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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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.

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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			