

# MONITORING & EVALUATION FRAMEWORK FOR ANTIRETROVIRAL TREATMENT FOR PREGNANT AND BREASTFEEDING WOMEN LIVING WITH HIV AND THEIR INFANTS





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# MONITORING & EVALUATION FRAMEWORK FOR ANTIRETROVIRAL TREATMENT FOR PREGNANT AND BREASTFEEDING WOMEN LIVING WITH HIV AND THEIR INFANTS

( IATT OPTION B/B+ M&E FRAMEWORK )

# ACRONYMS & ABBREVIATIONS

ANC	antenatal care
ART	antiretroviral therapy
AZT	azidothymidine (zidovudine)
CDC	US Centers for Disease Control and Prevention
CTX	cotrimoxazole
DBS	dried blood spot
DNA PCR	DNA polymerase chain reaction
EID	early infant diagnosis
GARPR	Global AIDS Response Progress Reporting
HEI	HIV-exposed infant
HIV	human immunodeficiency virus
IATT	Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children
ID	identity (usually refers to an identity code)
LTFU	loss to follow-up
M&E	monitoring and evaluation
MNCH	maternal, newborn and child health
MOH	ministry of health
NVP	nevirapine
OI	opportunistic infection
OR	operational research
PEPFAR	US President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission (of HIV)
PT	proficiency testing
TB	tuberculosis
UNICEF	United Nations Children's Fund
QA	quality assurance
QI	quality improvement
WHO	World Health Organization



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# EXECUTIVE SUMMARY

In June 2013, the World Health Organization (WHO) released the *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection*. The guidelines recommend the initiation of antiretroviral therapy (ART) for all pregnant and breastfeeding women with HIV and, in many settings, continuation on ART for life (known as Option B+).<sup>1</sup> Lifelong ART for all pregnant and breastfeeding women with HIV has the potential to impact the HIV epidemic by:

- Improving maternal health and reducing maternal mortality
- Preventing vertical and sexual transmission
- Preventing orphanhood
- Improving HIV free infant survival

As countries implement HIV treatment for all pregnant and breastfeeding women it is critical that programmes integrate prevention of mother to child transmission (PMTCT) and ART monitoring and evaluation (M&E) systems. A cornerstone of integrated systems is joint review of programme data on PMTCT and ART. By reviewing, adapting and enhancing current M&E systems to meet evolving programme needs, programme managers will be able to make changes designed to maximize the potential of PMTCT and HIV Care and Treatment programmes to improve health outcomes, prevent infections and save lives.

PMTCT programmes must also move beyond measuring coverage of testing and ART initiation toward intensified efforts measuring retention of mothers in HIV Care and Treatment Programmes and final outcomes for their infants to better understand programme quality. Specifically, treatment for all

pregnant and breastfeeding women will require integration of ART into Maternal, Newborn and Child Health (MNCH) settings. Delivery of ART services within the MNCH setting will require the measurement of retention for mothers on ART (also referred to as ART retention) to ensure the quality of care is the same for ART services delivered in an MNCH setting as in a dedicated HIV Care and Treatment setting. It is also an opportunity to improve retention for HIV-exposed infants (HEIs) until the end of the breastfeeding period when the final HIV status can be determined. Both maternal ART retention and final outcome for HEIs will require programmes to adapt current M&E systems to allow for cohort monitoring.

In addition, there is a need for enhanced monitoring during the early implementation phase of new treatment approaches (i.e. Option B or B+). Enhanced monitoring should be focused on commodity availability, quality assurance of rapid testing and early maternal retention on ART to trigger timely identification of implementation problems and challenges that need corrective action.

## MONITORING: ROUTINE AND ENHANCED

ROUTINE MONITORING provides information essential for the complete reporting of programme progress.

ENHANCED MONITORING is a tool for more intensive monitoring during early implementation of new treatment approaches (Option B or B+). Enhanced monitoring refers to the active collection of additional indicator data to trigger timely identification of implementation problems and challenges that need corrective action.

<sup>1</sup> Lifelong ART and Option B+ are used interchangeably throughout this document.

To guide successful implementation of lifelong ART for pregnant and breastfeeding women with HIV, PMTCT M&E systems should be adapted so that routine and enhanced data can be collected, reported and used to identify programme successes and challenges. Ideally, countries would share data documenting programme successes and challenges with immediate stakeholders as well as making reports publicly available for greater transparency. The M&E measures suggested throughout this framework are consistent with current *Global AIDS Response Progress Reporting* (GARPR) recommendations and

the forthcoming *WHO Consolidated HIV Strategic Information Guide for the Health Sector HIV Response*.

With global guidance in mind, this document is organized around a series of succinct recommendations for the operationalization of **monitoring, both routine** (Section 1) **and enhanced** (Section 2), and the evaluation (Section 3) of programmes implementing lifelong ART for pregnant and breastfeeding women and their infants. The key recommendations discussed throughout the document are summarized in the Table below.

■ Summary of recommendations for operationalizing M&E for lifelong ART for pregnant and breastfeeding women and their infants

Area of operationalization	Recommendations
<b>Routine monitoring</b>	<ol style="list-style-type: none"> <li>1. Convene an integrated programme monitoring technical working group that includes multi-disciplinary stakeholders (e.g. PMTCT, ART, M&amp;E).</li> <li>2. Review data collection tools to identify gaps, understand where data are collected and how to structure registers for cohort monitoring.</li> <li>3. Collect routine indicators for PMTCT and HIV Care and Treatment.</li> <li>4. Integrate reporting on PMTCT indicators from both MNCH and HIV Care and Treatment facilities at all levels.</li> <li>5. Assure sufficient human resources for consistent, high-quality programme monitoring.</li> <li>6. Review integrated data at facility, sub-national and national levels.</li> <li>7. Use programme data for quality improvement.</li> <li>8. Safeguard confidentiality and security of patient information and ensure patient rights are protected.</li> </ol>
<b>Enhanced monitoring</b>	<ol style="list-style-type: none"> <li>1. Select a subset of health facilities to conduct enhanced monitoring.</li> <li>2. Develop enhanced monitoring collection and reporting tools and define reporting periods.</li> <li>3. Collect enhanced monitoring indicators at a subset of sites.</li> <li>4. Implement regular, integrated data review meetings at facility, sub-national and national levels.</li> <li>5. Integrate enhanced monitoring into routine monitoring, quality improvement and evaluation activities for long term sustainability.</li> </ol>
<b>Evaluation</b>	<ol style="list-style-type: none"> <li>1. Conduct process and systems evaluations in the early phases of roll out.</li> <li>2. Conduct outcomes and effectiveness evaluations to better understand programme impact.</li> <li>3. Conduct operational research to inform best practices and optimal provision of clinical interventions for maximum impact.</li> </ol>

# INTRODUCTION

The purpose of this framework is to provide operational guidance on monitoring and evaluation of pregnant and breastfeeding women receiving ART for life and their HEIs. This document is organized around a series of recommendations for the operationalization of monitoring, both routine (Section 1) and enhanced (Section 2), and the evaluation (Section 3) of programmes implementing lifelong ART for pregnant and breastfeeding women and their infants. Each section begins with a brief summary of the programme changes and implications for M&E systems, followed by recommendations providing guidance for strengthened M&E.

## **SECTION 1: Operationalizing routine monitoring of programmes implementing lifelong ART for pregnant and breastfeeding women and their infants**

Outlines routine indicators for HIV Care and Treatment and PMTCT monitoring and proposes key data collection, reporting and use questions relevant for all MNCH and HIV Care and Treatment facilities. The assessment tool for mapping the current data collection systems to the recommended routine monitoring indicators suggested in Section 1 is included as Appendix 1. Indicator reference sheets for select routine monitoring indicators are included in Appendix 2.

## **SECTION 2: Operationalizing enhanced monitoring of programmes implementing lifelong ART for pregnant and breastfeeding women and their infants**

Recommends critical indicators to assess programme quality during early implementation in a sample of facilities providing lifelong ART to pregnant and breastfeeding women and their HEIs to assess programme quality and identify issues needing targeted intervention. Indicator reference sheets for all the enhanced monitoring indicators are included in Appendix 2.

## **SECTION 3: Evaluation of programmes implementing lifelong ART for pregnant and breastfeeding women and their infants**

Suggests evaluation approaches to review and assess programme functioning, test programme models, gauge success toward short- and long-term outcomes and document best practices.

## **APPENDICES**

Appendices includes tools to facilitate assessment of current data collection and reporting tools and indicator reference sheets.



## ALIGNMENT WITH GLOBAL GUIDANCE

The indicators suggested within the framework are harmonized with current GARPR guidance<sup>2</sup> as well as the forthcoming WHO *Consolidated HIV Strategic Information Guide for the Health Sector*.<sup>3</sup> This framework builds on these global guidance documents by highlighting specific issues for lifelong ART implementation such as 1) monitoring and reporting challenges that may be encountered through integration of PMTCT services within MNCH and HIV Care and Treatment settings; and 2) opportunities for collecting additional indicators that will provide data to inform the provision of lifelong ART to pregnant and breastfeeding women and care for their HEIs.

## AUDIENCE

The intended audience for this framework includes M&E officers; PMTCT, paediatric, MNCH and HIV Care and Treatment programme managers; and

other stakeholders (such as donors, implementing partners and civil society groups) in countries with generalized HIV epidemics and countries implementing the Option B/B+ approach to treatment. Strengthening the M&E framework for PMTCT programmes within country contexts will be most successful if approached through a collaborative, consultative process. Stakeholders may include national ministry of health departments of M&E, MNCH and HIV Care and Treatment; health care workers professional associations; quality management specialists; country-specific implementing partners; and technical working groups.

## THE NEED FOR OPERATIONAL GUIDANCE: TRANSITIONING PMTCT PROGRAMMES

Over the past decade, PMTCT programmes have rapidly evolved from delivering a single prophylactic drug to mothers to providing lifelong care and treatment for both mothers and children. The success of PMTCT programmes has contributed to remarkably improved outcomes for both mother and child. In many ways, what started out as an abbreviated mother-to-infant cascade of two services (HIV testing and counselling and provision

<sup>2</sup> Joint United Nations Programme on HIV/AIDS. Global AIDS Response Progress Reporting. Available online at: <http://www.unaids.org/en/dataanalysis/knowyourresponse/globalaidsprogressreporting>.

<sup>3</sup> World Health Organization. HIV Department. Available online at: <http://www.who.int/hiv/en/>. (Note: Final WHO Consolidated HIV Strategic Information Guide for the Health Sector to be published in 2015).

of prophylactic drugs) has become two distinct and long-term continua of care: one for mothers<sup>4</sup> and one for their children.<sup>5</sup> Figure 1 depicts the PMTCT continua of care for women living with HIV and their infants.

In June 2013 the World Health Organization (WHO) released the *Consolidated Guidelines on*

<sup>4</sup> The standard of comprehensive services for pregnant and breastfeeding women include: provision of ART, family planning; STI screening and referral for STI treatment; nutritional counselling (including folic acid or calcium supplementation); tetanus vaccination; screening for maternal anaemia; as well as standard HIV care services, such as TB screening, referral for TB treatment and CTX prophylaxis, clinical staging, treatment failure monitoring and other clinical services as defined in a country's national guidelines

<sup>5</sup> The standard for comprehensive services for HEIs includes: infant and young child feeding support and counselling, immunizations, and growth monitoring, as well as HIV-related services including CTX prophylaxis, HIV virologic testing (EID) by 2 months of age and follow-up until final HIV diagnosis at the end of the breastfeeding period.

*the Use of Antiretroviral Drugs for Treating and Preventing HIV infection.*<sup>6</sup> The guidelines endorse the initiation of ART for all pregnant and breastfeeding women with HIV. Lifelong ART for this population is recommended—particularly in generalized epidemics—regardless of CD4 cell count (Option B+) for both programmatic and operational reasons. Countries may also choose to stop ART once risk of mother-to-child transmission has passed (i.e. at the end of breastfeeding or after delivery if no breastfeeding), unless the woman is eligible for lifelong ART based on CD4 criteria (Option B). In either setting, the woman continues with routine

<sup>6</sup> World Health Organization. *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection.* Available online at: <http://www.who.int/hiv/pub/guidelines/arv2013/en/index.html>. Accessed August 2014.

**FIGURE 1** Continuum of care for pregnant and breastfeeding mothers and their children

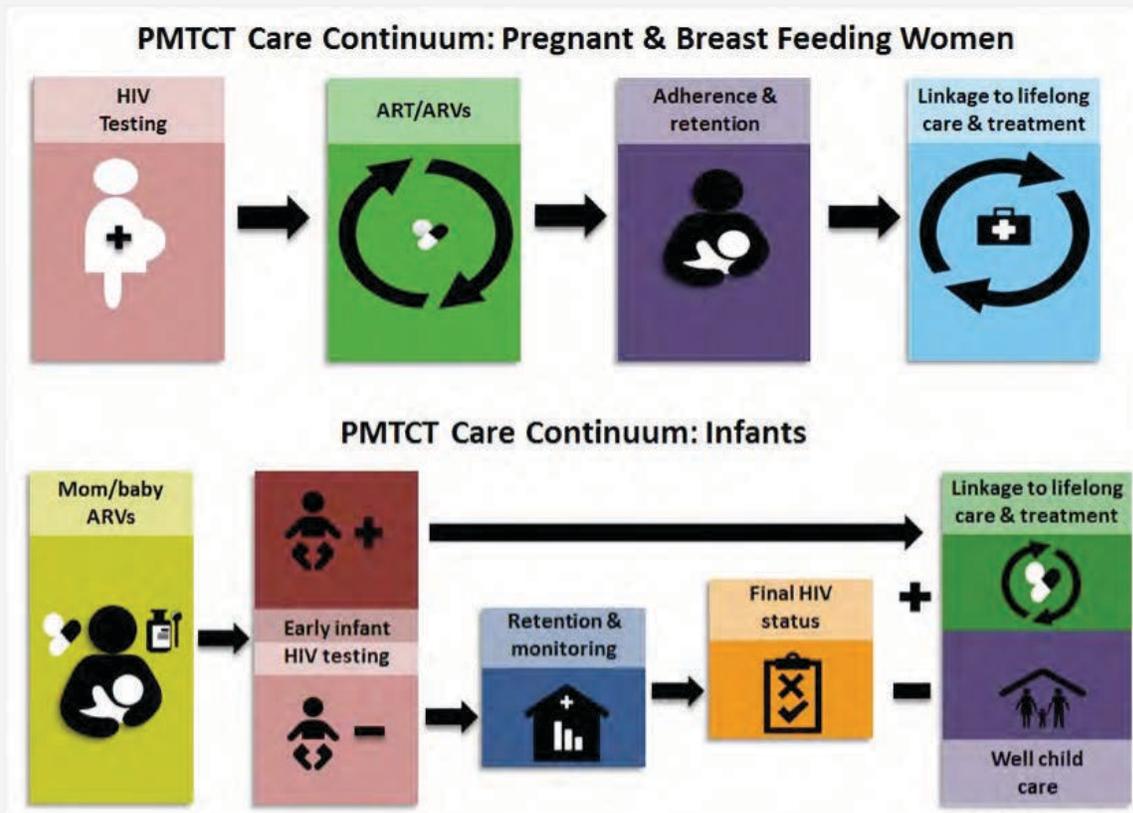


Figure 1 was provided courtesy of ICAP--Columbia University Credit: Teasdale and Abrams 2013

**FIGURE 2** PMTCT recommendations from WHO 2013 Consolidated Guidelines<sup>7</sup>

National PMTCT programme option	Pregnant and breastfeeding women with HIV		HIV-exposed infant	
	Regardless of WHO clinical stage or CD4 cell count		Breastfeeding	Replacement feeding
Use lifelong ART for all pregnant and breastfeeding women ("Option B+")	Initiate ART and maintain after delivery and cessation of breastfeeding		6 weeks of infant prophylaxis with once-daily NVP	4-6 weeks of infant prophylaxis with once-daily NVP (or twice-daily AZT)
Use lifelong ART for only pregnant and breastfeeding women eligible for treatment ("Option B")	Eligible for treatment <sup>a</sup> Initiate ART and maintain after delivery and cessation of breastfeeding <sup>b</sup>	Not eligible for treatment <sup>a</sup> Initiate ART and stop after delivery and cessation of breastfeeding <sup>bc</sup>		

<sup>a</sup> CD4 count is 500 cells/mm<sup>3</sup> or clinical stage 3 or 4 disease at the time of ART initiation or in accordance with national guidelines.

<sup>b</sup> Patients who develop clinical or laboratory criteria indication failure during pregnancy or the breastfeeding period should be assessed for second-line therapy.

<sup>c</sup> In the case of breastfeeding stop ART one week after breastfeeding ends. In the case of replacement feeding stop ART after delivery.

HIV follow-up care. Figure 2 summarizes differences between Option B+ and Option B.

Even in countries implementing Option B, almost 70% of women who present for PMTCT services will be eligible for lifelong ART based on the 2013 WHO guidelines recommending ART initiation at a CD4 less than or equal to 500 cells/mm<sup>3</sup>.<sup>8</sup> Therefore, throughout the document "lifelong ART" refers to the population of pregnant and breastfeeding women receiving ART for life under either Option B+ or Option B.

With the adoption of the 2013 WHO Guidelines most programmes have integrated previously

separate maternal and infant care continua within the MNCH service platform, meaning that the PMTCT services now include HIV Care and Treatment services and are routinely provided within the reproductive health continuum—e.g., family planning, antenatal care, postpartum care and child survival services. The integrated continuum also allows for delivery of care for both mothers and infants in the same location. Integrated delivery of HIV Care and Treatment within MNCH services—and following a mother with her infant as a pair—is expected to improve outcomes by facilitating retention, improving coordination of mother and infant care and linking children with HIV to treatment services.

To guide successful implementation of this new approach, this framework provides operational guidance on adapting of PMTCT and ART M&E systems to collect, report and use routine and enhanced data to identify programme successes and challenges.

<sup>7</sup> Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Chapter 7: Clinical Guidance Across the Continuum of Care: Antiretroviral Therapy. Available online at: [http://www.who.int/hiv/pub/guidelines/arv2013/art/arv2013\\_chapter07\\_low.pdf](http://www.who.int/hiv/pub/guidelines/arv2013/art/arv2013_chapter07_low.pdf). Accessed August 2014.

<sup>8</sup> Carter RJ, Dugan K, El-Sadr WM, Myer L, Otieno J, et al. CD4+ Cell Count Testing More Effective Than HIV Disease Clinical Staging in Identifying Pregnant and Postpartum Women Eligible for Antiretroviral Therapy in Resource-Limited Settings. *J Acquir Immune Defic Syndr*. 2010;55:404–410

# SECTION 1: OPERATIONALIZING ROUTINE MONITORING OF PROGRAMMES IMPLEMENTING LIFELONG ART FOR PREGNANT AND BREASTFEEDING WOMEN AND THEIR INFANTS

## PROGRAMME CHANGES AND IMPLICATIONS FOR ROUTINE MONITORING

Delivery of PMTCT services within the MNCH platform is well established. However, in most countries, initiating and maintaining women on ART within the MNCH platform is a new service delivery concept that has implications for how programme data are collected, reported and used. Adding further complexity to monitoring this population is that some women may already be on ART at the time they become pregnant, while others will initiate ART during pregnancy or the breastfeeding period, and may continue on ART at different clinics during the continuum of their MNCH and chronic ART care.

M&E of lifelong ART for all pregnant and breastfeeding women will require integration of:

- Systems that collect PMTCT and ART indicators in MNCH settings (testing, initiation and follow-up)
- Tools at the **facility**, sub-national and national level

### FACILITY

**FACILITY**, as used in this document, refers to any clinic, hospital or other institution at any level—primary, secondary or tertiary—where healthcare is provided.

## OPERATIONALIZING ROUTINE MONITORING: RECOMMENDATIONS AND GUIDANCE

### Routine Monitoring

- Collected at all sites, for all clients
- Provides information on progress
- Provides information for programme planning, including the implementation of desired changes

This section is organized around eight recommendations spanning routine monitoring data collection, reporting and use (Box 1).

