs and other key supplies. In Option B+, they can be adjusted to include any items to ensure that PMTCT commodities are well covered.

For countries which do not yet have a tool in use, several tools from various partners are found in the PSM Toolbox (see point 1 above). Using “stock” as a key search word, at least 47 tools will be found.



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9 Enhanced Monitoring & Evaluation Systems

9.1 Background Information

This document describes the characteristics of national and subnational M&E systems needed to optimize the monitoring and evaluation of programmes implementing Option B/B+ and targets MOH staff and M&E or Strategic Information specialists at the national level. Four key facets of an optimal M&E system are described, as well as critical operations research questions to consider prior to implementing Option B/B+.

Countries should have an M&E plan to monitor progress of national EMTCT efforts through 2015, including subnational monitoring [*See Global M&E Framework and strategy document (WHO, 2012)*.] National M&E systems should also meet the minimum standards outlined in the UNAIDS (2008) document *12 Components of a Functional National HIV M&E System.*

9.2 Six Key Points for M&E Systems

Key Point 1

PMTCT M&E and ART M&E systems must be integrated

Traditionally, PMTCT services are delivered in ANC sites and ART is initiated and delivered at ART sites using separate M&E systems and tools that typically do not link women across service delivery areas effectively. Given that Option B+ requires that ART services be integrated into the MNCH platform, M&E systems for ART and PMTCT will also need integration for accurate reporting of pregnant women newly initiating ART. An "integrated M&E system" is defined as a system where an individual patient can be followed from enrolment in first ANC visit through followup in ART services using a unique ART patient identification number to link a patient across registers, facilities and patient held cards across different service delivery areas.

Questions for country discussion:

- How will information on ART initiation be recorded if ART is initiated in ANC?
- If ART is not initiated in ANC, how is the woman's pregnancy clearly indicated in the ART register to permit tracking of pregnant women?
- How will the number of pregnant women initiating ART be aggregated for national reporting across service delivery models (e.g., pregnant women initiating ART in ANC or ART)?
- Will there be a single, consistent data source for pregnant women initiating ART for monthly aggregation and reporting? (Can the current drug-dispensing register be used to identify pregnant women starting and continuing ART?)

Key Point 2

Each pregnant woman should be assigned a unique patient identifier which permits tracking over time, and across service delivery areas when women's long term care is transferred from MNCH to ART and also links a mother to her infant.

Questions for country discussion:

- **Patient identifier (PID) for pregnant women:** Is there a single unique patient identifier for a pregnant woman? What programme does it represent (e.g., ANC number? MNCH number? Maternity number? ART number? Pre-ART? Other?) Who assigns the PID? Where is this number recorded? Registers, patient card, infant card?
- **Linking women across services and referral to ART:** Does the PID link a woman across services? Or does each programme assign a new PID? For example, does the woman use the same PID at ANC, maternity, postnatal care and ART? If the woman is referred to an ART programme at a different facility, is she assigned a new PID?
- **Linking mother and HIV exposed infant:** Is mother's PID recorded on infant records? Does infant receive a unique PID for tracking? Is the infant PID for HIV exposed infant follow up care (e.g., co-trimoxazole prophylaxis, PCR testing) linked with her ART number if she is determined HIV-infected?

Key Point 3

National M&E tools and methods must include longitudinal monitoring of pregnant women initiating Option B/B+ and mother-infant pairs in order to evaluate whether women who initiate ART during pregnancy remain on ART, and that infants receive clinical care, including determination of final HIV status.

