National Guideline for Prevention of Mother-to-child Transmission of HIV, Syphilis and Hepatitis B Virus

November, 2021
National Guideline for Prevention of Mother-to-child Transmission of HIV, Syphilis and Hepatitis B Virus
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Foreword

Ethiopia has transformed its prevention of mother to child transmission of HIV (PMTCT) program to EMTCT since 2013 by aligning itself with global initiatives. Ethiopia has demonstrated promising results that seek intensified and sustained programmatic implementation to ensure no child is born infected with HIV and congenital syphilis.

The lessons learnt in the implementation of the dual elimination of MTCT of HIV and syphilis as well the new WHO recommendation to consider working on elimination of MTCT of HBV have all encouraged Ethiopia to develop a new triple elimination strategy for the next five years (2021-2025). Implementation of this strategic plan requires an accompanying technical guideline that encourages integrated service delivery and ensures new developments on care and treatment of cases are duly included.

Essential triple EMTCT services include testing for HIV, syphilis and HBV in antenatal care (ANC) settings; prompt and efficacious interventions to treat women who test positive; prevent transmission of any of the infections to their children; counseling for women and their partners to reduce transmission risk and ensure appropriate treatment; encourage clean and safe delivery; appropriate follow up of exposed infants including provision of HBV vaccine birth dose; promoting optimal infant-feeding; and lifelong treatment and care for mothers living with HIV or those eligible for treatment for hepatitis B infections and treatment for syphilis.

MOH believes this new guideline will give the state-of-the-art guidance to all HCWs and other relevant cadres who are working at all levels to improve the life of mothers, their partners and children.

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Ministry of Health of Ethiopia
Acknowledgment

The expertise of many people has informed the review of this guideline. The FMOH thus would like to thank the following organizations for their inputs into the various sections of the draft: CDC, ICAP, UNICEF, UNAIDS, CHAI, FHAPCO and EPHI as well as health professional associations, private organizations and individuals who were part of this exercise. A note of acknowledgment goes to members of the PMTCT Technical Working Group and experts within the Ministry of Health. A word of thanks also goes to the editorial team for formatting and designing the guidelines. Ministry of health would like to extend appreciation to ICAP Ethiopia who has provided resources for the printing of this comprehensive and quality PMTCT guideline.

The guideline has undergone through numerous review meetings and consultative workshops. The Maternal and Child Health and Nutrition Directorate specifically appreciate the contributions of the following Contributors, Reviewers and Editors:

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<tr>
<td>Acronyms</td>
<td>Description</td>
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<td></td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>ANC</td>
<td>Ante-Natal Care</td>
<td></td>
</tr>
<tr>
<td>ARV</td>
<td>Anti-Retroviral</td>
<td></td>
</tr>
<tr>
<td>ART</td>
<td>Anti-Retroviral Therapy</td>
<td></td>
</tr>
<tr>
<td>CAC</td>
<td>Comprehensive Abortion Care</td>
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<tr>
<td>COC</td>
<td>Combined Oral Contraceptive</td>
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<tr>
<td>C/S</td>
<td>Caesarean Section</td>
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<tr>
<td>CPT</td>
<td>Co-trimoxazole Preventive Treatment</td>
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<tr>
<td>CQI</td>
<td>Continuous Quality Improvement</td>
<td></td>
</tr>
<tr>
<td>DBS</td>
<td>Dried Blood Sample</td>
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<tr>
<td>DNA-PCR</td>
<td>Di-ribonucleic Acid Polymerase Chain React</td>
<td></td>
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<tr>
<td>Dashboard</td>
<td>MNCH/PMTCT performance monitoring tool</td>
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<tr>
<td>DTG</td>
<td>Dolutegravir</td>
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<tr>
<td>EMTCT</td>
<td>Elimination Mother-to-child transmission</td>
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<tr>
<td>EID</td>
<td>Early Infant Diagnosis</td>
<td></td>
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<td>EFV</td>
<td>Efavirenz</td>
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<tr>
<td>GIPA</td>
<td>Great Involvement of PLHIV</td>
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<tr>
<td>HAART</td>
<td>Highly Active Anti-Retroviral Treatment</td>
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<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
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<td>HBV</td>
<td>Hepatitis B virus</td>
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<td>FP</td>
<td>Family Planning</td>
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<tr>
<td>HTC</td>
<td>HIV Testing and Counseling</td>
<td></td>
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<tr>
<td>HIV</td>
<td>Human Immuno-deficiency Virus</td>
<td></td>
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<tr>
<td>HMIS</td>
<td>Health Management Information System</td>
<td></td>
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<tr>
<td>IUCD</td>
<td>Intra Uterine Contraceptive Device</td>
<td></td>
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<tr>
<td>LPV/r Lo</td>
<td>Lopinavir/ritonavir</td>
<td></td>
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<td>MTCT</td>
<td>Mother-to-Child Transmission</td>
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1. Introduction

- Background
- Rationale for revision of the 2017 National PMTCT guideline
- Objective of the National guideline for triple elimination of Mother-to-Child Transmission of HIV, Syphilis and HBV
- Target audience of the guideline
- Key principles of the guideline
**1.1 Background**

**Epidemiology of HIV/AIDS**

HIV infection is one of the world's most serious public health problems. In 2019, there were more than 38.0 million [31.6 million–44.6 million] persons living with HIV, and more than 1.7 million [1.2 million–2.2 million] who had contracted the virus were children (0-14 Years). Over 61 percent of newly infected HIV patients live in Sub-Saharan Africa (UNAIDS; 2020). The national adult (15+) HIV prevalence is 0.96 %, according to the HIV Related Estimates and Projections in Ethiopia (2020). According to the (EDHS 2016), the urban prevalence was 2.9%, which is seven times higher than the rural prevalence (0.4%). In addition, the prediction (2020) shows that HIV prevalence varies by location, ranging from less than 0.15% in Ethiopia Somali to 3.99 % in Gambella regions.

The progress towards achieving the first 95 target has been far behind the track; only 79% of PLHIV know their HIV status. To accelerate the performance of the HIV case identification in Ethiopia for closing the gaps to treatment and achieve epidemic control, the remaining 21% of PLHIV need to be reached. (National HIV report, FY 2012). Free ARV service was launched in January 2005 and public hospitals start providing free ART in March 2005. Presently ART service is available in more than 1,474 health facilities. Based on the new spectrum estimate for 2020, ART coverage for adults (age >15) has reached 80.5 % (465,457) but the coverage remains low (41.12%) for children (age <15) living with HIV (17,670). According to EPHI 2020 /21 report (EFY2013) report, the national VL coverage was 74.5%, with a suppression rate of 95.1%. According to EPHI 2019 estimate, mothers needing ART for PMTCT across the nation were 18,677 of whom 17,164 received ART which is a 91.9% performance.

**Epidemiology of Syphilis**

Globally, an estimated 2 million pregnant women have active syphilis infections each year, but only about 10% of them are recognized and treated. More than 90% of these illnesses originate in low-resource environments. Syphilis is thought to affect 0.5 percent of men and women globally, with regional variations ranging from 0.1 to 1.6 percent. In the general population, this prevalence estimate amounts to 19.9 million cases of syphilis.

Syphilis is the second leading infectious cause of stillbirths globally, after ma-
laria. In 2012, Syphilis caused 350,000 adverse pregnancy outcomes globally including: 143,000 early fetal deaths/stillbirths; 62,000 neonatal deaths; 44,000 preterm/low birth rate babies; and 102,000 infants with clinical stigmata of congenital Syphilis. Up to 40% of babies born to women with untreated syphilis may result in still birth or neonatal death.

Congenital Syphilis is a significant, under-addressed public health priority. Untreated maternal infection leads to adverse pregnancy outcomes, including early fetal loss, spontaneous abortion, stillbirth, prematurity, low birth weight, neonatal and infant death, and congenital disease among newborns.

The WHO African Region had the greatest prevalence of syphilis in both men and women. According to recent research conducted in diverse geographic areas, the prevalence of syphilis in Ethiopia ranged from 0.6 percent to 5.1 percent. It is, however, more common among young and urban pregnant women. Guidelines recommend universal syphilis screening and treatment as part of routine practice in antenatal care settings in Ethiopia; however, the 2019/20 data has shown that only 65.9% of pregnant women were screened and those with positive result were treated for syphilis. Like in other countries, the building blocks for elimination of congenital syphilis are already in place.

**Epidemiology of Hepatitis B Virus**

Currently, hepatitis B virus (HBV) is a global public health problem with 296 million people diagnosed to have chronic HBV infection and 686,000 people dying each year from its complications, which include cirrhosis and hepatocellular carcinoma. About 2.6 million people living with HIV are also co-infected with HBV. In 2019, HBV was the cause for an estimated 820,000 deaths worldwide, and most deaths were from liver cirrhosis and primary hepatocellular carcinoma.

As of 2016, only 10% of all people estimated to be living with HBV knew that they were infected, and only 2.2% of the people diagnosed were on treatment. The proportion of children under five years of age with chronic HBV infection was under 1% in 2019, which has declined from around 5% in the pre-vaccine era, (from 1980s to the early 2000s). In countries where HBV infection prevalence is intermediate to high level, almost half of HBV infected patients have acquired it either through MTCT or in early childhood. The prevalence of chronic HBV infection varies from 0.1 to 20% in different areas of the world. Recently, WHO
reported that there was a significant decline in the number of chronic HBV infection. The prevalence of HBV is highest in Sub-Saharan Africa and East Asia. According to a systematic review and meta-analysis of HBV infection among pregnant women in Ethiopia, the prevalence ranged from 2.3 percent in southern Ethiopia to 7.9 percent in Gambella Hospital. The pooled prevalence of HBV infection among pregnant women was 4.8%. This suggests that the prevalence of HBV infection in Ethiopian pregnant women is intermediate. HBV testing and treatment coverage is inadequate in Ethiopia. It is not routinely done for pregnant women, indicating the need to largely invest in capacity building of the health system to achieve the global target of HBV elimination by 2030.

1.2. Rationale for the revision of the 2017 National PMTCT guideline

Ethiopia has been implementing the PMTCT program since 2001. The PMTCT service was initially started at limited health facilities with gradual scale up to most of the facilities throughout the country. During the subsequent years clinical and programmatic developments have been made on simplification of HIV treatment for pregnant and breastfeeding women through the introduction of a single fixed drug regimen. The PMTCT ART optimization has been implemented since 2020 and the first line regimen was changed to TDF+3TC+DTG. Additionally, the HEI ARV prophylaxis was changed from 6 weeks Nevirapine (NVP) to 6 weeks dual prophylaxis using NVP and AZT and additional 6 weeks of NVP.

In May 2016, the World Health Assembly approved three global health sector plans on HIV, viral hepatitis, and sexually transmitted diseases for the years 2016–21. These plans called for member states and the World Health Organization (WHO) to collaborate and achieve zero new HIV infections in babies by 2020, as well as the elimination of hepatitis B and syphilis as public health threats by 2025. HIV, hepatitis B virus (HBV), and syphilis all have the same maternal, neonatal, and child health (MNCH) service platform with similar control interventions. However, the planning, implementation, and reporting of these separate but linked programs frequently take place vertically, resulting in barriers and duplication of efforts.

To align with the global triple elimination, call to action, Ethiopia developed triple elimination MTCT strategic plan for the year 2021–2025. Implementing the
triple elimination strategy will bring client satisfaction by avoiding repeated sample taking and reduce the waiting time for the results. It is intended to provide guidance for individuals working on PMTCT programs in various sectors (public, private and the community) to deliver standardized and high-quality services. This guideline represents an important step towards achieving the national plan for the EMTCT of HIV, congenital syphilis, and hepatitis B virus infection.

1.3. Objectives of the guideline

General objective

The general objective of this guideline is to provide up-to-date and evidence-based clinical standards on EMTCT of HIV, syphilis, and hepatitis B virus.

Specific Objectives

1. To provide updated, evidence-based clinical recommendations for HIV, Syphilis and HBV in relation to PMTCT

2. To provide guidance on key operational and service delivery issues that need to be addressed to increase access to HIV services, to improve PMTCT quality, strengthen the continuum of HIV, syphilis, and hepatitis B care

3. To guide management of integrated MNCH/PMTCT/EID programs & service delivery for all HIV positive pregnant clients on ART and link their HEI in MNCH/PMTCT platform

4. To serve as a reference material for health service providers and program managers.

Target audience of this guideline

The guideline is intended to be used by:

- Health care workers at health facilities and communities (medical and public health specialists, physicians, health officers, Midwives, nurses, pharmacy personnel, laboratory technicians and other health care providers) and case managers providing care to people infected and affected with HIV, Syphilis and HBV

- HIV/AIDS, Syphilis and HBV program managers, health planners and re-
searchers

- Organizations involved drug procurement and supply management for HIV, Syphilis and HBV service delivery.
- Public and private health sector, civil society organizations, community-based organizations, faith-based organizations, Universities, health science colleges and other key stakeholders working on HIV/AIDS, Syphilis and HBV programs.
- Educational institutions and in-service trainers to provide standardized training packages consistent with the national program.

This guideline is also expected to serve as a resource for development of training materials for RMNCAH service providers, strengthen the referral system based on the health network model and coordinate all partners’ efforts working on health. In addition, it will serve as a document to guide advocacy efforts towards mobilizing resources internationally and nationally, monitoring and evaluation of the health response as envisioned by the MOH. Hence, to effectively implement PMTCT programs, this guideline needs to be available at all tiers of the health system.

**Key Principles of the National guideline for triple elimination of Mother-to-Child Transmission of HIV, Syphilis and HBV**

The Key principles of the National triple elimination guideline include:

**Equity:** Access to services must be equitable, i.e., HIV, Syphilis and HBV positive pregnant women should be prioritized

**Human rights:** Health providers and service delivery points must uphold the right of all persons irrespective of their HIV, Syphilis, and HBV status, to the highest attainable standard of health

**Gender sensitive/responsiveness:** Male partners should be involved and encouraged to participate in PMTCT programs and services.

**Adolescent sensitive:** PMTCT services should be responsive to the needs and preferences of adolescents.

**Integration and linkage:** PMTCT services must be integrated with other RMNCAH services and foster the triple elimination of MTCT of HIV, syphilis and HBV.

**Quality of services:** PMTCT services will need to maintain high and acceptable
quality of standards at all levels.

**Family Focused:** PMTCT services should be used as an entry point for the care of HIV, Syphilis and HBV care and prevention for the family

**Community involvement and mobilization:** Engaging the community, inclusive of PLHIV particularly mother support groups from the start, making them part of the program should be ensured to enhance acceptability and impact of MNCH/PMTCT/EID services. Women development army will need to be empowered to create demand in the community for improved service utilization, along with community HEP based HIV testing service linkage to prevention, treatment and care services.
2. PMTCT Services in the Health

- PMTCT approaches and implementation modalities
- Standard PMTCT services at each tier of the health system
- Differential Service Delivery (DSD) in PMTCT
2.1. Standard PMTCT service at each tier of the health system

PMTCT services should be available in all health facilities that provide RM-NCAH-N services and be an integral part of the service provided at each tier of the health system. Facilities with limited capacity to provide PMTCT services need to have a strong referral linkage to connect clients with nearby and easily accessible facilities that can provide PMTCT services.

Services that should be available at community and health system levels are described in Table 2.1 below.

Table 2.1: Services available at community and health facilities level

<table>
<thead>
<tr>
<th>Location</th>
<th>Activities</th>
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<tbody>
<tr>
<td><strong>Community level</strong></td>
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</tr>
<tr>
<td>Women development group</td>
<td>• Enhance social and behavioral communication on safer and responsible sexual practice</td>
</tr>
<tr>
<td></td>
<td>• Promote HIV, HBV, and STI prevention</td>
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<tr>
<td></td>
<td>• Promote male involvement in PMTCT</td>
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<td></td>
<td>• Support utilization of integrated MNCH/PMTCT services, i.e. early antenatal care follows up, birth preparedness, early referral to health facilities, promotion of early health seeking behavior</td>
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<td></td>
<td>• Strengthen peer support groups for HIV-positive women and men including the family</td>
</tr>
<tr>
<td>Religious Leaders, Community leaders and other influencers</td>
<td>• Provide quality integrated information and messages to improve community health literacy that eventually improve the quality of life for HIV, Syphilis and HBV infected mothers, partners and families.</td>
</tr>
<tr>
<td>Community Based Organizations</td>
<td>• Promote birth preparedness and complication readiness interventions, institutional delivery, postnatal care and family planning service uptake</td>
</tr>
<tr>
<td></td>
<td>• Promote and support mothers to exclusively breastfeed their infants up to six months of age</td>
</tr>
<tr>
<td></td>
<td>• Promote and support HIV testing for HIV exposed infants and children</td>
</tr>
<tr>
<td></td>
<td>• Promote and provide family planning information for the community</td>
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</tbody>
</table>
- Provide general information on avoidance of traditional harmful practices that can expose to HIV
- Provide information on importance of sunshine exposure and immunization for infants
- Promote balanced diet in the first one thousand days starting from in utero until the child is at least two to three years of age to prevent stunting
- Promote intake of variety of food for pregnant and lactating women
- Promote personal hygiene and proper disposal of soiled sanitary pads
- Promote protection of PLHIV from stigma and discrimination by encouraging open discussion
- Actively involved in identification of high risk individuals for testing
- Ensure and encourage mothers who are in care for continued follow up and adherence using mother support groups.

**PRIMARY HEALTH CARE UNIT**

**Health Post**

- Participate in all community activities listed above, PLUS:
- Promote and demonstrate condom use and application, and distribute to women and men
- Counsel on FP and provide available methods of choice to all women and men in need (Particular focus and attention to women and men who are HIV positive) or refer for methods unavailable at this level
- Provide Antenatal Care and promote skilled birth attendance
- Use standard precautions in provision of services to prevent infections
- Provide HTC by HEWs and urban health extension professionals inclusive of HIV & syphilis co testing when feasible, otherwise refer to health center
- Refer HIV and Syphilis positive clients to health centers for 2nd HTC and verification and management using referral system
• Involve in follow up of HIV positive pregnant and lactating mothers, families and HEI through shared confidentiality and family centered approach
• Initiate referral for all pregnant, laboring and lactating women and their newborns for evaluation including HIV, syphilis and HBV testing at health centers
• Provide diagnostic service, insecticide treated bed nets and treatment to pregnant women and their families in malaria endemic areas
• Counsel HIV positive clients on prevention with positives (PWP)
• Provide counseling on infant feeding according to the 2016 Adolescent, Maternal Infant and Young Child feeding I Nutrition Guideline
• Record and report on PMTCT indicators for health post
• Work in collaboration with health facilities in tracing clients lost to follow-up care Provide ongoing counseling on PMTCT/EID based on shared confidentiality by HEW level 4/UHEP.
• Screen for TB and refer to health center for further management
• Ensure and encourage mothers who are in care for continued follow up and adherence using mother support groups.

Health centers
• Ensure an uninterrupted availability of all the services listed above, PLUS:
  • Provide Antenatal Care and skilled birth attendance
  • Provide HTS (HIV testing services) using the standard/dual testing algorithm and provide verification test for those that tested HIV positive before initiation of ART
  • Provide early diagnosis and treatment of STIs
  • Ensure strong coordination, continuation, collaboration, and better Performance of PMTCT services within the RMNCAYH-N platform.
• Ensure strong coordination and collaboration with regional and central Laboratories for quality assurance and timely reporting of test results.

• Initiate and/or refill ART to all HIV positive pregnant, laboring and lactating women by staff trained in competency based comprehensive PMTCT

• Ensure newly diagnosed HIV positive pregnant and lactating mothers, have initiated ART and have intensive adherence counseling by health service provider and mother mentors accordingly

• Facilitate monitoring of viral suppression with viral load testing for HIV positive pregnant and lactating mothers per the national PMTCT guideline.

• Ensure that sound professional ethics and behavior is practiced among duty bearers to protect, fulfill and respect the rights of clients.

• Link concordant male partners to ART units.

• Provide PrEP to discordant male partners in the same settings

• Provide ARV prophylaxis for PMTCT with regular follow-up to all infants born to HIV-positive mothers

• Provide prophylaxis and treatment for opportunistic infections

• Provide syphilis treatment to those tested positive to eliminate congenital syphilis in the newborn.

• Screen pregnant, lactating women for TB and provide INH prophylaxis for those screened negative.

• Diagnose and treat UTI, anemia, TB, malaria and intestinal parasites and screen clients for cervical cancer

• Provide EID services including POC diagnosis/DBS collection and sample referral services for HIV exposed infants and children
• Ensure and encourage mothers who are in care for continued follow up and adherence using mother support groups.
• Provide HBV screening and prophylaxis to those pregnant women tested positive when they are not eligible for treatment; refer if they require treatment

Primary hospital

All the services listed above, PLUS:
• Provide ultrasound and radiological investigations
• Screen and refer for cervical cancer treatment
• Perform Comprehensive emergency obstetric and newborn care
• Provide Safe blood transfusion

General hospital

All the services listed above, PLUS:
• Provide obstetric surgical interventions of complicated cases
• Provide HBV screening, prophylaxis and treatment to those pregnant women tested positive
• Provide cervical cancer treatment if available

Specialized hospitals

All the services listed above, PLUS:
• Provide diagnosis and treatment of all referral cases (difficult and complicated cases including HIV, syphilis and HBV drug resistance and management of birth defects)

2.2 Differential Service Delivery (DSD) in PMTCT

PMTCT DSD includes the following activities

1. Multi Month Dispensing (3MMD) for PMTCT
2. Point of Care (POC) for VL Testing, among Pregnant /BF Women
3. Point of Care (POC) EID for HEIs
4. Family Planning Integration

3MMD for PMTCT

Multi-month dispensing (MMD) of antiretroviral drugs has become a key strategy for reaching the 95–95–95 targets for HIV testing, antiretroviral treatment
(ART), and viral suppression to control the HIV epidemic. Under MMD, stable clients on ART receive several months of drug regimens thus eliminating the need for monthly clinic visits. Research has shown that patients enrolled in MMD have significantly greater treatment adherence and retention than patients following a monthly drug regimen. MMD is provided through standard care differentiated service delivery (DSD) models. MMD includes 3 months ARVs (3MMD) provision to PMTCT clients whenever consistency of services is not reliable such as during pandemics and humanitarian emergency. MoH has already endorsed and implemented PMTCT 3MMD since 2020 due to COVID 19 pandemic.

**Point-of-care (POC) for VL among pregnant/BF women**

POC tests can be used to monitor HIV viral load in HIV infected pregnant and lactation women. The test measures the number of HIV RNA copies per milliliter (copies/mL) of blood and is used to determine how well treatment is working. An increase in viral load above 50 copies/ml indicates that the clients are either not adhering to the drug treatment regimen or the regimen has lost its effectiveness; both scenarios require timely intervention to ensure patients remain in good health.

Traditionally, viral load testing requires sending samples to an off-site laboratory equipped to process them. Transporting samples from the clinic to the lab and results from the lab to the clinic can lead to long delays before test results are available and shared with patients. The process can significantly delay clinical actions such as adherence counseling and switching treatment regimens, leading to detrimental health outcomes. POC technologies allow HIV viral load tests to be conducted within hours of sample collection at the same health facility, getting results to clients sooner.

**Point-of-care (POC) for HEIs**

The use of POC reduces the Turn Around Time (TAT) of EID and helps in early identification and ARV treatment of HIV infected infants.

**Family planning integration**

The integration of family planning and HIV services is an approach in which both services are provided together to deliver more comprehensive care to clients and improve sexual and reproductive health outcomes. By utilizing mul-
mple entry points, effective and efficient integration of services reduces the time required to get the services. It allows clients of HIV services to access family planning and safe pregnancy services and achieves their fertility intentions more easily. It includes the delivery of both services at the same time and location as well as referrals from one service to the other.