### BOX 1

#### Recommendations for operationalizing routine monitoring

1. Convene an integrated programme monitoring technical working group that includes multiple stakeholders (e.g. PMTCT, ART, M&E).
2. Review data collection tools to identify gaps, understand where data are collected and how to structure registers for cohort monitoring.
3. Collect routine indicators for PMTCT and HIV Care and Treatment.
4. Integrate reporting on PMTCT indicators from both MNCH and HIV Care and Treatment facilities at all levels.
5. Assure sufficient human resources for consistent, high-quality programme monitoring.
6. Review integrated data at facility, sub-national and national levels.
7. Use programme data for quality improvement.
8. Safeguard confidentiality and security of patient information and ensure patient rights are protected.

## INTEGRATED PROGRAMME MONITORING TECHNICAL WORKING GROUP

- **Objective:** To advise on the facility, sub-national, and national level collection, reporting and use of M&E data related to lifelong ART of pregnant and breastfeeding women with HIV and their infants.
- **Overall purpose:** To support pregnant and breastfeeding women with HIV to initiate lifelong ART in a timely manner, stay in care and receive needed follow up for their HEIs. It is recognized that the success of lifelong ART is dependent on the engagement and support in the communities.

## RECOMMENDATION 1: CONVENE AN INTEGRATED PROGRAMME MONITORING TECHNICAL WORKING GROUP THAT INCLUDES MULTIDISCIPLINARY STAKEHOLDERS (E.G. PMTCT, ART, M&E).

Convene an **integrated programme monitoring technical working group** comprised of M&E, PMTCT, HIV Care and Treatment, Laboratory, and MNCH programme managers as well as representatives from provider organizations such as nursing councils, health care facilities and community-based organizations including patient advocates. This technical working group should be convened at national, subnational and facility levels to provide input into proposed changes to the current M&E tools and system, analyze monitoring data, identify gaps and brainstorm solutions. Different levels may analyze and use data differently, but a forum for review at all levels is necessary.

## RECOMMENDATION 2: REVIEW DATA COLLECTION TOOLS TO IDENTIFY GAPS, UNDERSTAND WHERE DATA ARE COLLECTED AND HOW TO STRUCTURE REGISTERS FOR COHORT MONITORING.

Programme monitoring tools may need to be updated to collect the recommended indicators listed in Table 2 (see Recommendation 3). The integrated programme monitoring technical work group should review monitoring tools such as registers and facility-based patient cards/charts for PMTCT, HEIs and HIV Care and Treatment to ensure necessary data elements are collected for integrated programme monitoring. A tool to facilitate this process can be found in Appendix 1.

One of the most critical changes is the need to modify tools and systems to monitor retention for both mothers on ART and HEI to final status. Both longitudinal registers and adoption of a **cohort monitoring approach** are required for routine retention assessment.

### COHORT & COHORT MONITORING / REPORTING

A COHORT is simply a group of people with something in common, for example a group of women who are initiated on ART during the month of October 2014.

COHORT MONITORING or REPORTING is the tracking and reporting of information about this particular group of people (e.g., women who initiated ART in October 2014) as they go through time (e.g., what percentage of women in this particular group are still alive and on treatment at 12 months after initiating ART?).

## ANC Cohorts

The common event for ANC cohorts is the month of the pregnant women's first ANC visit. Unlike other cohorts, ANC cohorts are not often used to measure retention, but instead to improve data quality on important ANC indicators. This is especially true in programmes where women may have more than one HIV test during the antenatal period and newly diagnosed HIV+ pregnant women may not initiate at the first ANC visit or may transition from ARV prophylaxis to ART regimen as ART programs in MNCH are implemented. Data from multiple visits will be summarized to report indicators at a later point in time. In the context of PMTCT, ANC registers support the tracking of critical information including:

- The number of women attending ANC;
- Women with known status, those who were tested and positive as well as those who were known positive at entry; and
- Coverage of ART for HIV-infected pregnant women (importantly this includes those newly initiating as well as those already on treatment).

## ART Cohorts

The common event for ART cohorts is the month of ART initiation. ART cohort monitoring is used to measure retention of HIV-infected women who were pregnant or breastfeeding when they initiated ART and should continue through 24 months to cover the end of the breastfeeding period.

Regardless of whether ART is provided in the HIV Care and Treatment facility or at an MNCH site ART registers should be used for all women initiating treatment and should include a field for documenting whether a woman is pregnant or breastfeeding at ART initiation.

## BENEFITS OF LONGITUDINAL REGISTERS IN THE CONTEXT OF PMTCT

In a longitudinal register, each patient is registered by name and by unique numeric identifier. Over the course of subsequent visits, patient monitoring data will be entered in the same place within the register (e.g. same row). Longitudinal registers improve data quality by ensuring patient data are only reported once for each patient, allow for monitoring receipt of services over time, and support tracking of retention within the programme.

- **ANC registers:** Over the course of ANC, longitudinal registers allow for accurate accounting of important ANC indicators such as attendance through the recommended four ANC visits and receipt of ANC services such as tetanus immunization and syphilis testing. For PMTCT, the longitudinal register allows for monitoring of both initial and repeat (where indicated) HIV testing and ART coverage (including those already on ART prior to pregnancy).
- **ART registers:** Pregnant and breastfeeding women on ART should be monitored through a longitudinal ART register, ideally that which is used for other ART clients. This will ensure pregnant and breastfeeding women with HIV are registered in the Care and Treatment programme and are being monitored with the same quality of care indicators as other ART clients. In addition, this will facilitate enrollment of these women in cohorts to track retention.
- **HEI Register:** In order to ensure all HEIs are monitored through final outcome, a birth cohort register or card system is recommended. This supports registration and retention monitoring of all HEIs and provides a way to track receipt of HEI care services such as testing, cotrimoxazole, feeding choice and linkage to ART for infants who become HIV-infected.

In addition, the standard data monitoring protocol for pregnant and breastfeeding women initiating and receiving follow-up HIV Care and Treatment in MNCH should include:

- Standard documentation for identifying and tracking patients that have defaulted on their appointments or transferred out, including evidence of defaulted patients brought back into care and use of information to update the ART register;
- Standard procedures to ensure clinical information, including drug prescriptions, is updated on the patient ART file/card, the ART register and the electronic ART patient database, where available; and
- For MNCH facilities that anticipate a high volume of women (e.g. more than 500) on ART at any one time, electronic monitoring systems are recommended to reduce the reporting burden on facility staff and can greatly improve patient monitoring and analysis.

Expanded guidance on implementing cohort monitoring for ART retention is included in the ART retention indicator reference sheets in Appendix 2 (2G and 2H).

### HIV-Exposed Infant Cohort

The common event for cohorts of HEIs is their month of birth referred to as “birth cohorts”. Birth cohort monitoring is used to measure the percentage of HEIs with a final outcome documented, including whether there is a final confirmation of HIV status. Monitoring HEIs can be challenging because HEIs require follow-up until final HIV testing at 18 months or at least six weeks after complete cessation of all breastfeeding (if beyond 18 months). Birth cohort reporting can reduce data collection burden at the site.

To report on birth cohorts programmes must use registers or facility held HEI cards that collect

longitudinal information on follow-up and are organized by birth month of infants. Two examples of how this could be accomplished are:

1. Birth month register: Utilize the existing exposed infant register but re-organize the standard operating procedures to use one page for each birth month rather than the month of registration (e.g. all children born in January 2014 are registered on one page no matter what month they are registered for services); and
2. Birth month card system: Complete monthly follow up reporting forms directly from HEI cards which are kept in a binder that is organized by birth month (i.e. no HIV-exposed register is used).

Both approaches allow a paper-based health facility to quickly identify the number of HIV-exposed infants registered in the birth cohort.

### Mother infant pairs

Monitoring of any of these three cohorts can be challenging using a Mother-infant pair register, see Appendix 3 for more details.

### Beyond the tools: Standard Operating Procedures at Health Facilities

While reviewing data collection tools, programmes should discuss the standard operating procedures and data flow at health facilities that utilize the tools. Table 1 describes important questions to consider regarding assigning identity codes (IDs) to patients, storing health records at facilities and linking patient files for easier reference. When reviewing data collection tools, include health care workers and data clerks at facilities for feedback on the usability of the tools.

**TABLE 1: Questions and recommended guidance for standard operating procedures to implement data collection tools**

Operational question	Implementation guidance
How are ART IDs assigned for pregnant and breastfeeding women with HIV and for infants with HIV?	<ul style="list-style-type: none"> <li>Programmes and facilities should have standard operating procedures for assigning a unique national ART ID to all women and infants initiating lifelong ART in MNCH settings.</li> <li>Women on ART who become pregnant should keep their original ART number even if ART care is transferred from an HIV Care and Treatment clinic to an MNCH setting. A woman should keep the same ART ID throughout her life, across multiple pregnancies.</li> </ul>
Where should HIV Care and Treatment facility-based patient files be located?	<ul style="list-style-type: none"> <li>HIV Care and Treatment facility-based patient files should be housed where the patient receives HIV Care and Treatment. For example, if a woman is receiving HIV care in MNCH, her HIV Care and Treatment file should be located at MNCH.</li> <li>Both the MNCH and HIV Care and Treatment programmes should develop a standard procedure for ART patient data sharing so that the ART register is routinely updated.</li> </ul>
How are ART, ANC and other IDs linked to each other?	<ul style="list-style-type: none"> <li>For each mother-infant pair, programmes should ensure registers and facility-based files as well as patient-held cards are linked. At a minimum, the mother's ART ID should be documented in the ANC register and the ANC ID documented in the ART card/file. Other IDs that could be used for linkage include MNCH ID, HEI ID and ART ID for the infant (if HIV-infected).</li> <li>Programmes should also consider ways to link other family members (e.g., HEIs, partners and other children) to the mother-infant pair. Tools could also include a space for these family member ID numbers.</li> </ul>
Where are HEI unique IDs generated? How are the mother and infant IDs linked?	<ul style="list-style-type: none"> <li>HEI IDs may be generated and reported from MNCH settings or from HIV Care and Treatment settings depending on the national guidelines/standard operating procedures.</li> <li>HEI services should be provided in the same location as services for the mother. Regardless of where HEI services are provided, data collection tools and systems should ensure that the mother's ANC and ART IDs can be linked with the HEI ID and paediatric ART ID to facilitate retention and follow-up of mothers and their infants. This can be achieved by adding a field (column) for maternal ID to an HEI register or data element to the HEI card, or by filing facility-based files for mothers and infants in the same folder.</li> </ul>
How is transfer done?	<ul style="list-style-type: none"> <li>If a mother-infant pair is transferred between sites, the mother and the infant should keep their originally assigned unique identifiers. Transfer out and transfer in should be documented using the national standard operating procedures on ART transfers.</li> <li>Whether pregnant women already on ART are transferring from the HIV Care and Treatment clinic to MNCH to HIV Care and Treatment, facility-based files should move with the client(s) to the new site.</li> </ul>



### RECOMMENDATION 3: COLLECT ROUTINE INDICATORS FOR PMTCT AND HIV CARE AND TREATMENT.

As HIV Care and Treatment provision is integrated within the MNCH setting, it is essential that MNCH service delivery points collect, report and use not only indicators for PMTCT, but also for HIV Care and Treatment as listed in Table 2. Indicator reference sheets for globally-reported indicators can be found online through the GARPR system.<sup>9</sup> Indicator reference sheets for indicators that are not globally reported can be found in Appendix 2.

Some of the routine indicators for PMTCT and

HIV Care and Treatment described below may be new to the PMTCT programme context and reflect integration of HIV services. For example, monitoring TB screening for pregnant and breastfeeding women with HIV within MNCH settings has the potential to improve overall health outcomes for women and children. Calculating percentage of infants with HIV initiating treatment is important because it serves as an outcome measurement for infants who are infected and serves as a metric for linkages between MNCH and HIV Care and Treatment. Finally, as ART is expanded and more health care workers are capacitated to initiate and manage patients on ART, monitoring expansion of task sharing is critical to understanding how workers are affected by added responsibilities in patient care, data collection, reporting and use.

<sup>9</sup> Indicator reference sheets are updated annually. For 2015, GARPR indicators can be found at: <http://www.unaids.org/en/dataanalysis/knowyourresponse/globalaidsprogressreporting>

**TABLE 2:** Routine PMTCT and HIV Care and Treatment indicators to be collected and reported at facilities implementing integrated services

Indicators currently collected and reported <sup>10</sup>	Disaggregations currently collected and reported	Location of indicator reference sheet
1. Number of pregnant women attending ANC at least once during the reporting period	<ul style="list-style-type: none"> <li>None</li> </ul>	GARPR 2015 #3.11
2. Percentage of pregnant women who know their HIV status (i.e. test results)	<ul style="list-style-type: none"> <li>New positives</li> <li>Known positives at entry to ANC</li> </ul>	GARPR 2015 #3.4
3. Percentage of HIV-positive pregnant women who received antiretroviral medicine to reduce the risk of mother to child transmission	<ul style="list-style-type: none"> <li>Newly initiated on treatment during the current pregnancy</li> <li>Already on treatment before the pregnancy</li> <li>Maternal triple ARV prophylaxis (prophylaxis component of WHO Option B during pregnancy and delivery)</li> <li>Maternal AZT (prophylaxis component of WHO Option A during pregnancy and delivery)<sup>11</sup></li> <li>Single-dose nevirapine (sd-NVP) to the mother during pregnancy or delivery<sup>11</sup></li> <li>Other (usually limited to countries still providing maternal AZT started late in the pregnancy)</li> </ul>	GARPR 2015 #3.1
4. Number of adults and children with HIV infection newly enrolled on ART <sup>13</sup>	<ul style="list-style-type: none"> <li>Pregnancy status at ART initiation</li> <li>Breastfeeding status at ART initiation</li> <li>By age<sup>12</sup></li> </ul>	GARPR 2015 #4.1 (Additional)
5. Percentage of adults and children with HIV infection currently receiving ART	<ul style="list-style-type: none"> <li>By age<sup>12</sup></li> </ul>	GARPR 2015 #4.1
6. Percentage of adults and children with HIV known to be on treatment 12 months after initiation of ART <sup>14</sup>	<ul style="list-style-type: none"> <li>Pregnancy status at ART initiation</li> <li>Breastfeeding status at ART initiation</li> <li>By age<sup>12</sup></li> </ul>	GARPR 2015 #4.2
7. Percentage of adults and children in HIV care who had their TB status assessed and recorded during their last visit. <sup>15</sup>	<ul style="list-style-type: none"> <li>By age<sup>12</sup></li> </ul>	GARPR 2015 #5.4
8. Percentage of infants born to women with HIV started on CTX prophylaxis within two months of birth	<ul style="list-style-type: none"> <li>None</li> </ul>	GARPR 2015 #3.9
9. Percentage of infants born to women with HIV receiving a virological test for HIV within 2 months of birth	<ul style="list-style-type: none"> <li>Number of HEI with a positive virological test result by 2 months</li> </ul>	GARPR 2015 #3.2
10. Percentage of infants with HIV who initiate ART by 12 months of age	<ul style="list-style-type: none"> <li>None</li> </ul>	Appendix 2A
11. Percentage of birth cohort of HIV-exposed infants with an outcome by 18 month visit	<ul style="list-style-type: none"> <li>HIV-infected</li> <li>HIV-uninfected</li> <li>In care but not tested</li> <li>Lost to follow up</li> <li>Died</li> <li>Transferred out</li> </ul>	Appendix 2B
12. Number of health facilities that offer ART	<ul style="list-style-type: none"> <li>Type of health facility (e.g. hospital, health centre, ANC)</li> <li>Paediatric ART</li> </ul>	GARPR 2015 #4.3.a and #4.3.b (paediatric ART)
13. Percentage of health facilities dispensing ARVs that experienced a stock-out of at least one required ARV in the last 12 months	<ul style="list-style-type: none"> <li>Sector (i.e. public, private)</li> </ul>	GARPR 2015 #4.4
14. Number of health care workers trained in the initiation and management of lifelong ART for pregnant and breastfeeding women and their children by work cadre	<ul style="list-style-type: none"> <li>Type of work cadre (i.e. medical doctor, clinical officer, nurse, midwife, other)</li> <li>Service population (i.e. Paediatric ART, ART for pregnant and breastfeeding women)</li> </ul>	Appendix 2C

## RECOMMENDATION 4: INTEGRATE REPORTING ON PMTCT INDICATORS FROM BOTH MNCH AND HIV CARE AND TREATMENT FACILITIES AT ALL LEVELS.

Routine PMTCT and ART data should be reported through a system that facilitates integrated data review and use. This may require new forms, tool revision and a change in data reporting practices at all levels—facility, sub-national and national. If information on ART initiation and follow-up is collected separately from MNCH and HIV Care and Treatment sites, programmes should develop standard operating procedures that describe how data are reviewed, including how aggregation between MNCH and HIV Care and Treatment occurs to avoid duplication of pregnant and breastfeeding women who may be counted in multiple programme areas.

### INTEGRATED PROGRAMME MONITORING (See also Recommendation 1)

Where PMTCT and HIV Care and Treatment are managed by separate ministry of health departments, regular programme review meetings should be convened to overcome institutional barriers, promote cross-programme data collection and evaluation of programme roll-out. These meetings should include the review of not only routine monitoring data, but also enhanced monitoring data.

<sup>10</sup> In order to stay consistent with Global Guidance, indicators #4–7 reflect exact language from GARPR 2015. When using these indicators to monitoring within a PMTCT context, however, ‘adults’ would refer to ‘pregnant and breastfeeding mothers’.

<sup>11</sup> While maternal AZT/extended infant nevirapine (Option A) or SD-NVP are no longer recommended by WHO, some countries may continue to use them in PMTCT programmes in the short term as they transition to implementing the 2013 *Consolidated Guidelines*. For programmes in which Option A and SD-NVP are still being provided, they should continue to be monitored and reported, but global guidance recommends they be phased out as soon as possible, and they should not be counted as “effective prophylaxis”.

## RECOMMENDATION 5: ASSURE SUFFICIENT HUMAN RESOURCES FOR CONSISTENT, HIGH-QUALITY PROGRAMME MONITORING.

As countries operationalize M&E activities related to implementing lifelong ART for pregnant and breastfeeding women and their children, there will be increased human resource needs. In many contexts, the facilities where lifelong ART is implemented may not have dedicated data clerks or M&E officers available to take responsibility for data management and reporting. Therefore, facility, sub-national and national level programme managers should consider M&E staffing needs at all levels.

The integrated programme monitoring technical working group mentioned in Recommendation 1 is well-placed to discuss staffing needs at all levels and make recommendations to the Ministry of Health.

## RECOMMENDATION 6: REVIEW INTEGRATED DATA AT FACILITY, SUB-NATIONAL AND NATIONAL LEVELS.

Integrated data reviews include the review of routine programme data along with enhanced data. Because enhanced monitoring indicators are meant to rapidly identify problems not necessarily identified in routine monitoring, regular review of both routine and enhanced monitoring (see Section 2) data will strengthen the use of data for quality and improved programme roll-out.

<sup>12</sup> See WHO’s *Consolidated Strategic Information Guide for the Health Sector* for final global guidance on age bands.

<sup>13</sup> Number of adults with HIV infection newly enrolled on ART is a disaggregation of the GARPR indicator on ART coverage #4.1 Percentage of adults and children currently receiving antiretroviral therapy. In the GARPR document “New on ART” is regarded as an “additional” metric.

<sup>14</sup> As detailed in the GARPR 2014 #4.2 Indicator Reference Sheet—if comprehensive cohort patient registries are available, then it is encouraged for countries to also track retention on treatment at 24, 36 and 48 months and yearly thereafter.

<sup>15</sup> “Assessment for TB status” refers to screening for TB symptoms using the WHO-recommended symptom screening algorithm for intensified TB case finding.

Regular—monthly or quarterly—programme data review meetings at facility, sub-national and national levels should be implemented with key stakeholders to discuss the data findings across PMTCT and HIV Care and Treatment programme areas, including HIV-exposed and HIV-infected infant data. These discussions can be included in the Integrated Programme Monitoring Technical Working Group meetings outlined in Routine Monitoring Recommendation 4.

Figure 3 on page 16, depicts the PMTCT **cascade** for the mother from pregnancy to 12 months post ART initiation. The first three bars of the cascade illustrate:

- The number of pregnant women in a given population;
- The number of women who attend the ANC clinic at least once; and
- The uptake of testing and resulting number of pregnant women who know their HIV status.

The three right-hand bars in the cascade measure:

- The number of HIV-infected women identified; and
- The uptake and retention of ART for pregnant women identified as HIV-infected.