Questions for country discussion:

- Are current PMTCT tools visit based or longitudinal? If visit-based, how feasible is it to introduce longitudinal registers?
- Does the current M&E system report retention of PMTCT or ART cohorts? What is the feasibility of reporting retention of pregnant and postpartum women on ART, 6, 12 and 24 months after ART initiation? Is there a system to identify women and infants who are lost to and require follow up? What is the feasibility of introducing a national indicator on retention of pregnant women and mother-baby pairs?
- Does M&E system use cohort reporting? [*see Malawi National M&E tools for useful examples*]

- How does the national programme intend to monitor retention following implementation of Option B+:
  - Retention of pregnant women 6, 12 and 24 months after initiating Option B/B+ treatment
  - Retention of women enrolled in PMTCT (possible outcomes: attendance at 4 ANC visits, ARV prophylaxis/ART dispensed or initiated; facility deliveries, infant ARV doses provided)
  - Retention of mother-baby pairs from first ANC visit through determination of final infant HIV status at 18 months
  - Retention of HIV-exposed infants (HEI) in follow up care and linkage to ART for children determined to be HIV-infected
  - Retention of HIV infected infants and children who started ART

Key Point 4

Data should be reviewed quarterly at district level and at least annually at national level and results used for quality improvement and programme adjustment.

Questions for country discussion:

- Is there an annual data review/validation process that includes M&E and programme personnel?
- Is there a system for using data for quality improvement at each level of the system? What mechanisms exist for programme and M&E staff to collaboratively develop tools and training materials to optimize documentation of Option B+ critical at the planning phase?
- Is there a system for disseminating and reviewing subnational data and using data for programme review and progress towards targets?
- Key indicators for programme review might include: 1) What is the retention rate of pregnant women 6 and 12 months after ART initiation? 2) What proportion of HIV exposed infants are enrolled in HEI follow up care and received co-trimoxazole and EID by 8 weeks of age; 3) What proportion of women initiating ART obtain CD4 (or VL) testing within 6 months of initiation; 4) What is the proportion of HIV exposed infants from the PMTCT cohort who have a final status at 18 months?
- If country sees the need for revising tools (registers, patient cards for ART, introduction of longitudinal registers for mother-infant pair, HEI follow up), what is the process for reviewing and revising tools? Timeframe?

- Have the financial costs for annual data review meeting, revising tools, printing registers, patient cards, training materials and training sessions been included in programme budget?

Key Point 5

Routine data quality assurance activities should be included in programme implementation plans in order to accurately measure achievements of a new programme. Assessing the accuracy and completeness of routine indicators is a key activity.

Questions for country discussion:

- Data quality:
  - Are data quality audits or assessments conducted routinely (at least annually) at facility, district and national level?
- Will districts verify that facilities are using the most recent version of the national data collection tools? Are all staff trained on how to use the data collection tools?
- How do current data collection tools impact data quality? What steps are taken to avoid double counting of women receiving services at different service delivery areas?
- How will districts validate the accuracy of monthly programme data after implementation of Option B/B+? Will this require updating current methods for validation?
- Quality of clinical services:
  - What site supervision systems are currently in place to ensure quality service provision and data collection? Is the routinely collected M&E data used for assessment and improvement of quality of care? What other measures are used to assess quality of care in-country?
- Have health care workers been trained in latest national ARV guidelines? Are current ARV regimens available at the facility? Have registers and patient tools been updated to reflect latest national ARV guidelines? Is there a process in place to do so?

Key Point 6

Operations research questions should be defined from the onset and integrated into programme roll-out.

There is currently limited evidence to guide many decisions about programme implementation. Where possible, comparisons of different service delivery approaches can be built into operational plans, although specific protocols and additional data collection may be required. MOH staff, M&E specialists and programme implementers at the national level should prioritize programme implementation questions and coordinate operations research efforts among donors as they roll-out their programmes.