Integration refers to the delivery of health services and is therefore one part of a broader set of linkages between family planning and HIV policies, programs, funding, and advocacy. These linkages are essential to meet the needs of women and their families and to achieve international development goals, such as an AIDS-free generation and greater access to reproductive health services.
3. The Four-Pronged Approach to PMTCT

- Prong 1: Primary Prevention of HIV, Syphilis and Hepatitis B infection
- Prong 2: Prevention of unintended pregnancies in HIV positive women
- Prong 3: Prevention of HIV, Syphilis and Hepatitis B transmission from women to their infants
  - Prevention of MTCT of HIV
  - Prevention of MTCT of syphilis
  - Prevention of EMTCT of HBV
- Prong 4: Treatment, care and support for HIV, Syphilis and Hep B virus positive mothers, their exposed, infants, partners and family
  - Basic principles in the use of ARV drugs for PMTCT
  - Treatment of Hep B virus
- Additional elements of clinical care
Ethiopia has long adopted the WHO PMTCT strategy of the 4-pronged approach towards the provision of HIV prevention, care and treatment for pregnant, laboring and breastfeeding women, and their infants and partners. Addressing all the four prongs has the potential to interrupt the HIV infection at each component of the PMTCT approach. To maximally utilize the benefits of the comprehensive and integrated PMTCT program, all the four prongs need to be implemented synchronously, i.e., the HIV prevention strategy (structural, behavioral and bio-medical preventions), reproductive health program services and community involvement should be consolidated effectively.

Through time, available global evidence has shown that it is possible not only to prevent but also to eliminate MTCT of infections including HIV, syphilis and HBV.

EMTCT of HIV, syphilis, and HBV can be achieved by applying the protective measures starting from primary prevention of acquiring these infections, preventing unintended pregnancies, and continuing with preventing the vertical transmission by practicing safe pregnancy and delivery interventions, and administering prophylactic and/or therapeutic medications.

Table 3.1: PMTCT four pronged approaches and corresponding strategic interventions.

<table>
<thead>
<tr>
<th>Prevention areas</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Primary prevention of HIV, Syphilis and HBV infections</td>
<td>General for HIV, Syphilis and HBV</td>
</tr>
<tr>
<td></td>
<td>• Behavioral Change Communication on HIV and HBV risk reduction including all STIs through women development group, mass communication strategy and other proven mechanisms to protect men, women, boys and girls of reproductive age and health literacy through all appropriate means using all available new technologies.</td>
</tr>
<tr>
<td></td>
<td>• Promote ABCD (Abstinence, Be-faithful, use Condom (correct and consistent use of condoms) and Discussion on sex and sexuality issues)</td>
</tr>
<tr>
<td></td>
<td>• Discourage sharing sharp objects and needles since HIV, syphilis and HBV can be transmitted through them.</td>
</tr>
</tbody>
</table>
- Discourage early sexual debut as well as practices with multiple partners to reduce the risks of HIV transmission, cervical cancer and other STIs.

- Provide counseling and testing services for HIV, Syphilis and HBV following the National testing Guideline, for couple, partner and biological children and promote the benefits of early diagnosis and treatment initiation.

- Integrate risk-based HIV testing and counseling in all family planning services for early diagnosis of HIV infection with linkage to care and treatment including adherence to family planning methods.

- Encourage open discussion on reproductive health issues among couples, between parents and their children, and adolescents

- Enhance early diagnosis and treatment of HIV, Syphilis and HBV

- Adhere to Universal Precaution procedures for prevention of infections in healthcare settings.

- Ensure utilization of safe blood for transfusion

- Promote Positive Health Dignity and Prevention (PHDP)

- Screen all pregnant women at least at first contact for HIV, Syphilis (using the dual HIV/Syphilis RDT) and for HBV.

  For pregnant women who already know their HIV status, test for syphilis (using syphilis only kit) and HBV.

**For HIV**

- Promote safer sex practices among discordant couples; provide ART to the HIV positive partner and consider PrEP provision based on eligibility criteria for the sero-discordant partner

- Promote utilization of HIV self-test kit for ICT

- Promote early infant male circumcision and Voluntary Male Medical Circumcision (VMMC) in settings where male circumcision is not routinely done.
• Provide PEP (Post exposure prophylaxis), for HIV, following occupational exposure and sexual assault per national guidelines recommendations.

For Syphilis

• Treat sex partners of patients with primary, secondary, or early latent syphilis, presumptively as for early syphilis at the time of examination, unless symptoms of tertiary or neuro-syphilis are present

• Test for syphilis any woman who delivers a still born infant after 20 weeks of gestation,

• Identify and test symptomatic patients for syphilis

For HBV

• All pregnant women should be tested for hepatitis B surface anti-gen (HBsAg) at least once and as early as possible in the pregnancy

• All Infants and Neonates should have mandatory vaccination according to the recommended National EPI Schedule Plus birth dose of HBV vaccine.

• Note that evidences are showing that for full prevention of HBV infections, 4 doses of the vaccine should be given at standard intervals 0 (within 24 hours of birth), 6, 10 and 14 weeks.

General for HIV, Syphilis and HBV

• Provide safe pregnancy counseling

• Promote Correct and consistent use of condom

For HIV

• Provide service for FP method of choices for HIV positive women in PMTCT /ART

• Integrate family planning services with PMTCT/ART services.

• Provide 24/7 emergency contraceptives for HIV positive women and girls

• Provide safe pregnancy counseling
3. Prevention of HIV, Syphilis and HBV transmission from infected women to their infants

- Involve mother mentors in support groups to provide family planning information for individuals and couples

**General for HIV, Syphilis and HBV**

Ensure availability of antiretroviral drugs for HIV and HBV, and penicillin for syphilis and other appropriate supplies for PMTCT

Provide appropriate counseling on infant feeding and support for exclusive breastfeeding including maternal nutrition specially to prevent HIV transmission

Promote early ANC/HIV, syphilis & HBV testing, early ART initiation and safer obstetric practices

Involve and encourage mutual disclosure and couple’s counseling and testing.

**For HIV and HBV**

Ensure counseling and testing of HBV is integrated into ANC, labor & delivery and postnatal care and FP services and management of cases accordingly

Ensure that clients (mothers and babies) and essential data recorded during L&D are linked with ANC and PNC settings (Mother-baby cohort follow up)

**For HIV**

Provide lifelong ART for pregnant, laboring and breastfeeding women to improve their own health within the RMNCAH platform.

Provide ARV prophylaxis to HIV exposed infants.

Do VL monitoring and adherence counseling for mothers, and follow-up and tracing for both infants and mothers

Promote male partner testing with emphasis on risk-based testing and when a male partner tests HIV positive, link with the ART unit, provide treatment, care, and support

Promote disclosure counseling and manage accordingly, as well as in the emergency and birth preparedness planning during pregnancy and delivery
Promote greater involvement of people living with or affected by HIV/AIDS (GIPA) principle by involving mother mentors groups (MSG) in supporting the psychological and emotional effect posed by HIV and other STIs including syphilis and Hepatitis B; supporting ART adherence and mother baby follow up; and in assisting mutual disclosure and partner involvement in HIV prevention, treatment care and support of their families including ICT, Self-test, Cervical cancer (CxCa) and mental health screening.

Augment competency based comprehensive PMTCT trainings by involving expert patient trainers of mother mentors during all types of training.

Provide quality service for all women and children under RMNCAH platform through application of CQI models, dashboard and PMTCT cohort for performance monitoring.

**Syphilis**

Ensure counseling and testing services are integrated into ANC and manage syphilis accordingly.

Ensure that clients (mothers and babies) essential data recorded during ANC.

Promote male partner testing for syphilis positive pregnant women; and when a male partner tests syphilis positive, provide treatment.

**HBV**

Pregnant women testing positive for HBV infection receive Tenofovir prophylaxis from the 28th week of pregnancy until at least birth, to prevent mother-to-child transmission of HBV.
### General for HIV, Syphilis and HBV

#### For HIV

Provide lifelong and optimized ART for pregnant, laboring and breastfeeding women living with HIV to improve their own health, and prophylaxis for their newborns within the RMNCAH platform.

Monitoring viral suppression with viral load testing for newly HIV positive pregnant mothers at 3 months of ART initiation, at 34–36 weeks of GA or delivery at the latest, followed by three months after delivery and then every 6 months.

For those who are already on ART with previous VL test conducted more than three months back repeat VL test at 1st ANC contact /PMTCT visit, at 34–36 weeks of gestational age (or at the latest at delivery) and 3 months after delivery and every six months thereafter until MTCT risk ends.

For all breastfeeding women, regardless of when ART was initiated: conduct a viral load test three months after delivery and every six months thereafter to detect viremia episodes during the postnatal period.

Ensure appropriate follow-up for HIV-exposed infants including cotrimoxazole, ARV prophylaxis, early infant diagnosis, and link HIV infected infants for early ART initiation.

Provide routine screening, prophylaxis, and management for tuberculosis per national guidelines recommendations. Provide treatment and support for co-morbidities for HIV positive pregnant and lactating women.

Support initiatives organized for infants and HIV-infected women including nutritional support.

Provide Cervical Cancer and Mental health screening to eligible pregnant and breastfeeding HIV positive women in PMTCT settings.

Promote mother mentor groups to support retention in care, complement ongoing treatment adherence counseling, HIV exposed infant follow up including EID, and palliative care at facility and family level.
For Syphilis
Provide appropriate staging and treatment of syphilis positive women and infants
Provide appropriate syphilis treatment with Penicillin
Support initiatives organized for syphilis infected women and infants
Provide palliative care for syphilis affected at facility and family level.
Proper documentation of treatment and follow up at ANC, Labor, and delivery and postpartum follow up

For HBV
For HBV positive eligible pregnant women, provide treatment and follow up per the national guideline
Provide lifelong ART for HIV/HBV co-infected pregnant, laboring and breastfeeding women to improve their own health, and prophylaxis for their newborns within the RMNCAH platform.

3.1 Primary Prevention of HIV/Syphilis/HBV Infection

The most effective way to ensure that HIV/syphilis/ HBV not be transmitted to children is through prevention of infection among parents and potential parents. Furthermore, addressing factors that make girls and women especially vulnerable to HIV/syphilis/ HBV infection and limit their access to care are critical interventions that require focused approach. Additionally, male involvement in PMTCT programs could empower pregnant and breastfeeding women for a joint decision-making on health issues.

3.1.1 Interventions for primary prevention of HIV

Promote safer and responsible sexual behavior and practices

Safer sexual behavior includes delaying sexual debut, practicing abstinence, being faithful to sexual partner, practicing correct and consistent condom use and reducing the number of sexual partners. Safer sex practices can be promoted through the following approaches:

- Use health extension workers/women development group for community education
• Design community messages that are appropriate for high-risk individuals
• Assist individuals to make personal risk reduction plans through HIV counseling and testing
• Promote and supply male & female condoms to men, women and adolescents in the community as an integrated component of healthcare at different entry units (family planning, antenatal care, HIV counseling and testing including Self-test, provision of PrEP, HIV care, STI services including syphilis and Hepatitis B)
• Promote dual protection methods routinely, during family planning counseling
• Promote male involvement in HIV prevention at all levels using locally acceptable and culturally sensitive approaches
• Promote early infant male circumcision and voluntary male medical circumcision, where relevant
• Provide early diagnosis and treatment of STIs

Early diagnosis and treatment of STIs can reduce the HIV incidence in the general population by up to 40%. Information on transmission of STIs & HIV, and HIV testing, and counseling services should be available whenever and whatever care is provided. Similarly, HIV clients always need to be offered STI screening. Partner screening and treatment should be routinely available as part of STI services.

Provide HIV testing services (HTS) to adults and adolescents

Knowledge of HIV status is an entry to access HIV care and treatment, including PMTCT services. Providing HIV testing services to all pregnant, laboring and lactating women with unknown status, STI clients; at risk adolescents, young adults and children is a national priority. Provider-initiated risk-based approaches also need to be promoted to increase the availability of testing, reduce stigma, and reach people in need of testing and treatment.

Couple counseling enhances opportunities to prevent mother-to-child transmission of HIV. Both partners must know their HIV status to contend with HIV and plan their future. Couple counseling also helps to ease tension and diffuse blame as well as relieve the burden to disclose results and persuade partner to be tested. Couple counseling facilitates communication and cooperation re-
quired for risk reduction. Couple counseling should be based on mutual disclosure and consent. A client should not be forced to disclose to their partner; instead, should be encouraged to go through couple counseling.

**Pre-Exposure prophylaxis**

Pre – Exposure Prophylaxis (PrEP) is defined by the World Health Organization as the use of antiretroviral drugs by HIV-negative people before potential exposure to prevent the acquisition of HIV. Global evidence show that PrEP is effective infection reduction intervention when properly combined with other HIV prevention services.

MOH is scaling up PrEP service nationwide to contribute for the reduction of new HIV infection. PrEP of HIV is the use of ARV drugs by people who are not infected with HIV but at a substantial risk of infection to block the acquisition of HIV. Substantial risk of HIV infection is provisionally defined as an incidence of HIV higher than 3 per 100 person-years in the absence of PrEP. Oral PrEP containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches. Each country may have its own targets group for PrEP based on WHO guidance.

The target beneficiaries for PrEP service in Ethiopia are:

- Consenting HIV Negative FSWs
- HIV negative partners of sero-discordant couples.
- HIV negative pregnant and breast-feeding women at substantial risk of HIV infection during antenatal and postnatal follow up visit with HIV positive partner, which also required conducting routine partner testing for HIV.

The nationally recommended PrEP drug is a fixed dose combination that contains Tenofovir 300mg and Lamivudine 300mg once daily for the identified target groups. It is highly recommended to provide 3 MMDs of PrEP drugs when situations dictate.

Additional PrEP services include counseling on correct and consistent use of condoms, routine screening of STIs, HIV testing, assessments of adherence and retention as part of combination HIV prevention package.
3.1.2 Primary prevention of syphilis

- Reduction of the average rate of sexual exposure to STIs through alteration of sexual risk behaviors and behavioral norms among both susceptible and infected persons in all population groups. The necessary changes include reduction in the total number of sexual partners and the number of concurrent sexual partners. Also recommended intensive behavioral counseling for all sexually active adolescents and adults who are at increased risk for STIs.

- Reduction of the efficiency of transmission through the promotion of safer sexual practices, the use of condoms during casual or commercial sex, vaccination against HBV and HPV infection, male circumcision (which reduces risk of acquisition of HIV infection, chancroid, and perhaps other STIs), and a growing number of other approaches (e.g. early detection and treatment of other STIs to reduce the efficiency of sexual transmission of HIV) leads to reduced MTCT of all the three problems. Longitudinal studies have shown that consistent condom use is associated with significant protection of both males and females against all STIs that have been examined, including HIV and HPV, infections as well as gonorrhea and chlamydial infection.

- Shortening of the duration of infectivity of STIs through early detection and curative or suppressive treatment of patients and their sexual partners. The availability of curative therapy for syphilis infection and suppressive therapy for HIV and HBV infections exemplifies new opportunities for shortening infectivity in major STIs.

- Patient Counseling and Education: Intrauterine transmission of Syphilis can have debilitating effects on pregnant women, their fetuses, and their partners. Patient education should be provided for all pregnant women and their sex partners about Syphilis along with counseling on the possibility of self/perinatal infections and complications that may arise, and provided access to recommended screening and treatment, if needed.

- Avoid sharing needles for those using injected drugs, as syphilis can also be transmitted through shared needles.

- Behavioral Change Communication on syphilis risk reduction through women development group, mass communication strategy and other proven mechanisms to protect men, women, boys and girls of repro-
ductive age and health literacy through all appropriate means using all available new technologies. Encourage open discussion on reproductive health issues among couples, and between parents and their children.

- Discourage early sexual debut as well as practices with multiple partners to reduce the risks of STIs
- Testing and management of pregnant women and their partners: All pregnant women should be screened for syphilis at the first prenatal visit, even if they have been tested previously. Data regarding congenital syphilis is scarce in our country, therefore more focus should be on strong implementation of screening and timely testing of pregnant women along with risk reduction and linkage to treatment. Testing in the third trimester of pregnancy for women who visit late facilities for ANC can also reduce congenital syphilis cases. Partners of pregnant women with syphilis should be evaluated, tested, and treated to achieve PMTCT of syphilis. Any woman who delivers a still born infant after 20 weeks of gestation, should be tested for syphilis.

3.1.3 Primary prevention of HBV

The Ministry of Health (MOH) considers viral hepatitis Prevention and Control measures in line with the current drive to strengthen health systems which includes reaching every child with immunization programs that include hepatitis B vaccine, protecting against mother-to-child transmission of viruses, ensuring the safety of blood transfusion services and injection practices.

The health education and counseling should focus on providing information on the cause and transmission of HBV infection, its consequences including MTCT, available prophylaxis, the importance of complying with treatment regimens and, how to reduce risk through condom use (including demonstrating the correct way to use a condom and promoting condom use), and contact treatment/partner management. Achieving behavioral change and risk reduction through patient counseling and education is key to PMTCT of HBV.

Behavioral Change Communication on HBV risk reduction through women development group, mass communication strategy and other proven mechanisms to protect men, women, boys and girls of reproductive age and health literacy through all appropriate means using all available new technologies.
Testing and management/prophylaxis

All pregnant women should be routinely tested for hepatitis B surface antigen (HBsAg) at the first prenatal visit even if they have been previously vaccinated or tested. Women who are HBsAg positive should be provided with, or referred for, counseling and medical management. All Infants and Neonates should have mandatory vaccination according to the recommended National EPI schedule; all infants should receive 4 doses vaccination of Hepatitis B vaccine at standard intervals 0 (within 24 hours of birth), 6, 10 and 14 weeks.

This guideline expects all to adhere to Universal Precaution procedures for prevention of infections in healthcare settings. Education on the importance of maintaining environmental and hygiene practice to minimize risk of exposure for HCW at the health facility level. Implementing standard operating procedures (SOPs) with emphasis on hand washing after procedures, wearing of protective gears (gloves, clothing, glasses), safe disposal of sharps, and high-level disinfection of equipment helps to minimize acquiring HBV infection. Improved access to safe blood and screening of all collected blood for HBV helps to minimize infections. Proper training of HCW in their respective fields to enhance preventive practice measures is very important.

Discouraging early sexual debut as well as practices with multiple partners to reduce the risks of HBV transmission is one of the primary prevention interventions to minimize the transmission in HBV.

3.2. Prevention of Unintended Pregnancies in HIV-Positive Women

Prevention of unintended pregnancy in the general population is critical to prevent transmission of HIV to children since many women and men do not know their HIV status. Moreover, integrating family planning and HIV services is a cost-effective approach to service delivery that offers more women living with HIV access to options for family planning and reduce the number of new pediatrics infections through mother-to-child transmission. Improving family planning services to prevent unintended pregnancy among HIV-positive women is one of the methods to preventing HIV infection in children. As The 2019 WHO, providing contraceptive services in the context of HIV treatment programs recommendation states no contraceptive method is contraindicated because of having HIV or using ART, although interactions with some ARV drugs may re-
duce the effectiveness of some hormonal contraceptives. A woman using HIV medication can use all contraceptive methods if she is properly counseled about the risks and benefits and makes an informed decision.

3.2.1. Family Planning Services

It is critically important to recognize the differences in need and desire for contraception among women of childbearing age and childbearing potential. A one-size-fits-all approach cannot be applied to women living with HIV in all their diversity, and contraceptive considerations must focus on the situations, circumstances, needs and preferences of individual. All women go through different seasons of sexual and reproductive healthcare need and reproductive intent throughout their life-course. A client-centered approach is paramount. Provide all available reproductive choices for people living with HIV and their families. Family planning behaviors of individuals and communities are influenced by a multifaceted and interrelated determinant at the individual, interpersonal, community, services and enabling environment level.

When providing family planning counseling, providers should:

- Respect the right of all women, regardless of HIV status, to decide the number and timing of children
- Counsel HIV positive women on all options of family planning
- Encourage dual protection using two forms of contraception where one should be condom
- Provide condoms wherever possible and refer clients to a convenient and affordable source
- Provide integrated FP/HIV and STI services at all levels of care
- Provide full information about the possibility of transmitting HIV to a child
- Offer information about prevention and referral for HIV counseling and testing
- Counsel men and women who know they are positive, assisting them to make well-informed decisions to meet their family planning needs

The following three key communication approaches need to be incorporated in FP communication

- Behavior Change Communication (BCC) to engage in face-to-face dialogue with individuals or groups to inform and motivate them with the objective to promote and sustain Family Planning behavior change at individual, community, and household levels.
• Social Mobilization to promote engagement and ensure harnessing institutions opportunities, community networks, and health development armies, social/civic and religious groups in enhancing demand for and sustainable uptake of family planning services and family planning behaviors.

• Advocacy to inform and motivate leaders and public figures to ensure that enabling environment is created to support the overall communication campaigns to achieve family planning program objectives and development goals at national, regional, woreda and community levels.

**Contraceptive information**

Clients should be given adequate information in easily understood ways to help them make an informed, voluntary choice of a contraceptive method. This information should at least include:

- The effectiveness of the method
- The factors that impact effectiveness
- The duration the method can be used
- Correct use of the method
- Follow-up required for the method
- How the method works
- Common side-effects of the method
- The health benefits and risks of the method
- The privacy of the method
- The signs and symptoms that would necessitate a return to the clinic when using the method
- Information on return to fertility after discontinuing method use
- full explanation on permanent methods being irreversible
- Information on sexually transmitted infection protection and dual contraceptive method use, using condoms
- Cost of the method, if any

**Considerations for HIV-positive women on ART and Contraceptives**

Some ARVs interact with contraceptives and result in decreased efficacy of contraception. Specifically, women on, Efavirenz (EFV), Lopinavir/ritonavir (LPV/r), and Ritonavir (RTV) who are also using contraceptives (COC, POC, and Implants) should be monitored closely, counseled, and offered on dual
protection methods. Hormonal IUD has interactions with all groups of ARVs and should be cautiously evaluated for risk/benefit. The Cu-IUD (a long-acting reversible method) is a very effective method of contraception, appropriate for women, that does not interact with ARV drugs. Women using progestogen-only injectable contraceptives (DMPA and NET-EN) are unlikely to experience reduced effectiveness when taking these ARV drugs.

Permanent methods of contraception (female and male sterilization) are very effective non-hormonal methods of contraception that do not interact with ARV drugs.

Male and female condoms are non-hormonal methods and do not interact with ARV drugs and can be used for sexually transmitted infection prevention and HIV prevention in sero-discordant couples. When used in addition to a hormonal contraceptive method (dual method), they maximize prevention of pregnancy and sexually transmitted infections and HIV infection and offer additional protection from pregnancy if a primary contraceptive method fails.

Considerations for HIV-positive women on Rifampicin, anti-epileptics, anti-fungal medications and COCs:

TB therapy with Rifampicin/rifapentine, anti-epileptic, and anti-fungal medications can interact with COCs resulting in decreased protection against pregnancy. Therefore, any woman taking Rifampicin, anti-epileptic and anti-fungal drugs along with COCs should be informed about this risk and offered dual protection. TB medications are not considered to reduce the effectiveness of the DMPA progestogen-only injectable.