### CASCADES

One way to analyse programme data is through graphic CASCADES that illustrate patient retention and loss over time periods or across different interventions. Presenting data in this way allows for visualization of patient attrition and rapid identification of critical time points or areas for intervention.

In the example in Figure 3, of the 100,000 estimated pregnant women:

- 90,000 (90%) attended their first ANC visit (ANC 1). Of those 90,000 women, 80,000 (89%) had their HIV status documented;

- Of the 20,000 pregnant women identified as living with HIV, 17,000 (85%) were newly initiated on ART (for the purposes of this example, assume that none of the women identified with HIV were previously started on ART); and
- Of those who initiated ART, 13,600 (80%) were known to still be taking ART at 12 months after initiation.

As HIV programmes expand under new treatment guidelines, over time an increasing number of women will already be on ART when they become pregnant and the number of women newly initiating on ART during pregnancy should decline.

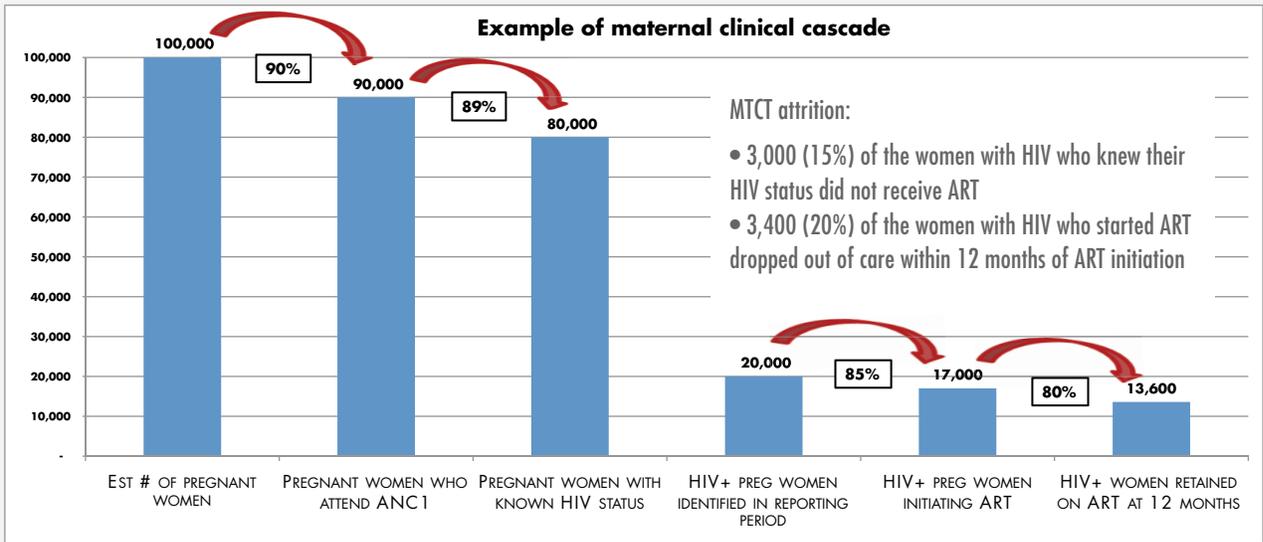
In Figure 3, of the 20,000 pregnant women with HIV identified in the reporting period, 3,000 (15%) did NOT receive ART. Of the 17,000 women initiated, 3,400 (20%) were not retained at 12 months after ART initiation. “Drop off” of women across the cascade may occur for a number of reasons, including having moved, died, becoming too sick to pick up medications or simply having chosen not to continue ART. In reviewing the data, it helps to identify the number of women who “dropped off” to help quantify the magnitude of attrition.

Figure 4 is another example cascade which includes both maternal and infant indicators so that infant outcomes can be reviewed. Figure 4 includes

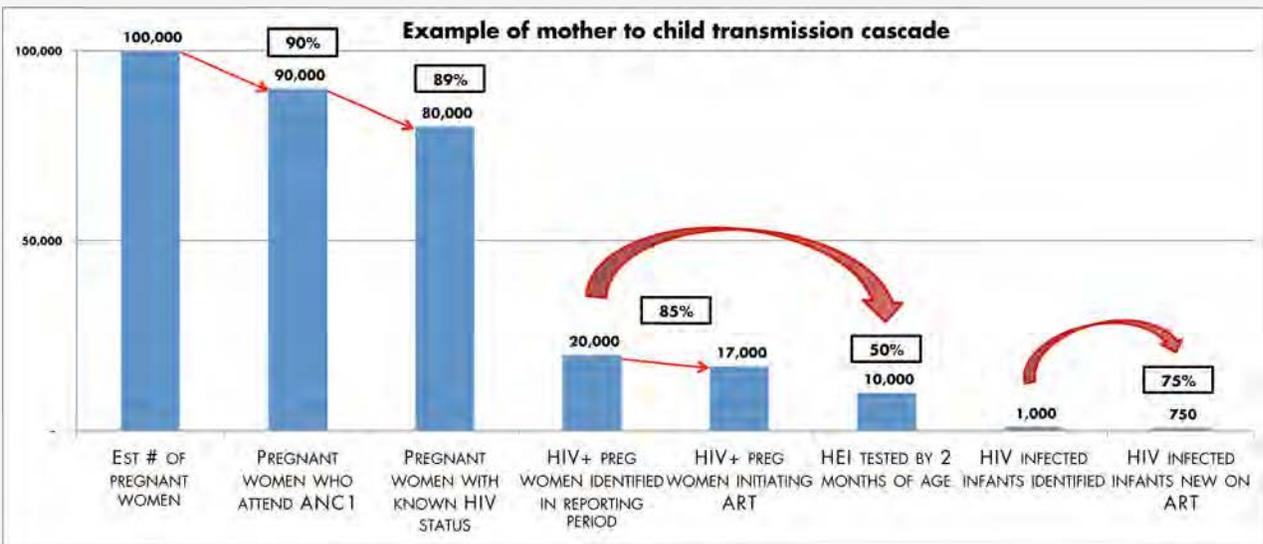
- Number of HEIs tested through early infant diagnosis (EID);
- HIV status of HEIs; and
- Linkages into treatment and initiation on ART for infants with HIV.

By using a cascade to illustrate maternal and infant indicators, the full PMTCT continuum of care can be analysed at a glance to identify where attrition is high so that interventions can be appropriately targeted.

**FIGURE 3** Example of maternal clinical cascade with linkages and coverage between interventions



**FIGURE 4** Example of PMTCT clinical cascade including both the mother and child



In Figure 4 approximately half of the HEIs identified in the reporting period received EID testing. Or, put another way, of the 20,000 pregnant women with HIV identified in the reporting period, 10,000 (50%) of their HEIs were not tested for HIV. Based on this example, interventions to expand access and linkages to EID services could be a programmatic action resulting from data review.

**RECOMMENDATION 7: USE PROGRAMME DATA FOR QUALITY IMPROVEMENT.**

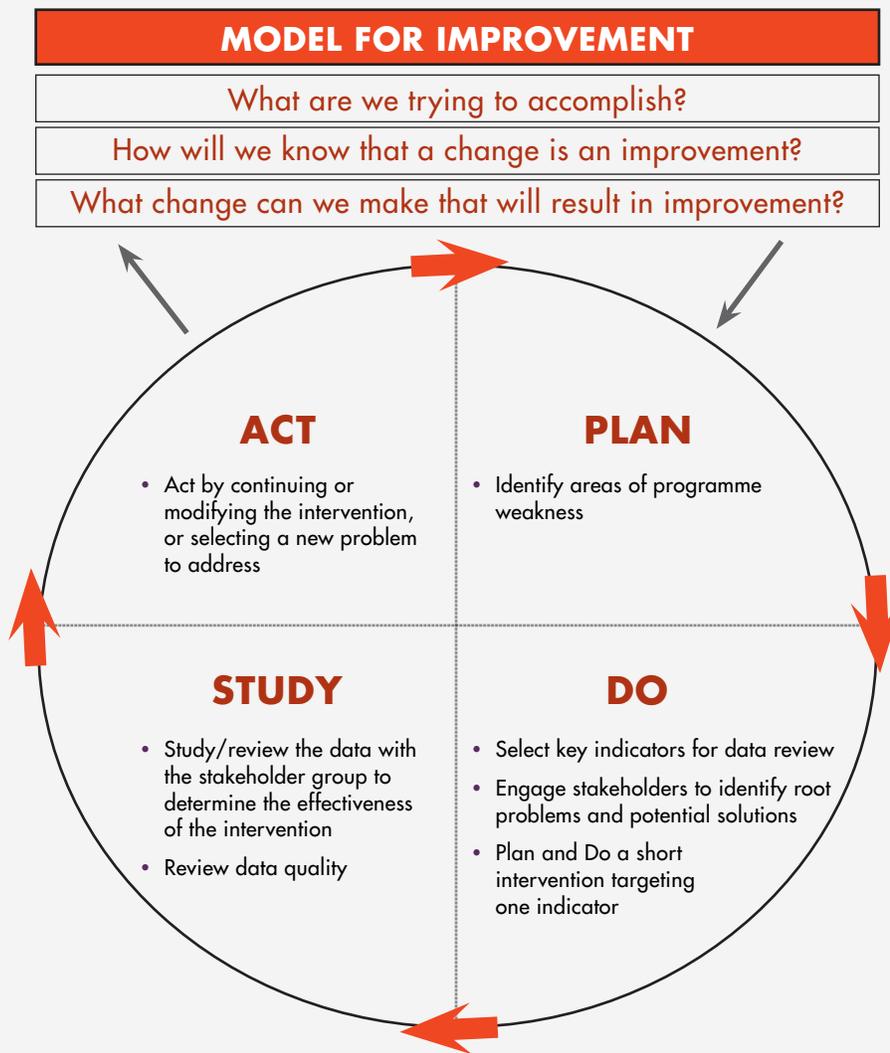
Data should be reviewed and incorporated into a quality improvement plan that addresses identified bottlenecks, gaps or specific challenges. Improvement in these indicators can be used to benchmark effectiveness of the improvement plan or intervention. Quality committees at facility, sub-national and national levels should be established to facilitate the quality improvement process.

The graphic below is a well-known methodology for quality improvement processes.

**RECOMMENDATION 8: SAFEGUARD CONFIDENTIALITY AND SECURITY OF PATIENT INFORMATION AND ENSURE PATIENT RIGHTS ARE PROTECTED.**

In any clinical setting, much identifiable information is collected from patients, whether those patients are adult or paediatric. It is critically important that facility and programme staff develop standard operating procedures to ensure that data are secure and the identities of facility clients are protected. This means ensuring data collection tools such as registers and patient files, whether paper or electronic, are kept in secure locations where only appropriate facility staff have access and that public dissemination of data is only in aggregate and always in an ethical manner.

**FIGURE 5**



## Monitoring Option B: Special Considerations and Additional Recommendations

Both country programmes implementing Option B and those implementing Option B+ follow women on ART. Programme monitoring in Option B settings has the unique challenges of:

- Measuring retention on ART through the end of the MTCT risk period (i.e., the end of breastfeeding).
- Ensuring quality of care where some women initiate ART before programme staff determine whether they will continue for life (i.e., before determining CD4 count), making it difficult through programme monitoring tools to distinguish women who are on ART for life from those who do not meet CD4 eligibility criteria and will stop ART at the completion of breastfeeding.

Given these challenges, the following recommendations should be considered when monitoring Option B:

- **All women initiating ART, regardless of eligibility for lifelong ART, should receive ART IDs and be registered in the HIV Care and Treatment programme.** In countries implementing Option B, the majority of women who present for PMTCT will be eligible for lifelong ART based on CD4 criteria; some may not have access to CD4. As most women in Option B settings will soon be eligible for lifelong ART, treatment records and national ART IDs should be retained to ensure ongoing data collection for the woman. Women on Option B should continue to be followed after they stop breastfeeding and their CD4 monitored regularly to ensure timely initiation of lifelong ART when indicated.
- **Retention of all pregnant and breastfeeding women initiating ART should be monitored.** Programmes should include all women initiated as ART clients in the 12 month retention on ART calculation. In Option B settings, the HIV Care and Treatment programme should add an additional outcome (register column) entitled “completed ART for PMTCT”. When calculating percentage of women alive and on ART 12 months after ART initiation, programmes should remove women who completed ART (e.g., stopped breastfeeding) from both numerator and denominator. (If not breastfeeding, then ART is stopped and she is no longer at risk of transmitting HIV to her infant.)
- **To promote quality of care, countries should use facility-based ART files to monitor ALL pregnant and breastfeeding women on ART regardless of whether they are to stop ART at the end of the MTCT risk period.** The file should include a tick-box or ART number space that would only be completed once eligibility for lifelong ART is determined; this differentiates the lifelong ART clients from those who are either eligible to stop ART or those whose eligibility is unknown.

### ROUTINE MONITORING OF HEIs, INCLUDING INFANTS WITH HIV

The 2013 WHO *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* recommend ART for all children with HIV under 5 years of age regardless of CD4 status. As a result, national programmes are decentralizing paediatric ART while implementing lifelong ART for pregnant and breastfeeding women. Registers and patient files for paediatric HIV Care and Treatment monitoring should be available in these settings and appropriate age disaggregation of the routine indicators should be reported accordingly.

In settings where national guidelines support breastfeeding of HEIs for at least the first 12 months of life, repeat antibody testing of all HIV-exposed children at 18 months of age and/or at least 6 weeks after cessation of breastfeeding is recommended to determine final HIV status. An indicator for reporting this information is included in Section 2 (See Table 2, Indicator 11). This indicator can measure progress toward ensuring that all infants born to HIV-positive women have

either confirmed HIV-infection and are linked to ART services or are confirmed as HIV-uninfected based on a negative 18-month HIV antibody test.

#### MINIMIZING HEI LOSS TO FOLLOW-UP

HEIs are particularly vulnerable to LOSS TO FOLLOW-UP (LTFU) when they are diagnosed as HIV-infected and must be linked to ART services. Programmes should modify their HEI registers to include the ART ID number to verify enrolment into ART services instead of simply marking that the child was referred to ART. Referral alone does not ensure that the child was successfully enrolled.

<sup>16</sup> As detailed in the GARPR 2015 #4.2 Indicator Reference Sheet—if comprehensive cohort patient registries are available, then it is encouraged for countries to also track retention on treatment at 24, 36 and 48 months and yearly thereafter.

<sup>17</sup> “Assessment for TB status” refers to screening for TB symptoms using the WHO-recommended symptom screening algorithm for intensified TB case finding.

<sup>18</sup> Ensuring that all early infant HIV diagnosis programmes adhere to high quality assurance is critical to ensuring that HIV-exposed and infected infants and children receive the best care services possible. The *Guide to the Implementation of Services for Early Diagnosis of HIV in Infants in Resource-Limited Settings* (2010) offers quality assurance guidance for infant HIV testing.

**TABLE 3: Routine Indicators pertaining to paediatric population and appropriate age disaggregation**

Routine Indicator Pertaining to Children	Age Disaggregations
Routine Indicator 4: Number of children and adults with HIV infection newly enrolled on ART	<ul style="list-style-type: none"> <li>By age. Age disaggregation is important; refer to the WHO <i>Consolidated HIV Strategic Information Guide for the Health Sector HIV Response</i> for final global guidance on age bands.</li> </ul>
Routine Indicator 5: Number of children and adults currently receiving ART	
Routine Indicator 6: Percent of children and adults known to be alive and on treatment 12 <sup>16</sup> after initiation of ART	
Routine Indicator 7: Percentage of children and adults in HIV care who had their TB status assessed and recorded during their last visit <sup>17</sup>	
Enhanced Indicator 7: Percentage of ART patients with an undetectable viral load at 12 months after initiation of ART	
Routine Indicator 9: Percentage of infants born to women with HIV receiving a virological test for HIV within 2 months of birth <sup>18</sup>	<ul style="list-style-type: none"> <li>Number of HEIs with a positive virological test result by 2 months</li> </ul>

## SECTION 2:

## ENHANCED MONITORING FOR PROGRAMMES IMPLEMENTING LIFELONG ART FOR PREGNANT AND BREASTFEEDING WOMEN AND THEIR INFANTS

### PROGRAMME SHIFTS NECESSITATE ADDITIONAL DATA

As programmes shift towards provision of lifelong ART for pregnant and breastfeeding women and their infants, it is important to collect **enhanced indicators** at a subset of sites to assess programme achievements and identify programme challenges, similar to the WHO concept of early warning indicators at sentinel sites.<sup>19</sup>

After early programme shifts, enhanced indicators can also be a tool for more intensive monitoring to ensure programme quality is maintained. The information collected through monitoring both routine and enhanced indicators will be used by programme stakeholders in various ways depending on the programme context. In addition, each programme should use monitoring information in ways relevant to their programme theory of change (i.e. logic of how they intend to reach desired outcomes).

<sup>19</sup> A complete list of HIV drug resistance early warning indicators can be found in the following document: WHO. Meeting Report of Assessment of the HIV Drug Resistance Early Warning Indicators 11-12 August 2011. Geneva, Switzerland.

This section is organized around five recommendations spanning enhanced monitoring data collection, reporting and use for programmes implementing lifelong ART for pregnant and breastfeeding women and their children. Box 3 lists the recommendations.

### ENHANCED MONITORING

ENHANCED MONITORING refers to the collection of additional or enhanced indicators to trigger timely identification of implementation problems and challenges that need corrective action.

Specific areas of concern during the early programme transition include commodity availability, quality assurance of rapid testing, and early maternal retention on ART.

By conducting enhanced monitoring, facility and programme staff will be able to rapidly identify these issues and minimize potential risks of ARV stock outs, misdiagnoses and LTFU.



### Recommendations for Operationalizing Enhanced Monitoring

1. Select a subset of health facilities to conduct enhanced monitoring.
2. Develop enhanced monitoring collection and reporting tools and define reporting periods.
3. Collect enhanced monitoring indicators at a subset of sites.
4. Implement regular, integrated data review meetings at facility, sub-national and national levels.
5. Integrate enhanced monitoring into routine monitoring, quality improvement and evaluation activities for long term sustainability.

## OPERATIONALIZING ENHANCED MONITORING INDICATORS: RECOMMENDATIONS AND GUIDANCE

### RECOMMENDATION 1: SELECT A SUBSET OF HEALTH FACILITIES TO CONDUCT ENHANCED MONITORING

Enhanced monitoring is not intended to be conducted at all sites nor at a nationally representative selection of sites. Enhanced monitoring should be conducted at a **purposeful sampling** of sites.

- For countries with fewer than 1,000 facilities delivering lifelong ART: select 15 to 30 facilities for enhanced monitoring.
- For countries with more than 1,000 facilities delivering lifelong ART: select 30 to 60 facilities.

The number of sites for conducting enhanced monitoring is suggested here as a recommendation,

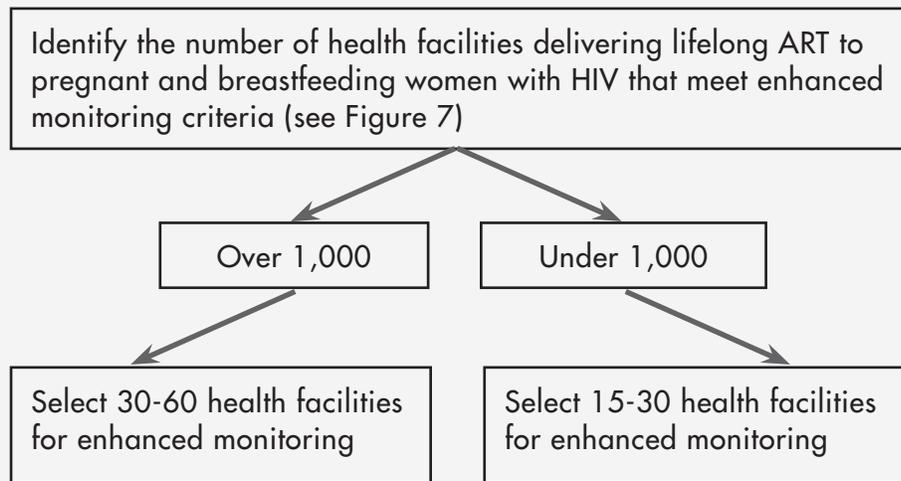
with an emphasis towards ease of implementation at purposefully selected sites. Countries can select more sites than recommended depending on capacity.

The rationale is to sample enough sites to offer a reasonably representative view of Option B/B+ implementation, while ensuring a feasible sample size for enhanced data collection, reporting and use.