Questions for country discussion:

- Data collection:
  - Is there a data collection mechanism to review operational bottlenecks?
  - Do any data gaps exist? What data needs exist beyond data captured within routine monitoring? Is it feasible to establish sentinel cohort monitoring systems to provide more comprehensive review of programme outcomes and impact of Option B+ implementation?
- Integration and human resources:
  - How can the workforce and configuration of MNCH clinics be organized to manage the additional tasks and workload involved in initiating HIV-infected pregnant women on lifelong ART and engaging them in care?
  - How does increased workload affect other MNCH services?
- Acceptability/Feasibility of lifelong therapy:
  - What regimen options exist for HIV-infected pregnant women who decline lifelong ART?
  - Are there any myths and misconceptions around ART? What are community, facility and health care worker perceptions of Option B+?
- Programme outcomes:
  - Birth outcomes and toxicity monitoring of women and exposed infants since there is limited experience with the use of the recommended drugs in pregnancy, particularly first trimester exposures.
- Retention/Referral:
  - How will facilities with PMTCT programmes, but no ART services ensure functional linkages?
  - How can women and their infants be tracked across services delivery sites (i.e., ANC, MNCH, HIV clinics) to ensure an uninterrupted continuum of care?
  - What are the roles/functions of peer educators, community health workers and other community organisations to optimize retention in ART for post-partum

women? And what model of community support works best?

- Adherence:
  - What are the factors associated with ART adherence?
  - What is the best way to measure adherence in the absence of viral load monitoring?
- Equity:
  - How can male partner access to ART be assured in a resource constrained environment?
  - How will community messaging address the conflicting messages that all pregnant HIV infected women should start on ART for life for the benefit of themselves, their babies and partners, but other adults including partners and non pregnant women need to wait for decreased CD4 counts before starting ART?
- Logistics:
  - How can commodity forecasting be optimized to ensure an uninterrupted supply of test kits, ARV drugs, etc.?
  - What is the best configuration of clinic space and flow when integrating ART services into ANC?

Table 1: Key M&E discussion points by service delivery model

	MODEL 1	MODEL 2	MODEL 3	MODEL 4
ART INITIATION	ANC	ANC	ANC	ART
ART FOLLOW UP	MNCH until child is 18 months of age	ANC thru delivery, then transfer in to ART clinic	ANC thru postpartum visit at 6 weeks, then transfer in to ART clinic	ART
UNIQUE PATIENT ID ASSIGNED	ANC	ANC	ANC	ART
PROCEDURE FOR REGISTERING PREGNANT WOMAN ON ART	Transfer in	Transfer in	Transfer in	New patient
TO AVOID UNDERESTIMATION OF PREG WOMEN INITIATING ART	Record ART regimen, initiation date	Record ART regimen, initiation date	Record ART regimen, initiation date	Record pregnancy status
MEASURE RETENTION OF WOMEN ON ART AT 6 MONTHS	MNCH	ART	ART	ART
FOLLOW UP OF HIV-EXPOSED INFANT	MNCH (care for infant coordinated with ART follow up visits for mother)	HIV exposed infant follow up clinic/ Immunisation/ Under 5 clinic	HIV exposed infant follow up clinic/ Immunisation/ Under 5 clinic	Immunisation/ Under 5 clinic
MEASURE RETENTION OF MOTHER-INFANT PAIR AT 12 MONTHS OF AGE	MNCH mother and infant patient records	Longitudinal/ Integrated mom-baby register	Longitudinal/ Integrated mom-baby register	Longitudinal/ Integrated mom-baby register

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10

Community Engagement:

a. A Guide for Ministries of Health (MOHs)

b. Frequently Asked Questions for Civil Society Organisations to Use in Dialogue with Ministries of Health

✓Quick Checklist: Has my country...

- ☐ Identified our 'communities' to engage with
- ☐ Mapped the structures in place to support community engagement
- ☐ Consulted with women living with HIV on Option B/B+
- ☐ Developed clear communication lines and materials with community stakeholders on Option B/B+
- ☐ Highlighted community engagement activities in revised national strategic documents
- ☐ Budgeted community engagement activities in national strategic documents
- ☐ Implemented community engagement activities with community stakeholders, especially women living with HIV
- ☐ Committed to using and supporting ongoing evidence-gathering to make sure that the voices and experiences of communities are heard and addressed
- ☐ Adapted and/or used community engagement indicators to monitor progress

10a.1 Background

Who is this for?