Brief information on the use of contraceptive method among HIV-positive women and those on ART is stipulated in Table 3.2 below.
<table>
<thead>
<tr>
<th>Method</th>
<th>Use in HIV-positive women</th>
<th>Use in HIV-positive women on ART</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male condom</td>
<td>Highly recommended.</td>
<td>Highly recommended</td>
<td>Requires partner cooperation and correct technique; effectiveness depends on consistent and correct use. Protects against transmission of STIs and HIV. Latex condoms are more effective.</td>
</tr>
<tr>
<td>Spermicidal use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Nonoxynol-9)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>For clients at high risk of HIV or who are HIV-positive.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female condom</td>
<td>Highly recommended.</td>
<td>Highly recommended</td>
<td>Limited availability and lack of knowledge on consistent and correct use may limit usefulness. Protects against transmission of STIs and HIV.</td>
</tr>
<tr>
<td>Spermicidal use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Nonoxynol-9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For clients at high risk of HIV or who are HIV-positive.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copper(Cu) IUD</td>
<td>May be used; follow-up is recommended</td>
<td>May be used follow up recommended.</td>
<td>NOT recommended for use in women with PID in the last six months or other active STI. Offers no STI/HIV protection, therefore provide condoms in addition.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td>Restrictions for Use</td>
<td>Interactions with ARVs</td>
<td>Unsuitable Use Note</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
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</tr>
<tr>
<td>Progesterone only injectable (DMPA Implants)</td>
<td>No restrictions</td>
<td>May use with follow-up. Drug interaction with some ARV likely.</td>
<td>Unclear interaction of steroids and immune function. Offers no STI/HIV protection, therefore provide condoms in addition.</td>
</tr>
<tr>
<td>Combined Oral Contraceptives (COC)</td>
<td>No restrictions</td>
<td>Interactions with some ARVs likely. Dual protection recommended.</td>
<td>Interaction with some ARVs may reduce effectiveness of COCs. May use with follow-up. Offers no STI/HIV protection, therefore provide condoms in addition.</td>
</tr>
<tr>
<td>Surgical Sterilization</td>
<td>No restrictions</td>
<td>No restrictions for use. Women with advanced HIV disease may be at slightly higher risk of surgical complications. Consider delaying surgery pending initiation of ART.</td>
<td>Offers no STI/HIV protection therefore provide condoms in addition.</td>
</tr>
<tr>
<td>Locational Amenorrhea Method</td>
<td>No restrictions</td>
<td>No restrictions for use</td>
<td>Important to review on-going risk of MTCT for HIV+ women during breastfeeding. Offers no STI/HIV protection therefore provide condoms in addition.</td>
</tr>
<tr>
<td>Emergency Contraception (EC) (Postinor-2, or use COC pill) IUCD</td>
<td>No restrictions Restricted in the presence of active STI</td>
<td>No restrictions. In patients using Efavirenz, there is potential failure of progesterone component therefore may need to increase progesterone dose when used for EC.</td>
<td>EC should be given to women who request it. Women who have been raped should be offered EC. Oral contraception can be used within 72 hours while IUCD can be used within the first 5 days</td>
</tr>
<tr>
<td>Dual protection</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Dual protection should be recommended to all women and men.</td>
</tr>
</tbody>
</table>
Table 3.3 Key contraceptives interactions and suggested management

<table>
<thead>
<tr>
<th>COMBINED HORMONAL CONTRACEPTIVES</th>
<th>Key interactions</th>
<th>Effect</th>
<th>Suggested management</th>
</tr>
</thead>
<tbody>
<tr>
<td>COC pills), progestogen-only pills or LNG and ETG implants</td>
<td>ARV drugs (NNRTIs) EFV, NVP (PIs) ATV/r, LPV/r, DRV/r and RTV</td>
<td>Decrease the effectiveness of COCs</td>
<td>Counsel and offer on dual protection methods.</td>
</tr>
<tr>
<td></td>
<td>Anticonvulsant therapy phenytoin, carbamazepine, barbiturates, primidone,</td>
<td>Decrease the effectiveness of COCs</td>
<td>Use alternative or additional (dual) contraceptive methods</td>
</tr>
<tr>
<td></td>
<td>TB treatment and prevention Rifampicin or Rifabutin rifapentine</td>
<td>Decrease the effectiveness of COCs</td>
<td>Use alternative or additional (dual) contraceptive methods</td>
</tr>
</tbody>
</table>

3.3. Prevention of HIV, syphilis, and hepatitis B virus transmission from mother to child

Interventions aimed to prevent mother-to-child transmission of HIV, syphilis and Hepatitis B go together with strengthening maternal and child health services as well as other reproductive/sexual health programs. Many strategies for preventing MTCT benefit all women who are, or may become, pregnant. PMTCT services should be available to all women attending antenatal, delivery and postpartum services. Quality antenatal, delivery and postpartum care should be provided to all women.

Pregnancy itself does not necessarily affect the outcome of HIV, syphilis and
HBV infection, but HIV, syphilis and HBV may affect pregnancy outcomes in several ways: HIV, syphilis and HBV-positive pregnant women are at increased risk for premature deliveries, small for gestational age babies and stillbirth. Other health issues associated with HIV infection, such as anemia and malnutrition, also can lead to birth complications and negative birth outcomes.

ANC for All Pregnant Women

Antenatal care must be available to all pregnant women regardless of HIV status. All women need information on HIV prevention through safer sex practices, diagnosis and treatment of syphilis, and hepatitis, and infant feeding counseling and support.

Antenatal care services for all pregnant women should include:

- **Client history**: Obtain routine data including medical, obstetric, and psychosocial history.

- **Physical examination**: Thorough general physical examination, focusing on abdominal and pelvic exams.

- **Lab. Profile**: Routine tests for syphilis, hepatitis B, Hemoglobin, blood group, urinalysis and provide rapid HIV testing to the pregnant woman and her partner if accompanying her.

- **Provide Tetanus and diphtheria (Td) vaccination**

- **Family planning** counseling on the available family planning options for the specific client.

- **Provide Nutritional assessment** (MUAC and weight gain) and nutrition counseling and counseling on realistic diet adjustment to meet the increased need of pregnancy and people living with HIV.

- Provide counseling on **iron/folate supplementation**

- **Infant feeding** counseling with emphasis on exclusive breastfeeding for the first six months.

- Routine offer of **HIV counseling and testing** as well as syphilis, HBV and partner testing.

- Counseling on **danger signs of obstetric complications**, on birth preparedness and complication readiness, and safer sex practices.
• Counsel on the importance of regular follow up visits and need for institutional delivery.
• Counsel on malaria prevention and treatment for those from/travel to malaria endemic areas

3.3.1 Prevention of MTCT of HIV

3.3.1.1 Risk of MTCT during Pregnancy, Labor, Childbirth, and Breastfeeding

Vertical transmission of HIV can occur during antepartum, intrapartum and postpartum period at variable rate, depending on the timing of infection and the availability of services for preventing mother-to-child transmission.

The table below describes the rate of mother-to-child transmission in the absence of intervention (Table 3.4). However, many medical advances have made it possible to dramatically reduce the risk of MTCT of HIV. Effective use of available medications, appropriate labor and delivery protocols, and optimal breastfeeding practices can reduce a child’s overall risk to less than 5%. For example, provision of ART to a mother throughout the breastfeeding period can reduce the risk of postnatal MTCT by more than 50%.

Table 3.4: Estimated Risk of MTCT

<table>
<thead>
<tr>
<th>Timing</th>
<th>Transmission rate without intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>During pregnancy</td>
<td>10–25%</td>
</tr>
<tr>
<td>During labor and delivery</td>
<td>35–40%</td>
</tr>
<tr>
<td>Overall, with breastfeeding up to 6–24 Months</td>
<td>35–40%</td>
</tr>
</tbody>
</table>

Note: Rates of transmission vary because of differences in population characteristics such as maternal CD4+ counts, RNA viral load, exclusivity, and duration of breastfeeding

March 2014 *Supplement to 2013 consolidated guidelines
Risk Factors for MTCT of HIV

Several factors put a woman at a higher risk of transmitting HIV to her child:

**Maternal Factors**
- High maternal viral load, such as due to recent HIV infection and advanced HIV infection
- Low CD4 count
- Viral or parasitic placental infections during pregnancy, labor, and childbirth
- Maternal malnutrition
- Nipple fissures, cracks, mastitis, and breast abscess
- Poor ART adherence

**Infant factors**
- First infant in multiple birth
- Prematurity and low birth weight
- Longer duration of breastfeeding
- Mixed feeding during the first six months of life
- Oral diseases in the child

**Obstetric and Delivery Practices**
- Rupture of membrane for more than four hours
- Injury to birth canal during childbirth (vaginal and cervical tears)
- Antepartum procedures (e.g. amniocentesis, external cephalic version)
- Invasive childbirth procedures (e.g. episiotomy, fetal scalp monitoring)
- Vaginal delivery with high viral load
- Instrumental delivery (Vacuum, forceps assisted)
- Delayed infant drying with clean towels and delayed eye care
- Routine infant airway suctioning

**Care for HIV+ Women**

**Pre-Conceptual Care**
- Give accurate information on risk of MTCT
- Counsel to bring informed decision to conceive
- Explain availability of family planning options
- Describe effects of HIV on pregnancy outcomes
- Discuss the benefits of involvement and HIV testing of partner
- Counsel on the best possible health and nutritional status
  - Adequate calorie intake to maintain a healthy weight, and additional iron, folate at least three months prior to pregnancy; encourage consumption of foods rich in iron (e.g. beans, lentils, green leafy vegetables, meat, and liver) and use of iodized salt.
- Provide advice on malaria prevention in malaria endemic areas
- Counsel the Prevention, screening and treatment of STIs before pregnancy
- Prophylaxis and treatment of opportunistic infections
- Discuss the risks of pregnancy until six months after recovery from any chronic infections, such as TB or other opportunistic infections

**ANC for HIV positive pregnant women**

All HIV positive women need to be transferred to ANC clinic as soon as pregnancy is confirmed. In addition to the ANC that is offered to every woman, HIV positive pregnant women need visits for:
- Periodic thorough clinical assessment
- Initiation of recommended and safe ART regimen if not started
- Monitoring and support for ART adherence
- Prevention and early treatment of opportunistic infections
- CD4 count determination for baseline
- Viral load monitoring to detect emergence of virological failure.

For the best pregnancy outcome and reduction of potential risk, HIV positive
pregnant women should be assessed for:

- History of HIV-related illness
- Duration of knowledge of HIV-positive status
- Symptoms of AIDS as per WHO Clinical Staging
- HIV and health status of other children, if any, and partner
- Partner testing/management and disclosure
- Any medications for HIV-related illness taken during the current pregnancy (e.g., medications for TB, malaria, hepatitis, or any antibiotics for opportunistic infections)
- Any potential factor that can hamper the adherence to ART (such as alcohol or substance use, mental illness, and stigma).
- Non-communicable diseases (NCD) such as diabetes, goiter, cancer, and heart disease.
- Laboratory investigations as needed to diagnose opportunistic infections
- Nutritional status (through anthropometric measurements such as MUAC and weight).

HIV Counseling and Testing during Antenatal Care

PITC

Compared with other approaches, routine provider-initiated HIV testing and counseling using the opt-out approach for all pregnant women has resulted in greater acceptability, increased opportunity to prevent MTCT, and minimize stigma. All information about HIV testing must be kept confidential and testing should be voluntary. All forms of HIV testing and counseling should be voluntary and adhere to the five C’s: consent, confidentiality, counseling, correct test results and connections to care, treatment and prevention services.

The pregnant woman should be given the results of a rapid HIV test immediately whenever possible. Knowledge of HIV status is a very important step in providing appropriate recommendations and treatment for HIV-positive women and their partners when indicated.

Provider-initiated routine counseling and testing using the opt-out approach is recommended for all clients seen within the context of maternal care (i.e., antenatal, labor, postpartum). This means HIV testing is offered as a routine component of standard maternal/child health care. The client is given pretest
information with a group or individually on HIV/AIDS and PMTCT and is informed that her routine antenatal laboratory tests will include an HIV test. The provider also must inform the client that she has the right to say “no” (to opt out), and this decision by no means affects the non-HIV care services she will get from the health facility.

The pretest information can be provided as part of a group session or incorporated into general health talks especially when the client load is high. If clients have additional questions or concerns, individual counseling can be used after a group session. Also, pretest counseling for couples should always be encouraged and should last 5–15 minutes.

If the HIV test result for pregnant woman is negative during early pregnancy, Retesting can be done during late pregnancy, labor or postnatal period based on risk assessment.

**Key points to remember:**

- Provider-initiated HIV testing, and counseling should be offered to all pregnant women
- Pretest information can be offered individually or in a group
- If a patient refuses HIV testing, explore the reasons for the refusal and address any concerns or misconceptions.
- The client can be encouraged to test, but do not pressure or coerce a client to HIV test. The client has the right to refuse.
- If the test is negative, retesting can be done in late pregnancy, delivery and post-natal based on risk assessment.
- All information about the client should be kept confidential.

**NB.** Dual HIV and syphilis rapid diagnostic test shall be the first test in HIV testing strategies and algorithms in antenatal care

For key messages during the pre-test session, refer to the diagram on the next page
HIV Testing and Counseling (HTC) Antenatal Care Settings

Large Group/Small Group/Individual/Couple
Pre-test Session Provide information on:
- Testing process and is offered to all clients
- Discordance and partner HIV testing
- PMTCT, support services, and antenatal care

PMTCT, support services, and antenatal care

Provider routinely offers HIV test

HIV Test Declined: Offer individual counseling Address barriers to testing Discuss:
- Risk reduction
- Exclusive breastfeeding Antenatal and postnatal care and safe delivery
- Re-offer HIV test or develop plan to return for HIV test
- Infant care Provide referral/take home information

HIV-negative Post-test Counseling: Provide HIV test result Discuss:
- Risk based Partner HIV testing
- Disclosure Risk reduction
- Antenatal and postnatal care and safe delivery
- Exclusive breastfeeding Infant follow up and care
- Provide referral/take home information

HIV-positive confirmed, Post-test Counseling:
** Provide confirmed HIV test result and support. Discuss:
- WHO clinical staging, CD4 count and screening for OIs
- Initiation of ART for all pregnant women living with HIV following expedited adherence counseling;
- Support exclusive breastfeeding for 6 months and initiate complimentary feeding with semisolid feeds.
- Continue breastfeeding for 18-24 months
- Partner HIV testing and disclosure
- Index Case Testing
- Risk reduction
- Antenatal and postnatal care and safe delivery
- Treatment and support services for client and family
- Infant follow up and importance of early infant diagnosis

Subsequent healthcare Visits: Review messages and referrals Re-offer HIV test

Subsequent healthcare visits: Review post-test counseling and referral

Figure 3.1 HIV Testing and Counseling (HTC) Antenatal Care setting
*Follow national rapid testing algorithm/guidelines. Rapid testing with same day results is highly recommended. Mothers clearly counseled for the need to have two tests if the first test is positive from the beginning.

** Re testing /Verification test with rapid test must be initiated in ANC unit possibly by different experienced health worker in HIV testing, using different sample but the same algorithm before post-test counseling. If Test discordant occurs, the third blinded test should be performed by laboratory personnel.
**HIV Self-Testing**

HIV Self-Test (HIVST) is an innovative approach to deliver HIV testing services and contribute more for the national case finding efforts. HIVST should be offered as an additional approach to HIV testing services.

HIV self-testing (HIVST) refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he/she trusts. As with all approaches to HIV testing, HIVST should always be voluntary, not coercive, or mandatory.

Women and partner who opted not to be tested by providers for various reasons may benefit from HIV self-testing. The need of immediate notification of status should be clearly communicated to the client to do confirmatory testing for positives using the national algorithm. All self-testers with a non-reactive self-result should retest (after 6 weeks) if they might have been exposed to HIV in the preceding 6 weeks or are at high ongoing risk.

**Partner and family-based Index Case Testing**

An index case is defined as an individual who is found HIV positive through HIV testing. When counsellors identify index women whose sexual partners or eligible biological children are not tested for HIV, they should immediately provide testing services to all family members based on national guideline.

Index case testing is a high yield, targeted testing approach for identifying and linking new HIV infected individuals to treatment services. This approach needs to be optimally utilized for case detection and to break the HIV transmission cycle. Some of the PLHIV might have not yet disclosed their HIV status to their partners while others have partners with ongoing risk. It is expected that at least 1.5 adult partners elicited per index case.

**Retest for HIV negative**

Re-testing is recommended for persons who tested negative but have an ongoing risk:

- Pregnant women, who have tested HIV negative in the first/second trimester of pregnancy; retest during third trimester or labor or postpartum based on risk
- Clients who presented with STI (after 3 months)
• Have specific incidents of known HIV exposure within the past three months (after 3 months)
• Discordant Couple, retest after 6-12 month
• Occupational exposure or sexually assaulted client who started PEP, re-test at 6 weeks, 3 months and 6 months

**HIV Testing and Counseling during Labor**

As many pregnant women attend health facilities for the first time during labor, HIV testing, and counseling should be offered routinely for all pregnant women admitted for delivery that were not tested at ANC as well as their partners. Active identification of women in labor with unknown HIV status (never tested previously) offering HIV testing and counseling shall be part of the standard delivery care. Women tested negative during or prior to the first trimester should also be offered a Retest based on their risk. HIV-positive women identified during delivery shall receive antiretroviral treatment immediately before delivery and get linked for follow up of PNC for themselves and their infants.

The right of women to decline HIV testing must always be respected. The approach and timing of pre- and post-test sessions will be guided by the stage of labor in which a woman presents. If in advanced labor, HTC can be offered immediately after delivery before discharge so the baby can still receive ARV prophylaxis and both mother and baby can receive or be referred for other HIV prevention interventions, treatment, care and support services. Before discharging the client, the cohort registration should be completed.

The pretest session in labor should be very short (2–5 minutes) and provide sufficient information to enable the woman to make an informed decision on whether to accept the test or not. If all components cannot be completed because a woman is in active labor, complete at an appropriate time as soon after delivery as possible.

The messages and action steps for routine offer of HIV testing and counseling to all women in labor should be conducted according to the following protocol (Fig 3.2).
Pre-Test Session
Determine HIV test history
Do risk assessment
Discuss benefits of test, prophylaxis and treatment

Offer HIV test for all clients with unknown HIV status, for those with substantial risks and who have previous HIV negative test result

Rapid test performed

HIV test declined

HIV-negative Post-test Counseling:
Provide HIV test result
Discuss:
Partner HIV testing

Use safer obstetrical practices, deliver infant, and provide postnatal care

HIV Test Follow-Up: Address barriers to testing and re-offer test
Discuss:
Risk reduction Exclusive breastfeeding
Postnatal and infant care
Provide referral/take home information

Subsequent Healthcare Visits: Review messages and referrals
Re-offer HIV test

Continued Post-test Counseling:
Discuss:
Partner HIV testing and disclosure
Risk reduction
Exclusive breastfeeding
Postnatal and infant care
Provide referral/take home information

Subsequent Healthcare Visits: Review post-test counseling and referrals

Continued Post-test Counseling:
Confirm test result and provide support
Discuss:
Exclusive breastfeeding and safe BF practices
Initiation of breast feeding within one hour
Complementary feeding at six months
Maternal nutrition during breastfeeding
Clinical care for client
Partner HIV testing and disclosure Adherence support and risk reduction Treatment and support services for client and family
Discuss importance of VL monitoring 3 months after delivery
Postnatal care for mother Follow up of infant and early infant diagnosis
Provide referral/take home information

Subsequent Healthcare Visits:
Review post-test counseling and referrals

Figure 3.2. Testing and Counseling (TC) for Prevention of Mother-to-Child HIV Transmission (PMTCT) in Labour and Delivery

Re-test before initiating of ART-verification
It is required that all clients linked to care and treatment services need to have a repeat HIV testing done before treatment is initiated. Retesting aims to rule out possible technical errors, including specimen mix-up through mislabeling and transcription errors, as well as random error either due to the provider or
Retesting a person diagnosed to be HIV positive to verify the diagnosis should include:

- Take a new specimen for each newly and previously diagnosed individual, preferably conducted by a different provider using the current testing algorithm, prior to initiation of ART.
- Retesting that is preferably conducted at a different site/unit, ideally the site where the decision about ART initiation will be made. For PMTCT, where there are providers other than who did the first test, retesting could be done at the PMTCT unit.
- If the Retesting result is negative, the client should be referred to the facility laboratory. If the facility does not have laboratory, the client should be referred and linked to the nearest facility where there is laboratory service.
- Testing at L&D for pregnant mother with unknown status will be done. If positive, provide ART for the mother and ARV prophylaxis for the infant. After delivery, perform retesting and if the positive test is verified, continue ART; If verification test is negative, send the mother to facility laboratory or nearest facility where there is laboratory service. If the verification status is the same upon retesting, the person’s HIV-positive status should be considered as verified and continued with ART.

**ART for the mother**

- All HIV positive pregnant, laboring and lactating mothers will be initiated on ART for life TDF + 3TC + DTG (TLD).
- Pregnant women with WHO clinical stage 1 and 2 can safely be initiated on ART in ANC; however, those diagnosed with advanced HIV disease at ANC (WHO stage 3 and 4) and have opportunistic infections should promptly be provided treatment of OI and initiation of ART in consultation with ART clinic provider. On-going care and treatment initiation will be followed per the client status.
- ARV drugs refill and follow up treatment for HIV positive transferred-out mothers from ART will be done at the ANC unit by trained health workers.

**Adherence to treatment:**

- Pregnant and postpartum women have adherence challenges due to multiple factors such as morning sickness and postpartum depression.
and require additional support throughout pregnancy and following childbirth.

- Adherence limiting factors should be assessed and addressed as promptly as possible to start pregnant women on ART within the shortest possible time.

- Continuous monitoring and support for adherence should be provided at RMNCAH setting to ensure pregnant mothers comply with treatment recommendations.

- Adherence support mechanisms such as MSGs and case managers/adherence supporters should be established and involved at all levels of the health system.

- Mechanism for retention of patients and tracing of lost to follow up should be in place in all facilities that provide PMTCT services. Tracing pregnant women lost from care should be initiated within seven days of a missed appointment.

- Modern technologies such as m-health can be used to improve access and adherence to treatment.

**Prophylaxis and treatment for opportunistic infections:**

- Provide routine Trimethoprim–Sulfamethoxazole (TMP-SMT) or cotrimoxazole prophylaxis for all pregnant women living with HIV with clinical stage 2, 3, 4 disease or CD4 count below or equal to 350 /mm3.

- Provide other OI prophylaxis (such as TPT) and treatment for opportunistic infections as per the national guidelines.

**Tuberculosis (TB)**

- Screen all HIV positive pregnant and lactating women for tuberculosis by asking the woman for presence of fever, cough of any duration, weight loss (or poor weight gain if pregnant), and night sweat per national TB and HIV guidelines recommendations.

- All HIV positive pregnant and breastfeeding women with presumptive TB should be investigated for TB using GeneXpert MTB/RIF assay and with radiography at hospital level if feasible and deemed necessary.

- Link pregnant and postnatal women with TB diagnosis to TB clinic and follow-up their status during RMNCAH visits.

**Malaria**

- All pregnant women residing in malaria endemic areas should be advised to use insecticide treated bed nets, preferably the long-lasting in-
secticide treated bed-nets (LLITN), to prevent malaria.

- All HIV-positive pregnant women diagnosed with malaria should receive treatment as per the national guidelines for malaria.

**Nutrition during pregnancy**

- The combined additional energy demands of HIV infection and pregnancy may lead to inadequate weight gain during pregnancy and result in birth complications. Women should be screened for malnutrition using MUAC at the first ANC visit.
- HIV-positive pregnant women should be counseled to eat at least one extra meal per day, and weight gain should be monitored on a regular basis to ensure weight gain of approximately 2 kilograms per month during the second and third trimesters.
- Weight gain of one kilogram or less per month is a sign of a serious problem that should be assessed and managed. Counseling on nutrition and household food safety; and personal hygiene are critical for reducing the risk of nutrient loss due to infections.

**Infant feeding**

- Counsel HIV-positive pregnant women on the importance of exclusive breastfeeding for the first six months of life, followed by introduction of appropriate complementary feeding at six months with continued breastfeeding.