#### PURPOSEFUL SAMPLING

For enhanced monitoring, it is helpful to select facilities that keep good records and have sufficient M&E resources. It is also advantageous to select facilities that are high volume and located in high prevalence areas. Both of these non-random sampling criteria are considered **PURPOSEFUL SAMPLING**. Purposeful sampling can support the collection of a sufficient amount of information in a timely manner—which, in this case, is more important than representative sampling.

**FIGURE 6** Sampling Strategy 1: Determining the number of facilities for enhanced monitoring



### Use a purposeful sampling approach

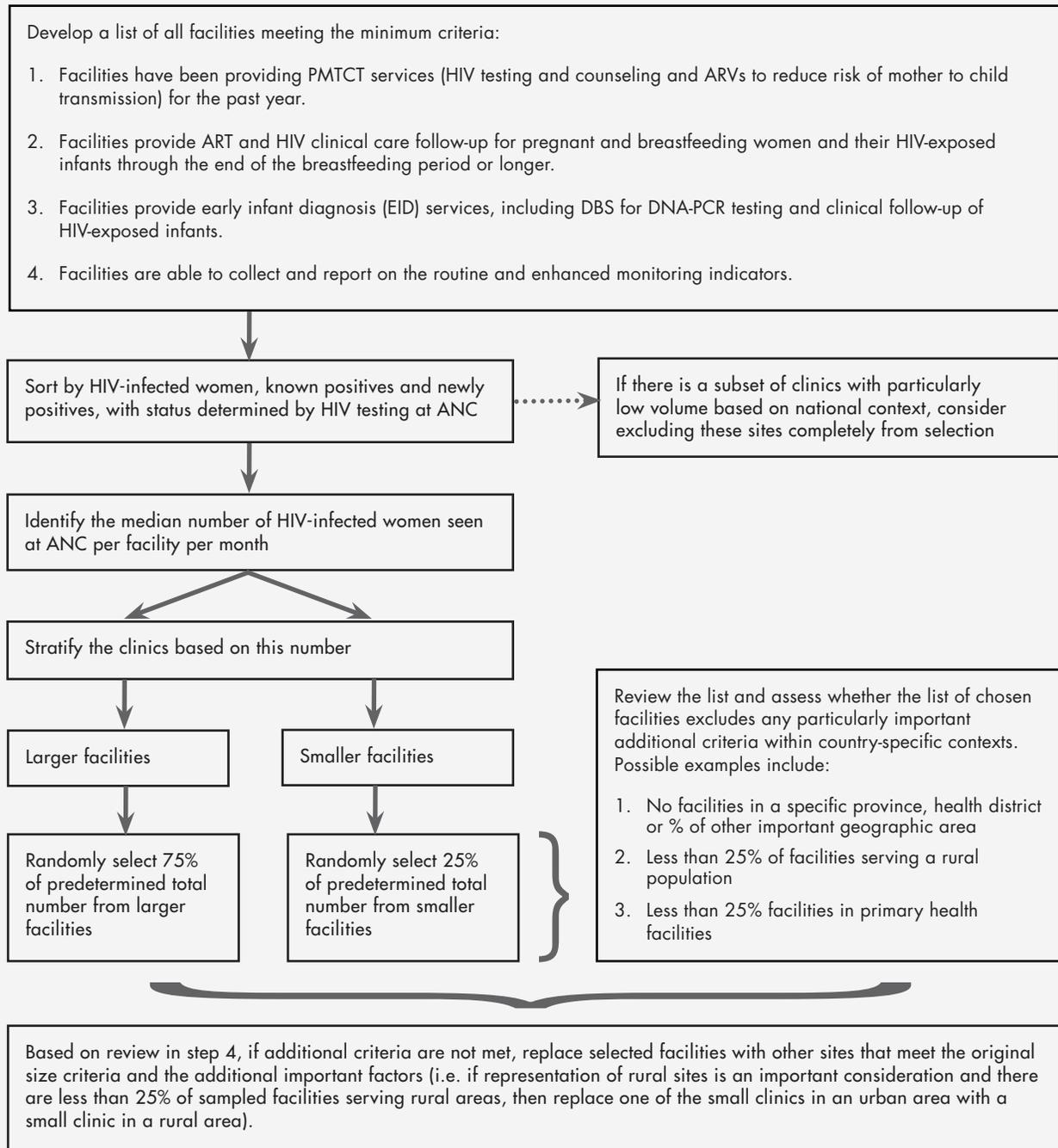
Enhanced monitoring sites should be able to collect, report and use routine and enhanced indicators together to give a more complete picture of the quality and outcomes of maternal and infant care. A programme may choose to implement enhanced monitoring in facilities with electronic medical records; this may have limited generalizability to paper-based facilities but could still provide very useful information in the early phases of lifelong ART implementation. Ultimately, obtaining useful

enhanced monitoring information to improve programme roll out and operations is most important as long as the limitations of the data are recognized and acknowledged. Once the total number of health facilities is determined, the national programme should work with stakeholders to take into account:

- Ease of implementation;
- Representativeness of collected information;
- Roll-out strategy; and
- Need for rapid identification of and response to problems.

Figure 7 describes a purposeful sampling strategy to select health facilities for enhanced monitoring. It oversamples larger clinics because of their greater impact on the national programme; however, it also allows for collection of information from smaller clinics with lower patient volume.

**FIGURE 7** Sampling Strategy 2: Determining the facilities for enhanced monitoring



## RECOMMENDATION 2: DEVELOP ENHANCED MONITORING COLLECTION AND REPORTING TOOLS AND DEFINE REPORTING PERIODS.

While some of the enhanced monitoring indicators may already be a part of facility level data collection (such as stock outs and other early warning indicators), unique data collection and reporting tools for the enhanced monitoring indicators will likely need to be developed, pilot tested and rolled out at sites conducting enhanced monitoring.

Enhanced monitoring data collection and reporting tools should be developed to support interoperability with routine data collection and reporting tools. Enhanced monitoring indicators should be reported from the facility to sub-national and national levels at least quarterly, preferably monthly. This will allow for a rapid data flow and allow programme managers at a national level to review programme data in a timely manner.

## RECOMMENDATION 3: COLLECT ENHANCED MONITORING INDICATORS AT A SUBSET OF SITES.

Enhanced indicators provide for the timely identification of programme implementation problems/challenges to enable programme staff to take immediate corrective actions. Table 4 lists enhanced monitoring indicators and the rationale for collection. The indicator reference sheets are included in Appendix 2.

### INTEGRATED DATA COLLECTION AND REPORTING

ENHANCED MONITORING INDICATORS should be collected and reported together with routine programme indicators. Data collection and report tools should be discussed and agreed by the integrated programme monitoring technical working group review meetings outlined under Routine Monitoring Recommendation 4, above.



**TABLE 4: Recommended enhanced monitoring indicators to be collected at a subset of sites implementing integrated PMTCT and HIV Care and Treatment services**

Indicator	Rationale
1. Percentage of HIV testing sites that participate in an HIV rapid test proficiency testing (PT) programme and receive satisfactory scores	<ul style="list-style-type: none"> <li>As part of a comprehensive quality assurance system, ongoing successful participation of staff in HIV rapid test PT programmes improves the reliability and accuracy of HIV rapid testing and prevents misdiagnosis, thereby minimizing the likelihood that a false positive result would result in initiation of a women or child on lifelong ART in error. See Appendix 2D.</li> </ul>
2. Percentage of HIV rapid testing sites using both the screening and confirmatory test results to allow for monitoring of HIV rapid test register	<ul style="list-style-type: none"> <li>Accuracy and reliability of rapid test results are critical to preventing misdiagnosis.</li> <li>Use of a standardized rapid test register (or the revision of existing ANC registers to include columns for initial and confirmatory test results) is a critical component of a comprehensive HIV rapid test quality assurance programme. Such a register serves as both a job aid and supervisory tool to support correct implementation of the HIV rapid testing algorithm. See Appendix 2E.</li> </ul>
3. Percentage of facilities reporting at least one stock-out of critical commodities (either rapid test kits, or maternal ART, or EID DBS test kits) within the previous 3 months	<ul style="list-style-type: none"> <li>Monitoring commodities helps the programme prevent stock-outs and address stock management and distribution issues before they become crisis situations.</li> <li>This indicator is designed to identify gaps at the end of the supply chain with the recognition that more thorough investigation is needed to determine bottlenecks and identify solutions.</li> <li>If stock-outs are experienced for any of these commodities, the availability of other diagnosis, care and treatment commodities is likely to be compromised as well. See Appendix 2F.</li> </ul>
4. Percent of pregnant or breastfeeding women with HIV who are retained on treatment one month after initiating ART	<ul style="list-style-type: none"> <li>Early experience with lifelong ART suggests there may be a large LTFU among pregnant women between ART initiation (visit 1) and the next visit (visit 2). Failure to return for visit 2 may indicate poor retention or may mean that ART was never actually initiated.</li> <li>Given the critical importance of retention to the success of both PMTCT and ART outcomes, this early follow-up monitoring will help programmes determine how best to focus ART initiation and client tracking interventions. See Appendix 2G.</li> </ul>
5. Percentage of pregnant and breastfeeding women with HIV who are retained on ART at 3, 6 and 9 months after initiation <sup>20</sup>	<ul style="list-style-type: none"> <li>Observational evaluations have demonstrated pregnant and breastfeeding women are particularly vulnerable to LTFU.</li> <li>Given the critical importance of early adherence and retention in preventing vertical transmission, identifying whether pregnant and breastfeeding women newly initiated on ART have high rates of defaulting during the first year is an important proxy of programme success and necessary for determining appropriate interventions. See Appendix 2H.</li> </ul>
6. Percentage of eligible pregnant women with HIV initiating CTX prophylaxis	<ul style="list-style-type: none"> <li>CTX prophylaxis is a simple and cost-effective intervention that reduces the risk of opportunistic infections (OIs) and mortality in HIV-infected adults, as well as prevention of malaria and urinary tract infection in pregnant women.</li> <li>WHO guidelines offer countries the choice to provide CTX to all HIV-infected patients or according to disease stage; this indicator may be most useful for programmes implementing universal CTX for pregnant women, given the challenges in describing the number of patients eligible for the intervention when disease stage is used. See Appendix 2I.</li> </ul>
7. Percentage of ART patients with an undetectable viral load at 12 months after initiation of ART by pregnancy and breastfeeding status at initiation	<ul style="list-style-type: none"> <li>Viral load at 12 months after ART initiation serves as a biologic marker of ART effectiveness.</li> <li>Unsuppressed viral load can indicate poor treatment adherence, and lead to both increased risk of transmission and the development and spread of drug resistance.</li> <li>This indicator does not replace the ART retention indicator since only those who have a viral load measured are included.</li> <li>Determination of overall programme success, therefore, needs to include assessment of both retention and viral suppression at 12 months. See Appendix 2J.</li> </ul>
8. Percentage of HEIs who are retained on CTX 6 months after birth (or after initiating care services)	<ul style="list-style-type: none"> <li>WHO 2013 <i>Consolidated Guidelines</i> recommend all HEIs initiate CTX 4–6 weeks after birth and continue until breastfeeding ends and HIV infection is excluded.</li> <li>In most resource-limited settings breastfeeding continues beyond the first year of life; therefore, indicators that describe the provision of CTX prophylaxis at 6 months can be a useful proxy for early retention of HEIs in care. See Appendix 2K.</li> </ul>

## RECOMMENDATION 4: IMPLEMENT REGULAR, INTEGRATED DATA REVIEW MEETINGS AT FACILITY, SUB-NATIONAL AND NATIONAL LEVELS.

Review of enhanced monitoring should also include review of available routine data as well. These integrated data reviews should occur with facility staff as well as sub-national and national programme level officers, ideally included in the integrated programme monitoring technical working group meetings outlined in Routine Monitoring Recommendations 4 and 6 in Section 1, above.

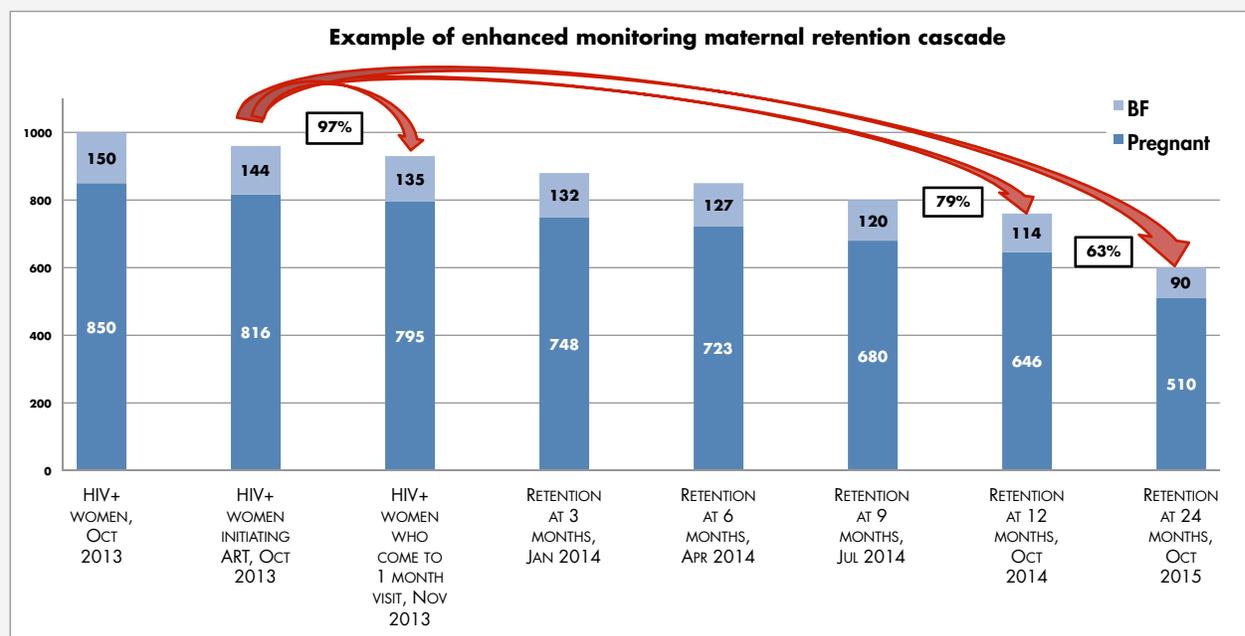
Facilities implementing enhanced monitoring should consider formatting data from routine reports as a cascade (see Figure 8) to visualize uptake of interventions and identify where patient drop off is occurring. Figure 8 is a maternal ART retention cascade illustrating enhanced and routine monitoring data together for a specific cohort of women.

<sup>20</sup> Percentage of HIV-infected pregnant and breastfeeding women who are retained and on ART at 12, 24, 36, 48 months after initiation, is suggested as a routine monitoring indicator in Table 2.

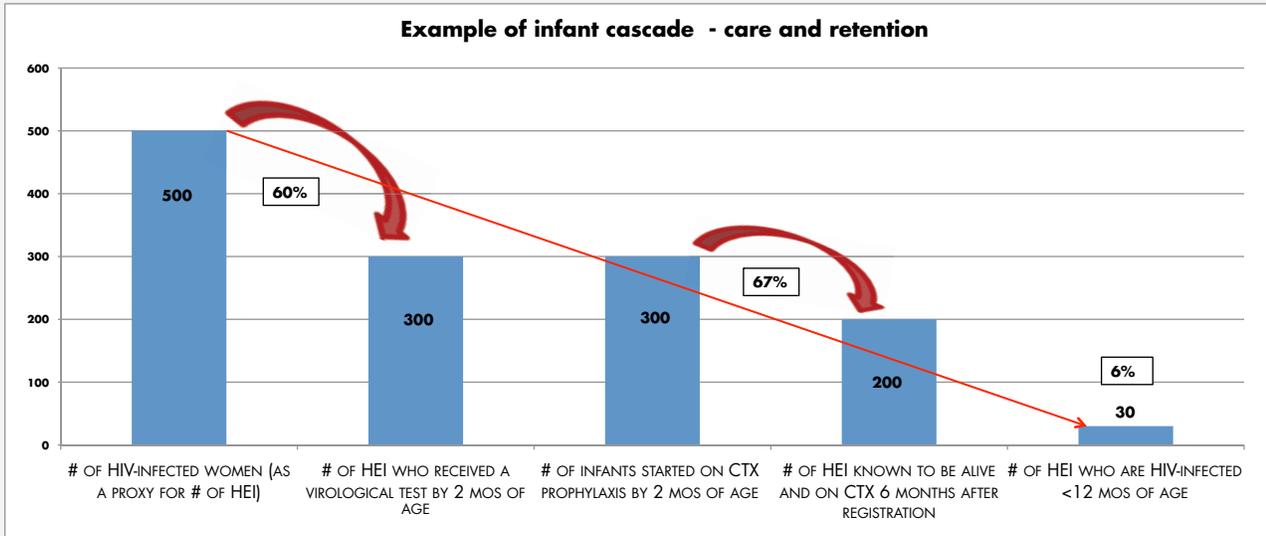
By plotting the retention of both pregnant and breastfeeding women at early time points, and at 12 months and beyond, facility staff and national programme managers can gain a better understanding of LTFU over time and if there is a difference in retention in HIV Care and Treatment between women who initiate ART when pregnant and those who initiate while breastfeeding, as well as those already on ART when pregnant. As an example, Figure 8 illustrates that:

- 4% (40/1,000) of HIV+ clients in this particular cohort either elected not to take ART or dropped out of care before they could be initiated.
- The percentage of women who were breastfeeding when they initiated ART and those who were pregnant when they initiated ART who were still on ART 24 months later was exactly the same: 63% (90/144 and 510/816).
- In the first year, women dropped out of care at a rate of about 2–6% per quarter. The total dropout rate in the first 12 months was 21% (200/960), a 12-month retention on ART of 79%.
- About 21% of clients dropped out of care in the 2nd year (between months 12 and 24) (160/760), yielding a 24 month retention on ART of 63%.

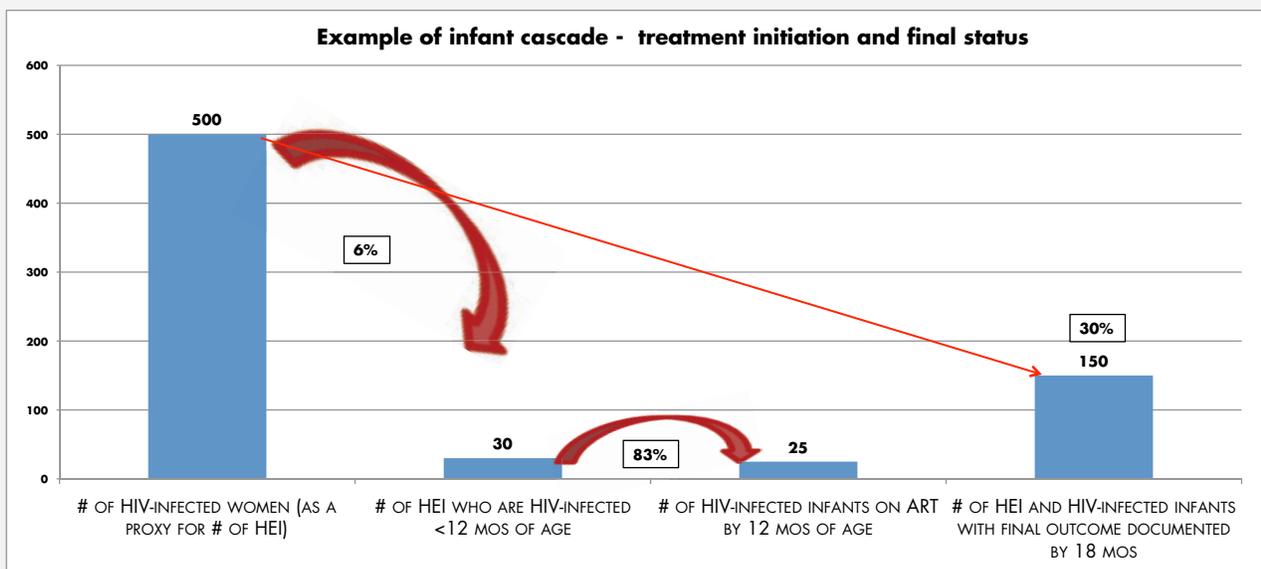
**FIGURE 8** Example of enhanced monitoring of maternal retention cascade



**FIGURE 9** Cohort of infants born in October 2013, clinical care and retention cascade



**FIGURE 10** Cohort of infants born in October 2013, treatment initiation and final status





Comparison of these findings with national targets is likely to suggest the need for additional review and trouble shooting to determine the reasons for LTFU and interventions to improve long-term retention in care.