This guide is intended to help Ministries of Health better engage communities as they contemplate, plan for, and/or implement a policy change towards Option B/B+ as the national strategy for ending vertical transmission of HIV (also known as "EMTCT") and promoting the health of mothers living with HIV.

What is "community engagement" in the context of Option B/B+?

Community engagement refers to the process where the "community" (especially including women living with HIV) works collaboratively with national and local health authorities, facility and community based medical service providers, legislators, advocacy groups, and donors to develop, implement, and monitor Global Plan related care.

Involving communities in national level discussions around planning for and implementing the transition to either Option B/B+ means that community members become a key partner in:

- Increasing the uptake of EMTCT services through demand creation and providing peer support

- Improving the supply of EMTCT services through task shifting to community cadres (community health workers, mentor mothers, lay counselors, etc.)
- Monitoring EMTCT service quality and holding providers accountable
- Creating an enabling environment for EMTCT scale-up by empowering women and their communities to access health care under a rights-based approach

Why should Ministries of Health engage communities when planning for and implementing a shift to Option B/B+?

Communities need a clear understanding of proposed changes. For any programme or policy change to be successful, the communities affected must have a clear understanding of the current policy and changes being proposed so that they can give input and participate in decision-making and implementation.

Communities are key EMTCT stakeholders. Many community organisations and networks are involved in delivering EMTCT services (e.g. faith-based organisations (FBO)), educating community members about EMTCT services (e.g. community-based organisations), and providing supportive services (e.g. mentor mother programmes and support groups). As such, they are key stakeholders in EMTCT programmes. They must be involved in the planning and implementing of Option B/B+ programmes because they are the ones who will be educating community members and providing services.

Involving communities ensure that voices of women living with HIV are heard when developing and monitoring programmes and policies that impact them directly. Involving communities, especially women living with HIV, when considering, planning and/or implementing a programmatic change towards Option B/B+, ensures that programme beneficiaries can contribute to the resulting programmes and policies. This ensures that programmes meet the needs of women living with HIV and will empower them to seek services. Additionally, engaging women living with HIV in accountability efforts can ensure that programmes continue to meet the needs of women living with HIV.

Key Principle

Ensure that communities, especially women living with HIV, are meaningfully engaged throughout the continuum of the process, from planning to implementation to ongoing monitoring and accountability.

10a.2 Five Phases of Community Engagement

Phase 1: Planning

Step 1

Determine who the "community" is and who you want to and/or should engage in this effort.

- Consider the main stakeholders of programmes to prevent vertical transmission of HIV in your country, including women living with HIV, their partners and families, care providers in the facility and in the community, networks and organisations of people living with HIV, community-based organisations, faith-based organisations, etc.
- Consider how the EMTCT response is coordinated in your country (e.g. National AIDS Advisory Council, PMTCT Technical Working Group, Country Coordinating Mechanism, etc.). Identify the civil society representatives on those bodies.
- Understand what roles within current EMTCT efforts are played by civil society, including networks of women living with HIV, mentor mothers, faith-based organisations, and community-based organisations (e.g. demand creators, service providers, advocates, beneficiaries, etc.).
- Once you have identified the key community stakeholders, ensure they are well represented and involved in the two steps described below.

Step 2

Assess your country's national policy, legal and programme environment.

- Assess what structures exist and should be used to support community engagement (e.g. National AIDS Advisory Council, PMTCT Technical Working Group, Country Coordinating Mechanism, etc.).
  - If there is no formal community engagement mechanism, develop a mechanism in the Option B/B+ plan.
- Consult women living with HIV about whether an Option B/B+ regimen takes into account their values, experiences, concerns, and priority needs.
  - Please note that such evidence may already exist in the form of national assessment reports (e.g. People Living with HIV Stigma Index, Missing the Target Reports, any national level consultations, etc.).
- Determine what kind of information women living with HIV, their communities, and caregivers already have about Option B/B+.