**Partners and family**

- Help women through the process of disclosure, involving partner and/or couple counseling, and on effective involvement of the family in care and support.

**Other Support**

- Counsel and refer to community care and support organizations and ensure feedback from the receiving end (refer to Community Care Guideline for detail).
- Engage mother mentors for ongoing counseling and HIV exposed infant follow up or involve HEWs (health post) for referral that ensures confidentiality of the client.

**Prevention**

- Counsel on primary prevention including condoms use, infant feeding, the use and provision of contraceptive methods including post-
Intrapartum care: Labor and Delivery

Most pediatrics HIV infection occurs through transmission from the mother during pregnancy, labor and delivery and breastfeeding and is a critical period for prevention of MTCT. Strategies that prevent MTCT, including standard infection prevention precautions and limiting/avoiding unnecessary obstetric interventions, are also protective for all women and their infants.

Intrapartum care and infection prevention include:

- Essential obstetric care for all mothers
- A skilled attendant at every birth.
- Early identification of danger signs and urgent referral to a facility where comprehensive obstetric care is available
- Safe delivery practices and avoiding invasive procedures when possible.
- Avoid artificial rupture of membrane to shorten labor
- No routine episiotomy
- Avoid use of vacuum extraction and forceps if possible
- Limit vaginal examinations during labor
- Treat acute chorioamnionitis promptly
- Provide early infant eye and cord care
- Safe delivery practices designed to protect health workers, mothers, family members, and babies and include:
  - Use of standard precautions at every delivery
  - Covering umbilical cord with gauze before cutting
  - Safe handling and disposal of placenta and soiled materials
  - Proper processing of used instruments.

Postpartum Care for all mothers and their infants

The postpartum period is a critical transition time for the woman, her newborn, and the family. Ideally, postpartum care should be provided by the health worker or skilled attendant present at delivery. The mother and newborn should be cared for together. Important components of care after delivery for the infant-mother pair are outlined in Table 3.5 below.

Postpartum care should be provided in the health facility for the first 24-48hrs and return for follow up care at 3-4days, 5-7days and 6 weeks, or at any point if complications arise. The following table illustrates the postpartum care component that needs to be provided for all mothers and newborns.
Table 3.5: Postpartum Care of All Women and their Infants

<table>
<thead>
<tr>
<th>First 24-48 hours</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
<td><strong>Infant</strong></td>
</tr>
<tr>
<td>• General well-being, micturition, &amp; other possible complaints</td>
<td>• Assess general condition of baby:</td>
</tr>
<tr>
<td>• Fundal height, distended bladder</td>
<td>– Observe for active movement (tone)</td>
</tr>
<tr>
<td>• Perineum, vaginal bleeding, lochia, hemorrhoid</td>
<td>– Observe how baby is breastfeeding (positioning and breast attachment)</td>
</tr>
<tr>
<td>• Thrombophlebitis, signs of thrombosis</td>
<td>– Observe skin for signs of pallor and jaundice (yellowish eyes and skin) refer if present</td>
</tr>
<tr>
<td>• Temperature, if infection is suspected</td>
<td>– Assess vital sign if baby is not active</td>
</tr>
<tr>
<td>• Supplementation of micronutrients (iron, folate, iodized salt)</td>
<td>• Start vaccination with BCG and OPV0, HBV vaccine Birth as per the EPI guidance</td>
</tr>
<tr>
<td>• Counsel on safe disposal of potentially infectious soiled pads or other materials</td>
<td>• Advise on direct sunlight exposure for 20 minutes covering eyes and genitals</td>
</tr>
<tr>
<td>• Advice/counseling on maternal and newborn nutritional, physical, psychological and cultural needs</td>
<td></td>
</tr>
<tr>
<td>• Information regarding danger signs, where to seek help</td>
<td></td>
</tr>
<tr>
<td>• Counsel on sexual issues related to postpartum period, including family planning and provision of contraceptive methods</td>
<td></td>
</tr>
<tr>
<td>• Offer HIV testing if not done already</td>
<td></td>
</tr>
</tbody>
</table>
### At 3-7 Days

<table>
<thead>
<tr>
<th>Mother</th>
<th>Infant</th>
</tr>
</thead>
<tbody>
<tr>
<td>- General well-being, micturition, &amp; other possible complaints</td>
<td>- Assess general condition of baby:</td>
</tr>
<tr>
<td>- Fundal height, distended bladder</td>
<td>- Observe for active movement (tone)</td>
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<tr>
<td></td>
<td>jaundice (yellowish eyes and skin)</td>
</tr>
<tr>
<td></td>
<td>refer if present</td>
</tr>
<tr>
<td>- Supplementation of micronutrients (iron, folate, iodized salt)</td>
<td>- Assess vital sign if baby is not active</td>
</tr>
<tr>
<td>- Counsel on safe disposal of potentially infectious soiled pads or</td>
<td>- Give vaccination for BCG and OPV1 if not</td>
</tr>
<tr>
<td>other materials</td>
<td>given already</td>
</tr>
<tr>
<td>- Advice/counseling on maternal and newborn nutritional, physical,</td>
<td>- Advise on direct sunlight exposure for 20</td>
</tr>
<tr>
<td>psychological and cultural needs</td>
<td>minutes covering eyes and genitals</td>
</tr>
<tr>
<td>- Information regarding danger signs, where to seek help</td>
<td></td>
</tr>
<tr>
<td>- Counsel on sexual issues related to postpartum period, including</td>
<td></td>
</tr>
<tr>
<td>family planning and provision of contraceptive methods</td>
<td></td>
</tr>
<tr>
<td>- Offer HIV testing if not done already</td>
<td></td>
</tr>
</tbody>
</table>
At 6 weeks

- Assessment for signs of postpartum complications
- Assessment of nutritional status (MUAC and/or weight)
- Counsel on appropriate nutrition and micronutrient supplementation
- Counsel on family planning options and safe sex practices
- Counsel on breastfeeding and support as needed
- Counsel on personal hygiene and disposal of soiled pads.
- Micronutrient supplementation as appropriate
- Encourage on continued use of ITN for women living in malaria endemic areas
- Offer HIV testing if not already done

- Identify signs of complications
- Follow up on healthy baby care including developmental milestones
- Routine assessment including checking for weight gain
- Immunization: first dose of OPV, pentavalent vaccine, pneumococcal vaccine (PCV) and Rotavirus vaccine
- Plan for revisit and immunization of baby

The mother was not counseled and tested for HIV during pregnancy or labor and delivery provide counseling and testing services during postpartum so that the infant can get timely prophylaxes in case the mother’s test is positive. Provision of timely HTC greatly improves the success of PMTCT.

Postpartum care for HIV-positive women

In addition to routine postpartum care that is offered to all mothers, HIV-positive women should receive:

- Antiretroviral treatment:
  - If mother was identified as HIV-positive during labor and delivery,
initiate her on ART.
- Ensure linkage of all newly identified HIV positive mothers and HIV exposed infants to ANC clinic.
- If mother is on antiretroviral treatment, ensure she continues to take her medications during labor and postpartum period and check for adherence

- Extra nutrition and micronutrient supplement: continue iron and folate supplement for at least 6 weeks postpartum and longer if indicated; additional two varied meals per day are recommended to meet energy need and avoid malnutrition while breastfeeding.
- Counseling on how to express breast milk in case of engorgement or breast health problems.
- Refer if situation is unresolved and use the breast that is not swollen to feed the baby and seek medical help before it gets worse.
- Close monitoring for secondary postpartum hemorrhage, which may be more dangerous if a woman anemic.
- Early recognition and treatment of infections, including urinary tract infection, reproductive tract or obstetric infections (endometritis, wound infection from C/S or episiotomy/laceration repair), mastitis and breast abscess and respiratory infection
- Counseling regarding early initiation of family planning within three to four weeks of delivery; particularly if the woman chooses not to breastfeed, causing early return to normal fertility
- Reinforcement of safe sexual practice and need for dual protection
- Counseling about safe disposal of potentially infectious soiled sanitary pads or other garments
- A plan for an on-going care and follow up with appropriate HIV care services should be initiated.
- Information about social services and support in the community to assure long term support needs to be given to patient and her family.

Start ART as early as possible to all pregnant & breastfeeding women living with HIV regardless of their WHO clinical stages and CD4 counts. For women identified at labor & delivery, provide ART the same hour with brief counseling and provide detailed counseling on ARVs & Adherence after delivery.

Table 3.6: Summary of first-line ART regimens for adults, adolescents,
### pregnant and breast-feeding women

<table>
<thead>
<tr>
<th>Population</th>
<th>Preferred first Line Regimens</th>
<th>Alternative First Line regimens</th>
<th>Special circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>All pregnant and breast-feeding women, adolescent pregnant women weight ≥30 kg</td>
<td>TDF+ 3TC+ DTG* (FDC)</td>
<td>TDF + 3TC + EFV**</td>
<td>AZT+ 3TC + AT-V/r***</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + DTG</td>
<td>TDF+ 3TC+ ATV/r</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + EFV</td>
<td>ABC+ 3TC + DTG</td>
</tr>
</tbody>
</table>

### Care for HIV exposed Infants

#### A. Key principles for the care of infants born to HIV-positive mothers

- Respect confidentiality of the mother and family
- Care for the newborn like any other newborn but pay particular attention to infection prevention procedures.

#### B. Essential Newborn Care

- Wipe infant’s mouth and nostrils with gauze when the head is delivered
- Use airway suction only when meconium-stained liquid is present, and it is clinically indicated. Use mechanical suction <100mm Hg or bulb suction; never use mouth operated suction
- Clamp cord after birth and avoid milking the cord. Cover cord with gloved hand or gauze before cutting to avoid splashing of blood to the eyes
- Handle newborn with gloves
- Keep baby warm (skin to skin contact with mother)
- Clean all injection sites with antiseptic and dispose of needles and syringes into puncture-resistant sharp containers (refer to National Infection Prevention Guidelines for details)
- Administer eye care with antibiotic (Tetracycline 1% eye ointment) as soon as possible after birth
- Provide vitamin K

#### C. Immunization

- Give the newborn all routine immunizations, per national schedules
- Administer BCG, OPV 0, and HBV vaccines Birth dose,
• Pentavalent (DPT-HepB-Hib), PCV, Rota, measles, OPV & IPV vaccine
• Refer to national EPI recommendations for details.

D. Infant feeding

• Support initiation of breastfeeding within one hour of delivery
• Promote and support exclusive breastfeeding for the first six months for all infants, including HIV-exposed infants:
• Breastfeeding should be on demand, which is usually 8-12 times per day
• Inform mother that formula feeding can increase the risk of illness and death from contaminated water and bottles and that breastfed babies are more likely to grow and develop well.
• Explain to the mother that even if there is a small risk of HIV transmission through breastfeeding, breast milk is shown to give the best chance of health and survival even for babies born to HIV-positive mothers
• Encourage mothers to breastfeed exclusively for the first 6 months
• Explain the risks of replacement feeding and inform mothers that replacement feeding is not recommended for any infant; however, feeding choice of the mother should be respected with appropriate counseling.
• Provide practical/hands-on help to the mother for successful breastfeeding
• Counsel mothers on safe breastfeeding practice and support her practice with correct positioning and attachment to prevent mastitis and injury to mother’s nipples
• Advise the mother to return immediately if she encounters breast or nipple problems, or if baby has difficulty feeding. If she has sores on one breast, she should express, and heat treat or throw out that milk and feed from the other breast.
• Promptly manage breast problems such as mastitis, cracked nipples etc.
• Ensure breastfeeding mothers are on ART
• Provide nutritional and psychosocial support to mothers
• In settings where health services provide and support lifelong ART, including adherence counseling, and promote and support breastfeeding among women living with HIV, the duration of breastfeeding should not be restricted.
• Mothers living with HIV and health-care workers can be reassured that ART reduces the risk of postnatal HIV transmission in the context of mixed
feeding. Although exclusive breastfeeding is recommended, practicing mixed feeding is not a reason to stop breastfeeding in the presence of ARV drugs.

- Introduce complementary feeding at 6 months. Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or longer (similar to the general population) while being fully supported for ART adherence (see the WHO consolidated guidelines on ARV drugs for interventions to optimize adherence).

E. ARV & co-trimoxazole prophylaxis for HEIs

- Administer Enhanced postnatal prophylaxis: AZT (twice daily) + NVP (once daily) for the first six weeks and thereafter NVP (once daily) alone for additional 6 weeks for the newborn; check adherence to infant prophylaxis during follow-up.
- Start co-trimoxazole prophylaxis for all HIV exposed infants at 6 weeks of age and continue until HIV negative status is confirmed.
- Counsel and encourage the mother on early intervention for any infection or illnesses.

Table 3.7: AZT+NVP prophylaxis dose for HEIs

<table>
<thead>
<tr>
<th>Infant age</th>
<th>NVP daily dosing</th>
<th>Dose in ml</th>
<th>AZT daily dose</th>
<th>Daily dose in ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 6 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth weight &lt; 2000 g</td>
<td>2mg/g daily once</td>
<td>0.2ml/kg once daily</td>
<td>2mg/kg twice daily</td>
<td>0.2ml/kg twice daily</td>
</tr>
<tr>
<td>Birth weight: 2000-2499 g</td>
<td>10 mg once daily</td>
<td>1ml once daily</td>
<td>10mg twice daily</td>
<td>1ml twice daily</td>
</tr>
<tr>
<td>Birth weight &gt; 2500 g</td>
<td>15mg once daily</td>
<td>1.5ml once daily</td>
<td>15mg twice daily</td>
<td>1.5ml twice daily</td>
</tr>
</tbody>
</table>
**Table 3.8: COTRIMOXAZOLE PROPHYLAXIS THERAPY (CPT)**

<table>
<thead>
<tr>
<th>Age</th>
<th>Suspension per 5ml (200/40mg)</th>
<th>Pediatric tablet (100/20mg)</th>
<th>Single strength adult tablet (400/80 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6 months</td>
<td>2.5 ml</td>
<td>1 tablet</td>
<td>¼ tablet</td>
</tr>
<tr>
<td>6 months – 5 years</td>
<td>5 ml</td>
<td>2 tablets</td>
<td>½ tablet</td>
</tr>
</tbody>
</table>

**F. HIV testing for HIV exposed Infants**

There are broadly two types of HIV testing that can be performed on infants: Serological/antibody tests, and virological/DNA PCR tests. For babies under the age of 18 months, antibody testing can be used as a screening tool to determine if a child has been exposed to HIV. However, they cannot be used to confirm if an infant has become infected. Therefore, all infants born to HIV-in-
Infected women should be tested using DNA PCR test at the age of 6 weeks. Additionally, do DNA PCR testing at 9 months of age for those who tested negative at 6 weeks of age (See table 3.9).

NB: Babies under the age of 18 months born to women of unknown HIV status should get an antibody test and, if found positive, should get a DNA PCR test to confirm HIV status of the infant.

- Perform DNA PCR testing for any HIV exposed child who presents outside the national infant testing algorithm with clinical symptoms, regardless of previous DNA PCR test results
- Ensure that indeterminate test results are retested immediately and given priority for rapid resolution.
- Ensure that confirmatory testing is undertaken following any positive result.

Table 3.9: HIV testing results interpretation in children

<table>
<thead>
<tr>
<th>Age</th>
<th>HIV testing</th>
<th>Interpretation of results</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18 months</td>
<td>HIV antibody test (rapid HIV test)</td>
<td>If positive, test does not reliably confirm HIV infection but shows child has been exposed to HIV as passive transfer of maternal antibodies can cause positive test results. If negative and not breastfed for last 12 or more weeks, the baby is neither exposed nor infected</td>
<td>Do DNA PCR test</td>
</tr>
<tr>
<td>HIV virological test (DNA PCR using DBS/whole blood) Used for diagnosis in HIV exposed infants and young children less than 18 months</td>
<td>Positive virological test results indicate child is infected</td>
<td>Take sample for repeat DNA PCR and Start ART immediately.</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Negative virological test in an infant with breastfeeding implies the child is not infected but still exposed</td>
<td>Repeat DNA PCR at 9 months. Start ART if result is positive after taking sample for confirmatory DNA PCR. Perform antibody test once breastfeeding is discontinued for 12 weeks or at 18 months of age if repeat PCR test result at 9 months is negative.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative virological test in an infant NEVER breastfed implies the child is most likely uninfected</td>
<td>Perform confirmatory antibody test at &gt; 18 months of age.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;18 months</td>
<td>HIV antibody test</td>
<td>Results valid as for adults. Negative= the child is not infected; Positive=the child is infected</td>
<td>If negative and still breastfeeding– repeat test once at &gt; 12 weeks after complete cessation of breastfeeding.</td>
</tr>
</tbody>
</table>
HIV-exposed infant or child (4–6 weeks to 18 months)

Conduct DNA PCR \(\text{a (at 4–6 weeks or at the earliest opportunity thereafter)}\)

Positive

Infant/child is infected

Immediately start ART \(\text{b}\)

Repeat DNA PCR to confirm Infection

Negative

HIV infection not detected but if infant/child is breastfed the risk of acquiring HIV infection remains until complete cessation of breastfeeding

Regular clinical monitoring

Conduct DNA PCR \(\text{b (at 9 months)}\)

Negative

HIV unlikely unless still breastfeeding \(\text{d}\)

Antibody testing at 18 months of age or 3 months after cessation of breastfeeding, whichever is later \(\text{e}\)

Positive

Infant/child is infected

Immediately start ART \(\text{b}; \) Repeat DNA PCR to confirm infection

---

**Figure 3.3 infant diagnosis algorithms**

**Note:**

- a Point-of-care DNA PCR can be used to diagnose HIV infection as well as to confirm positive results.
- b Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase retesting after a first positive DNA PCR is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third DNA PCR should be performed before interrupting ART.
- c For children who were never breastfed, additional testing following a negative DNA PCR at 4–6 weeks is included in this algorithm to account
for potential false-negative DNA PCR results.

- The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.

- If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age DNA PCR should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

- If a child tested negative for DNA PCR becomes symptomatic suggestive of HIV infection, do PCR test.

**DNA PCR testing at birth (Birth testing)**

Currently birth testing is not endorsed in our context as recommended by WHO 2021. It can be considered in the future after strengthening the POC EID services and ensuring the availability of ARV for the new born as an additional opportunity of testing to identify HIV infection in HEI.

**G. Monitor growth and development**

- At each postnatal visit, monitor growth and development and provide counseling and necessary referrals to promote optimal growth
- Explain the importance of monthly growth monitoring and promotion as HIV-exposed infants are more likely to experience growth problems.
- Assess growth and development with emphasis on the critical developmental milestones

**H. Follow-up care and treatment**

- Close follow-up for the first 24 hours, Follow-up visit at 3–7 days, 6 weeks, 10 weeks, 14 weeks, then monthly until six months, and thereafter every 3
months until 18 months if infant is asymptomatic (Table 3.10).

- During the postnatal period, the mother and newborn should be seen together in ANC unit to follow the mother and HEI as a cohort to be able to see the outcome of PMTCT interventions.
- Early neonatal care should be closely linked with on-going services for health care, including Integrated Management of Childhood Illnesses wherever it is implemented.
- Reassess fully (history and physical examination that includes growth and development, screening for TB, laboratory investigations) at each follow-up visit.
- Whenever possible manage the child in the same clinic as the mother or refer to HIV/ART clinic if child:
  - has a positive virological test
  - is suspected of having symptomatic HIV or displays any severe classification possibly due to HIV or has positive antibody test under 18 months and has 2 or more of the following: oral thrush, severe pneumonia or severe sepsis
  - Presents with severe acute malnutrition or moderate acute malnutrition that does not respond normally to treatment

Table 3.10: Follow up visit schedule for HIV exposed infants

<table>
<thead>
<tr>
<th>Age in weeks/months</th>
<th>At birth</th>
<th>6 weeks</th>
<th>10 weeks</th>
<th>14 weeks</th>
<th>5 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
<th>15 months</th>
<th>18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Physical exam</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Growth assessment</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Developmental assessent</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Infant feeding counseling</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
### Determination of HIV status

| **ARV (AZT+NVP) for the first 6 weeks** | **x** | | | |
| **ARV (NVP alone) for additional 6 weeks** | **x** | **x** |
| **Cotrimoxazole Preventive Therapy** | **x** | Continue until HIV is excluded and infant is no longer at risk from breastfeeding |

#### TB Risk Assessment

- At each visit

#### Immunizations

- x x x x x x x

#### Adherence counseling

- x x x x x x x x

#### Vitamin A

- x x x

*This is the minimum; children should be seen more frequently if clinically indicated.

### 3.4 Prevention of congenital syphilis

Syphilis is a sexually transmitted infection that can have multiple different presentations but also be asymptomatic. Syphilis can be transmitted sexually, vertically from mother to child and directly through blood transmission.

The signs of secondary syphilis occur six to eight weeks after the primary ulcer (chancre) and include a generalized rash (including palms and soles), flu-like symptoms, flat wart-like genital lesions (Condyloma Lata), mouth ulcers and patchy hair loss. Tertiary syphilis occurs many years later and affects skin, bone, heart and nervous system. A genital ulcer caused by syphilis will resolve spontaneously within four to six weeks without treatment; however, the syphilis infection persists, and the ulcer resolving does not represent cure.

Syphilis remains a significant cause of preventable perinatal death. Although approximately 80% of women infected with Syphilis in Sub-Saharan Africa do
attend Antenatal Care (ANC) services at least once, during these visits only an estimated 39% of women are actually screened for Syphilis. In Ethiopia, syphilis prevalence estimates for women attending ANC ranged from 0.90% to 2.10%, with only an estimated 65.9% of women receiving screening for syphilis. Many women may remain undetected and untreated. Adverse pregnancy outcomes occur in up to 80% of syphilis seropositive, untreated pregnant women. Greater emphasis is therefore needed on the process of screening and effectively treating mothers, their partners, and their infants affected by syphilis.

The risk of fetal infection during untreated early maternal syphilis is ~75–95%, decreasing to ~35% for maternal syphilis of >2 years’ duration. Adequate treatment of the woman before the 16th week of pregnancy should prevent fetal damage, and treatment before the third trimester should adequately treat the infected fetus. Untreated maternal infection may result in a rate of fetal loss of up to 40% with stillbirth (more common than abortion because of the late onset of fetal pathology), prematurity, neonatal death, or nonfatal congenital syphilis. Among infants born alive, only fulminant congenital syphilis is clinically apparent at birth, and these babies have a very poor prognosis. The most common clinical problem is the healthy appearing baby born to a mother with a positive serologic test.

**Risks for congenital syphilis:**

**Low risk:**
- Mother is treated appropriately >4 weeks before birth
- Treatment completed > 4 weeks before birth
- Mother treated with the correct penicillin regimen for the stage of syphilis
- Maternal 4-fold drop in RPR achieved
- Final RPR titer ≤ 1:4 (VDRL 1:2)

**High risk:** situations where infants require further evaluation and treatment at birth include the following:
- Maternal syphilis not treated or inadequately treated, or treatment inadequately
- Documented
- Maternal syphilis treated but with inadequate follow-up or without a satisfactory 4-fold drop in RPR titer
- Treatment of syphilis in pregnancy with a non-penicillin regimen includ-
ing ceftriaxone

- Treatment of the mother < 30 days prior to the birth (maternal treatment unlikely to have adequately treated the fetus)
- Final RPR titer > 1:4 (VDRL > 1:2)
- Abnormal fetal ultrasound findings

3.4.1 Screening for syphilis during ANC

WHO recommends screening all pregnant women for Syphilis at the first antenatal care visit. Effective prevention and detection of congenital syphilis depends on the identification of syphilis in pregnant women. But still Syphilis-infected pregnant women often go undiagnosed and untreated. Early diagnosis and treatment of Syphilis in pregnant women has been proven as an effective strategy in the prevention of both adverse outcomes of pregnancy and Mother-To-Child-Transmission.