Figures 9 and 10 focus on the HIV Care and Treatment cascade for HEIs and combines several indicators to assess retention of HEIs in care through a final outcome status. Because HEIs should receive multiple interventions from birth through the breast-feeding period, this cascade is most useful if applied to a cohort of infants based on birth month.

Figure 9 illustrates that for this particular cohort of HEIs:

- Only 60% (300/500) were provided with an EID test and given CTX as per national guidelines. Assuming the national target is, for example 90% for both indicators, the cascade illustrates that effort is needed in this area.
- The 4th bar illustrates that 67% of HEIs were retained in care and 33% (100/300) of HEIs from 2 to 6 months of age are LTFU.
- The perinatal transmission rate at 12 months (not yet the final transmission rate) might be estimated at somewhere between 6% (30 infected/500 exposed) and 10% (30 infected/300 with some virologic testing).

High LTFU at 6 months and low coverage of CTX and EID testing indicate that additional efforts are

needed to retain HEIs in care. The cascade in Figure 10 shows the treatment initiation and documented final status of HEIs.

- Out of the initial cohort of 500 infants, only 30% (150/500) had final HIV outcome documented by 18 months; conversely 70% (350/500) were LTFU, an unacceptable percentage by any national standard.
- Of the infants identified as HIV-infected, a high proportion (83%, 25/30) were initiated on ART by 12 months of age; conversely 17% (5/30) either dropped out of care or were not initiated on ART for some other reason.

Figure 9 and 10 when reviewed together suggest:

- LTFU in the first two months was 40% (200/500) whereas the LTFU from 2 to 18 months of age was 50% (150/300), suggesting that LTFU is highest immediately postpartum but remains high throughout the the 18 month risk period.
- Only 150 (50%) of the 300 HEI who had an initial test at 2 months of age have a final HIV status outcome documented.

In reviewing the example infant cascades together, programme managers and facility staff should identify programme bottlenecks to ensure HEI have follow-up and linkage to services until final HIV outcome is determined. Cascade graphs can serve as visual aides to identify areas where clients are lost to follow-up, in turn providing guidance for quality improvement efforts.



### RECOMMENDATION 5: INTEGRATE ENHANCED MONITORING INTO ROUTINE MONITORING, QUALITY IMPROVEMENT AND EVALUATION ACTIVITIES FOR LONG TERM SUSTAINABILITY.

Once enhanced monitoring demonstrates that implementation of lifelong ART for pregnant and breastfeeding women is yielding high-quality services, programmes might consider shifting away from enhanced monitoring data collection to long-term, national monitoring methods. Specifically, the following enhanced monitoring indicators can be integrated into quality improvement and supportive supervision activities, (again, similar to a strategy of early warning indicators).

- Rapid test quality
- Stock-outs
- Early ART retention
- CTX uptake among pregnant and breastfeeding women

The following enhanced indicators should be incorporated into routine programme monitoring systems or reviewed periodically through programme evaluation or other assessment activities:

- Infant CTX uptake at 6 months; and
- 12-month viral suppression for mothers and children with HIV.

Programme managers should set a timeline to review enhanced data indicators and their usefulness after at least 2 quarters of data have been accumulated. At that point, managers should decide which indicators should continue to be collected as part of enhanced monitoring, which should be incorporated into routine monitoring, and which are no longer useful and should be dropped.

# SECTION 3: EVALUATION OF PROGRAMMES IMPLEMENTING LIFELONG ART FOR PREGNANT AND BREASTFEEDING WOMEN AND THEIR INFANTS

## PROGRAMME CHANGES AND IMPLICATIONS FOR EVALUATION

Recommendations for monitoring the integration of PMTCT and HIV Care and Treatment programmes are presented in Sections 1 and 2. Changes in programme monitoring will result in new information and systems which can be utilized for programme evaluation. This section offers recommendations for evaluating process and systems, outcomes and effectiveness and operational research.

## OPERATIONALIZING EVALUATION: RECOMMENDATIONS AND GUIDANCE

### RECOMMENDATION 1: CONDUCT PROCESS AND SYSTEMS EVALUATIONS IN THE EARLY PHASES OF ROLL OUT

As PMTCT programmes transition to implementing lifelong HIV Care and Treatment services for pregnant and breastfeeding women, process and systems **evaluations** can provide early feedback on:

- Progress of operational implementation (e.g., whether programme activities are being implemented as planned); and
- Gaps in monitoring and monitoring tools.

## MONITORING VS EVALUATION

**MONITORING** is the routine collection and tracking of data about key programme indicators. In contrast, an **EVALUATION** assesses whether the intervention is achieving its objectives.

Both process and systems evaluations should be planned and implemented early on in the roll out of lifelong ART for pregnant and breastfeeding women.

The readiness assessment checklist for transitioning to and implementing ART for pregnant and breastfeeding women—included in the *IATT Toolkit, Expanding and simplifying treatment for pregnant women living with HIV: Managing the transition to Option B/B+*<sup>21</sup>—can be used to identify key content areas when planning a process or systems evaluation.

<sup>21</sup> Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children. Expanding and simplifying treatment for pregnant women living with HIV: Managing the transition to Option B/B+. Available at: <http://www.emtct-iatt.org/toolkit/>

## BOX 4

### Recommendations for operationalizing evaluation

1. Conduct process and systems evaluations in the early phases of roll out.
2. Conduct outcomes and effectiveness evaluations to understand programme impact.
3. Conduct operational research to inform best practices and optimal provision of clinical interventions for maximum impact.

## PROCESS AND SYSTEMS EVALUATIONS

Process evaluation uses indicators developed by programme managers to measure programme roll out. Process evaluation provides a snapshot of programme implementation and identifies areas where additional interventions or corrective actions are needed for successful scale-up.

Process evaluation involves analysis of routine and enhanced programme monitoring data, as well as additional information collected on a regular basis such as:

- Provider feedback
- Client perspectives
- Assessment of service quality

A systems evaluation reviews programme monitoring tools to assess whether or not they adequately collect and report the data necessary to monitor and evaluate the programme.

Timing of process and systems evaluations will depend on national context and programme need, but as a general rule:

- National level: process and systems evaluations should be conducted in the first year.
- Sub-national level: process and systems evaluation should be conducted in the first 3–6 months.

### OUTCOMES VS EFFECTIVENESS EVALUATION

An **OUTCOMES EVALUATION** looks at how well a programme met each indicator. An **EFFECTIVENESS EVALUATION** asks how well a programme meets its overall goal (eg. decreasing infant HIV infections, improving maternal health).

Timing of outcome and effectiveness evaluations: These evaluations are conducted as the programme matures, after the early implementation phase but not necessarily after full scale-up. Outcome and effectiveness evaluations are most often led at the national programme level.<sup>22</sup>

## RECOMMENDATION 2: CONDUCT OUTCOMES AND EFFECTIVENESS EVALUATIONS TO UNDERSTAND PROGRAMME IMPACT.

**Outcomes and effectiveness evaluations** examine a programme's progress toward goals of reducing new paediatric infections and decreasing maternal and infant morbidity and mortality. An assessment of short-, mid- and long-term maternal and infant outcomes can demonstrate how well the programme is functioning. Short-, mid- and long-term outcomes of interest may include:

- Provision of maternal ART;
- Provision of infant and maternal CTX prophylaxis;
- Maternal and infant retention;
- Maternal ART during breastfeeding;
- Maternal viral suppression; and
- Final outcome for HEIs (after cessation of breastfeeding).

The WHO publication *Measuring the impact of national PMTCT programmes: a short guide on methods*<sup>22</sup> can be used as an additional resource when planning outcome or effectiveness evaluations.

### Cohort information as a tool for evaluation

Mother and infant cohorts are rich data sources for outcome and effectiveness evaluations. These cohorts allow for determination of vertical transmission rates; retention along both maternal and infant cascades; and linkage to and receipt of HIV Care and Treatment services. Specific areas of interest for which cohort analysis is particularly valuable are listed in Table 5.

The estimation of mother-to-child transmission rates is of particular interest given that <5% transmission is

<sup>22</sup> World Health Organization. *Measuring the impact of National PMTCT Programmes: A Short Guide on Methods* (2012). Available online at: [http://www.who.int/hiv/pub/mtct/national\\_pmtct\\_guide/en/index.html](http://www.who.int/hiv/pub/mtct/national_pmtct_guide/en/index.html). Accessed May 2014

## SUGGESTED PROCESS AND SYSTEMS EVALUATION QUESTIONS

1. Intended programme implementation (Process evaluation questions)
  - a. Descriptive assessment of programme: Who is the programme serving? What services are provided?
  - b. Comparison of select routine indicators for monitoring ANC, PMTCT and ART services pre- and post- implementation of Option B+.
  
2. Systems essential for successful implementation (Systems evaluation questions)
  - a. M&E: Are all data collection systems (registers, patient cards, health files, reporting tools, etc.) being used appropriately? Are these tools able to collect and report on all of the data elements needed? Are additional tools being used to fill gaps? If new M&E tools are being implemented, are staff completing them correctly or are there training gaps?
  - b. Commodities: Are essential HIV diagnosis, care and treatment commodities available?
  - c. Quality assurance: Are systems in place to ensure quality assurance of rapid HIV testing?
  - d. Training: Have a sufficient number of staff been trained in Option B+? Are job aids available?
  - e. Supportive supervision: Is supportive supervision and/or clinical mentoring occurring with the frequency intended and needed?
  - f. Retention: Are systems in place for tracking mothers and infants to identify and reach out to those who are lost to follow-up?
  
3. Satisfaction with the new model of care? (Systems evaluation questions)
  - a. Clients: Do women feel they are being provided with adequate counselling and information? Are support services available?
  - b. Health care workers: Do health care workers feel training and mentorship are adequate? Are they able to address the clients' needs? Are there additional tools or job aids that would be helpful? What suggestions do they have to improve service delivery?

**TABLE 5:** Maternal and infant outcomes of interest that can be ascertained using programme cohorts

Maternal cohort	<ul style="list-style-type: none"> <li>• Retention on ART</li> <li>• Viral suppression</li> </ul>	<ul style="list-style-type: none"> <li>• Incidence of opportunistic infections, including TB</li> <li>• Maternal survival</li> </ul>
HIV-exposed infant cohort	<ul style="list-style-type: none"> <li>• Estimation of early, late and final transmission rate (programme impact if sample is representative of infants from PMTCT)</li> <li>• Retention in care</li> </ul>	<ul style="list-style-type: none"> <li>• Nutritional status over time</li> <li>• Final HIV status at end of breastfeeding</li> <li>• Infant HIV-free survival</li> <li>• Initiation of ART for infants identified as HIV-infected</li> </ul>
Maternal-infant pair cohort	<ul style="list-style-type: none"> <li>• Impact of maternal characteristics and vital status on retention of infants during the MTCT risk period</li> </ul>	<ul style="list-style-type: none"> <li>• Association of maternal and infant demographic and clinical characteristics with MTCT risk. (e.g., timing of ART initiation, retention, adherence, viral suppression)</li> </ul>



one of the primary goals of the Global Plan.<sup>23</sup>

Estimations of mother-to-child transmission rates using programme data may require:

- Linkage of maternal and infant records through the use of unique identifiers;
- HEI DNA PCR testing coverage and results; and
- High levels (>80%) of retention in care and analysis of final infant outcome data.

Estimations of vertical transmission rates are more feasible where there are registers for HEI follow-up and where the HEI registers include demographic, clinical and follow-up information for mothers and infants through the breastfeeding period.

Transmission estimates based on programme data must always be interpreted with caution as they only account for transmission that has occurred among those engaged in PMTCT services. In addition to not including those not receiving PMTCT services, these estimates generally do not account for HIV transmission that may have occurred among infants who are LTFU or among those who have died before determination of HIV status. While the ultimate goal is to ascertain final infant HIV status at the end of the mother-to-child transmission risk period, interim

assessments (6, 12 and 18 months from delivery) are encouraged, given the challenges in tracking mother-infant pairs over time.

### RECOMMENDATION 3: CONDUCT OPERATIONAL RESEARCH TO INFORM BEST PRACTICES AND OPTIMAL PROVISION OF CLINICAL INTERVENTIONS FOR MAXIMUM IMPACT.

**Operational research** (OR) uses scientific methodologies to analyse or model the efficiency and effectiveness of various programme or systems interventions with the goal of maximizing the benefit of the clinical intervention. OR can assess which innovative solutions, policies or service delivery models improve programme effectiveness or efficiency to optimally allocate programme resources.

#### OPERATIONAL RESEARCH

OR is typically funded as one to five year projects to address programme barriers. It is typically conducted by a specialist agency or academic institution and takes place in predetermined clinical settings. The data from OR may or may not be representative of the majority of healthcare settings in that country but the intent is to provide valuable information that can be used for quality improvement.

<sup>23</sup> Joint United Nations Programme on HIV/AIDS. *Global Plan Towards the Elimination Of New HIV Infections Among Children by 2015 And Keeping Their Mothers Alive*. Available online at: <http://www.zero-hiv.org/>. Accessed August 2014.



### SUGGESTED QUESTIONS FOR OUTCOME AND EFFECTIVENESS EVALUATIONS

- Does implementation of lifelong ART in MNCH result in improved coverage of HIV services for pregnant and breastfeeding women?
- What is the effectiveness of the programme on maternal health—specifically major maternal morbidities related to HIV including TB, pneumonia and sepsis?
- Are women living with HIV increasingly delivering in health facilities?
- Is the unmet need for family planning decreasing among postpartum women?
- Are women already on ART (before their pregnancy) virally suppressed during pregnancy?
- What is the effectiveness of the programme on reducing vertical transmission and improving infant and child HIV-free survival?
- Have early and longer-term maternal and infant outcomes (longer-term retention and viral suppression of mothers on ART, retention of mother-infant pairs, maternal and perinatal morbidities, maternal and infant mortality) improved after implementation of lifelong ART?
- Has coverage of DNA PCR (i.e. virological) testing at 2 months and retention of infants through determination of final HIV status improved following implementation of lifelong ART?
- What is the effectiveness of the programme on birth outcomes, including stillbirth, preterm birth and early neonatal mortality?
- Has immunization coverage of HEIs improved?



## SUGGESTED EVALUATION QUESTIONS FOR OPERATIONAL RESEARCH

### 1. Identification, initiation, retention and viral suppression

- a. What are the barriers (individual, system and community) to accessing antenatal care and PMTCT services and how can they be addressed?
- b. What interventions are most effective for rapid initiation of ART in pregnant and breastfeeding women to maximize adherence and minimize transmission?
- c. What are the reasons women decline ART or do not initiate ART until the breastfeeding period, and what interventions are needed to support earlier initiation?
- d. What are the correlates of short- and long-term adherence and retention in newly identified HIV-positive pregnant and breastfeeding women?
- e. To what extent does reviewing monitoring data from multiple programmes or service areas highlight LTFU or other patient follow up challenges (such as MNCH data paired with PMTCT and ART data)?
- f. What interventions can be implemented to systematically identify women who seroconvert during pregnancy and/or breastfeeding?
- g. Are there differences in adherence and retention behavior between women of reproductive age who start lifelong treatment in PMTCT settings and women who start in HIV Care and Treatment settings?
- h. Are there specific points along the MNCH continuum (delivery, end of routine immunizations, end of breastfeeding) that correlate with drop-offs in retention of mother-infant pairs?
- i. What are effective strategies for identifying

the HIV status of male partners and older children of women with HIV and engaging those who are HIV-positive in HIV Care and Treatment?

### 2. Service provision and delivery model(s)

- a. What are the training needs of MNCH staff to provide enhanced/integrated care?
- b. How are quality assurance systems for rapid HIV testing minimizing misdiagnoses?
- c. What are the most efficient strategies for integrating care for HIV-exposed infants and children with HIV into MNCH settings (e.g., how feasible is a family-based model of care? Could the model also be extended to include the male partner)?
- d. What are the most effective models for programme design and management (i.e. training, supervision, mentoring, space and location) to enroll pregnant and breastfeeding women with HIV in care and retain them and their HIV-exposed infants in HIV care beyond pregnancy to maximize maternal and infant health?
- e. How can other services such as family planning, TB screening and treatment, EID and pediatric HIV care be most effectively and efficiently incorporated into MNCH settings?
- f. To what extent does implementing lifelong HIV Care and Treatment services within MNCH settings affect the quality of ANC services?
- g. How can HEI services be integrated with other healthcare system entry points (i.e. immunization, under-5 clinics, etc.)?

# CONCLUSION

Lifelong ART for pregnant and breastfeeding women with HIV is already impacting the global epidemic by decreasing mother-to-child transmission of HIV and improving the health of mothers and their infants. As countries implement lifelong ART, improved monitoring systems and programme evaluations are needed to continue to inform programme planning and decision making through measuring and reporting key findings.

This document has laid out recommendations and guidance for operationalizing M&E within the new programmatic paradigms. The overarching recommendations are summarized in Table 6 below. By reviewing, adapting and updating current monitoring systems and continuously evaluating programmes, improving transparency and access to data, ministries of health around the world will be able to collect the data they need to maximize the potential of PMTCT/ART services in MNCH and HIV Care and Treatment programmes to improve health outcomes, prevent infections and save lives.

■ **TABLE 6:** Summary of proposed recommendations for routine and enhanced monitoring and evaluation of programmes implementing lifelong ART for pregnant and breastfeeding women with HIV and their infants

Area of operationalization	Recommendation
Routine monitoring	<ol style="list-style-type: none"> <li>1. Convene an integrated programme monitoring technical working group that includes multidisciplinary stakeholders (e.g. PMTCT, ART, M&amp;E).</li> <li>2. Review data collection tools to identify gaps, understand where data are collected and reported and ensure systems are integrated.</li> <li>3. Collect routine indicators for PMTCT and HIV Care and Treatment.</li> <li>4. Integrate reporting on PMTCT indicators from both MNCH and HIV Care and Treatment facilities at all levels.</li> <li>5. Assure sufficient human resources for consistent, high-quality programme monitoring.</li> <li>6. Review integrated data at facility, sub-national and national levels.</li> <li>7. Use programme data for quality improvement.</li> <li>8. Safeguard confidentiality and security of patient information and ensure patient rights are protected.</li> </ol>
Enhanced monitoring	<ol style="list-style-type: none"> <li>1. Select a subset of health facilities to conduct enhanced monitoring.</li> <li>2. Develop enhanced monitoring collection and reporting tools and define reporting periods.</li> <li>3. Collect enhanced monitoring indicators at a subset of sites.</li> <li>4. Implement regular, integrated data review meetings at facility, sub-national and national levels.</li> <li>5. Integrate enhanced monitoring into routine monitoring, quality improvement and evaluation activities for long term sustainability.</li> </ol>
Evaluation	<ol style="list-style-type: none"> <li>1. Conduct process and systems evaluations in the early phases of roll out.</li> <li>2. Conduct outcomes and effectiveness evaluations to understand programme impact.</li> <li>3. Conduct operational research to inform best practices and optimal provision of clinical interventions for maximum impact.</li> </ol>



Lifelong ART for pregnant and breastfeeding women with HIV and follow-up of their HIV-exposed and infected infants has the potential to substantially impact the health of women and children worldwide.