- If such evidence does not exist, inform organisations and networks of people living with HIV about where you are in the process of switching to Option B/B+ and consult the community about the aforementioned issue. This is a prime opportunity to partner with community members to conduct this assessment.

- Develop clear communication with community groups throughout the process (i.e. informing communities that a policy change is being considered, where you are in the process of thinking about this policy change, the advantages/disadvantages of the policy change to Option B/B+, what changes will be implemented if Option B/B+ is chosen, and how communities can be involved in the process of shifting to Option B/B+). At a minimum, it will be very important to ensure that communities understand what Option B/B+ is and what the differences are between Option B/B+ and current treatment regimens.
- After ensuring that the communities have enough information about Option B/B+, give the community an opportunity to share their feedback and potential concerns with you.

Step 3

Improve the level and quality of involvement of communities in the move toward Option B/B+.

- If your country has already decided to move towards Option B/B+ and will be updating a national strategy accordingly, be sure that it includes a strong community engagement component. Minimum community engagement activities include the following:
  - Establish and strengthen community-based support services (including FBOs) to provide adherence, counselling, nutrition, referrals to existing support services, etc.
  - Train community workers (e.g. people living with HIV, community health workers, mentor mothers, peer educators, etc.) to assist in delivering supportive services within facilities and communities and to ensure linkages to and retention in facility care.
  - Support and provide community education and awareness in the following areas:
    - Identify and/or provide suitable IEC materials to community workers and community groups about Option B/B+ or develop them with the leaders of community groups
    - Provide resources and training to community workers and groups to enable them to create awareness about the areas listed
  - Strengthen and encourage community-led programme accountability
- Develop SMART[b] activities, inputs, outputs, outcomes, objectives and goals in relation to the aforementioned minimum community engagement activities.

[b] Specific, measurable, attainable, realistic and time-bound

- Adequately budget for the aforementioned minimum community engagement activities in national plans.
  - Ensure that staff are available to support partnerships with communities and to facilitate/coordinate, as needed, the aforementioned community engagement activities

Phase 2: Implementation

Implement Steps 1-3 above and the affiliated plans in partnership with communities, especially networks of women and men living with HIV, civil society, and all relevant and appropriate stakeholders.

Phase 3: Alignment into the national response to HIV (integration/coordination)

Step 1

In cooperation with partners, ensure that the community engagement principles and activities are integrated into the broader work in the national response to HIV, which includes:

- national strategic plans
- resource mobilisation for HIV, development and economic empowerment
- legal and policy reform
- health and communities systems strengthening
- mainstreaming HIV into sectoral work

Step 2

Ensure coordination, constructive dialogue, and information-sharing between diverse groups of partners regarding the community engagement activities.

Step 3

Foster partnerships through inclusive coordination mechanisms that are adequately resourced. Existing coordination mechanisms (e.g. National AIDS Advisory Council, EMTCT Technical Working Group, Country Coordinating Mechanism, etc.) may need to be reviewed and strengthened, and civil society coordination bodies may have to be developed and supported.

Phase 4: Continuous evidence gathering; make use of existing data

Step 1

Gather evidence on a continuous basis at all phases of implementation (i.e. during development, roll-out, adaptation and improvement) with the meaningful involvement and leadership of communities, especially women living with HIV.

- Example 1: The Missing the Target (MTT) 9 report assesses EMTCT programmes in ten countries and discusses key actions needed to reach EMTCT goals. Using such existing data and recommendations can support the programme or policy change towards Option B/B+. Additionally, re-using the MTT model to assess the progress and success of the shift towards Option B/B+ after plans are implemented can further support measurement of the effectiveness and impact of the plans.
- Example 2: The PLHIV Stigma Index can provide invaluable evidence on what actions need to be taken towards reducing stigma and discrimination. Re-implementing the PLHIV Stigma Index after those actions have taken place can support measurement of the effectiveness and impact of those actions.