It is important to know what type of test is being used to test for syphilis. Older syphilis tests are of the RPR type (non-treponemal test). False positive RPRs can occur. It is therefore good practice to confirm any positive RPR with a TPHA/FTA test (treponemal test). TPHA remains positive for life, but an RPR changes in titer in response to treatment or disease progression. Consider re-infection if the RPR titer increases by four times or more. Conversely, if a TPHA is used as the first test (as what is used in the HIV-syphilis combination or standalone syphilis rapid test), the positive result should be confirmed using an RPR. The RPR will determine if the positive TPHA result indicates a current active infection or an earlier infection.

- Routine serologic screening of pregnant women during the first prenatal visit.
- Additional testing at 28 weeks’ gestation using RPR and again at delivery is warranted for women who are at increased risk or living in communities with increased prevalence of syphilis infection.
- Routine screening of newborn sera or umbilical cord blood is not recommended, as diagnosis at this time does not prevent symptomatic congenital syphilis in some newborns.
- No mother or newborn infant should leave the hospital without maternal serologic status having been documented at least once during pregnancy, and preferably again at delivery if at risk.

NB: dual HIV &syphilis testing recommended for all pregnant women
coming for ANC.

**Dual Detection of HIV and Syphilis for ANC Program**

WHO recommends that pregnant women receive testing for HIV, syphilis and hepatitis B (HBsAg) at least once during pregnancy, preferably in the first trimester. Dual HIV/syphilis rapid diagnostic tests (RDTs) can be used as the first test for pregnant women as part of antenatal care (ANC). These simple tests can be used at the point-of-care and are cost-saving compared to standard testing in ANC. They enable more women to be diagnosed with HIV and syphilis so that they can access treatment and prevent transmission to their children.

Dual/HIV syphilis RDTs detects antibodies to both Treponemal pallidum (TP) (the cause of syphilis infection) and HIV. Like other RDTs used for HIV alone, they do not require refrigeration. Available products currently do not discriminate between active or past syphilis infections. This means that, if a person has had syphilis that is treated/resolved, and treponemal antibodies persist, the dual/HIV syphilis RDT may produce a reactive result for syphilis.

**Advantages of rapid dual HIV/syphilis tests in ANC**

Use of a dual HIV/syphilis RDT as the first test in ANC offers the opportunity to test for both infections with a single finger prick. Results are available quickly, enabling many to start either or both HIV treatment and syphilis treatment with benzathine penicillin.

All women whose dual HIV/syphilis test results include a reactive TP (syphilis) result should be treated using benzathine penicillin and referred for further testing to provide final diagnosis of active syphilis.

**Dual HIV/syphilis rapid testing strategy and algorithm for ANC**

The testing strategy needed for dual detection of HIV and syphilis (Fig. 3.4) differs from the recommended strategies for separately testing for HIV or syphilis.

It is important not to use the rapid dual HIV/syphilis test for:

1. Women with HIV taking antiretroviral therapy (ART);
2. Women already diagnosed with and treated for syphilis during their current pregnancy; and
3. Retesting for HIV
Fig.3.4: Dual HV/Syphilis rapid diagnostic test algorithm

A1 is a dual HIV/syphilis rapid diagnostic test (RDT)
A2 and A3 (Assay 2 and Assay 3) are HIV RDTs or enzyme immunoassays (EIAs).

When resolving discrepant results, all reactive TP (syphilis) results, including
A1: TP+ or Repeat A1:TP+, should be referred for treatment and further testing according to national guidelines.

When resolving discrepant results, if A1 and Repeat A1 are both TP (syphilis) nonreactive results, report syphilis negative.

**3.4.2 Basic management of syphilis to prevent MTCT of congenital syphilis**

Penicillin G is the drug of choice for all stages of syphilis. T. pallidum can be killed by very low concentrations of penicillin G, although a long period of exposure to penicillin is required because of the unusually slow rate of multiplication of the organism. The efficacy of penicillin against syphilis remains undiminished after 70 years of use, and there is no evidence of penicillin resistance in T. pallidum.

**A. Management of Syphilis positive pregnant mothers**

**Table 3.11 Management of Syphilis positive pregnant mothers**

<table>
<thead>
<tr>
<th>STAGE</th>
<th>Preferred Tx without penicillin allergy</th>
<th>Alternative Tx with penicillin allergy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early syphilis in pregnancy (primary, secondary, early latent but excluding neurosyphilis)</td>
<td>Trimester 1 or 2 (up to and including 27 weeks): Benzathine benzyl penicillin tetra hydrate 2,400,000 units/4.6 ml intramuscularly as a single dose</td>
<td>Desensitize and treat With penicillin. If desensitization not possible use Erythromycin 500mg 6 hourly/PO for 14 days</td>
</tr>
<tr>
<td></td>
<td>Trimester 3 (from week 28 to term): Benzathine benzyl penicillin tetra hydrate 2,400,000 units/4.6 ml intramuscularly, on days 1 and 8 (2 doses)</td>
<td></td>
</tr>
<tr>
<td>Late syphilis in pregnancy and syphilis of unknown duration (all three trimesters)</td>
<td>Benzathine Benzyl penicillin tetra hydrate 2,400,000 units/4.6 ml weekly on days 1, 8 and 15 (three doses). If there is any doubt about the time of acquisition in latent disease, it should be treated as late latent syphilis.</td>
<td>Desensitize and treat With penicillin. If desensitization not possible use Erythromycin 500mg 6 hourly/PO for 28 days</td>
</tr>
</tbody>
</table>
Neurosyphilis
(all trimesters)

Aqueous crystalline penicillin G (18–24 mU/d IV, given as 3–4 mU q4h or continuous infusion) for 10–14 days; or

Aqueous procaine penicillin G (2.4 mU/d IM) plus oral probenecid (500 mg qid), both for 10–14 days

Desensitize and treat with penicillin.

- Primary and secondary syphilis are easy to treat with a penicillin injection.
- Penicillin is one of the most widely used antibiotics and is usually effective in treating syphilis.
- People who are allergic to penicillin will likely be treated with a different antibiotic, such as:
  - Erythromycin
  - Azithromycin (Azithromycin tabs 2G STAT)
  - Ceftriaxone (IM Ceftriaxone 1G OD for 14 days)

Remarks: Although erythromycin and azithromycin treat the pregnant women, they do not cross the placental barrier completely and as a result the fetus is not treated. It is therefore necessary to treat the newborn infant soon after delivery.

NB: If the mother was treated with non-penicillin treatment, the baby should be treated as having congenital syphilis.

B. Diagnosis and treatment of neonates born to syphilis positive mother

I. Diagnosis of congenital Syphilis in neonates

- The diagnosis of congenital syphilis can be difficult, as maternal Non-treponemal and Treponemal IgG antibodies can be transferred through the placenta to the fetus, complicating the interpretation of reactive serologic tests for syphilis in neonates.
- Therefore, treatment decisions frequently must be made on the basis of:-
  - Identification of syphilis in the mother;
  - Adequacy of maternal treatment
  - Presence of clinical, laboratory, or radiographic evidence of syphilis in the neonate ;( bone abnormalities)
  - Presence of neonatal nontreponemal serologic titers (not specific
can be maternal)

NB: Any neonate at risk for congenital syphilis should receive a full evaluation and testing for HIV infection as well.

II. Treatment of congenital Syphilis in infants

In infants with confirmed congenital syphilis or infants who are clinically normal, but whose mothers had untreated syphilis, inadequately treated syphilis (including treatment within 30 days of delivery) or syphilis that were treated with non-penicillin regimens, treat the infant with aqueous benzyl penicillin or procaine penicillin.

Table 3.12 Treatment of congenital Syphilis in infants

<table>
<thead>
<tr>
<th>Stage</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants with Congenital syphilis</td>
<td>Benzyl penicillin 100 000–150 000 U/kg/day IV for 10–15 days (IV 50,000 units/kg/dose BID during the first 7 days of life and then TID thereafter) OR Procaine penicillin 50 000 U/kg/day IM daily for 10–15 days</td>
</tr>
</tbody>
</table>

NB: If more than 1 day of therapy is missed, the entire course should be restarted.

If a non-penicillin G agent is used, close clinical, serologic, and CSF follow-up is required in consultation with an expert.

- Neonates with a negative nontreponemal test at birth and whose mothers were seroreactive at delivery should be retested at 3 months to rule out serologically negative incubating congenital syphilis at the time of birth.
- Treponemal tests should not be used to evaluate treatment response because the results are qualitative and passive transfer of maternal IgG treponemal antibody might persist for at least 15 months.
- Infant treponemal tests can be positive due to passively transferred antibodies but this should usually disappear by 15 months of age.
- Positive treponemal tests after 18 months is diagnostic of congenital syphilis

Infants born to mothers with syphilis and HIV require the same evaluation, therapy or follow-up as is recommended for all infants exposed to syphilis in-utero.
### A. Treatment of Syphilis for sexual partners

#### Table 3.13 Treatment of Syphilis for sexual partners

<table>
<thead>
<tr>
<th>STAGE</th>
<th>Preferred Tx without penicillin allergy</th>
<th>Alternative Tx with penicillin allergy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary, secondary, or early latent</td>
<td>CSF normal or not examined: Penicillin G Benzathine (single dose of 2.4M IU IM) OR Procaine Penicillin 1.2MU Daily for 10 days CSF abnormal: Treat as neurosyphilis.</td>
<td>CSF normal or not examined: Tetracycline HCl (500 mg PO qid) or Doxycycline (100 mg PO bid) for 2 weeks CSF abnormal: Treat as neurosyphilis.</td>
</tr>
<tr>
<td>Late latent (or latent of unknown duration), cardiovascular, or benign tertiary</td>
<td>CSF normal or not examined: Penicillin G Benzathine (2.4 mU IM weekly for 3 weeks) CSF abnormal: Treat as neurosyphilis.</td>
<td>CSF normal and patient not infected with HIV: Tetracycline HCl (500 mg PO qid) or Doxycycline (100 mg PO bid) for 4 weeks CSF normal and patient infected with HIV: Desensitize and treat with penicillin if compliance cannot be assured. CSF abnormal: Treat as neurosyphilis.</td>
</tr>
<tr>
<td>Neurosyphilis (asymptomatic or symptomatic)</td>
<td>Aqueous crystalline penicillin G (18–24 mU/d IV, given as 3–4 mU q4h or continuous infusion) for 10–14 days; or Aqueous procaine penicillin G (2.4 mU/d IM) plus oral probenecid (500 mg qid), both for 10–14 days</td>
<td>Desensitize and treat with penicillin.</td>
</tr>
</tbody>
</table>
The Jarisch-Herxheimer reaction occurs in ~50% of patients with primary syphilis, 90% of those with secondary syphilis, and a lower proportion of persons with later-stage disease.

- Self-limited reaction to anti-treponemal therapy
  - Fever, malaise, nausea/vomiting, sweating, and headache; may be associated with chills and exacerbation of secondary rash. In secondary syphilis, erythema and edema of the cutaneous lesions may increase.
- Occurs within 12-24 hours after treatment with penicillin.
- Not an allergic reaction to penicillin
- More frequent after treatment with penicillin and treatment of early syphilis
- Antipyretics can be used to manage symptoms, but they have not been proven to prevent this reaction.
- Pregnant women should be informed of this possible reaction, that it may precipitate early labor, and to call obstetrician if problems develop. Steroid therapy is not required for this mild transient reaction.

Follow up

- Primary or secondary syphilis
  - Reexamine at 6 and 12 months.
  - Follow-up titers should be compared to the maximum or baseline non-treponemal titer obtained on day of treatment.
- Latent syphilis
  - Reexamine at 6, 12, and 24 months.
- HIV-infected patients
  - 3, 6, 9, 12 and 24 months for primary or secondary syphilis
  - 6, 12, 18, and 24 months for latent syphilis
- Neurosyphilis
  - Serologic testing as above
  - Repeat CSF examination at 6-month intervals until normal
- Congenital Syphilis
  - If a non-penicillin G agent is used, close clinical, serologic, and CSF follow-up is required in consultation with an expert.
  - Neonates with a negative nontreponemal test at birth and whose moth-
ers were sero-reactive at delivery should be retested at 3 months to rule out serologically negative incubating congenital syphilis at the time of birth.

- Treponemal tests should not be used to evaluate treatment response because the results are qualitative and passive transfer of maternal IgG treponemal antibody might persist for at least 15 months.
- Infant treponemal tests can be positive due to passively transferred antibodies but this should usually disappear by 15 months of age.
- Positive treponemal tests after 18 months is diagnostic of congenital syphilis

3.5 Prevention of MTCT of Hepatitis B

Hepatitis B Virus (HBV) is a DNA virus, which causes acute and chronic hepatitis that could range from asymptomatic carrier states to fulminant liver failure. Acute Hepatitis B virus is usually self-limited and resolves but in few groups of individuals it may progress. Diagnosis and treatment of HBV should aim in viral suppression and prevention of complications such as cirrhosis, and hepatocellular carcinoma and end stage liver disease, and prevention of MTCT. HBV is prevalent in Ethiopia and based on few studies it has a prevalence of 8-12%. A systematic review and meta-analysis of HBV infection among pregnant women in Ethiopia indicated that the prevalence among the included studies ranges from a minimum of 2.3% in southern Ethiopia to a maximum of 7.9% in Gambella Hospital. The pooled prevalence of HBV infection among pregnant women was 4.8%. Hepatitis B virus causes both acute and chronic infection. If left untreated, chronic HBV infection can cause liver cirrhosis, liver failure and hepatocellular carcinoma.

Transmission of HBV from mother to child is more common in children born to women who have a high viral load and/or are positive for the hepatitis B e antigen (HBeAg). Besides, pregnant women tested positive for HBV infection (HBsAg positive) with an HBV DNA $\geq 5.3 \log_{10} \text{IU/mL} \geq 200,000 \text{IU/mL}$ must receive antiviral prophylaxis to prevent transmission of HBV from mother-to-child. Regardless of HBsAg status of the mother during pregnancy, a timely birth dose of hepatitis B vaccine for the infant must be given to prevent HBV transmission from the mother to the child. In contrast, maternal HBIG administration does not provide additional protection to the infant. Very high maternal concentrations of HBV DNA, typically observed in HBeAg-positive women, are
associated with an elevated risk of transmission (ranging from 20% in Asia to 32% in Africa), despite vaccine prophylaxis and HBIG. This compares to less than 1% transmission in Asia and Africa among HBeAg-negative women. Evidence suggests that the use of antivirals may suppress HBV DNA levels and reduce transmission of HBV to infants of HBsAg-positive women. Therefore, the use of antiviral prophylaxis during pregnancy for pregnant women with high HBV DNA levels is essential to prevent perinatal HBV infection. The use of antiviral prophylaxis in addition to infant immunization is consistent with approaches used to prevent mother-to-child transmission of HIV and syphilis.

This provides opportunities for integrated triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B. In addition, 6.1% of women with HIV infection have coinfection with HBV. HIV treatment with tenofovir-based antiretroviral therapy (ART) for women living with HIV provides an opportunity to simultaneously treat those with HBV coinfection, and reduce mother-to-child transmission of HBV alongside that of HIV.

3.5.1 Screening for Hepatitis B during ANC

All pregnant women should be tested for hepatitis B surface antigen (HBsAg) at least once and as early as possible particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

**Lab investigation using serological markers for HBV**

**Hepatitis B surface antigen (HBsAg)**
- HBV envelope protein and excess coat particles detectable in the blood in acute and chronic hepatitis B infection
- Hepatitis B core antigen (HBCAg)
- HBV core protein: The core protein is coated with HBsAg and therefore not found free in serum
- Hepatitis B e antigen (HBeAg)
- Viral protein found in the high replicative phase of hepatitis B. HBeAg is usually a marker of high levels of replication with wild-type virus but is not essential for viral replication
- Hepatitis B surface antibody (anti-HBs)
- Antibody to HBsAg: Develops in response to HBV vaccination and during recovery from acute hepatitis B, denoting past infection and immunity

**Anti-HBe**
- Antibody to HBeAg: Detected in persons with lower levels of HBV replication but
also in HBeAg-negative disease (i.e., HBV that does not express HBeAg)

**Hepatitis B core antibody (anti-HBc)**

- Antibody to hepatitis B core (capsid) protein: Anti-HBc antibodies are not neutralizing antibodies and are detected in both acute and chronic infection.

**IgM anti-HBc**

- Subclass of anti-HBc. Detected in acute hepatitis B but can be detected by sensitive assays in active chronic HBV.

**IgG anti-HBc:** Subclass of anti-HBc detected in past or current infection.

For serologic lab tests algorithm, refer figure 3.5 below.
3.5.2. Prophylaxis for the mother to prevent mother-to-child transmission of HBV

Since the indications for treatment in HBV-infected pregnant women are the same as that for other adults, all pregnant women should first be assessed for eligibility for long-term treatment based on their own health needs before initiation of prophylaxis. If not eligible for treatment, providing prophylaxis with antivirals during the third trimester of pregnancy is effective in reducing mother-to-child transmission of HBV.

- Pregnant women tested positive for HBV infection (HBsAg positive) with an HBV DNA $\geq 5.3 \text{ log}_{10} \text{ IU/mL} \geq 200,000 \text{ IU/mL}$ should receive tenofovir 300mg daily prophylaxis from the 28th week of pregnancy until at least birth to prevent mother-to-child transmission of HBV.
- In settings in which antenatal HBV DNA testing is not available, HBeAg testing can be used as an alternative to HBV DNA testing to determine eligibility for tenofovir prophylaxis to prevent mother-to-child transmission of HBV.
- Pregnant or postpartum women should be linked to chronic care for Tenofovir treatment when there is cirrhosis or persistently elevated alanine aminotransferase plus HBV viral load $\geq 5.3 \text{ log}_{10} \text{ IU/ml} \text{ (or } > 20,000 \text{ IU/ml) or HBeAg positive.}$

3.5.3. Infant intervention for the prevention of hepatitis B

Birth dose of hepatitis B vaccine:

Regardless of HBsAg status of the mother during pregnancy, all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, and that the birth dose be followed by three doses of hepatitis B vaccine at least four weeks apart (at 6th week, 10th week and 14th week of age) to complete the primary series.

**Hepatitis B immune globulin (HBIG) for HBV exposed infants:**

If available, it is recommended to give single dose hepatitis B immune globulin (HBIG) shortly after birth for infants born to HBsAg positive mothers (especially
if HBeAg positive or with high HBV DNA).

### 3.6 Treatment, Care and Support for HIV Positive Mother and Her Exposed Infant

#### Basic Principles for use of Antiretroviral Drug for PMTCT

- PMTCT services are provided in RMNCAH platform
- All HIV positive pregnant and lactating women should be initiated on ART irrespective of CD4 count and WHO clinical stage
- Adherence counselling should be provided at all antenatal care and postnatal visits to ensure that viral suppression is maintained throughout pregnancy and breast-feeding.
- Viral load should be done for newly HIV positive pregnant mothers at 3 months, at 34–36 weeks of GA or delivery at the latest, followed by three months after delivery and then every 6 months.
- For women already on ART, conduct VL testing at 1st contact at ANC (VL result conducted in the last 3 months before 1st contact can also be used), at 34–36 weeks of GA or delivery at the latest, followed by three months after delivery and then every 6 months. For details see table 3.14
- CD4 count should be done as a baseline and as required for OI monitoring and management purposes
- Family planning counseling should begin during ANC visit and FP options chosen and need to be attached on the integrated maternal or women’s card so that she is provided the option when she is back at six weeks postpartum
- Postpartum family planning counseling and method provision should be given to all HIV positive mothers in an integrated manner in the ART unit and in RMNCAH platform
- Transfer out HIV positive pregnant women on ART to ANC unit per national recommendations and register for Mother–baby–pair cohort follow up for nearly two years in RMNCAH platform.
- Transfer out HIV positive mothers who are under ANC registered for mother–baby–pair cohort follow up, following cessation of breastfeeding and testing the child post weaning, to ART unit after ensuring issues of accessibility and adherence are addressed.
ART (Antiretroviral Therapy): is the use of 3 or more ARV drugs simultaneously to treat HIV infection. ART is a life-long treatment for the mother that can also significantly reduce MTCT.

ARV prophylaxis: is short-term use of ARV drug for HIV exposed infants to prevent mother to–Child transmission of HIV.

When to start ART in pregnant and breast-feeding women

Start ART as early as possible to all pregnant & breastfeeding women living with HIV regardless of their WHO clinical stages and CD4 counts. For women identified at labor & delivery, provide ART the same hour with brief counseling and provide detailed counseling on ARVs & Adherence after delivery.

What ART regimen to start

1. TDF+ 3TC + DTG: Triple ARV started as soon as diagnosed and continued for life
2. If HIV positive woman who is already on ART gets pregnant, she should stay on the same
3. Regimen if their VL is suppressed.
4. An infant born to a mother who is on ART will be put on Nevirapine + Zidovudine for 6 weeks starting at birth; and Nevirapine alone for the next 6 weeks.