## APPENDIX 1: ASSESSING COUNTRY SPECIFIC SERVICE DELIVERY MODEL(S) AND DATA COLLECTION SYSTEMS

Understanding where and how patient information is collected impacts programme monitoring, as well as subsequent reporting and data use. This appendix serves as a guide to national programme managers to facilitate assessment of current data collection and reporting tools, specifically to:

- Assess where data elements for routine indicators are collected and reported
- Identify missing routine indicators or data elements from monitoring systems

**Appendix 1, Table 1: Routine monitoring indicators and required data elements**

Routine monitoring Indicator	Data elements required	Where are data elements recorded? (Specify service delivery point within SDM) <sup>24</sup>	Register used	Data element (Name from register)	Are data elements included in monthly or quarterly report form? (Is there duplication in reporting?)
1. Number of pregnant women attending ANC at least once during the reporting period	Number of pregnant women attending ANC				
2. Percentage of pregnant women with a known HIV status	Number of pregnant women with known HIV status				
	• Number of new HIV-positive pregnant women				
	• Number of known HIV-positive pregnant women				
3. Percentage of pregnant women with HIV who received ARVs to reduce the risk of mother to child transmission	• Newly initiated on treatment during the current pregnancy				
	• Already on treatment before the pregnancy				
	• Maternal triple ARV prophylaxis (prophylaxis component of WHO Option B during pregnancy and delivery)				
	• Maternal AZT (prophylaxis component of WHO Option A during pregnancy and delivery)				
	• Single-dose nevirapine (sd-NVP) to the mother during pregnancy or delivery				
	• Other (usually limited to countries still providing maternal AZT started late in the pregnancy)				
4. Number of adults with HIV infection newly enrolled on antiretroviral therapy (ART)	Number of adults newly initiated on ART				
	• By pregnancy status at initiation				
	• By breastfeeding status at initiation				
5. Percentage of adults and children currently receiving (ART)	Number of adults and children currently receiving ART				
	• By age				

Routine monitoring Indicator	Data elements required	Where are data elements recorded? (Specify service delivery point within SDM) <sup>24</sup>	Register used	Data element (Name from register)	Are data elements included in monthly or quarterly report form? (Is there duplication in reporting?)
6. Percent of adults known to be alive and on treatment 12 months after initiation of ART	Number of adults known to be alive and on ART 12 months after ART initiation				
	<ul style="list-style-type: none"> <li>Of those who initiated ART during pregnancy</li> </ul>				
	<ul style="list-style-type: none"> <li>Of those who initiated ART during breastfeeding</li> </ul>				
	<ul style="list-style-type: none"> <li>By age</li> </ul>				
7. Percentage of adults in HIV care who had their TB status assessed and recorded during their last visit	Number of adults in HIV care who had their TB status assessed and recorded during their last visit <ul style="list-style-type: none"> <li>By age</li> </ul>				
8. Percentage of infants born to women with HIV started on CTX prophylaxis within two months of birth	Number of HEI started on CTX prophylaxis within two months of birth				
9. Percentage of infants born to women with HIV receiving a virological test for HIV within 2 months of birth	Number of HEI receiving a virological test for HIV within 2 months of birth				
	<ul style="list-style-type: none"> <li>Number with a positive PCR test result &lt;2M</li> </ul>				
10. Percentage of infants with HIV who initiate ART by 12 months of age (Note: Denominator is number of infants with positive virologic test by 12 months of age)	Number of infants with positive virologic test by 12 months of age (denominator)				
	Number of children newly initiated on ART				
	<ul style="list-style-type: none"> <li>Number of children newly initiated on ART by 1 year old</li> </ul>				
	<ul style="list-style-type: none"> <li>Number of children newly initiated on ART by 2 years old</li> </ul>				
11. Percentage of birth cohort HIV-exposed infants with an outcome by 18 month visit	<ul style="list-style-type: none"> <li>HIV-infected</li> <li>HIV-uninfected</li> <li>In care but not tested</li> <li>Lost to follow up</li> <li>Died</li> <li>Transferred out</li> </ul>				

<sup>24</sup> SDM = service delivery models, e.g., integrated services as offered within MNCH, HIV Care and Treatment etc

### Appendix 1, Table 2: Data elements for identifying and linking mother-infant pairs

Data element	Where is this element recorded? (e.g., registers, patient-held cards, patient files.)	At what service delivery location are these tools located?	Is element linked with other relevant data elements within register or other tools?
ART patient ID			
• Mother's ART ID			
• Infant or child ART ID			
ANC ID or Safe Motherhood Number			
HIV-exposed infant ID			
Mother's status at ART initiation (pregnant or breastfeeding)			
Mother's ART start date			
Mother's ART regimen			
Mother's CD4 cell count at time of initiation (or near—within 6 months or less)			
Mother's viral load at 12 months			
Infant's viral load at 12 months			
Suppression at 12 months			

## APPENDIX 2A: PERCENTAGE OF INFANTS WITH HIV WHO INITIATE ART BY 12 MONTHS OF AGE

### Routine Indicator 10: Percentage of infants with HIV who initiate ART by 12 months of age

<b>Indicator code:</b>	The percent of infants with HIV who initiate ART by 12 months of age
------------------------	--

**Purpose:** The purpose of this indicator is to measure the proportion between the number of infants with HIV tested <12 months and the number of HIV-positive infants who initiate treatment <12 months of age. This represents an important linkage between PMTCT and Paediatric continuum.

<b>Numerator:</b>	The number of infants with HIV who are newly enrolled on ART by 12 months of age
<b>Denominator:</b>	The number of infants born to women with HIV who have an HIV-positive test by 12 months of age
<b>Disaggregation(s):</b>	N/A
<b>Data Source:</b>	Numerator: Facility ART registers/databases, programme monitoring tools or drug supply management systems. Denominator: HIV-exposed infant registers or other tools that can enumerate the number of infants with HIV by 12 months of age.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level. Data analysis and review should be done monthly or quarterly to monitor progress towards achieving the targets and to identify and correct any data quality issue.

**Method of Measurement:** Two data elements from already existing indicators are used to measure and quantify the linkage between the number of HIV-positive infants <12 months of age and the number of HIV-positive infants who are enrolled on ART by 12 months of age.

**Numerator:**

The numerator is generated by counting the number of infants (<12 months of age) who are newly enrolled in ART in the reporting period, in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards).

Patients with records that transfer in from another facility, or who temporarily stopped ART and have started again in the time period should not be counted.

NEW is a state defined by an individual's beginning in a programme. It is expected that the characteristics of new clients are recorded at the time they newly initiate into a programme.

**Denominator:**

The denominator is comprised of the number of infants who test HIV-positive before 12 months of age. This may be the same number reported from the EID indicator.

**Explanation of Numerator:** The numerator can be generated by counting the number of infants (<1 year old) who are newly enrolled in ART in the reporting period, in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards).

**Explanation of Denominator:** The denominator can be generated by counting the number of infants (<1 year old) who are diagnosed as HIV-infected.

## APPENDIX 2B: PERCENTAGE OF BIRTH COHORT OF HIV-EXPOSED INFANTS WITH AN OUTCOME BY 18 MONTH VISIT

### Routine Indicator 11: Percentage of birth cohort of HIV-exposed infants with an outcome by 18 month visit

<b>Indicator code:</b>	Percentage of birth cohort of HIV-exposed infants with an outcome by 18 month visit
<b>Purpose:</b>	In settings where national guidelines support breastfeeding of HIV-exposed infants, antibody testing of all HIV-exposed children at 18 months of age and/or 6 weeks after cessation of breastfeeding is recommended to determine final HIV status of HIV-exposed children. To accomplish this goal many countries have implemented HIV-exposed infant service delivery models that identify infants at birth or the first infant follow-up visit and track them through the end of the breastfeeding period. In settings where national guidelines recommend HIV-antibody testing at 18 months of life, this indicator measures progress toward ensuring that all infants born to HIV-positive women have an outcome documented.
<b>Numerator:</b>	Number of HIV-exposed infants registered in the birth cohort at any time between 0 and 18 months of age (including transfer-ins)
<b>Denominator:</b>	N/A
<b>Disaggregation(s):</b>	<ul style="list-style-type: none"> <li>• HIV-uninfected not breastfeeding = Number of HIV-exposed infants with a negative 18 month visit antibody test documented who are not breastfeeding.</li> <li>• HIV-uninfected still breastfeeding = Number of HIV-exposed infants with a negative 18 month visit antibody test documented but who are still breastfeeding.</li> <li>• HIV-uninfected breastfeeding status unknown = Number of HIV-exposed infants with a negative 18 month visit antibody test documented but whose breastfeeding status is not documented.</li> <li>• In care but no test done = Number of HIV-exposed infants who attended 18 month visit but no antibody test result is documented.</li> <li>• Lost to follow-up = Number of HIV-exposed infants who did not attend the 18 month visit.</li> <li>• Died = Number of HIV-exposed infants who are documented to have died without confirmation of HIV-infection between 0 and 18 months.</li> <li>• Transferred out = Number of HIV-exposed infants who transferred out between 0 and 18 months without confirmation of HIV-infection.</li> </ul>
<b>Data Source:</b>	Longitudinal HIV-exposed infant register or facility based HIV-exposed infant cards/charts. If available, electronic patient level databases that include HIV-exposed infants can also be utilized.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level and aggregated at least monthly at the facility level. Above the facility level, data should be collected and aggregated in time for sub-national and national reporting cycles.

**Method of Measurement:** To report on this indicator sites would ideally use registers or facility-based files for HIV exposed infants that collect longitudinal information on follow-up and are organized by birth month of infants. This methodology is referred to as birth cohort reporting.

Two examples of birth cohort reporting:

1. In Kenya, this indicator was first piloted by CDC Kenya and the Ministry of Health in Western Kenya and is currently being integrated into the national HIV summary reporting tool (MOH 731), which is part of the Kenya Health Information System (DHIS 2). As part of this process, data from the facility HIV exposed infant longitudinal follow-up register, which organizes infants by birth-month cohorts, is aggregated into a report summarizing outcomes for infants attaining 24 months of age during each month. Reports are submitted monthly with other facility reports.

2. In Malawi, clinic staff complete monthly follow-up reporting forms as part of the national quarterly supervision visits using data collected directly from HIV-exposed infant files, which are kept in a binder that is organized by birth month (no HIV exposed register is used).

Both approaches allow a paper-based health facility to identify the number of HIV-exposed infants registered in the birth cohort at any time between 0 and 18 months of age (denominator).

**Explanation of Numerator:**

- Although 18 month outcomes are discussed, it is recommended to collect these outcomes at 24 months or two year birth cohorts instead of 18 month cohorts for two practical reasons: 1) this allows for children who present several months late to their 18 month visit to be included in the numerator and 2) cohort reporting is easiest when monthly reporting by facilities is used and where the birth month and the reporting month are the same calendar month (i.e. for infants born in January 2012 their 24 month reporting month would be January 2014, rather than using the 18 month reporting month of July 2013). It is recommended facilities assess outcomes for respective cohorts reaching 24 months on a monthly basis and submit reports upward alongside other routine monthly reports.
- By design, the aggregate numerator should equal the programme denominator value at a site level. This allows for facilities to check that all HIV-exposed infants have an outcome assigned to them during the reporting process. Data utilization requires reviewing the disaggregated data to understand the specific outcomes of interest. (see interpretation below).
- In settings where HIV-exposed infant registers do not allow for documentation of all disaggregated outcomes, country teams should report only on available disaggregates (ie. HIV-infected linked to ART, HIV-infected not linked to ART, and HIV-uninfected unknown breastfeeding status) even if the aggregate indicator is less than 100%.

**Explanation of Denominator:**

- The denominator includes those “Transferred In” and those “Transferred Out”, as described above, the inclusion of Transfer-Ins/Outs provides a quality check whereby facilities can ensure all exposed infants have an outcome assigned to them during the reporting process such that the sum of the numerator disaggregation equals the value of the denominator. However when interpreting this indicator across multiple sites (at a district or national level) it is necessary to exclude “Transferred Out” from the denominator to avoid double counting outcomes for infants that transfer between sites.
- Country teams should ensure that all facilities are reporting on the same birth month. Teams may also wish to only collect the data across facilities every quarter and/or wish to ‘lag’ by 1–3 months the cohort-months comprising the quarterly cohort in order to allow sufficient time for reporting from data sources (i.e. implementing partners and/or national systems).

**Interpretation:** This In reporting an infant’s final HIV test after cessation of breastfeeding, the indicator can provide information on the quality of services for HIV-exposed infants, the coverage of testing for infant diagnosis, and the effectiveness of the PMTCT services that programmes can use to measure their progress toward elimination of mother-to-child transmission of HIV.

When interpreting final outcomes both the programme denominator described above or an estimated denominator should be used to review performance. The programme denominator is useful in assessing quality of services for those infants registered at the site and the estimated denominator is a better measure of overall programme performance.

SUB-ANALYSIS BASED ON OUTCOME DATA: Based on the above outcomes, three additional indicators can be assessed using the following data points.

Indicator	Numerator	Denominator
Percentage of HIV-exposed infants who have a final HIV status by 18 month visit (Final HIV status)	HIV-infected plus HIV-uninfected not breastfeeding	Programme or Estimated
Percentage of identified HIV-exposed infants who are alive and HIV-uninfected at 18 month visit (HIV-free survival)	HIV-uninfected	Programme or Estimated
Percentage of identified infants with HIV who are linked to ART services (Linkage to ART)	HIV-infected linked to ART	HIV-infected

**Additional References:** *If registers are revised, it is important for programmes to consider other indicators that could be collected using similar birth cohort methodology. Examples of additional indicators include: coverage of DNA PCR testing at 6–8 weeks of age, coverage and positivity of rapid testing at 9 months of age, percentage of mothers “alive and on” ART in Option B/B+ settings, and/or CTX prophylaxis retention for HIV-exposed infants. Even with additional indicators it is recommended to limit the summarization of cohort data to only 2 time points in paper based systems (i.e. 1 year and 2 years of life).*

## APPENDIX 2C: NUMBER OF HEALTH CARE WORKERS TRAINED IN THE INITIATION AND MANAGEMENT OF LIFELONG ART

Routine Indicator 14: Number of health care workers trained in the initiation and management of lifelong ART for pregnant and breastfeeding women and their children by work cadre management

<b>Indicator code:</b>	Number of health care workers trained in the initiation and management of lifelong ART
<b>Purpose:</b>	Lack of trained health workers is a major barrier to scaling up HIV/AIDS services. Ensuring a sufficient workforce that is trained and able to initiate and manage clients on ART is critical to the roll out of treatment programmes.
	National HIV programmes are expanding their services to provide treatment for all pregnant and breastfeeding women with HIV, irrespective of CD4 count or clinical stage. Additional staff will need to be trained on the initiation and management of ART requiring policies that support task-sharing ART responsibilities to health care providers who may not have otherwise been responsible for initiating and managing clients on ART.
	This indicator seeks to monitor the expanded training of treatment initiation and management as countries implement Options B and B+ for pregnant and breastfeeding women with HIV.
<b>Numerator:</b>	Number of health care workers trained in the initiation and management of ART
<b>Denominator:</b>	N/A
<b>Disaggregation(s):</b>	By: Type of worker cadre <ul style="list-style-type: none"> <li>• Medical officers</li> <li>• Clinical officers</li> <li>• Nurses</li> <li>• Midwives or nurse/midwives</li> <li>• Other type of health care worker</li> </ul> By: Service population <ul style="list-style-type: none"> <li>• Pediatric ART</li> <li>• ART for pregnant and breastfeeding women</li> </ul>
<b>Data Source:</b>	Programme reports, Human Resource Information Systems, educational institutions, professional associations, Ministry of Education, Labor or Health.
<b>Data Collection Frequency:</b>	Data collection and reporting should be done so it is harmonized with other routine data collection and reporting processes, whether quarterly, semi-annually or annually.

**Method of Measurement:** The number is the sum of health care workers who successfully completed an in-service training programme within the reporting period. Individuals will not count as having successfully completed their training unless they meet the minimum requirements as defined by international or national standards of ART initiation and management. In the absence of international or national standards, the minimum requirement should be determined by the national programme.

### Explanation:

Training is a learning activity taking place in in-country, another country or in a setting predominantly intended for teaching or facilitating the development of certain knowledge, skills or attitudes of the participants with formally designated instructors or lead persons, learning objectives and outcomes, conducted full-time or intermittently.

Training refers to training or retraining of individuals and must follow a curriculum with stated (documented) objectives and/or expected competencies. Training may include traditional, class-room type approaches to training as well as on the job or “hands-on” training such as clinical mentoring or structured supervision so long as the following three criteria are met:

- Training objectives are clearly defined and documented;
- Participation in training is documented (e.g. through sign-in sheets or some other type of auditable training); and
- The programme clearly defines what it means to complete training (e.g. attend at least four days of a five-day workshop, achieve stated key competencies, routine XX% on post-test exam, etc.).

The unit of measure is the number of persons trained or retrained. A person is counted as having been trained if he or she participates in a workshop or course, with a specific training subject on ART initiation and management. Only participants who complete the full training course should be counted.

An individual should only be counted once they have completed the training. Individuals that are mid-way through a training course should be counted in the next reporting period. Individuals attending more than one training in a particular programme area during a reporting period should only be counted once. Individuals participating in training that covers more than one programme area may be counted in each of the respective areas.

If two partners are providing different aspects of training to the same individuals in the same programme area (e.g. one partner provides classroom training, another provides clinical mentoring), each partner should report the number of persons uniquely trained by their respective organization, but should note which partner is providing the complementary training role and estimate the number of persons counted by both partners.

In-service training programmes are for practicing providers to refresh skills and knowledge or add new material and examples of best practices needed to fulfill their current job responsibilities. In-service training may update existing knowledge and skills, or add new ones. Care should be taken to base trainee selection on content and skill needs. It requires a shorter, more focused period of time than pre-service education, and is often more “hands-on”. It can be a workplace activity (led by staff, peers or guest lecturers) or an external event.

In-service training can occur through structured learning and follow-up activities, or through less structured means, to solve problems or fill identified performance gaps. In-service training can consist of short non-degree technical courses in academic or in other settings, non-academic seminars, workshops, on-the-job learning experiences, observational study tours or distance learning exercises or interventions.

An in-service training programme must meet national or international standards and have specific learning objectives, a course curriculum, expected knowledge, skills and competencies to be gained by participants, as well as documented minimum requirements for course completion. The duration and intensity of training will vary by cadre; however, all training programmes should have at a minimum the criteria listed above.

**Types of in-service training:**

1. Continuing education: Education/training offered to current providers to either update or add new knowledge and skills. While in-service training is often limited to practitioners in the public sector and/or managed by the Ministry of Health (or similar entity), continuing education is often used to describe education/training that is provided by other sources, such as professional associations, that reaches private sector practitioners and which can be linked to re-licensure and/or certification.
2. On-the-job training: Instruction in a specific task or skill is provided via mentoring by a practitioner using explanations, demonstration, practice and feedback. On-the-job training may be combined with academic or technical training to provide a practical experience component.
3. Computer based training or e-learning: An interactive learning experience in which the computer provides most of the stimuli, the learner responds, and the computer analyzes the responses and provides feedback to the learner. Components most often consist of drill-and practice, tutorial or simulation activities offered alone or as supplements to traditional instruction. CBT is sometimes also used as a component of a pre-service education course.
4. Distance learning: Distance learning is characterized by a geographic separation of instructor and learner where learners work on their own. It uses a range of mechanisms such as self-guided lesson plans, mailings, radio and computer-based activities. Usually it is tied to an educational facility and uses sequential instructional material that is corrected by the instructor. Regardless of methodologies chosen, it requires motivation on the part of the learner and regular feedback on the part of the learning institution. It can also be used for pre-service education.

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**Explanation of Numerator:** The numerator is expressed as the sum of all health care workers trained on the initiation and management of ART.

**Explanation of Denominator:** N/A

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**Interpretation:** This indicator does not measure the quality of the training, nor does it measure the outcomes of the training in terms of the competencies of individuals trained, nor their job performance. This indicator does not measure the placement or retention in the health workforce of trained individuals.

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**Additional References:** *Language defining and explaining ‘training’ included in this reference sheet was originally developed as part of the PEPFAR in-service training indicator (also known as H2.3.D) in the PEPFAR NGI Reference Guide. NGI were used from 2009–2013 to describe PEPFAR programmes and achievements. Published (v1) July 2009. Version 1.2 available online at: <http://www.pepfar.gov/documents/organization/206097.pdf>.*

## APPENDIX 2D: PERCENTAGE OF HIV TESTING SITES THAT PARTICIPATE IN AN HIV RAPID TEST PROFICIENCY TESTING (PT) PROGRAMME AND RECEIVE SATISFACTORY SCORES

### Enhanced Monitoring Indicator 1: Percentage of HIV testing sites that participate in an HIV rapid test proficiency testing (PT) programme and receive satisfactory scores

<b>Indicator:</b>	Percentage of HIV testing sites that participate in an HIV rapid test proficiency testing (PT) programme and receive satisfactory scores *
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**Purpose:** The main purpose of this indicator is to monitor and improve the quality of HIV rapid testing. This indicator will:

1. Demonstrate that the sites are participating in a HIV rapid test PT programme.
2. Demonstrate that the sites participating in the HIV rapid test PT programme have successfully passed PT during the reporting period or PT round.\*\*

\* HIV rapid test PT programmes can use liquid or dried tube specimens (DTS) to create their proficiency panels.