Phase 5: Monitoring and evaluation (M&E)

Step 1

Use appropriate indicators for community engagement, especially with respect to the move towards Option B/B+, in the following areas:

- Establish and strengthen community-based support services (including FBOs) in relation to Option B/B+.
- Train community workers (e.g. people living with HIV, community health workers, mentor mothers, peer educators, etc.) to assist in delivering supportive services within facilities and communities and to ensure linkage to and retention in facility care.
- Support and provide community education and awareness in the following areas:
  - Identify and/or provide suitable IEC materials to community workers and community groups about Option B/B+ or develop them with the leaders of community groups.
  - Provide resources and training to community workers and groups to enable them to create awareness about the areas listed.
- Strengthen and encourage community-led programme accountability.

Step 2

Dedicate adequate resources (human, technical and financial) in the operationalisation of an M&E framework and mechanism for community engagement in the Option B/B+ process.

Step 3

Ensure that M&E of community engagement is an on-going aspect of every action.

Step 4

Ensure that communities can lead or participate in M&E efforts.

Resources

1 IATT Toolkit: Key Considerations Document (see Section 1)

2 Advancing the Sexual and Reproductive Health and Rights of PLHIV - A Guidance Package (2010). Available at: www.gnpplus.net/programmes/sexual-and-reproductive-health-and-human-rights/policy-guidance.

3 Good Practice Guide: Greater Involvement of People Living with HIV (GIPA) (July 2010). Available at: http://www.gnpplus.net/en/programmes/empowerment/gipa-report-card/1642-good-practice-guide-greater-involvement-of-people-living-with-hiv-gipa

4 MTT9: The Long Walk -Ensuring comprehensive care for women and families to end vertical transmission of HIV (December 2011). Available at: http://www.itpcglobal.org/atomic-documents/11057/11059/MTT9%20report.pdf

5 Positive Health, Dignity and Prevention Policy Framework (2012). Available at: http://www.gnpplus.net/images/stories/PHDP/GNP_PHDP_ENG_V4ia_2.pd

10b.1 Background

Purpose

The purpose of this tool is to equip Civil Society Organisations (CSOs) and Networks of Women/People Living with HIV with the information necessary to actively engage in national level discussions around the transition to offering pregnant women ART through the breastfeeding period (Option B) or for life (Option B+). The questions outlined below provide examples of the important issues that CSOs and Networks should encourage Ministries of Health to answer during the various implementation stages of a new treatment regimen to prevent vertical transmission and support mothers to stay healthy and alive.

Audience

This tool is intended to be used by members of CSOs and Networks of Women/People Living with HIV. CSOs in this context include community-based organisations, lay workers (e.g. mentor mothers, community health workers, peer counselors etc.), faith-based organisations, treatment activists, youth groups and other groups outside of government and business that are working to further the health and rights of women, children and families.

The tool was developed by the Community Engagement Working Group of the Inter-Agency Task Team on Prevention of HIV Infection in Pregnant Women, Mothers and their Children. The goal is to ensure that communities, especially women living with HIV of reproductive age, are engaged in all stages of the transition to Option B/B+. The purpose of this tool is not to advocate for any particular strategy for preventing vertical transmission, but rather to ensure that the views and concerns of CSOs and Networks of Women/People Living with HIV are seriously considered in the planning, implementation, and ongoing monitoring of service delivery to prevent vertical transmission at the national level.

PMTCT Options

Table 1: What is the difference between Option A, Option B, and B+?

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

Table 2: What are the benefits and potential challenges of Options B/ B+?