Table 3.14: Summary of first-line ART regimens for adults, adolescents, pregnant and breastfeeding Women

<table>
<thead>
<tr>
<th>Population</th>
<th>Preferred first-line regimens</th>
<th>Alternative first-line regimens</th>
<th>Special circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant, childbearing and breastfeeding women, Adolescents (10 to 19 years OR weight ≥30 kg) (including those with TB/ HIV- co infection)</td>
<td>TDF+ 3TC+ DTG* (FDC)</td>
<td>TDF + 3TC + EFV</td>
<td>AZT+ 3TC + ATV/r</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + DTG</td>
<td>TDF+ 3TC+ ATV/r</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + EFV</td>
<td>ABC+ 3TC+ DTG</td>
</tr>
</tbody>
</table>
Rationale for using TDF/3TC/DTG in HIV positive pregnant women

- TDF is more suitable for HIV+ pregnant women than AZT, because it does not cause anemia, which is common during pregnancy; and is less likely to cause long-term side effects.
- TDF/3TC also treats Hepatitis B virus co-infection

Benefits of DTG as preferred first line ARV

- More rapid and higher viral suppression
- Faster CD4 cell count recovery rates
- Higher genetic barrier against drug resistance
- Safer - lower risk of toxicity
- Lower potential for drug–drug interactions

Monitoring of drug toxicities and substitution of ARV

Major types of ARV toxicities

The major causes of drug discontinuation in the first 3–6 months after initiating ART are due to drug toxicities; and hence, they must be closely monitored. They typically occur from few weeks to months after ART initiation or change. The most common side effects of ARV drugs recommended for Ethiopia in these national guidelines are provided in the table below.
Table 3.15 Types of toxicities associated with first, second and third-line ARV drugs

<table>
<thead>
<tr>
<th>ARV drug</th>
<th>Major types of toxicity</th>
<th>Risk factors</th>
<th>Suggested management</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>Hypersensitivity reaction.</td>
<td></td>
<td>Substitute with TDF or AZT for first line, substitute with TDF, for second line.</td>
<td></td>
</tr>
<tr>
<td>ATV/r</td>
<td>Electrocardiographic Abnormalities (PR and QRS interval prolongation).</td>
<td>Pre-existing conduction system disease: concomitant use of other drugs that may prolong the PR interval</td>
<td>Use with caution in people with preexisting conduction disease or who are on concomitant drugs they may prolong the PR or QRS interval</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indirect hyperbilirubinemia (clinical jaundice)</td>
<td>Underlying hepatic disease, HBV and HCV co-infection; Concomitant use of hepatotoxic drugs.</td>
<td>This phenomenon is clinically benign but potentially stigmatizing. Substitute with LPV/r only if adherence compromised.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal stone</td>
<td>History of renal stone.</td>
<td>Substitute with LPV/r.</td>
<td></td>
</tr>
<tr>
<td>AZT</td>
<td>Anemia, neutropenia</td>
<td>Baseline anemia or neutropenia CD4 count ≤200 cells/mm3.</td>
<td>Avoid use of AZT for people with HIV and severe anemia at baseline (hemoglobin &lt;7.0 g/dl) as first-line therapy. Substitute with TDF or ABC.</td>
<td></td>
</tr>
<tr>
<td>Drug</td>
<td>Side Effect</td>
<td></td>
<td></td>
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<td>------------------------------------------------------------------------------</td>
<td></td>
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<tr>
<td>DRV/r</td>
<td><strong>Hepatotoxicity</strong>&lt;br&gt;Underlying hepatic disease, HBV and HCV coinfection; concomitant use of hepatotoxic drugs.&lt;br&gt;Substitute with ATV/r or LPV/r. When it is used in third-line ART, limited options are available.&lt;br&gt;Usual adult dose of DRV/r 600/100 mg twice daily.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTG*</td>
<td><strong>Hepatotoxicity</strong>&lt;br&gt;Hypersensitivity reactions.&lt;br&gt;Hepatitis B or C coinfection, Liver disease.&lt;br&gt;If DTG is used in first-line ART, and there are hypersensitivity reactions, substitute with another therapeutic class (EFV or boosted PIs).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LPV/r</td>
<td><strong>Electrocardiographic abnormalities</strong> (PR and QT interval prolongation, torsade’s de pointes).&lt;br&gt;People with pre-existing conduction system disease; concomitant use of other drugs that may prolong the PR interval, Congenital long QT syndrome, Hypokalemia Concomitant use of drugs that may prolong the QT interval&lt;br&gt;Use with caution in people with pre-existing conduction disease or those on concomitant drugs that may prolong the PR or QRS intervals.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Condition</td>
<td>Associated Factors</td>
<td>Recommended Actions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hepatotoxicity</td>
<td>Underlying hepatic disease, HBV and HCV co-infection, Concomitant use of hepatotoxic drug</td>
<td>If LPV/r is used in children, substitute with DTG or EFV according to age. ATV can be used for children older than 6 years. If LPV/r is used in second-line ART for adults, use ATV/r. If boosted PIs are contraindicated and the person has failed an NNRTI based first line ART use DTG or consult specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>Advanced HIV disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe diarrhoea</td>
<td>Substitute with ATV/r</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Risk of prematurity, Lipoatrophy or metabolic syndrome, dyslipidemia or pancreatitis</td>
<td>Risk factors unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NVP (For HEIs prophylaxis)</td>
<td>There are rare reports of Hypersensitivity and hepatotoxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use AZT only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EFV</td>
<td>Persistent central nervous system toxicity (such as abnormal dreams, depression or mental confusion)</td>
<td>Depression or other mental disorder (previous or at baseline) Daytime dosing</td>
<td>DTG or boosted PI</td>
<td></td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td>Hepatotoxicity</td>
<td>Underlying hepatic disease – HBV and HCV co-infection Concomitant use of hepatotoxic drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Convulsions</td>
<td>History of seizure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe skin Hypersensitivity reaction.</td>
<td>Risk factors unknown.</td>
<td>Use DTG or boosted PI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gynecomastia</td>
<td>Risk factor unknown.</td>
<td>Use DTG or boosted PI</td>
<td></td>
</tr>
<tr>
<td>TDF</td>
<td>Chronic kidney disease, acute renal injury, Fanconi syndrome.</td>
<td>Underlying renal disease; older age; BMI &lt;18.5 (or body weight &lt;50 kg); untreated diabetes mellitus; untreated hypertension; Concomitant use of nephrotoxic drugs or a boosted PI.</td>
<td>Substitute with AZT or ABC. Do not initiate TDF at eGFR &lt;50 mL/min, uncontrolled hypertension, untreated diabetes, or presence of renal failure. It is recommended to monitor growth in children taking TDF containing regimen.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Decreases in bone mineral Density.</td>
<td>History of osteomalacia and pathological fracture; risk factors for osteoporosis or bone loss.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lactic acidosis or severe hepatomegaly with steatosis.</td>
<td>Prolonged exposure to nucleoside analogues; Obesity.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Drug interactions**

Providers should be aware of all drugs that people with HIV are taking when ART is initiated and new drugs that are added during treatment maintenance.
### Table 3.16 Key ARV drug interactions and suggested management

<table>
<thead>
<tr>
<th>ARV drugs</th>
<th>Key interactions</th>
<th>Effect</th>
<th>Suggested management</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT</td>
<td>Ribavirin and pegylated interferonalpha-2a</td>
<td>Substitute with TDF</td>
<td></td>
</tr>
<tr>
<td>EFV</td>
<td>Amodiaquine</td>
<td>Use an alternative anti-malarial agent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
<td>Adjust the methadone dose as appropriate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Estrogen-based hormonal contraception</td>
<td>Use alternative or additional contraceptive methods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Astemizole and terfenadine</td>
<td>Use an alternative anti-histamine agent</td>
<td></td>
</tr>
<tr>
<td>Boosted PI (AT-V/r, LPV/r)</td>
<td>Rifampicin</td>
<td>Substitute rifampicin with rifabutin, Adjust the PI dose or substitute with DTG and if not available with three NRTIs (for children)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lovastatin and simvastatin</td>
<td>Increase concentration</td>
<td>Use an alternative dyslipidemic agent (for example pravastatin)</td>
</tr>
<tr>
<td></td>
<td>Halofantrine and lumefantrine</td>
<td>Use an alternative anti-malarial agent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Estrogen-based hormonal contraception</td>
<td>Use alternative or additional contraceptive methods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methadone and Buprenorphine</td>
<td>Adjust methadone and buprenorphine doses as appropriate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Astemizole and terfenadine</td>
<td>Use alternative antihistamine agent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rifapentine</td>
<td>Reduce serum level</td>
<td>Do not provide 3HP with protease inhibitors and consider 6H in this case</td>
</tr>
<tr>
<td>Drug</td>
<td>Interactions</td>
<td>Consequences</td>
<td>Recommendations</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
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<td>-----------------</td>
</tr>
<tr>
<td>TDF</td>
<td>nephrotoxic drugs [e.g. aminoglycosides, amphotericin B, ganciclovir, pentamidine, vancomycin or interleukin-2]</td>
<td>Exacerbate nephrotoxicity</td>
<td>Avoid concurrent use</td>
</tr>
<tr>
<td>ritonavir boosted PIs</td>
<td></td>
<td></td>
<td>Closely monitor renal function</td>
</tr>
<tr>
<td>DTG</td>
<td>Carbamazepine, Phenobarbital and phenytoin</td>
<td>Use alternative anticonvulsant agent or if not possible substitute DTG with EFV and for children below 3 years substitute with boosted PIs</td>
<td></td>
</tr>
<tr>
<td>Polyvalent Cation products containing Mg, Al, Fe, Ca, and Zn</td>
<td>Absorption of DTG is affected/reduced</td>
<td>Use DTG at least 2 hours before or at least 6 hours after supplements containing polyvalent cations, including but not limited to – Fe-, Ca-, Mg-, or Zn-multivitamin supplements; mineral supplements, cation containing laxatives and Al-, Ca- or Mg- containing antacids. Monitor for virological efficacy.</td>
<td></td>
</tr>
<tr>
<td>Rifampicin,</td>
<td>Increases metabolism of DTG, and hence reduces concentration of DTG in the blood.</td>
<td>DTG 50mg BID. For pediatrics DTG BID by weight band</td>
<td></td>
</tr>
<tr>
<td>Rifapentine</td>
<td>Co-administration of dolutegravir-based ART and 3HP was well-tolerated in PLHIV (Though Dolutegravir trough concentrations are decreased by 50% when given with 3HP)</td>
<td>Doses of 10, 25, and 50 mg of DTG were equally effective in terms of virologic suppression (No dose adjustment needed)</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td></td>
</tr>
<tr>
<td>Metformin</td>
<td>DTG increases metformin levels, which may lead to hypoglycemia.</td>
<td>Start metformin at lowest dose and titrate based on glycemic control. Monitor for adverse events of metformin. Or adjust metformin dosing if already on metformin. When starting or stopping DTG in patients on metformin dose adjustment of metformin may be necessary to maintain optimal glycemic control and/or minimize adverse events of metformin.</td>
<td></td>
</tr>
</tbody>
</table>

**Treatment monitoring algorithm for pregnant and breastfeeding women**

Implementation considerations for treatment monitoring of pregnant and breastfeeding women
### Table 3.17 Implementation considerations for treatment monitoring of pregnant and breastfeeding women

Whenever possible, use same-day point-of-care testing for viral load testing of pregnant and breastfeeding women to expedite the return of results and clinical decision-making. If this is not available, viral load specimens and results for pregnant and breastfeeding women should be given priority across the laboratory referral process (including specimen collection, testing and return of results).

For all pregnant women, regardless of ART initiation timing: conduct viral load testing at 34–36 weeks of gestation (or at the latest at delivery) to identify women who may be at risk of treatment failure and/or may deliver infants at higher risk of perinatal transmission.

**Action:** if viral load >1000 copies/ml, follow the treatment monitoring algorithm and provide enhanced postnatal prophylaxis for the infant.

In addition:

a) **For pregnant women receiving ART before conception:** conduct a viral load test at the first antenatal care visit (or when first presenting) to identify women at increased risk of in utero transmission.

**Action:** If viral load >1000 copies/ml, follow treatment monitoring algorithm.

b) **For pregnant women starting ART during pregnancy:** conduct a viral load by three months after ART initiation to ensure that there has been rapid viral suppression.

**Action:** If viral load >1000 copies/ml, follow the treatment monitoring algorithm.

For all breastfeeding women, regardless of when ART was initiated: conduct a viral load test three months after delivery and every six months thereafter to detect viraemic episodes during the postnatal period.

**Action:** if viral load >1000 copies/ml, follow the treatment monitoring algorithm.

**Conduct infant HIV testing immediately and consider re-initiating enhanced postnatal prophylaxis for the infant.**

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*National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus*
a. See Fig 3.6.

b. See the programmatic update on HIV diagnosis and ARV use in HIV-exposed infants.

c. If viral load testing is expected to be undertaken in close proximity to the planned viral load at 34–36 weeks of gestation (see above), the first viral load test can be delayed until weeks 34–36 of gestation.

d. Conduct same-day testing using point-of-care infant diagnosis, where available, to expedite the return of results.

e. Consider reinitiating and continuing enhanced postnatal prophylaxis until the results are returned or same day testing is negative. Begin ART if the infant is diagnosed with HIV (see the programmatic update on HIV diagnosis and ARV use in HIV-exposed infants).

SOURCE WHO consolidated HIV prevention testing and treatment service delivery monitoring guideline July 2021

The point of care viral load determination is being implemented targeting pregnant and lactating women and those who have previous high viral load.
Routine viral load monitoring for early detection of treatment failure: obtain and review result by 3 months after ART initiation, 34-36 weeks or at the latest at delivery 3 months after delivery and six months thereafter

- **Undetectable (<50 copies/ml)**
  - Maintain RV drug

- **Viral load >50 to <1000 copies/ml)**
  - Provide enhanced adherence counseling: repeat viral load testing after 3 months. ****
    - **Undetectable (<50 copies/ml)**
      - Maintain ARV drug regimen
    - **Viral load >50 to <1000 copies/ml)**
      - Maintain ARV drug regimen, but continued enhanced adherence counseling and repeat viral load testing after 3 months
    - **Viral load >1000 copies/ml)**
      - Switch to appropriate regimen

---

**Figure 3.6 Algorithm for diagnosis and management of treatment failure**

**Enhanced Adherence Support (EAS)**

Enhanced Adherence Support is important for patients that have unsuppressed VL, persisted or new immunosuppression, developing new OI or have multiple adherence barriers. It shall be systematic and with documenting, the interventions provided during the EAS period.
### Table 4.18: Summary of components of EAS

#### Enhanced adherence support sessions overview

<table>
<thead>
<tr>
<th>Session</th>
<th>Activities</th>
</tr>
</thead>
</table>
| **First Session** | - Review cognitive, behavioral, emotional and socio-economic barriers to adherence:  
  - Treatment literacy  
  - Medications: dosage, timing, storage  
  - Side effects  
  - Motivation  
  - Mental health screening (screen for depression and other common mental problems using national mental health assessment tool)  
  - Action:  
    - Discuss risk reduction (e.g. for substance abuse)  
    - Discuss patient’s support systems  
    - Assist patient to develop adherence plan to address the identified issues.  
  - Referrals and networking. |
| **Second Session** | - Review adherence plan from the first session and discuss any challenges.  
  - Identify other possible gaps and issues emerging.  
  - Action  
    - Assist patient to modify the adherence plan to address the identified issues.  
  - Referrals and networking. |
| **Third Session**  | - Review adherence plan from the first and second session and discuss any challenges.  
  - Identify other possible gaps and issues emerging.  
  - Action  
  - Assist patient to modify the adherence plan to address the identified issues.  
  - Decision on repeat VL based on current adherence: |
• If the adherence is good, plan repeat VL testing after a month and explain possible ways forward, emphasizing the role of the patient and the health facility in terms of strengthening adherence. The EAS may be discontinued based on the second VL result.
• If adherence challenges persist, plan further monthly EAS sessions before repeating the VL until adherence are improved. This time additional efforts are required for the EAS depending on the client’s situation.

### Fourth Session (3 months/90 days from the first session)

• Take the second VL sample for the client showing good adherence.
• All efforts should be employed to get the VL result as soon as possible. As soon as the VL results received, discuss the result with the patient.
• Plan the way forward:
  1. If VL is < 50 copies/ml, maintain the current regimen and encourage adherence
  2. If VL is 50–1000 copies/ml, continue the current regimen and the monthly EAS for the next 3 months.
  3. If VL is > 1000 copies/ml, switch to appropriate regimen (second or third line).

### Basic Principles for use of Antiretroviral Drug and Vaccines for PMTCT of HBV

Hepatitis B infection requires a longer period of therapy. If patients do not adhere to treatment, there might be reactivation of the virus characterized by raised liver enzymes and signs of liver failure that could be fatal. Therefore, patients are advised to take their drugs in accordance with the instructions and at a regular time. For effective long-term management, objective monitoring of adherence to anti-viral is recommended:

- **Self-report:** Regular counseling and checking with patients or caregiver on the mission does or adherence to the therapy
- **Viral load monitoring:** HBV DNA viral load (every 12 months, if testing available)
- **Pharmacy refill records:** Monitoring the delay to pick up anti-vi-
ral from the pharmacy can be an important and simple tool to identify patients requiring an assessment of their adherence.

The aim of monitoring while on treatment is to assess adherence, evaluate the effectiveness of therapy, check for evidence of progression of liver disease, adverse events and assess for indications for stopping treatment.

However, after the patient took the drug for 3-5 years period, in the following selected scenarios, the treating physician can decide to stop the anti-viral medication and closely follow the patient. In this condition, the physician should make sure that patient would adhere to follow-up for early signs of worsening. It is important to note that the treatment duration of cirrhotic patients (Compensated or decompensated) is life long and are not included in the stoppage criteria: -

- In patients who have HBeAg positive
- Sero conversion of HBeAg and developing Anti-HBe
- Undetectable viral load (HBV DNA) and
- Persistently normal ALT

When the above scenarios are fulfilled, treatment should be continued for another 12 months before it is discontinued

- Regardless of prior HBeAg status, treatment can be stopped one year after HBsAg becomes negative (a rare occurrence).
Figure 3.7: HBV TREATMENT ALGORITHM, (adapted from the WHO)

Goal of CHB treatment

- The primary goal of antiviral therapy in hepatitis B is to achieve HBsAg eradication.
- The secondary goals are:
  - Change of CHB into inactive stage, carrier state;
  - Achieve virological remission;
  - Inhibition of progression of liver injury
  - Preventions of HCC and Cirrhosis and ultimately improvement of survival.
  - Prevention of hepatitis B transmission to others through reduction of viral load.

First line antiviral treatment for adults
Recommended drugs for the treatment of CHB and their doses in adults with normal renal function. TDF and ETV has been recommended due to high barrier to resistance.

- **First Line:** Tenofovir (TDF) 300 mg PO/day in all adults (12 years and older, at least 35kg) with indication for anti-viral treatment. (See Annex for renal adjustment)
- **Second line:** Entecavir (ETV) 0.5–1mg PO/day an adults with renal dysfunction and in children aged 2–11 years
- In patients with HIV co-infection, Ensure that the regimen contains TDF

**N.B.** See below for renal adjustment of Tenofovir and Entecavir

Table 3.19: Recommended dosing in adults with renal impairment

<table>
<thead>
<tr>
<th>Category of patients</th>
<th>Recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimated GFR</td>
</tr>
<tr>
<td>≥50</td>
<td>30–49</td>
</tr>
<tr>
<td>10–29</td>
<td>&lt;10</td>
</tr>
</tbody>
</table>

- **Tenofovir**
  - One 300 mg Tablet every 24 hours (7.5 scoops of powder every 24 hours)
  - One 300 mg tablet every 48 hours (or 160 mg [3 scoops] of powder every 24 hours)
  - One 300 mg tablet every 72–96 hours (or 60 mg [1.5 scoops] of powder every 24 hours)
  - Every 7 days or one 300 mg tablet following completion of approximately every 12 hours of dialysis (or 20 mg [0.5 scoops] of powder following completion of approximately every 12 hours of dialysis)

- **Entecavir**
  - 0.5–1mg PO/day in all adults with renal dysfunction and in children aged 2–11 years
### Entecavir Dosage

<table>
<thead>
<tr>
<th>Drug</th>
<th>0.5 mg once daily</th>
<th>0.25 mg once daily OR 0.5 mg every 48 Hours</th>
<th>0.15 mg once daily OR 0.5 mg every 72 hours</th>
<th>0.05 mg once daily OR 0.5 mg every 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entecavir</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entecavir (decompensated liver disease)</td>
<td>1 mg once daily</td>
<td>0.5 mg once daily OR 1 mg every 48 Hours</td>
<td>0.3 mg once daily OR 1 mg every 72 hours</td>
<td>0.1 mg once daily OR 1 mg every 7 days</td>
</tr>
</tbody>
</table>

### HBV treatment (Enticavir) interaction with pregnancy

Enticavir should be used during pregnancy only if clearly needed and the benefit outweighs the risk to the fetus. (Insufficient data available on use of this drug in pregnant women to inform a drug-related risk).

### Entecavir Breastfeeding Warnings

An alternative agent may be preferred, particularly while breastfeeding newborn or preterm infants. (Due to limited studies, Breastfeeding is not recommended during use of this drug).

### Side effects requiring immediate medical attention

Along with its needed effects, entecavir may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

**Incidence not known**

- Abdominal or stomach discomfort
- Cough
- Decreased appetite
- Diarrhea
- Difficulty with swallowing
- Dizziness
- Fast heartbeat
- Fast, shallow breathing
• General feeling of discomfort
• Hives, itching, or rash
• Muscle pain or cramping
• Nausea
• Puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
• Right upper abdominal or stomach pain and fullness
• Sleepiness
• Tightness in the chest
• Unusual tiredness or weakness

**Side effects not requiring immediate medical attention**

Some side effects of entecavir may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine.

**Less common**

• Acid or sour stomach
• Belching
• Headache
• Heartburn
• Indigestion
• Stomach discomfort, upset, or pain

**Rare**

• Trouble sleeping
• Unusual drowsiness

**Incidence not known**

• Hair loss
• Thinning of the hair

**Additional Elements of Clinical Care**

**Infection Prevention**

Standard precautions apply to both clients and providers attending health care facilities and are designed for the care of everyone, whether potentially infected with HIV or other infections (e.g. Hepatitis, TB). Standard precautions involve physical, mechanical, or chemical barriers between microorganisms and an individual to prevent transmission. Standard precautions apply to
blood and body fluids, secretions and excretions, non-intact skin, and mucous membranes. Standard precautions should be routinely practiced in health care settings, not just based on the nature of procedures or actual or assumed HIV status.

Key components of infection prevention are:

- Hand washing before and after all patient contact
- Use of gloves and other protective barriers when exposed to potentially infected body fluids, mucous membranes, broken skin, or contaminated waste material
- Use of physical barriers (apron, face-mask, goggles) in situations where splashes or spills expected
- Use of antiseptic agents for cleaning the skin or mucous membrane prior to surgical procedures, cleaning wounds, doing hand scrubs
- Use of safe work practices including not recapping or bending needles, using proper surgical procedures, cleaning wounds, doing hand scrubs
- Safe disposal of infectious waste materials to protect those who handle them
- Safe disposal of sharp needles, scalpels, and other sharp instruments
- Processing of instruments, and other items after use by first decontaminating and thoroughly cleaning them, and then sterilizing or applying high-level disinfectant application

**Reducing occupational exposure and risk of HIV transmission**

HIV transmission to health care workers is a serious potential hazard and a source of concern and anxiety. Exposure that could put health care workers at significant risk include either of the following, and involves blood, tissue or other body fluids containing visible blood:

- Percutaneous needle injury
- Contact with mucous membrane or non-intact skin

Blood through needle stick injuries is the primary route of occupational exposure, though exposure through other infected body fluids and mucous membrane through contact is also possible. Patient to-provider transmission can be prevented or minimized through appropriate infection prevention measures, including adherence to standard precautions, safe occupational health measures and ongoing education.
Post-exposure Prophylaxis (PEP) for occupational exposure

Short course antiretroviral drugs can reduce the likelihood of infection following HIV exposure by as much as 80%. Post exposure prophylaxis should be administered as soon as possible after the incident (within 1-2 hours). However, it is not advisable to consider PEP beyond 72 hours post exposure. Prophylaxis is to be given for 28 days. Early rapid testing of the source patient can help determine the need for PEP and may eliminate unnecessary antiretroviral use. HIV testing should be offered following occupational exposure immediately after the incident. If result is positive there is no need for PEP, but if negative PEP should be administered as soon as possible as outlined above and then repeat HIV testing at 6 weeks, 3 months, and 6 months. Currently, there is no single recommended PEP regimen, but as with antiretroviral use a dual or triple drug therapy is recommended depending on: the type of injury and transmission medium, the source client’s status, HIV viral load and treatment history if known and the ARV drugs available in the facility. The health worker must have access to a full month’s supply of ARV once started.
4. Monitoring and Evaluation

- Introduction
- PMTCT routine program monitoring
- Indicators for PMTCT
- PMTCT data recording and reporting standard tools
- Data Abstraction for the monthly PMTCT service delivery report
- Data reporting Procedure
- Monitoring and evaluation of the PMTCT service at each level of the health care system
- Data quality assurance procedures
- Data use at different levels
- Record keeping procedures
- Mother–baby cohort
- Evaluation of the PMTCT services at the facility and national level
4.1 Introduction

Monitoring and evaluation (M&E) are the techniques we use to find out how well our health program is achieving what it set out to do. M&E can highlight whether the program is still on the right road, how far it has travelled, and it still will go. Generally, it plays an important role in the management of health programs to ensure resources are appropriately utilized, services are accessed, activities occur in a timely manner, and expected results are achieved. This management function facilitates the most effective and efficient use of human and financial resources for the achievement of elimination of mother-to-child transmission targets which is especially relevant in areas where resources are limited.

Monitoring the PMTCT program will help:

- Assess program performance
- Detect and correct implementation challenges
- Make efficient use of PMTCT program resources

Evaluation will help:

- What works well and what could be improved in a program or initiative.
- Enhancing the chance that the initiative’s goals and objectives are being achieved.
- Determining value for money (i.e., allocated resources are yielding the greatest benefit for clients and stakeholders)
- Identifying what components of an initiative work/do not work and why.