\*\* Successfully passing requires 100% reporting accuracy on the proficiency test panel by the site. All staff that performs HIV rapid tests in a site should undergo proficiency testing to assess the individual competency of each tester. A site can report 100% routine only if each tester has 100% reporting accuracy on the proficiency panel.

% of sites PARTICIPATING in HIV rapid test PT programme =  $(P/N) \times 100$

% of sites PASSING the HIV rapid test PT programme =  $(S/P) \times 100$

N = Number of sites performing HIV rapid testing

P = Number of sites participating in the HIV Rapid Test PT programme during the reporting period or PT round. (i.e. receive panels and return the results)

S = Number of HIV testing sites passing the HIV Rapid Test PT programme during the reporting period or PT round. (i.e. accurately report 100% of the results on the proficiency panel)

<b>Numerator:</b>	For the % of sites participating in HIV rapid test PT programme: P = Number of HIV testing sites participating in the HIV Rapid Test PT programme  For the % of sites passing the HIV rapid test PT programme: S = Number of HIV testing sites passing the HIV rapid test PT programme
<b>Denominator:</b>	For the % of sites participating in HIV Rapid Test PT programme: N = Number of sites performing HIV rapid testing  For the % of sites passing the HIV rapid test PT programme: P = Number of HIV testing sites participating in the HIV Rapid Test proficiency testing programme.
<b>Disaggregation(s):</b>	None
<b>Data Source:</b>	Data should be available from the National Reference Laboratory or similar body implementing PT programmes in the country
<b>Data Collection Frequency:</b>	Monthly or quarterly or after every PT round which falls during the reporting period

**Method of Measurement:** This indicator measures the percentage of sites that participated in and successfully passed HIV rapid test proficiency testing.

**Explanation of Numerator:** Number of HIV rapid testing sites that participate in and pass a national HIV rapid test PT programme.

**Explanation of Denominator:** Number of HIV rapid testing sites with the capacity to perform HIV rapid testing.

**Interpretation:** This indicator measures the coverage of the HIV rapid test proficiency programme and the quality of HIV rapid testing in sites participating in the programme. Calculating the % of sites participating in the HIV rapid test PT programme provides information about the coverage of the PT programme and the progress towards the goal of 100% participation of testing sites. Calculating the % of sites passing the HIV rapid test PT programme provides critical information about the quality of rapid testing. The percentage of HIV testing sites passing the HIV rapid test proficiency programme will reach 100% when all participating HIV testing sites accurately report all results on the proficiency panel. Any site with <100% on proficiency testing requires immediate technical assistance (i.e. site supervision) to review testing practices and implement corrective actions.

Site level proficiency testing indicates the quality of test site operations. Only by providing to proficiency panel to every tester in the site can the quality of individual personnel performance be assessed. Proficiency testing for every staff member performing HIV rapid tests should be conducted.

## APPENDIX 2E: PERCENTAGE OF HIV RAPID TESTING SITES USING A STANDARD HIV RAPID TEST REGISTER TO RECORD AND MONITOR THE QUALITY OF HIV RAPID TESTING

### Enhanced monitoring indicator 2: Percentage of HIV rapid testing sites using a standard HIV rapid test register to record and monitor the quality of HIV rapid testing

<b>Indicator:</b>	Percentage of HIV rapid testing sites using a standard HIV rapid test register to record and monitor the quality of HIV rapid testing
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**Purpose:** The main purpose of this indicator is to monitor and improve the quality of HIV rapid testing. This indicator will: Demonstrate that the testing sites have effectively implemented the standardized HIV Rapid Test logbook as an ongoing QA monitoring tool

1. Demonstrate that the testing sites have effectively implemented the standardized HIV rapid test register as an ongoing QA monitoring tool.
2. Demonstrate that the sites utilizing the HIV rapid test register have acceptable testing performance during the reporting period.\*\*

\* Or incorporating key QA elements into existing HIV/HIV rapid test registers

\*\* Demonstrating acceptable testing performance requires each site to have:

- >98% agreement rate between the 1st rapid test and the 2nd rapid test in the testing algorithm AND/OR
- <1% of HIV rapid tests performed have invalid results

**% of sites USING a standardized HIV rapid test register as an ongoing QA monitoring tool** =  $(L/N) \times 100$

**% of sites with acceptable testing performance using register data** =  $(P/L) \times 100$

**% of invalid results for each test used in the algorithm** =  $(IN1/T) \times 100$  or  $(IN2/T) \times 100$

**% Agreement between test 1 and test 2 for SERIAL algorithm** =  $(CS/R) \times 100$

**% Agreement between test 1 and test 2 for PARALLEL algorithm** =  $R - [(NG1 - NG2) + (PO1 - PO2)] / R \times 100$

N = Number of sites that perform HIV rapid testing

L = Number of HIV testing sites that have implemented the standardized HIV Rapid Test logbook as an ongoing QA monitoring tool

P = Number of HIV testing sites with acceptable testing performance using logbook data during the reporting period. (i.e., have >98% agreement between the 2 rapid tests used in the testing algorithm AND/OR <1% invalid test results )

CS = Number of concordant results between test 1 and test 2 for a SERIAL algorithm (i.e., positive and negative)

R = Number of patients tested (i.e., positive results + negative results; all invalid results excluded)

T = Number of HIV rapid tests performed (i.e. positive + negative + invalid)

IN1 = Number of invalid test1 results during reporting period

IN2 = Number of invalid test2 results during reporting period

NG1 = Number of negative test1 results during reporting period

NG2 = Number of negative test2 results during reporting period

PO1 = Number of positive test1 results during reporting period

PO2 = Number of positive test2 results during reporting period

<b>Numerator:</b>	<p>For % of sites USING standardized HIV rapid test register as an ongoing QA monitoring tool L = Number of HIV testing sites that have implemented the rapid test QA register</p> <p>For % of sites with acceptable testing performance using register data : P = Number of HIV testing sites demonstrating acceptable testing performance using register data during the reporting period. (i.e. have &lt;1% invalid test results AND/OR &gt;98% agreement between the 2 rapid tests used in the testing algorithm)</p>
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<b>Denominator:</b>	For % of sites USING standardized HIV rapid test register as an ongoing QA monitoring tool: N = Number of sites that perform HIV rapid testing  For % of sites demonstrating acceptable testing performance using register data L = Number of HIV testing sites that have implemented the standardized rapid test register
<b>Disaggregation(s):</b>	None
<b>Data Source:</b>	The rapid test register monthly summary data sheets
<b>Data Collection Frequency:</b>	Monthly

**Method of Measurement:** This indicator measures the percentage of sites that have implemented the standardized HIV rapid test QA register as an ongoing QA monitoring tool and the percentage of sites with acceptable testing performance using register data during the reporting period.

**Explanation of Numerator:** Number of sites that use the standardized HIV rapid test QA register as an ongoing QA monitoring tool and have acceptable testing performance demonstrated by register data

**Explanation of Denominator:** Number of HIV rapid testing sites with capacity to perform HIV rapid testing.

**Interpretation:** This indicator measures the uptake of the standardized HIV rapid test QA register as an ongoing QA monitoring tool and the monitors the accuracy of HIV testing. Calculating the % of sites using a standardized HIV rapid test register provides information about the uptake of the standardized register and progress towards the goal of 100% coverage of testing sites utilizing the register. Calculating the % of sites with acceptable testing performance using register data provides critical information about the quality of rapid testing. The percentage of HIV testing sites with acceptable testing performance will reach 100% when all HIV testing sites have >98% agreement between the 2 rapid test used in the testing algorithm AND/OR <1% invalid test results. Any site with testing performance with <98% agreement between test 1 and test AND/OR >1% invalid test results requires immediate site supervision to review testing practices and implement corrective actions. All sites should be trained how to conduct their own routine standardized register reviews to identify any problems with test kits or individual personnel performance.

## APPENDIX 2F: PERCENTAGE OF FACILITIES REPORTING AT LEAST ONE STOCK-OUT OF CRITICAL COMMODITIES (EITHER RAPID TEST KITS, OR TDF-3TC (OR FTC)-EFV OR EID DBS TEST KITS) WITHIN THE PREVIOUS 3 MONTHS

Enhanced Indicator 3: Percentage of facilities reporting at least one stock-out of critical commodities (either rapid test kits, or TDF-3TC (or FTC)-EFV or EID DBS test kits) within the previous 3 months

<b>Indicator:</b>	Percentage of facilities reporting at least one stock-out of critical commodities (either rapid test kits, or TDF-3TC (or FTC)-EFV or EID DBS test kits) within the previous 3 months
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**Purpose:** This indicator assesses the availability of tracer commodities critical to diagnosing and treating HIV-positive pregnant and breastfeeding women and their infants at the facility level. It is designed to identify gaps at the end of the supply chain with the recognition that more thorough investigation would be needed to determine upstream bottlenecks and potential solutions. It is intended to be collected and reported by health care providers, but could also be collected as one element of a supportive supervision visit. Rapid test kits, TDF-3TC (or FTC)-EFV and EID DBS supplies are recommended as tracer commodities due to the fact that an Option B+ programme would not be functional without them. However it is recognized that if stock outs are being experienced with any of these commodities, the availability of other diagnosis or care and treatment commodities are likely to be compromised as well.

<b>Numerator:</b>	Number of Option B+ facilities reporting an actual or potential stock-out of a critical Option B+ commodity within the previous 3 months.
<b>Denominator:</b>	Total number of Option B+ facilities reporting an actual or potential stock-out of a critical Option B+ commodity in the past 3 months.
<b>Data Source:</b>	ANC register, ART register, HIV Testing and Counselling register, HEI register, dispensing register, stock cards
<b>Data Collection Frequency:</b>	This indicator should be collected at minimum every quarter. More frequent collection would allow for more real-time response to stock-out issues. The time period for assessment could be modified based on data collection frequency (i.e. actual or potential stock-outs within the last 1-month instead of 3-months).
<b>Disaggregation(s):</b>	<ul style="list-style-type: none"> <li>• Rapid Test Kits</li> <li>• TDF-3TC (or FTC)-EFV</li> <li>• EID DBS supplies</li> </ul>

**Explanation of Numerator:** The numerator is defined as the number of Option B+ facilities that experienced either an actual or potential stock out. This should be assessed as follows:

- Actual stock out: Facility had no supply of the commodity in stock for at least 1 day.
- Potential stock out: Facility made an emergency order, borrowed from another facility, rationed or prioritized certain patient populations (e.g. pregnant women) to stretch the supply, or refrained from new initiations.

**Rapid Test Kits:** Actual stock outs should be assessed by first reviewing the ANC register over the past 3 months to identify any days in which no rapid testing was conducted. Identification of a gap in testing should prompt the question as to whether or not this was due to a stock-out, or another cause (such as staffing).

**TDF-3TC (or FTC)-EFV:** Actual stock outs should first be assessed by reviewing the dispensing register to determine if there were any days during the past 3 months in which no TDF-3TC (or FTC)-EFV was provided, or periods where smaller quantities than routine were provided (evidence of rationing). Identification of a gap in ARV dispensations should prompt the question as to whether or not this was due to a stock out, or another cause (such as staffing).

**EID DBS supplies** (a collection card, alcohol swabs, gauze, lancets and latex gloves [or a DBS bundle]): Actual stock outs should first be assessed by reviewing the HEI or EID register to determine if there were any infants who did not have a DBS collected for EID during the past 3 months. If no explanation was noted for the lack of DBS collection, further investigation either through review of stock cards or questioning of staff should identify whether or not this was due to a stock out, or another cause (such as staffing).

**Explanation of Denominator:** Total number of facilities offering HTC and lifelong ART for all HIV-positive pregnant and breastfeeding women (Option B+).

**Interpretation:** This indicator would provide a rapid facility level overview of availability of key commodities as Option B+ rolls out. It is suggested that this indicator be interpreted within the context of other facility information such as the size of the population served by the facility (pregnant women attending ANC, HIV positive pregnant and breastfeeding women on ART and HEIs) and whether or not other HIV-related services (especially HTC, treatment and EID) are offered at the same facility. This allows for a more complete understanding of whether Option B+ commodities are part of larger commodity procurements at this site, or whether this is a stand-alone B+ site managing and procuring its own commodities. Additionally, this information can help prioritize programmatic intervention. An additional question to consider asking is: Did you receive the commodities and quantities that you ordered (or commodities and quantities that were expected) in your last procurement? This question can provide some insight into whether the problem is related to site-level forecasting or higher level forecasting or distribution challenges.

## APPENDIX 2G: PERCENT OF PREGNANT OR BREASTFEEDING WOMEN LIVING WITH HIV WHO ARE RETAINED ON TREATMENT ONE MONTH AFTER INITIATING ART

Enhanced monitoring indicator 4: Percent of pregnant or breastfeeding women living with HIV who are retained on treatment one month after initiating ART

<b>Indicator</b>	Percent of pregnant or breastfeeding women living with HIV who are retained on treatment one month after initiating ART
<b>Purpose:</b>	High retention is one important measure of programme success and is a proxy for overall quality of programme.
<b>Numerator:</b>	Number of pregnant and breastfeeding women who are alive and on treatment at 1 month after initiating ART.
<b>Denominator:</b>	Total number of pregnant and breastfeeding women who initiated ART in the month prior to the reporting period, including those who have died, those who have stopped ART and those lost to follow-up.
<b>Disaggregation(s):</b>	Pregnancy status at initiation of ART Breastfeeding status at initiation of ART
<b>Data Source:</b>	Programme monitoring tools; ART registers/databases and cohort/group analysis forms.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level. Data should be aggregated at least monthly at the facility level though the data could be reviewed and collected less frequently, e.g. monthly or quarterly, for the purposes of programme management and review.

**Explanation of Numerator:** The numerator requires that pregnant and breastfeeding women must be alive and on ART at 1 month after their initiation of treatment.

For a comprehensive understanding of retention, the following data must be collected:

- Number of pregnant and breastfeeding women in the ART monthly cohort initiating ART at 1 month prior to the reporting month (denominator).
- Number of pregnant and breastfeeding women still alive and on ART at 1 month after initiating treatment (numerator).

The date of initiation of ART is defined as the date the ART regimen dispensed is first documented by the facility excluding those patients categorized by the facility as “re-initiating” ART or a “transfer-in” (see below for description of ART initiation date for transfer-in patients).

The reporting month is defined as a 1-month period that has ended within a pre-defined number of months from the submission of the report. The pre-defined number of months can be determined by national reporting requirements, but the relationship between the reporting month and the ART initiation month is fixed. If the reporting month is October 2012, countries calculate this indicator by using all patients who were registered for care during September 2012. The following chart identifies the ART initiation and reporting month pairs:

<b>Reporting Month</b>	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
<b>ART Initiation Month</b>	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov

A 1-month outcome is defined as the outcome, i.e. whether the patient is still alive and on ART, dead or lost to follow-up, 1 month after starting. While many HIV Care and Treatment programmes wait 90 days between last scheduled visit and formally labeling a patient lost to follow-up. For the purposes of this indicator a patient with an unknown status at 1 month, that is not formally lost to follow-up but also missing drug pickup at 1 month, is not considered to be on ART.

For example, a patient who initiated ART in September 2012 would be considered “alive and on ART at 1 month” (in October 2012) if: the patient visited the facility and received ARVs in October 2012. However, the patient would NOT be considered “alive and on ART at 1 month” if she did NOT visit the facility in October 2012.

At the facility level, patients who have transferred in should be counted if they have a documented ART initiation date within the month of interest. Conversely, patients who transferred out of the facility should not be counted in that facility’s cohort. (see explanation of Denominator for more details on patients who transfer out).

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For those patients who started ART in September 2012, if at any point during the period up to the end of October 2012 these patients die, are lost to follow-up (and do not return), or stop treatment (and do not restart), then at month 12 (October 2012), they are NOT on ART and NOT included in the retention numerator.

All facilities providing treatment should have an established tracking protocol for late patients. For facilities collecting and reporting on this indicator, as soon as a patient is noted as being late for her visit, the facility should implement their patient tracker protocol to notify the patient of her late status and bring her in for her scheduled appointment and drug refills.

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**Explanation of Denominator:** The denominator is the total number of pregnant and breastfeeding women in the (monthly) ART monthly cohort who initiated ART at a point 1 month prior to the beginning of the reporting month, regardless of their outcome. (died, LTFU, stopped); this includes those “New” on ART. At the facility level, the Transfers Out (TO) will be taken out of the denominator as well as the numerator. It is assumed that if a patient transfers out from an ART facility, that patient will be a “transfer in” at a new ART facility. Logically, facilities and programmes may visualize this calculation of the denominator as the facility or programme is no longer responsible for an ART patient who has officially transferred out to another ART facility.

For example, for the reporting month October, 2012, this will include all patients who started ART during September 2012. This includes all patients, both those on ART as well as those who are dead, have transferred in, have stopped treatment or are lost to follow-up.

This indicator should NOT be estimated. This indicator should be calculated directly from information gathered in standard cohort ART registers or tabular analysis from electronic patient level databases.

HIV programmes should ensure that all facilities are reporting on the same 1-month ART cohort. Only facilities that have been operational for at least 2 months prior to the end of the reporting period should report, so that all facilities report on the same 1 month ART start-up groups. Programmes may also wish to only collect the data across facilities every quarter and they may also wish to lag by one to three months the cohort-months comprising the quarterly cohort in order to allow sufficient time for reporting from data sources (i.e., implementing partners and/or national systems).

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## APPENDIX 2H: PERCENTAGE OF PREGNANT AND BREASTFEEDING WOMEN WITH HIV WHO ARE RETAINED ON ART AT 3, 6 AND 9 MONTHS AFTER INITIATION

Enhanced Monitoring Indicator 5: Percentage of pregnant and breastfeeding women with HIV who are retained on ART at 3, 6 and 9 months after initiation\*

<b>Indicator:</b>	Percentage of pregnant and breastfeeding women with HIV who are retained on ART at 3, 6 and 9 months after initiation
<b>Purpose:</b>	High retention is one important measure of programme success and is a proxy for overall quality of programme.
<b>Numerator:</b>	Number of women who are still alive and on treatment at 3 months after initiating ART during pregnancy or the breastfeeding period.
<b>Denominator:</b>	Total number of women who initiated ART in the 3 months prior to the beginning of the reporting period who were pregnant or breastfeeding, including those who have died, those who have stopped ART and those lost to follow-up.
<b>Disaggregation(s):</b>	<ul style="list-style-type: none"> <li>• <b>Pregnancy status</b> at initiation of ART</li> <li>• <b>Breastfeeding status</b> at initiation of ART</li> </ul>
<b>Data Source:</b>	Programme monitoring tools; ART registers/databases and cohort/group analysis forms.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level. Data should be aggregated at least monthly at the facility level though the data could be reviewed and collected less frequently, e.g. monthly or quarterly, for the purposes of programme management and review.

### Method of Measurement:

**Explanation of Numerator:** The numerator requires that female patients must be alive and on ART at 3 months after their initiation of treatment during pregnancy or breastfeeding.

For a comprehensive understanding of retention, the following data must be collected:

- Number of pregnant and breastfeeding women in the ART monthly cohort initiating ART 3 months prior to the reporting month (denominator).
- Number of pregnant and breastfeeding women still alive and on ART at 3 months after initiating treatment (numerator).

The date of initiation of ART is defined as the date the ART regimen dispensed is first documented by the facility excluding those patients categorized by the facility as “re-initiating” ART or a “transfer-in” (see below for description of ART initiation date for transfer-in patients).

The reporting month is defined as a month that has ended within a pre-defined number of months from the submission of the report. The pre-defined number of months can be determined by national reporting requirements, but the relationship between the reporting month and the ART initiation month is fixed. If the reporting month is October 2012, countries calculate this indicator by using all patients who were registered for care during July 2012. The following chart identifies the ART initiation and reporting month pairs:

<b>Reporting Month</b>	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
<b>Month</b>	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep

A 3-month outcome is defined as the outcome, i.e. whether the patient is still alive and on ART, dead or lost to follow-up, 3 months after starting. A patient with an unknown status at 3 months, that is not formally lost to follow-up but also missing drug pick up at 3 months, is not considered to be on ART.