	POTENTIAL BENEFITS OF OPTION B	POTENTIAL CHALLENGES OF OPTION B
FOR A WOMAN LIVING WITH HIV	Increased access to treatment because: • Women do not have to wait for a CD4 count test before starting treatment. • Treatment can be started at primary care health facilities, reducing the distance that women have to travel to receive treatment. Women continue same treatment regimen between pregnancy/postpartum period (unlike Option A). Triple ARVs provided throughout breastfeeding period may encourage women to breastfeed longer improving child health, reducing stigma and discrimination, and reducing household expenditures for infant formula.	Potential impact on later treatment: women might develop resistance from starting ARVs during pregnancy and then stopping after breastfeeding that could limit her treatment choices later. A CD4 count test is needed after the risk of vertical transmission has ended (i.e. after childbirth or breastfeeding) to decide if the woman should continue taking ART for her own health.
FOR THE MINISTRY OF HEALTH AND OTHER HEALTHCARE PROVIDERS	Simplifies treatment as the same regimen is provided to all women.	Higher cost in comparison to Option A. Lack of involvement of women living with HIV and their communities in decisions relating to Option B at the national level.

POTENTIAL BENEFITS OF OPTION B+	POTENTIAL CHALLENGES OF OPTION B+	
Increased access to treatment because: • Women do not have to wait for a CD4 count test before starting treatment. • Treatment can be started at primary care health facilities, reducing the distance that women have to travel to receive treatment. Women may live longer and healthier lives due to starting treatment earlier. Reduced risk of transmitting to HIV-negative sex partner(s). May reduce the risk that a woman will develop resistance to ARVs resulting from stopping and starting ARVs after each pregnancy. Provides extended protection for future pregnancies from the time of conception. This is especially important in settings where women have short inter-pregnancy intervals.	Ensuring women are able to make informed choices around starting treatment for life. Concerns raised that women's choice around when to start lifelong ART, including the choice to decline lifelong ART during pregnancy, may not be respected. Lack of information including treatment literacy tools and counseling messages limits women's ability to make informed decisions on starting lifelong ART during pregnancy. Inadequate psychosocial and nutritional support services to support women in coping with their HIV diagnosis, to continuously take their medications, and to stay connected with health facilities.	**FOR A WOMAN LIVING WITH HIV**
Simplifies treatment as: • The same regimen is provided to all women regardless of their CD4 count. • There is no change in regimen between pregnancy/postpartum period (unlike Option A). • It does not require mothers, with support of their doctors, to decide whether ART should be stopped or continued after the risk of vertical transmission has ended (as in Option B).	Sustainability of Option B+: Ability of countries to ensure continuous supply of ARVs and comprehensive prevention of vertical transmission services given the increased demand on HIV treatment services associated with Option B+. This is of particular concern in countries with regular ARV stock-outs. Poor ART adherence and/or women not remaining in HIV clinical care after delivering their child could lead to widespread ARV drug resistance. Equity of offering pregnant women lifelong treatment at higher CD4 counts and not other population groups (i.e. fathers, non-pregnant women). Lack of involvement of women living with HIV and their communities in decisions relating to Option B+ at the national level. Several investments by MOH will be needed in human resources, infrastructure, and supply chain management to effectively scale-up ART services to all sites that provide antenatal care. Policies and procedures will need to be developed to support nurses to effectively initiate and prescribe ART.	**FOR THE MINISTRY OF HEALTH AND OTHER HEALTHCARE PROVIDERS**

10b.2 What questions must CSOs & networks of women/people living with HIV be asking?

Involvement of CSOs and networks of women/people living with HIV

CSOs and Networks of Women/People Living with HIV must be involved in the planning, implementation and monitoring of Option B/B+ to ensure that their perspectives inform the resulting programmes and policies. Meaningfully engaging and supporting CSOs and Networks of Women/People Living with HIV in the development of information materials and data collection tools as well as in the review and analysis of national programme data will result in a better understanding of the issues and will ensure that services meet the needs of women.