4.2 PMTCT routine program monitoring

The PMTCT activities will be monitored through the national Health Management Information System (HMIS) using various facility-based patient records, registers, and reporting formats. Other key program information can be monitored using administrative records at different level.

Routine PMTCT monitoring includes tracking of all activities aimed at providing the minimum package of services, such as:

- HIV testing and counseling for pregnant women
- HIV testing and counseling for eligible index family members
- ARV for treatment of HIV positive pregnant and breastfeeding women
- Provision of prophylaxis for HBsAg positive pregnant and lactating wom-
• PrEP provision for discordant couples
• ARV prophylaxis for HIV-exposed infants
• CPT for HIV exposed infant
• TB preventive therapy for eligible pregnant and breast-feeding women
• Early infant diagnosis for HIV exposed infants at 6 weeks
• DNA/PCR test at 9 months for HIV negative HEI
• Determine final HIV status of infants at 18 months of age
• Routine viral load monitoring as per the national recommendation for pregnant/BF women
• Routine testing and treatment on syphilis and hepatitis for pregnant women.
• Linkage to EPI for birth dose of HBV
• Provision of multi month ART dispensing (MMD) to eligible clients
• Partner testing for both Syphilis and HBV
• Follow-up of HIV positive mothers and their HIV-exposed children
• Counseling and support for infant feeding practices
• Family planning counseling and referral services

The national PMTCT routine monitoring system includes:

1. Clearly defined indicators (as per HMIS) data collection and reporting procedure
2. Standard data capturing tools (cards and registers)
3. Descriptions of data flow and responsibilities at each level of the health-care system
4. Data use at different levels (unit/department, facility, woreda, regional and national)
5. Data quality assurance procedures
6. Monitoring HIV, Syphilis and HBV care and treatment in RMNCAH-N platform

4.3 Indicators for PMTCT in the HMIS

Indicators for PMTCT included in the HMIS for mothers and infants born to HIV positive mothers. Data on Syphilis and HBV are also traced in HMIS. There are also additional indicators which are important to inform the PMTCT program
which are under other MNCH unit and DPC.

**Maternal indicators (retention on ART for HIV positive PBFW, Syphilis and HBV)**

- Percentage of pregnant and lactating women who were tested for HIV and know their results
- Percentage of HIV positive pregnant and lactating women who received ART at ANC, L & D, P & C for the first time
- Percentage of HIV positive women who get pregnant while on ART and linked to ANC
- Percentage of women on ART for PMTCT
- % of pregnant women who were tested for HBV
- % of pregnant women who are indicated for prophylaxis who received HBV prophylaxis
- % of pregnant women indicated for long-term treatment who are linked to care
- Number/% of pregnant women tested for syphilis at ANC
- Number/% of pregnant women tested for syphilis by dual HIV and syphilis test
- Percentage positive among those tested for syphilis
- Percentage of pregnant women adequately treated for syphilis with benzathine penicillin
- Percentage of pregnant/breast feeding women who put on 3-month multi-month dispensing (MMD) among those eligible
- Number of Discordant couples who took PrEP in the PMTCT setting
- Percentage of pregnant/breast feeding women who received routine viral load testing
- Percentage of HIV positive pregnant & BF women with a suppressed viral load (<50 copies/ml)
- percentage HIV positive pregnant & BF women receiving EAC
- Percentage of pregnant, laboring & lactating women for whom partner HIV testing performed
- Percentage of partners of HBV positive pregnant women who are tested for HBV
- Percentage of Partners of Syphilis positive pregnant women who are tested for syphilis
• Percentage of partners testing positive for syphilis among those tested
• Percentage of Partners of Syphilis positive pregnant women who are treated for syphilis
• Percentage of HIV infected women on HIV care and using modern family planning method.
• Percentage of Pregnant and lactating women still alive at 3, 6, 12, and 24 months since maternal PMTCT enrollment

Exposed infant indicators

• Percentage of infants born to HIV-infected women receiving a virological test for HIV within 12 months of birth (disaggregating by 0–2 months, 2–12 months)
• Percentage of infants born to HIV-infected women who were started on cotrimoxazole prophylaxis at 6 weeks of birth
• Percentage of infants born to HIV-infected women receiving Dual antiretroviral prophylaxis (AZT+NVP) for prevention of mother-to-child transmission
• Percentage of HIV exposed infants receiving HIV (confirmatory test antibody test) by 18 months of birth
• Percentage of HIV infected infants identified with positive test result (HIV positive at 4–6 weeks, 9 months, 18 months)
• Percentage of HIV infected infants identified with positive virological test who are initiated on ART
• Number of live births who received an HBV birth dose within 24 hours after birth
• Percentage of children under one year of age who have received third dose of Penta valent vaccine (HBV)
• Percentage of HEI still alive at, 12, 18, 24 and 30 months since maternal PMTCT enrollment
• Percentage of congenital syphilis
• Percentage of infants with congenital syphilis adequately treated
• Percentage of stillbirths attributable to maternal syphilis

4.4. PMTCT data recording and reporting standard tools

The PMTCT program uses standard HMIS tools to collect and document information on PMTCT program which includes:-
Facility-based paper system

- Integrated antenatal, labor & delivery, newborn, and postnatal care card
- HIV Exposed Infant follow up card
- HIV Care/ART Follow-up form (the blue card)
- ART intake forms (A-B)
- HMIS registers (ANC, L&D, Postnatal care, Under-five children register, Mother-Baby Pair Cohort register)
- Monthly HMIS service delivery report with PMTCT component (Annex B)
- Cohort follow up wall chart at facility levels
- Mother Baby Pair Cohort analysis reporting format
- Transfer in and transfer out forms
- Internal and external Referral form
- Appointment Calendar book
- National PMTCT dashboard for monitoring performances at all level
- HBV monthly reporting format
- HBV treatment register
- Description of the above listed paper-based tools

Integrated ANC, L&D, NB & PNC Card:

This integrated Card is used to record health information for each pregnant client including HIV, syphilis and HBV test results, malaria treatments given, immunizations, vitamins, ART dispensed to the mother during ANC. It also contains information on ARV dispensed and taken during L&D for both the mother and the newborn baby and postpartum follow up information.

HIV/Care follow-up card (blue):

This card is used to record patient HIV information following diagnoses with HIV. Information from the follow up card is used to update the ART register and the Mother-Baby- Cohort register (Integrated RMNCAH/PMTCT).

ART intake form (A to B):

Should be completed by PMTCT health care providers for all clients on ART including pregnant and lactating women and is used to take basic baseline information about the women enrolled into the PMTCT program. It has two components.

1. Socio demographics & family care
2. Past and present illness & PHDP (Positive Health Dignity Prevention)

**HIV-exposed infant card:**

The HIV-exposed infant card is designed to be completed at ANC/PMTCT clinic. If the pregnancy results in live birth(s), an HIV-exposed infant card is prepared for each live child and attached to the mother’s card. The card needs to show the provision of dual ARV prophylaxis (AZT+NVP) for six weeks and NVP only for additional six weeks after delivery. Other key services like the provision of CPT, growth monitoring, EID testing should also be recorded appropriately.

**Family matrix form/**

This form helps to list out family members of the index case for the regular assessment of HIV status. ANC/PMTCT provider should attach one family matrix form for each index case folder.

**HMIS registers:**

The following three registers are used to document key information of pregnant/breastfeeding women at ANC, L&D and postnatal irrespective HIV status. Any women:

- Antenatal Care register (for every pregnant woman)
- Labor and Delivery register (for every laboring mother)
- Postnatal Care register (for every client receiving postnatal care)

**ICT Register:**

This register should be kept at the ANC/PMTCT clinic. The registers help to document the HIV status of family members of the index case like partner, eligible biological children’s (<15 years). ANC/PMTCT provider should regularly assess the testing status of the family members. The ICT report should be combined with the ART monthly ICT report.

**Integrated MNCH/PMTCT Register:**

Available in all PMTCT providing facilities and used to record the follow-up care provided to HIV positive mothers and their HIV-exposed infants including ART, TPT, CPT, ARV Prophylaxis for HEI, infant HIV test maternal VL testing and DNA/PCR/Rapid HIV Antibody test for HEI. All HIV positive pregnant and lactating women should be recorded in the PMTCT register. The register has left,
and right part arranged to capture key maternal and infant outcomes like alive on ART, lost, death, TO and other key services.

**Transfer- in and transfer-out Form:**

The transfer-in and transfer-out forms will be used to facilitate health care delivery for clients transferred within the same facility as well as those transferred to another facility.

**Reporting Forms:**

**Monthly reporting form:** The PMTCT monthly reporting format is part of the routine medical service delivery report form (DHIS2 data collecting tool) and the report will be collected monthly with the service delivery report form. Important information/ data/ indicators that are not captured by the monthly PMTCT service delivery report (HMIS monitoring), can be collected, and utilized by the facility or the Ministry as per the guiding principle indicated under continuous quality improvement (CQI) which includes using during periodic surveys or supportive supervision. (See Annex B: monthly PMTCT reporting format).

**HBV monthly reporting format:** the report will be collected monthly with the service delivery report form. This reporting format address three PMTCT indicators listed above.

**HBV monthly reporting format:** the report will be collected monthly with the service delivery report form. This reporting format address three PMTCT indicators listed above.

**Mother and Baby Cohort report form:** The cohort analysis report contains information on the status of HIV positive mothers at 3, 6, 12 and 24 months since maternal PMTCT enrolment & HIV exposed infants at 12,18,24 and 30 months. This cohort reporting forms helps to update the mother and baby wall charts. The data source for the monthly cohort reporting form is the integrated MNCH/ PMTCT register. (Annex C).

**Data Abstraction/Extraction for the monthly PMTCT service delivery report:**

In order to collect the right data for the monthly report, health care providers need to know where and how to extract data. DHIS2 data abstraction and extraction principle will be utilized.
• For HIV testing abstract data from ANC, L&D & PNC registers.
• For partner HIV test abstract data from ANC, Land D and PNC registers
• For Syphilis testing abstract data from ANC registers.
• For syphilis treatment abstract data from ANC register
• For HBV testing abstract data from ANC register.
• For ART uptake, abstract data from MNCH/PMTCT (Mother-Baby-Cohort) register including new and already on ART,
• For HBV prophylaxis uptake, data abstract from HBV treatment register
• For PrEP uptake, abstract data from PrEP register
• For HBV BD immunization uptake, abstract data from immunization register
• For HIV exposed infant related reports, extract data from MNCH/PMTCT (Mother-Baby-Pair Cohort register).
• For PMTCT cohort report, extract data from MNCH/PMTCT (Mother-Baby-Pair Cohort register).
• For modern FP utilization report, extract data from MNCH/PMTCT (Mother-Baby-Cohort register).

Data reporting procedure

Reporting: PMTCT data is reported monthly according to the HMIS procedures.

Feedback: Providing feedback is an essential aspect of program monitoring. Feedback helps stakeholders identify successes, problems and activities that need to be completed to meet program goals. Feedback is done at all levels and in both directions before the next reporting month.

Monitoring & Evaluation of the PMTCT services (PMTCT of HIV, Syphilis and HBV) at each level of the health care system

Different responsibilities are given at each level of program management to ensure the proper flow of PMTCT monitoring and evaluation information (data) from the health facility to the National level and feedback from respective levels.

At health facility level

Trained health workers at PMTCT health facilities will be responsible for completing the following: integrated ANC, L&D & PNC (Maternal) card; ART Intake forms (A & B); HIV/Care follow up card; HIV-exposed Infant card; family matrix
form; HMIS register (ANC, Postnatal, Labor and Delivery); integrated MNCH/ PMTCT (Mother-Baby-Cohort register), ICT register and PrEP register. Health facility management/MDT is responsible to conduct data quality assurance before reporting to the next level. Health facilities are required to use PMTCT dashboard to regularly assess key indicator performance.

**At the woreda level**

The woreda HMIS coordinator/Performance monitoring Team (PMT) must work in collaboration with PMTCT trained providers/data clerks to ensure that PMTCT information collected monthly from all PMTCT/ART health facilities on timely manner. The coordinators/PMT should check the report for completeness, accuracy, and its timely submission to the zonal /regional HIMS coordinators. The Woreda is also expected to organize quarterly woreda level review meeting to assess the performances.

On a quarterly basis, the woreda PMTCT focal person compile service utilization and coverage by comparing selected PMTCT indicators from different facilities to identify facilities with performance gaps, challenges, and barriers. Performance monitoring mechanisms like dashboard shall be used at woreda and at different levels of the health structure to ensure transparency and accountability for actions.

**At the zonal level**

Regional states that have zonal departments, intermediary between woreda and the respective regional office, ensure direct and smooth flow of PMTCT information collected monthly from the woredas. HMIS coordinators must work in collaboration with woreda PMTCT focal persons and HMIS coordinator to ensure that PMTCT services and HMIS reports are accurately compiled and submitted to regional health bureau’s HMIS coordinator. On a quarterly basis, the Zonal PMTCT focal person compiles service utilization and coverage by comparing select PMTCT indicators from different woredas and/or facilities to identify facilities with performance gaps, challenges, and barriers. The Zone is also expected to organize quarterly Zonal level review meeting to assess the performances.

**At Regional level**

The regional health bureau is responsible for compiling, analyzing, aggregat-
ing, and sending all PMTCT reports to the MOH Policy and Planning Directorate. On a quarterly basis, the regional PMTCT focal person compiles service utilization and coverage by comparing selected PMTCT indicators from different zones/woredas/facilities to identify performance gaps, challenges and barriers and take correction action. The region is also expected to organize quarterly regional level review meeting to assess the performances.

**At National level**

The national level has the overall responsibility for monitoring and evaluating the nation-wide PMTCT program. The FMOH/PMTCT case team under the MCH directorate conduct review meeting at the end of each quarter to share reports analyze data and provide feedback to regions on the national program, regional achievements, and gaps of implementation. The analysis and coordination inform policy development, planning, and decision-making.

**Data quality assurance procedures**

Data quality assurance is one of the components of the M&E system. Once data are collected, the data are checked for any inaccuracies and obvious errors at every level. The data quality assurance (DQA) is done at two levels: facility level and administrative level (district health offices). At facility level, such a mechanism is the Lot Quality Assurance Sampling (LQAS) methodology which is done on monthly basis. In this procedure randomly selected data elements from the monthly reports are checked against the register or source of the report. The findings are then compared to a standard Data Accuracy Table. The same procedure is done at district health offices on quarterly basis before the data are sent to the next higher reporting unit. Hence, in HMIS all reports are quality checked at every level, from the healthcare institution to the federal level. In addition data quality assurance can be assessed using site supervision for verification and supportive supervisions. Findings from supportive supervision should be compiled and analyzed and feedback provided.

**Data use at different levels**

The effective use of data at different reporting levels ensures smooth running of the program. Data is used at different levels of program management to inform planning, decision making, advocacy, resource allocation, and accountability.
At the national level

The national office uses data to:

- Develop program plans and budgets
- Provide feedback to regions to help identify and address problems to improve PMTCT services
- Ensure adequate coverage of PMTCT services and assure quality of services
- Disseminate national program data with relevant stakeholders

At Regional Health Bureau/Zone/Woreda level

Regional, zonal and woreda offices use data for a number of purposes:

- Provide feedback to Zones, woreda and healthcare facilities in an effort to help identify and address problems and improve implementation of PMTCT services
- Inform program planning and budgeting
- Ensure adequate coverage of PMTCT services within the area
- Report and exchange information with the national office

At Health facility level

Health care workers at PMTCT sites review the monthly reports to track program progress and gaps and improve implementation of PMTCT services. HMIS technicians conduct regular meetings with staff members to disseminate findings and review progress, problems, and challenges at health facility level. Data/information will be reviewed at performance monitoring team (PMT) Multi-disciplinary team (MDT) meetings if these are available and whenever possible.

Record keeping procedures

All patient records, registers and necessary reporting formats and documents should be maintained to ensure they are accurately completed, stored securely to prevent damage, remain confidential and easily retrievable.

Mother- baby cohort

A cohort is a group of people who share a common characteristic or experience within a defined period. Cohort monitoring is a process in which members of a cohort are followed overtime to measure an outcome. PMTCT cohort mon-
Monitoring is used to measure the PMTCT intervention outcome through longitudinal approach using cohort monitoring tools.

The PMTCT cohort monitoring has four components:

1. Population: HIV+ pregnant or breastfeeding women (for maternal), infant born from HIV positive pregnant/breast feed women
2. Shared event: maternal PMTCT enrollment (Month/Year) – Month 0
3. Time point: Month 3, Month 6, 12 and Month 24 (for maternal), for HEI, 12,18,24 and 30 months
4. Outcome: maternal retention in PMTCT program for maternal. And Final HIV status of HEI Cohort.

Maternal cohort outcome will be reported at facility level at 3, 6, 12 and 24 months since the mother’s PMTCT enrollment month which is month “zero.” And for HEI outcome will be reported at 12, 18, 24 and 30 months, the final outcome of HEI is measured at month 30 since maternal PMTCT enrollment month.

Enrollment to the PMTCT program

All HIV+ pregnant or breastfeeding women enrolled in the facility’s PMTCT program should be entered in the Register. This includes women who are:

1. Newly diagnosed HIV+
2. Known HIV+ before pregnancy

HIV+ pregnant or breastfeeding women should be entered in the facility’s Register when they enter the facility’s PMTCT program even if ART has not yet been initiated

PMTCT cohort monitoring tools

1. Integrated MNCH/PMTCT register
2. Maternal/HEI PMTCT cohort Report format
3. Maternal/HEI PMTCT cohort wall chart
4. Maternal/HEI PMTCT cohort SOP
5. PMTCT cohort monitoring Job Aid

Evaluation of the PMTCT service at the facility and national level

Evaluation is the episodic assessment of results that can be attributed to program activities; it uses monitoring data and often indicators that are not col-
lected through routine information systems. Evaluation allows exploration of the causes of failure to achieve expected results on schedule and the mid-course corrections that might be necessary. It assesses progress in program implementation and coverage and measure the effect of program activities on the target population.

The Ethiopian National Strategic Plan for Triple Elimination of Mother to Child Transmission of HIV (eMTCT of HIV & syphilis and hepatitis) listed selected outcome and impact targets to be achieved by 2025.

The evaluation will therefore be used to understand if the interventions are working/ making a difference by measuring the degree to which the desired/ planned change has occurred. Evaluation of the PMTCT service can be done using different mechanisms. Facilities can conduct self-assessments for selected indicators and analyze the findings/ performance for planned intervention. The FMOH at national level can perform an assessment or study (evaluation) of the service performance through surveys and operational research.

The following PMTCT service evaluation questions can be used to explain the level of achievement.

- What is the incidence of HIV in the reproductive age group?
- What is the incidence of HBV in the reproductive age group?
- What is the HIV test rate including disclosure and partner testing?
- What is the rate of HIV related maternal deaths?
- What is the rate of MTCT of HIV, HBV and syphilis?
- What are the rates of ART coverage, adherence and retention for the PMTCT services?
- What is the infection rate among HIV exposed infants?
- What is the impact of PMTCT program towards the elimination of HIV, HBV and syphilis?

The evaluation of the PMTCT shall be done periodically at all levels:

- At community level on awareness and service utilization,
- At health care delivery level on service quality, and performance,
- At Regional and national level on outcome and impact of the PMTCT service.
5. Continuous Quality Improvement of PMTCT Services
Quality Improvement (QI) is an approach to improve the service through the routine use of health and program data to meet patient and program needs. M&E data provides valuable information that can be used as part of efforts in continuous quality improvement (CQI). CQI represents one form of using data generated by M&E system to improve the quality of services.

**Key Principles of CQI in the Context of MNCH/PMTCT**

The CQI of Integrated PMTCT/MNCH care is expected to fulfill the following key principles:

- **Address Client satisfaction**– Focusing on the needs of HIV+ women to have HIV free baby,
- **Follow scientific approach** – to implement new approaches by implementing an improvement model– measuring → testing change → re-measuring → applying change.
- **Apply Team approach**– involving the leadership, knowledgeable staff from different units/work process (laboratory, pharmacy, ART, PMTCT/ MNCH etc.). It is also a complement to involve the community in the team.

Quality improvement activities to improve services shall be integrated into the routine flow of existing work. This avoids considering CQI activity as a separate program and additional burden to the routine work. Once the service shows improvement, the system starts functioning more efficiently and effectively and the tasks become simplified & harmonized further.

**How does CQI work for PMTCT?**

To implement CQI in PMTCT program, quality improvement initiatives shall be tuned for the PMTCT service. First define quality PMTCT service and set priorities to identify specific areas for improvement. Second, set up a system to define & measure performance measurement methods for improvement and set baseline use of existing data, or collect data that will be used to monitor successes. Third, establish a Team that identifies the gap between current and expected level of quality among front line providers and use appropriate method to close the gaps.

As the quality improvement is a team activity, the following are recommended steps a quality team can do to facilitate quality improvement initiatives in PMTCT service:
Step 1: Understand the process of PMTCT service provided in the clinic clearly articulating the process, and stating their outputs and outcomes. By doing so, the QI team can list implementation steps, develop a flow chart and identify potential barriers. Figure 1 gives an overview of the general steps taken in a typical MNCH/ PMTCT services.

Step 2: Measure quality standards through selected indicators (or performance measures) for the quality standard. Once these quality indicators are selected, the QI team will need to collect, investigate and present the results of their analysis during Multi-Disciplinary Team (MDT) meetings.

The HMIS indicators for MNCH/PMTCT will be used for measuring performance of MNCH/PMTCT service delivery at various points. Performance measurement tells what is really happening, as opposed to what we think is happening. It tells what is being documented in the clinic records and is available to help with the decision-making of providers who see the patient. It also tells whether tasks that are supposed to be done are being done, and done well.

Step 3: Develop a problem statement: Once gaps/ opportunities for improvement are recognized, the QI team will work on prioritizing for intervention. To prioritize areas of intervention, consider feasibility, and resource availability that the control QI team must solve the problem.

For addressing each of the problems selected, a clear and concise statement that the QI team has discussed and agreed upon should be used to state the problem in reference. Stating a problem statement helps the QI team to have a shared vision of the opportunity at hand. Problem statement shall be blame free and not discussing solutions.

Instead of presenting the Statement of the Problem as “Women are not tested at ANC because ANC staff do not offer HIV test. This increases missed opportunities of HIV testing of ANC attendants.” It is better to rewrite as “Number of ANC attendants that get tested for HIV averages at 45% of ANC attendants in
the months of April – June 2013. This has been stated as one of the missed opportunities in PMTCT.”

**Step 4: Analyze the root causes** of the problem stated, and brainstorm on improvement strategies to test.

**Step 5: Develop an aim statement.** After declaring the problem and analyzing the root causes of the stated problem, develop an aim statement articulating the area for improvement, its status, and its intended achievements. Aim statements should be Specific, Measurable, Actionable, Realistic, and Time bound (SMART) as follows.