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The numerator does **not** require patients to have been on ART continuously for the 3-month period. Patients may be included in the numerator (and denominator) if they have missed an appointment or drug pickup or temporarily stopped treatment during the 6 months since initiating treatment, as long as they are recorded as still being on treatment at month 3. For example, a patient who started ART in September 2012 would be considered “alive and on ART at 3 months” (in December 2012) if:

- The patient visited the facility and received ARVs in December 2012; OR
- The patient had enough ARVs to last through the end of December 2012 (month 3) based on the last drug pick-up (e.g., patient received 60 days of drug on November 15, or patient received 30 days of drug on December 1, etc.).

However, the patient would NOT be considered “alive and on ART at 3 months” if:

- The patient did NOT have enough ARVs to last through the end of December 2012 (e.g., patient received 30 days of drug on November 1); AND
- The patient did NOT visit the facility in December 2012.

At the facility level, patients who have transferred in with a known treatment initiation date that falls within the reporting period should be counted. Conversely, patients who transferred out of the facility should not be counted in that facility’s cohort. (See Explanation of denominator for more details on patients who transfer out.)

For those patients who started ART in September 2012, if at any point during the period October 2012 to December 2012 these patients die, are lost to follow-up (and do not return), or stop treatment (and do not restart), then at month 3 (December 2011), they are **NOT** on ART and **NOT** included in the retention numerator.

Conversely, a patient who started ART in September 2012 and who missed an appointment in December 2012, but is recorded as on ART in December 2011 (at month 3) is on ART and will be included in the numerator. The number of women on ART at 3 months includes patients who have transferred in (and their initiation date is known) at any point from initiation of treatment to the end of the 3-month period and excludes patients who have transferred out during this same period to reflect the net current cohort at each facility. What is important is that the patient who has started ART in September 2012 is recorded as being alive and on ART 3 months after initiation, regardless of what happens after that initiation date within the reporting period of interest (i.e. for this example, 1 October 2012 to 31 December 2011).

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## APPENDIX 2I: PERCENTAGE OF ELIGIBLE PREGNANT AND BREASTFEEDING WOMEN WITH HIV INITIATING CTX PROPHYLAXIS

### Enhanced Indicator 6: Percentage of eligible pregnant women and breastfeeding women with HIV initiating CTX prophylaxis

<b>Indicator code:</b>	Percentage of eligible pregnant and breastfeeding women with HIV initiating CTX prophylaxis
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**Purpose:** This indicator attempts to track progress in scale-up of CTX to pregnant and breastfeeding women with HIV in a country. The indicator does not attempt to capture interruptions in drug availability, patient retention or adherence to prescribed therapy.

CTX prophylaxis is a simple and cost-effective intervention that reduces the risk of opportunistic infections (OIs) and mortality in HIV-infected adults with other important benefits to pregnant women including malaria and urinary tract infection prophylaxis. The WHO guidelines offer countries a choice of whether to provide CTX to all HIV-infected patients or according to disease stage and this indicator may be most useful for programmes implementing universal CTX for pregnant women given the challenges in describing the number of patients eligible for the intervention when disease stage is used.

This indicator is important for:

- Assessing scale-up and coverage of CTX prophylaxis;
- Identifying gaps in services to improve scale-up and coverage; and
- Providing data to assess quality of care, specifically if this is an indicator collected for all HIV-infected patients as well as for pregnant and breastfeeding women with HIV, comparisons can be made between the quality of care received by pregnant and breastfeeding women initiating ART and all adult patients in the HIV Care and Treatment programme.

<b>Numerator:</b>	Number of eligible pregnant and breastfeeding women with HIV receiving CTX prophylaxis.
<b>Denominator:</b>	Number of pregnant and breastfeeding with HIV who are eligible for CTX, (according to national guidelines).
<b>Disaggregation(s):</b>	<ul style="list-style-type: none"> <li>• Pregnancy status at initiation of CTX</li> <li>• Breastfeeding status at initiation of CTX</li> </ul>
<b>Data Source:</b>	Programme monitoring tools; including Pre-Art and ART registers and electronic databases that routinely record provision of CTX, including pharmacy records.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level. Data should be aggregated at least monthly at the facility level though the data could be reviewed and collected less frequently, e.g. monthly or quarterly, for the purposes of programme management and review.

**Explanation of Numerator:** The numerator can be generated by counting the number of eligible HIV-infected individuals receiving CTX prophylaxis at some point during the reporting period.

Individuals should be considered to be “receiving” CTX prophylaxis if CTX has been prescribed and obtained by the patient (provided by a programme or procured by the patient e.g. from a pharmacy). The indicator is not meant to account for short term lapses in adherence or short term stock outs. If a patient received CTX at any time during the reporting period, the individual should be counted towards this indicator. If individuals are served by more than one programme that might provide CTX prophylaxis, the figure should be adjusted as needed so that the numerator represents only unique individuals receiving CTX within the reporting period.

Programmes should focus on compiling data for the numerator from patient registers at facilities. Where patient level data are not available, programmes may develop programme or facility level estimates of coverage with CTX and apply these estimates to the total number of individuals receiving care and support services through those programmes or facilities.

This indicator attempts to track progress in scale-up of CTX to HIV-infected individuals in a country. The indicator does not attempt to capture interruptions in drug availability or patient adherence to prescribed therapy. As programmes may have different guidelines for provision of CTX to HIV-infected pregnant women than for HIV-infected non-pregnant women, comparisons of aggregate estimates and proportions across groups must be interpreted with caution and with reference to eligibility criteria.

## APPENDIX 2J: PERCENTAGE OF ART PATIENTS WITH AN UNDETECTABLE VIRAL LOAD AT 12 MONTHS AFTER INITIATION OF ART BY PREGNANCY AND BREASTFEEDING STATUS AT INITIATION

Enhanced Indicator 7: Percentage of ART patients with an undetectable viral load at 12 months after initiation of ART by pregnancy and breastfeeding status at initiation

<b>Indicator:</b>	Percentage of ART patients with an undetectable viral load at 12 month after initiation of ART
<b>Purpose:</b>	ART is viewed by the scientific community as not only essential for decreasing morbidity and mortality, but also as a highly effective approach to prevent HIV transmission. This indicator monitors the proportion of adult and paediatric patients on ART with an undetectable viral load <1,000 copies/ml at 12 months, allowing HIV Care and Treatment programmes to evaluate to what degree they are improving the clinical outcomes of patients in care, which will guide the expansion of HIV Care and Treatment programmes. Unsuppressed viral load can be indicative of improper treatment adherence and can lead to the development and spread of drug resistance. Monitoring the programme level viral suppression is a critical quality of service indicator at the site and national programme levels.
<b>Numerator:</b>	Number of adult and paediatric patients with an undetectable viral load <1,000 copies/ml at 12 months.
<b>Denominator:</b>	Number of adults and children who initiated ART in the 12 months prior to the beginning of the reporting period with a viral load count at 12 month visit.
<b>Disaggregation(s):</b>	<ul style="list-style-type: none"> <li>• Pregnancy status at initiation</li> <li>• Breastfeeding status at initiation</li> </ul>
<b>Data Source:</b>	Patient charts; Laboratory registers/databases; Programme monitoring tools; ART registers/databases and cohort/group analysis forms.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level as part of routine service delivery. Data analysis and review should be collected every year.

**Method of Measurement:** This indicator is usually collected as part of a survey. Site selection and sampling size will be determined by the study team. The study team will also determine the appropriate number of patient charts that will be randomly selected for review at each of the sites visited. Smaller sites may be excluded from the sample for logistical reasons, as visiting many small sites may be expensive and time consuming. For large facilities, a sample of patients at each facility may be used.

To create a sample: determine the viral load of consecutive adult or paediatric patients on ART for 12–15 months attending a participating clinic for a routine visit until the required sample size for each clinic is reached.

**Explanation of Numerator:** Data for the numerator should be generated by counting the patients with a viral load count that is <1,000 copies/ml at their 12 month visit or closest visit (but no later than 15 months after ART initiation).

The numerator requires that adult and child patients must be alive and on ART at 12 months after their initiation of treatment. The reporting period is defined as a continuous 12-month period that has ended within a pre-defined number of months from the submission of the report. The pre-defined number of months can be determined by PEPFAR or national reporting requirements. If the PEPFAR reporting period is 1 October 2013 to 30 September 2014, countries will calculate this indicator by using all patients who started ART any time during the 12-month period from 1 October 2012 to 30 September 2013. A 12-month outcome is defined as the outcome (i.e. viral load) 12 months after starting. For example, patients who started ART during January 2013 will have reached their 12-month outcomes in January 2014.

The numerator does not require patients to have been on ART continuously for the 12-month period. Patients may be included in the numerator if they have missed an appointment or drug pick-up or temporarily stopped treatment during the 12 months since initiating treatment, as long as they are recorded as still being on treatment at month 12. On the contrary, those patients who have died, stopped treatment or been lost to follow-up as of 12 months since starting treatment should not be sampled, and therefore, will not be included in the numerator.

Conversely, a patient who started ART in September 2013 and who missed an appointment in December 2013, but is recorded as on ART in September 2014 (at month 12) is on ART and can be included in the sample population if a viral load count is available at 12–15 months. The number of adults and children on ART at 12 months includes patients who have transferred in (and their initiation date is known) at any point from initiation of treatment to the end of the 12-month period and excludes patients who have transferred out during this same period to reflect the net current cohort at each facility. What is important is that the patient who has started ART in September 2013 is recorded as being alive and on ART 12 months after initiation, regardless

of what happens after that initiation date within the reporting period of interest (i.e. for this example, 1 October 2013 to 30 September 2014). Patients who were on ART at month 12 but have since died, stopped treatment or been lost to follow-up can be included in the sample population for the numerator.

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**Explanation of Denominator:** The denominator is the number of adults and children who initiated ART 12 months prior to the beginning of the reporting period with a viral load count at the 12 month visit or closest visit (but no later than 15 months after ART initiation) excluding those who have died, stopped ART and those lost to follow-up.

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**Interpretation:** The survey objective is to determine the proportion of adult or paediatric patients successfully suppressing viral load (defined as viral load <1000 copies/ml). Assessing the ability of ART sites to achieve virologic suppression in each survey population can inform national HIV Care and Treatment programme monitoring and evaluation. This information could also contribute to quality improvement activities designed to maximize rates of viral suppression in patients on ART and therefore prevent the acquisition of HIV drug resistance (DR).

The programmatic implications of the survey results include, but are not limited to:

- Modification of national algorithms for management of suspected treatment failure, including targeted use of viral loads and intensification of adherence support;
- Modification of national guidelines for empiric second-line ARV regimens; and
- Support for national HIV Care and Treatment programme efforts to identify and correct factors associated with suboptimal rates of viral suppression to minimize acquisition of HIV DR in patients on ART.
- Support for the scheduled use of viral load testing as part of routine monitoring and supervision functions within the national HIV Care and Treatment programme.

The increasing ART coverage in resource-limited settings in the absence of routine viral load monitoring is raising concerns about the development of resistance to first-line ART regimens, long-term individual patient outcomes and increased risk of transmission of HIV, including drug-resistant HIV. To sustain the progress made in reducing morbidity and mortality from HIV through ART, it is important that HIV-infected patients continue to have access to safe, tolerable and potent ARVs. To accomplish this, the use of viral load testing to monitor HIV treatment will need to be expanded. Increasing the availability of viral load monitoring remains a challenge in most PEPFAR-supported countries. Wherever possible, national programmes should assist in expanding the capacity for VL testing through activities such as procurement of reagents and/or platforms and support for transportation systems for processing and shipment of specimens.

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#### **Additional References:**

- WHO *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy), and TB/HIV: standardized minimum data set and illustrative tools*. 2009.
  - *Meeting Report on Assessment of World Health Organization HIV Drugs Resistance Early Warning Indicators, 11-12 August 2011 – 2012* [http://www.who.int/hiv/pub/meetingreports/ewi\\_meeting\\_report/en/index.html](http://www.who.int/hiv/pub/meetingreports/ewi_meeting_report/en/index.html).
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## APPENDIX 2K: PERCENTAGE OF HEIs WHO ARE RETAINED ON CTX 6 MONTHS AFTER BIRTH (OR AFTER INITIATING CARE SERVICES)

Enhanced monitoring indicator 8: Percentage of HEIs who are retained on CTX 6 months after birth (or after initiating care services)

<b>Indicator code:</b>	Percentage of HEIs who are retained on CTX 6 months after birth (or after initiating care services)
<b>Purpose:</b>	High retention is one important measure of programme success and is a proxy for overall quality of programme.
<b>Numerator:</b>	Number of HEIs known to be alive and on CTX 6 months after birth.
<b>Denominator:</b>	Total number of HEIs ever initiated on CTX at the facility and who were born 6 months prior to the beginning of the reporting period.
<b>Disaggregation(s):</b>	None
<b>Data Source:</b>	Programme monitoring tools; HIV-exposed infant registers and cohort/group analysis forms.
<b>Data Collection Frequency:</b>	Data should be collected continuously at the facility level. Data should be aggregated at least monthly at the facility level though the data could be reviewed and collected less frequently, e.g. monthly or quarterly, for the purposes of programme management and review.

**Explanation of Numerator:** The numerator requires that HEIs must be alive and on CTX at 6 months after their date of birth.

For a comprehensive understanding of survival, the following data must be collected:

- Number of HEIs ever initiated on CTX who were born in the 6 months prior to the reporting month (denominator).
- Number of HEIs still alive and on CTX at the end of the reporting month (6 months after birth) (numerator).

The reporting month is defined as a 1-month period that has ended within a pre-defined number of months from the submission of the report. The pre-defined number of months can be determined by national reporting requirements. If the reporting month was October 2012, countries will calculate this indicator by using all patients who were born during April 2012. The following chart identifies the birth an reporting month pairs:

<b>Reporting Month</b>	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<i>(circle)</i>	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
<b>Birth Month</b>	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun

A 6-month outcome is defined as the outcome, i.e. whether the patient is still alive and on CTX, dead or lost to follow-up, 6 months after being enrolled in the birth cohort register. A patient with an unknown status at 6 months, who is not formally lost to follow-up but is missing drug pickup at 6 months, is not considered to be on CTX.

For example, a patient who was born in April 2012 would be considered “alive and on CTX at 6 months” (in October 2012) if:

- The patient’s first enrolment to the facility and first receipt of CTX occurred when he was 1 week old in April 2012 and he visited the facility and received CTX in October 2012 OR
- The patient’s first enrolment to the facility and first receipt of CTX occurred when he was 5 months old in September 2012 and visited the facility and received CTX in October 2012 OR
- The patient had enough CTX to last through the end of October 2012 (month 6) based on the last drug pick-up (e.g., patient received 60 days of drug on September 15, or patient received 30 days of drug on October 1, etc.)

However, the patient would NOT be considered “alive and on CTX at 6 months” if:

- The patient did NOT have enough CTX to last through the end of October 2012 (e.g., patient received 30 days of drug on August 1); AND
- The patient did NOT visit the facility in October 2012.

At the facility level, patients who have transferred in with a known birth date that falls within the reporting period should be counted. Conversely, patients who transferred out of the facility should not be counted in that facility’s cohort.

For those patients who were born in April 2012, if at any point during the period up to the end of October 2012 these patients die, are lost to follow-up (and do not return), or stop CTX (and do not restart), then at month 6 (October 2012), they are NOT on CTX and NOT included in the retention numerator.

For example, for the reporting period October 1, 2012 to Oct 31, 2012, this will include all patients who were born during April 2012. (see chart above) This includes all patients, both those on CTX as well as those who are dead, have stopped treatment or are lost to follow-up. Again the denominator includes patients that have transferred in (and their initiation date is known) and excludes patients that transferred out during the time period.

For programmes using the birth cohort reporting system, regardless of when the infant comes in for their first visit (whether at 2 weeks of age or 5 months of age), infants are enrolled by their birth month.

This indicator should NOT be estimated. This indicator should be calculated directly from information gathered in standard cohort HIV exposed infant registers or tabular analysis from electronic patient level databases.

Country teams should ensure that all facilities are reporting on the same birth month. Only facilities that have been operational for at least 6 months prior to the end of the reporting period should report, so that all facilities report on the same birth month. Teams may also wish to only collect the data across facilities every quarter and they may also wish to 'lag' by 1–3 months the cohort-months comprising the quarterly cohort in order to allow sufficient time for reporting from data sources (i.e. implementing partners and/or national systems).

### APPENDIX 3: COHORT MONITORING AND MOTHER-INFANT PAIR REGISTERS

To optimize postpartum follow up, many programmes have adopted the use of mother-infant pair (MIP) registers. For the purposes of this discussion, a MIP register starts with registration of a pregnant woman living with HIV in the PMTCT programme (i.e. first ANC visit). The woman is then followed longitudinally from pregnancy through the end of breastfeeding in this register. The infant’s birth date is recorded and HEI services are tracked on the same row as the mother. The benefit of a MIP register is that it allows for tracking of mothers living with HIV from ANC through postpartum, and can trigger follow-up for any mother who does not return for her own ART follow up or who does not bring the infant back for expected follow up care until final outcome diagnosis.

	Date of enrollment into the PMTCT programme	Mother’s ANC and postpartum information				Delivery information			HEI’s information			
1												
2												
3												

While a MIP register is useful for follow-up of a MIP through the PMTCT continuum, it is not well designed to monitor key PMTCT indicators such as retention of women on ART, or the proportion of HIV exposed infants who receive PCR testing by 2 months, or have a final HIV status by 18 months—which depend on defining cohorts of women and infants by the timing of an event (e.g. month of ART initiation, or month of infants birth).

For PMTCT programmes that are only using a MIP register (and not using ART or HEI birth cohort registers), programme outcomes such as ART retention, EID testing by 2 months of age, and final infant outcome could be monitored by filing patient cards or files by cohorts ordered by month/year of ART initiation for mother and month/year of birth for HEI. This method would allow for the critical M&E outcomes of maternal ART retention, early infant testing, and final infant outcome to be collected and reported, but it may have unintended consequences and should be piloted before adoption.

Another option is to retain separate ART and HEI registers to facilitate cohort monitoring. In these settings, it is important to consider including maternal information in the HEI register so that mother and infant records can be linked and use a separate appointment book to track MIPs. Both options are described below.

Information on mothers, and HEI	Advantages	Disadvantages	Considerations (or Solutions)
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**Mother infant pair register**

<p>MIP register includes maternal HIV care and treatment during ANC, delivery; postpartum ART and HEI follow-up on same row in register</p>	<ul style="list-style-type: none"> <li>• One register with all maternal and infant information in same place. Easy to see if mother or child is returning for scheduled clinic appointments.</li> <li>• Easy to track mother from ANC through postpartum period with all information in single register.</li> <li>• Can be used to document infant outcomes relative to mother's outcome.</li> </ul>	<ul style="list-style-type: none"> <li>• Women are entered in register according to date of first ANC visit.</li> <li>• Increased reporting burden on facility using MIP register to report indicators that require cohorts based on date of ART initiation, or month/year of birth (e.g., 6/12m ART retention; final HIV outcome of HIV exposed infants).</li> </ul>	<ul style="list-style-type: none"> <li>• Implement a cohort filing system for patient cards or files by date of ART initiation for mother and date of birth for HEI. This would allow for the critical M&amp;E outcomes of maternal ART retention, early infant testing, and final infant outcome to be collected and reported.</li> <li>• Additionally, use appointment book to highlight missed appointments for weekly tracking.</li> </ul>
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**Separate registers for ANC, maternity, ART (maternal) and HEI follow-up including testing; appointment book for tracking mother-infant pairs**

<p>Separate registers for: ANC (ANC services), ART (HIV care and ART outcomes), Maternity (delivery information), HEI (PCR testing at 2m of age, CTX, growth monitoring, final HIV status at 18 months of age).</p>	<ul style="list-style-type: none"> <li>• Easy to define ART cohorts for retention monitoring; infant birth cohorts for EID coverage, final HIV status.</li> <li>• Separate appointment book facilitates tracking of MIPs, especially if following up missing MIPs is job responsibility of specific HCWs.</li> </ul>	<ul style="list-style-type: none"> <li>• Increased documentation burden on health facility staff to complete multiple registers and appointment book.</li> <li>• Need to document the same information in different registers.</li> </ul>	<ul style="list-style-type: none"> <li>• Include maternal patient identification number in HEI register to link mother and infant records.</li> <li>• "Pre-register" infants by creating an infant card/file when the mother initiates ART then file mother and infant cards/files jointly prompting the health care worker to attend to and document information on both.</li> </ul>
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