- How will women living with HIV and community organisations be involved in the planning, implementation, monitoring and evaluation of Option B/B+?
- How will people living with HIV and CSOs be involved in delivering services to prevent vertical transmission (i.e. treatment supporters, mentor mothers, etc.)?
- What messages will communities receive about Option B/B+? How will these messages be developed and delivered?
- What resource mobilisation plans are in place to ensure adequate long-term funding of prevention of vertical transmission programmes?

Counseling and support services

Systems must be in place to support the provision of counseling and support services to women living with HIV to ensure that they are able to make an informed choice regarding if and when to start treatment and for how long. Women living with HIV must also be offered support services that enable them to adhere to treatment and prevent transmission of HIV to their partners and children. Community structures must also be in place to support women living with HIV outside of the health-care facility by addressing issues such as stigma and discrimination, disclosure, male involvement and gender based violence.

At the individual level:

- How will women receive counseling on Option B/B+ (i.e. what messages will they receive, who will provide them with counseling)?
- How are women supported to understand their choices regarding starting lifelong treatment during pregnancy (as is the case in Option B+)? How are they supported if they decline to start treatment for life following this counseling if that is their decision?
- What supportive services and counseling will be offered to women to ensure they are able to continuously take their medication and stay connected with health facilities (adherence counseling, food programmes, etc.?)

At the community level:

- What plans and strategies is the government using to increase male involvement in maternal and child health programmes in order to support uptake of and adherence to services to prevent vertical transmission?
- What strategies are in place to address gender-based violence related to HIV diagnosis and treatment and to support women who are experiencing gender-based violence?
- What strategies are in place to reduce stigma and discrimination experienced by women living with HIV at health facilities and within the community?

Ensuring the quality of service delivery

Plans must be developed to ensure that quality services to prevent vertical transmission are delivered to women living with HIV and governments and health care providers must be held accountable for the quality of the services they deliver. Mechanisms must be in place, which allow the community to provide feedback on the quality of HIV testing, access to and quality of HIV treatment and support services, and the realisation of their sexual and reproductive health rights. Assuring quality will be particularly challenging at primary health care centres and clinics that provide ANC but do not currently provide ART. These facilities are closest to communities but usually have the greatest needs around infrastructure (e.g. lack of water, electricity, means of transport) and human resources (e.g. lack of qualified staff). Recommendations by the community must be meaningfully considered and included in decision-making processes at the national level.

- How will government ensure there is enough trained staff to implement Option B/B+ (training for health care providers, plans for task shifting, etc.)?
- What is the plan to ensure the quality of HIV testing in antenatal settings to ensure women receive a correct diagnosis?
- What ARV regimen is being considered? Will the same ARV regimen be used in the prevention of vertical transmission and as the first-line ART regimen so that women do not have to switch regimens post-partum?
- What is government doing to ensure universal access to ART by both pregnant women and non-pregnant PLHIV who are eligible for ART under current guidelines (i.e. are funds adequate for drug procurement, supply chain issues addressed, etc.)? What plans are in place to scale-up ART services to primary health care centres and/or clinics that do not currently have these services?
- What are the plans for monitoring development of drug resistance?
- How will government ensure an adequate supply of 2nd and 3rd line regimens?
- What referral and/or tracking systems are in place between MNCH and ART to make sure women have continued access to ART following delivery? (This may be less of an issue at primary health care centres or clinics where the same provider may do both ANC and ART)
- What infant feeding messages and services will be offered to women post-delivery? How will they differ for women on ART?
- What are plans for ensuring that primary prevention (Prong 1) and family planning needs (Prong 2) receive equal attention and investment?

- How will governments and health providers ensure that the sexual and reproductive health rights and choices of women are protected in family planning and programmes to prevent vertical transmission? Will FP commodities and trained staff be available at primary health care centres and/or clinics?
- What community engagement indicators are being used to track: (1) demand creation, (2) service delivery, (3) accountability and (4) the success/failure of efforts to engage communities?

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

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