**Step 6: Test and implement the proposed intervention (a test-idea).** The test(s) can be several small tests or one large test of all proposed solutions. The continuous PDSA (Plan-Do-Study-Act) cycles are one of the tools used to test and implement newly proposed interventions. This is done by turning ideas into action and connecting actions taken to learning. Figure 4 and the descriptions below it spell out the details included in each phase of PDSA.
6. Bibliography

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12. C. Deme, B. Edao, G. Jaya et al., “Prevalence of hypertension, anemia,
asymptomatic urinary tract infection, syphilis, HIV and hepatitis B virus infection among pregnant women attending an antenatal clinic at a rural hospital in southern Ethiopia,” The Southeast Asian journal of tropical medicine and public health, vol. 47, no. 5, pp. 1032–1039, 2016


15. (WHO medical eligibility criteria for contraceptive use 1, 5th edition, 2015)

16. WHO Medical Eligibility Criteria for Starting Contraceptive Methods, 2015

17. March 2014 *Supplement to 2013 consolidated guidelines

18. Guideline: updates on HIV and infant feeding: the duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. World Health Organization 2016


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22. CHAI estimate for 2016, based on the methodology that was used by Lori Newman et al (2013)


7. Annexes

Annex A: Checklist for talking with parents about their child’s positive HIV test results

- Prepare to talk with parent or guardian,
- Make sure you have the child result and inform the parent you have it,
- Schedule an appointment,
- Greet the client and establish rapport
- Ask the parent or guardian whether they have had any questions since the child test
- Answer questions and let the client know that counseling will continue to be available to help with important decisions
- Inform the parent of the test result:
- Give the parent time. Ask, about the test result:
- Now that counseling will continue to be available
- State, in a neutral tone, result: now that counseling will continue to be available to help with important decisions commendations for
- Pause and wait for the parent to respond before continuing. Give the parent time to express any emotions
- If the parent would like to see proof of the result, provide it
- Check the parent would like to see proof of the result, Discuss and support the parents.
- Allow time for silence
- Reassure the family that, although there is no cure, there is treatment available and emphasize that children can live many years before they become sick with HIV-related illnesses. Talk about available antiretroviral treatments for HIV, and early initiation of treatment will benefit and protect the child from getting sick
- Recognize that many people may interpret this diagnosis as a death sentence
- Anticipate reactions of grief, shock, disbelief, denial, and anger. Offer appropriate support
- Discuss ways to keep the child healthy
- Emphasize the need for immunizations
- Talk about good nutrition, including the important of continuing breast-
feeding for as long as one year if the mother is still breastfeeding.

- Explain the importance of routinely monitoring the child, continuing breastfeeding for as long as one year if the mother is still breastfeeding.
- Stress the child should live an active life and play like other children whenever possible
- Review the importance of prompt medical attention as well as preventive care. If the baby is less than 12 months old, stress the importance of PCP prophylaxis; ensure access to Cotrimoxazole, and instruct the parent how to give the liquid. Communicate with the parent that the co-trimoxazole is not to prevent HIV infection.
- Review Standard Precautions for Infection Prevention
- Reassure the family that close familial contact and normal baby care do not transmit HIV
- Review measures for diaper/nappy changing (no gloves are necessary), blood spills (use a barrier), and open sores (they should be covered)
- Identify other family members who could be at risk for HIV infection
- Identify, counsel, and test siblings who could be at risk. Families must be given time and support to do this
- Identify a support system
- Identify a personal support system for the family
- Assess the psychological status of mother and other family members
- Refer family to a support group, if they are interested
- Provide the family with written material that they can take home if they are interested
- Review issues of confidentiality
- Introduce disclosure issues
- Explain how confidentiality is handled in the clinical setting
- Review and offer additional information as appropriate
### Annex B: Monthly HMIS service delivery report – PMTCT Indicators

<table>
<thead>
<tr>
<th>PMTCT Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Percentage of pregnant and lactating women who were tested for HIV and who know their result</td>
</tr>
<tr>
<td>[Numerator: No of pregnant women tested for HIV at ANC , L&amp;D, and PNC in the reporting month]</td>
</tr>
<tr>
<td>Denominator: Estimated number of pregnant women in the reporting month</td>
</tr>
<tr>
<td><strong>1.1</strong> Number of pregnant women tested and know their result during pregnancy</td>
</tr>
<tr>
<td><strong>1.2</strong> Number of pregnant women tested and know their result during labor &amp; delivery</td>
</tr>
<tr>
<td><strong>1.3</strong> Number of lactating women tested and know their result during the postpartum period</td>
</tr>
<tr>
<td><strong>1.4</strong> Number of women who knew their HIV status before the current pregnancy (on ART)</td>
</tr>
<tr>
<td><strong>2</strong> Number of women tested positive for HIV (Newly identified and already known )</td>
</tr>
<tr>
<td><strong>3</strong> Percentage of HIV positive pregnant and lactating women who received ART at ANC+L&amp;D+PNC for the first time and who get pregnant while on ART</td>
</tr>
<tr>
<td>[Numerator: Number of HIV positive pregnant and lactating women who received ART at ANC, L&amp;D and PNC for the first time and those women who get pregnant while on ART &amp; linked to ANC in the reporting period]</td>
</tr>
<tr>
<td>Denominator: Estimated HIV positive pregnant women in the year</td>
</tr>
<tr>
<td><strong>3.1</strong> Number of HIV Positive pregnant who received ART at ANC for the first time</td>
</tr>
<tr>
<td><strong>3.2</strong> Number of HIV positive Pregnant women who received ART to reduce the risk of mother to child transmission during L&amp;D for the first time</td>
</tr>
<tr>
<td><strong>3.3</strong> Number of HIV positive lactating women who received ART to reduce the risk of mother to child transmission during PNC for the first time</td>
</tr>
<tr>
<td><strong>3.4</strong> Number of HIV-positive women who get pregnant while on ART and linked to ANC</td>
</tr>
<tr>
<td><strong>4</strong> Percentage of HIV infected women using a modern family planning method</td>
</tr>
<tr>
<td>[Numerator: No. of HIV infected women aged 15–49 years attending PNC + ART reported the use of any method of modern family planning]</td>
</tr>
<tr>
<td>Denominator: No. of HIV positive women aged 15–49 years attending PNC + ART during the reporting month]</td>
</tr>
<tr>
<td><strong>4.1</strong> Number of HIV infected women aged 15–49 reported the use of any method of modern family planning</td>
</tr>
</tbody>
</table>
5. Percentage of partners of pregnant, laboring and lactating women tested for HIV during the reporting month
   (Numerator: Number of partners of pregnant, laboring and lactating women tested for HIV
   Denominator: Total number of pregnant, laboring and lactating women tested for HIV)

5.1 Number of partners of pregnant, laboring and lactating women tested for HIV whose test result is HIV negative

5.2 Number of partners of pregnant, laboring and lactating women tested for HIV whose test result is HIV positive

6. Percentage of pregnant/breast feeding women who received routine viral load testing
   [Numerator: No of HIV positive pregnant/breast feeding women who received routine viral load testing in the reporting month
   Denominator: Total number of HIV positive pregnant/breast feeding women in the reporting month]

7. Percentage of HIV positive pregnant & BF women with a suppressed viral load (<1000 copies/ml)
   [Numerator: No of HIV positive pregnant & BF women with a suppressed viral load (<1000 copies/ml) in the reporting month
   Denominator: Total number of HIV positive pregnant & BF women on ART in the reporting month]

8. No/% of pregnant women attending antenatal care tested for HBV
   [Numerator: No of pregnant women tested for HBV in the reporting month
   Denominator: Total number of pregnant women who attended first ANC visit in the reporting month]

9. Number of pregnant women who were received prophylaxis for HBV

10. Number % of pregnant women tested for syphilis
    [Numerator: No of pregnant women tested for syphilis in the reporting month
    Denominator: Total number of pregnant women who attended first ANC visit in the reporting month]

11. Number of Partners of Syphilis positive pregnant and lactating women who are tested for syphilis

12. Proportion of pregnant women treated for syphilis
    [Numerator: No of pregnant women treated for syphilis in the reporting month
    Denominator: Total number of pregnant women tested positive for syphilis in the reporting month]
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Numerator</th>
<th>Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Proportion of pregnant/breast feeding women who put on 3-month multi-month dispensing (MMD)</td>
<td>Number of pregnant/breast feeding women who put on 3-month multi-month dispensing (MMD) in the reporting month</td>
<td>Total Number of HIV positive pregnant/breast feeding women on ART in the reporting month</td>
</tr>
<tr>
<td>14</td>
<td>Number of Discordant couples who took PrEP in the PMTCT setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Percent of infants who received a HBV BD within 24 hours after birth.</td>
<td>No. of infants who received a HBV –BD within 24 hours after birth during the reporting month</td>
<td>Total # live births during the reporting period</td>
</tr>
<tr>
<td>16</td>
<td>Percent of children under one year of age who have received third dose of pentavalent vaccine</td>
<td>Number of infants who received third dose of pentavalent vaccine during the reporting month (8.1–8.6)</td>
<td>Total # live births during the reporting period</td>
</tr>
<tr>
<td>17</td>
<td>Percent of Congenital syphilis</td>
<td>No. of infants with of congenital syphilis during the reporting month</td>
<td>Total number of syphilis reactive women during pregnancy</td>
</tr>
<tr>
<td>18</td>
<td>Percentage of infants born to HIV infected women receiving a virological test for HIV within 12 months of birth</td>
<td>No. of HIV exposed infants who received an HIV DNA/PCR test within 12 months of birth, during the reporting month</td>
<td>Total # live births (HEIs) from estimated HIV+ pregnant women during the reporting period</td>
</tr>
<tr>
<td>18.1</td>
<td>Number of HIV exposed infants who received an HIV DNA/PCR test within 2 months of birth, during the reporting period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.2</td>
<td>Number of HIV exposed infants receiving HIV DNA/PCR test within 2 months of birth whose test result is HIV negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.3</td>
<td>Number of HIV exposed infants receiving HIV DNA/PCR test within 2 months of birth whose test result is HIV positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.4</td>
<td>Number of HIV exposed infants who received an HIV DNA/PCR test between 2 to 12 months, during the reporting period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.5</td>
<td>Number of HIV exposed infants receiving HIV DNA/PCR test within 2 to 12 months of birth whose test result is HIV Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.6</td>
<td>Number of HIV exposed infants receiving HIV DNA/PCR test within 2 to 12 months of birth whose test result is HIV positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>
| 19 | **Percentage of Infants born to HIV-infected women started co-trimoxazole prophylaxis within two months of birth**  
Numerator: Number of infants born to HIV infected women started on co-trimoxazole prophylaxis within two months of birth during the reporting period  
Denominator: Total # live births (HEIs) from estimated HIV+ pregnant women during the reporting period |
| 20 | **Percentage of infants born to HIV-infected women receiving antiretroviral (ARV) prophylaxis for prevention of mother-to-child transmission**  
[Numerator: Number of exposed infants received ARV prophylaxis for 12 weeks during the reporting period  
Denominator: Total number of expected live births from HIV positive mothers during the reporting period |
| 21 | **Percentage of HIV exposed infants receiving HIV confirmatory (antibody) test by 18 months**  
[Numerator: No of HIV exposed infants receiving HIV confirmatory (antibody test) by 18 months during the reporting month  
Denominator: Number of eligible HEI during the reporting month |
| 21.1 | **Number of HIV exposed infants receiving HIV confirmatory (antibody) by 18 months- whose test result is Negative** |
| 21.2 | **Number of HIV exposed infants receiving HIV confirmatory (antibody) by 18 months- whose test result is Positive** |
Annex C: Maternal Cohort Report form for the health facility

FEDERAL MINISTRY OF HEALTH OF ETHIOPIA
MATERNAL PMTCT COHORT REPORT FORM FOR THE HEALTH FACILITY

For this maternal cohort, record the number of women enrolled in PMTCT (Month 0). Assess the following at 3, 6, and 12 months since the mothers’ enrollment into PMTCT.

<table>
<thead>
<tr>
<th>Maternal Cohort Month 0 [mm/yy]</th>
<th>Maternal Cohort Month 3 [mm/yy]</th>
<th>Maternal Cohort Month 6 [mm/yy]</th>
<th>Maternal Cohort Month 12 [mm/yy]</th>
<th>Maternal Cohort Month 24 [mm/yy]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Number of HIV-infected women enrolled in PMTCT in this facility during this month and year (Month 0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UPDATE THE COHORT SIZE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B Total number of Transfer in (TI) since Month 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C Total number of Transfer out (TO) since Month 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Number of mothers in the current cohort = Net current cohort (A+B−C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RECORD MATERNAL OUTCOME</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E Mothers Alive and on ART</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F Lost to F/U (not seen &gt;1 month after scheduled appointment)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G Known dead</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CALCULATE MATERNAL RETENTION AND LTF (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H % of mothers in net current cohort Alive and on ART [(E/D) x 100% at 3, 6, and 12 months since PMTCT enrollment]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I % of mothers in net current cohort Lost to F/U [(F/D) x 100% at 3, 6, and 12 months since PMTCT enrollment]</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
### Annex D: HIV-EXPOSED INFANT (HEI) PMTCT COHORT REPORT FORM FOR THE HEALTH FACILITY

**FEDERAL MINISTRY OF HEALTH OF ETHIOPIA**

MATERNAL PMTCT COHORT REPORT FORM FOR THE HEALTH FACILITY

Maternal Enrollment Cohort Month: ___________ Year: ___________

Health Facility Name: __________________ Region: ___________ Woreda: ___________

Facility type: Health Center Hospital Other: __________________

Facility ownership: Public Private not for profit Private for profit Uniformed

For this HIV-exposed Infant (HEI) cohort, report the number of infants born to mothers who enrolled in PMTCT (shared event = maternal enrollment Month 0). Assess the following at 12, 18, 24 and 30 months since the mothers’ enrollment into PMTCT.

Fill in the exact Month/Year of 12, 18, 24 and 30 months from the month of maternal PMTCT enrollment (MATERNAL COHORT MONTH & YEAR).

<table>
<thead>
<tr>
<th>Maternal Cohort Month</th>
<th>Maternal Cohort Month</th>
<th>Maternal Cohort Month</th>
<th>Maternal Cohort Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>month 0 [mm/yy]</td>
<td>12 [mm/yy]</td>
<td>18 [mm/yy]</td>
<td>24 [mm/yy]</td>
</tr>
</tbody>
</table>

A. Number of HIV-infected women enrolled in PMTCT in this facility during this month and year (Month 0)

B. Total number of HEI Transfer In (TI) since Month 0

C. Number of HEI in the current cohort (A+B)

D. Total number of Transfer in (TI) since Month 0

**LOST TO FOLLOW UP – (report at MATERNAL COHORT MONTH 12, 18, 24)**

<table>
<thead>
<tr>
<th>HEI WITH DNA PCR COLLECTION – (report at MATERNAL COHORT MONTH 12, 18) # %* # %*</th>
</tr>
</thead>
<tbody>
<tr>
<td>E HEI with DNA PCR test collected by 2 months of age</td>
</tr>
<tr>
<td>F HEI with DNA PCR test collected between 2 and 12 months of age</td>
</tr>
</tbody>
</table>

**HEI FINAL OUTCOME – (report at MATERNAL COHORT MONTH 30) # %**

| G HEI discharged negative (DN) | # %* |
| H HEI diagnosed positive (P) | # %* |
| I Final HEI Lost to F/U | # %* |
| J HEI still exposed/breastfeeding (CPT) | # %* |
| K HEI known dead (D) | # %* |
| L HEI transferred out (TO to another facility--NOT to ART clinic) | # %* |

*Calculate percentages for HEI DNA PCR and Final Outcome as Number of infants with given outcome divided by the number of HEI in the current cohort. Cohort size is found in Row A for Maternal Cohort Month 12, and Row C for Maternal Cohort Months 18, 24, 30. For Month 12, use formula: #/Row A *100% For Months 18 and 30, use formula: #/Row C *100%
Annex E: HIV Exposed Infant (HEI) PMTCT Cohort wall chart

**HIV-EXPOSED INFANT (HEI) PMTCT COHORT WALL CHART**

**FACILITY NAME: _________________________**

HIV-exposed infant cohorts are defined by Month / Year of mother’s PMTCT Enrollment (Maternal Cohort Month 0)

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
</tr>
</tbody>
</table>

**HEI WITH DNA PCR COLLECTED (%)**  
- at MATERNAL COHORT MONTH 18

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
</tr>
</tbody>
</table>

**HEI FINAL OUTCOME (%)**  
- at MATERNAL COHORT MONTH 30

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
</tr>
</tbody>
</table>

**CALCULATIONS: HEI DNA PCR COVERAGE and FINAL OUTCOMES**

A. Number of HEI born to HIV+ mothers who enrolled in PMTCT during Maternal Cohort Month 0
B. Total number of HEI Transfer in (TI) since Maternal Cohort Month 0
C. Number of HEI in the current cohort (A+B)
D. HEI Lost to F/U

**HEI WITH DNA PCR COLLECTED (%)**  
- at MATERNAL COHORT MONTH 18

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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</tbody>
</table>

**HEI FINAL OUTCOME (%)**  
- at MATERNAL COHORT MONTH 30

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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<tbody>
<tr>
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<td>Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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</tbody>
</table>

**HEI WITH DNA PCR COLLECTED (%)**  
- at MATERNAL COHORT MONTH 18

<table>
<thead>
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<th>Month</th>
<th>Year</th>
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<tbody>
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<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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</tbody>
</table>

**HEI FINAL OUTCOME (%)**  
- at MATERNAL COHORT MONTH 30

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
</tr>
</tbody>
</table>

**HEI WITH DNA PCR COLLECTED (%)**  
- at MATERNAL COHORT MONTH 18

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<td>0 Month 12 Month 18 Month 24 Month 30</td>
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</table>

**HEI FINAL OUTCOME (%)**  
- at MATERNAL COHORT MONTH 30

<table>
<thead>
<tr>
<th>Month</th>
<th>Year</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Month 12 Month 18 Month 24 Month 30</td>
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<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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**HEI WITH DNA PCR COLLECTED (%)**  
- at MATERNAL COHORT MONTH 18

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<th>Month</th>
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<tbody>
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<td>Month 12 Month 18 Month 24 Month 30</td>
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**HEI FINAL OUTCOME (%)**  
- at MATERNAL COHORT MONTH 30

<table>
<thead>
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<th>Month</th>
<th>Year</th>
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<tbody>
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<tr>
<td>Month</td>
<td>0 Month 12 Month 18 Month 24 Month 30</td>
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</tbody>
</table>
**Annex F: Maternal PMTCT Cohort Wall Chart**

**MATERNAL PMTCT COHORT WALL CHART**

**FACILITY NAME:** ______________________

Maternal cohorts are defined by Month / Year of mother’s PMTCT Enrollment (Month 0)

<table>
<thead>
<tr>
<th>Month</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>12</th>
<th>24</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>12</th>
<th>24</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>12</th>
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<tbody>
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<tr>
<td>Number of HIV-infected women enrolled in PMTCT during this month and year</td>
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<tr>
<td>Total number of Transfer in (TI) since Month 0</td>
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<tr>
<td>Total number of Transfer out (TO) since Month 0</td>
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<tr>
<td>Number of mothers in the current cohort = net current cohort (A+B-C)</td>
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<tr>
<td>Mothers Alive and on ART</td>
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<tr>
<td>Lost to F/U (&gt;1 month)</td>
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<td>Known dead</td>
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</tr>
</tbody>
</table>

**MATERNAL OUTCOMES (%)**

-- at MATERNAL COHORT MONTH 3, 6, & 12

<table>
<thead>
<tr>
<th>Month</th>
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<th>3</th>
<th>6</th>
<th>12</th>
<th>24</th>
<th>0</th>
<th>3</th>
<th>6</th>
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<th>24</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>12</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H</strong></td>
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</tr>
<tr>
<td>% of mothers in current cohort retained in PMTCT (Alive and on ART) (E/D x 100%)</td>
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<td><strong>I</strong></td>
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</tr>
<tr>
<td>% of mothers in current cohort Lost to F/U (LTF) (F/D x 100%)</td>
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</tbody>
</table>
Annex G: Dashboard for monthly MNCH/PMTCT Performance Monitoring

<table>
<thead>
<tr>
<th>Region</th>
<th>Zone</th>
<th>Woreda/Sub city</th>
<th>No. of Health Facility</th>
<th>Total population</th>
<th>Total Estimated pregnant women/Annum</th>
<th>Total Estimated HIV positive Mothers needing PMTCT</th>
</tr>
</thead>
</table>

**DASHBOARD SCORING**

<table>
<thead>
<tr>
<th>Color</th>
<th>Percentage and Color and Scoring Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green:</td>
<td>80%-100%</td>
</tr>
<tr>
<td>Yellow:</td>
<td>60%-79%</td>
</tr>
<tr>
<td>Red:</td>
<td>&lt;60%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S. No</th>
<th>Variable Description, for the reporting period</th>
<th>Number</th>
<th>Percentage</th>
<th>Score Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Total # of HIV+ pregnant or lactating women that were enrolled in care in the facility (can be unit specific-ANC, L&amp;D, PNC) (ANC + Labor &amp; Delivery + PNC) = PMTCT register</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td># of HIV+ pregnant &amp; lactating women identified,(New)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td># of HIV+ women already on ART when coming to ANC/ L&amp;D/ PNC,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Of these, the # and % of HIV+ pregnant/ lactating women receiving ART (newly initiated on ART and Already on ART linked with ANC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Proportion of HIV+ women newly initiated on ART,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Total # and % of HIV+ pregnant/ lactating women receiving co-trimoxazole (CTX) according to national guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>% of HIV+ pregnant/ lactating women on ART with viral suppression (&lt;1000ml)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Total # and % of HIV+ pregnant/ lactating women - nutritional assessment done with MUAC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Total # and % of Malnourished HIV+ pregnant/ lactating women linked/ provided with nutritional care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Total # and % of HIV+ lactating women who received FP counselling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Total # and % of lactating HIV+ women using modern FP methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Total # and % of pregnant or lactating HIV+ women who are labeled LTFU (missed appointment for more than 31 days)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Description</td>
<td></td>
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<td>--------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>13</td>
<td>Total # of HIV exposed infants (HEIs) enrolled in care in the facility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Total # and % of HEIs enrolled in care and receiving NVP + AZT prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Total # and % of HEIs who had virologic testing for HIV at 6 to 8 weeks of age</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16</td>
<td>Total # and % of HEIs who had virologic testing for HIV from 2-12 months of age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Total # and % of HEIs Antibody testing done for HIV at 18 months of age to confirm HIV outcome</td>
<td></td>
<td></td>
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<tr>
<td>18</td>
<td>Total # and % of HEIs receiving Co-trimoxazole (CPT)</td>
<td></td>
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<tr>
<td>19</td>
<td>Total # and % of HEIs with a positive virologic test result</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>20</td>
<td>Total # and % of HEIs with positive virologic test result linked to HIV care (initiated ART)</td>
<td></td>
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<tr>
<td>21</td>
<td>Total # and % of male Partners tested &amp; know their HIV status during the reporting period (ANC/ L&amp;D/ PNC)</td>
<td></td>
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<tr>
<td>22</td>
<td>Total # and % of pregnant women tested for Syphilis</td>
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<tr>
<td>23</td>
<td>Total # and % of pregnant women reactive for Syphilis test and treated</td>
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<tr>
<td>24</td>
<td>Total # and % of pregnant women tested for HBV</td>
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<td></td>
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<tr>
<td>25</td>
<td>Total # and % of pregnant women received HBV prophylaxis</td>
<td></td>
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</tr>
</tbody>
</table>

Name and responsibility of the reporter _______________________
Month________________ Year _______________________

National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus
Annex H: Checklist for PMTCT Monthly Site Supervision

Continuous and regular supportive supervision is the key to sustainable improvement of the PMTCT service delivery and for the improvement of RMNCAH/SRH service in general. Before going for the supportive supervision, supervisors should have basic data and information about the service they are going to supervise.

1. **Identification**

Month: [ ] Date of visit: [ ]
Name of site visited: [ ] Region: [ ] Zone: [ ] Woreda: [ ]
Telephone: [ ] e-mail of supervisor/team leader: [ ]

<table>
<thead>
<tr>
<th>2. Leadership (program management)</th>
<th>Yes</th>
<th>No</th>
<th>If no write the reason why</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is focal person assigned for PMTCT</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Functioning TWG for E-MTCT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. **Human Resource**

- Enough trained staff deployed per facility (4 of supervisor/team)

4. **Finance management**

- Is enough budgets allocated for PMTCT? (comment on source of budget)
- If source of fund is of partners, is there an outstanding fund? (fund that was not liquidated timely)

5. **Integrated Service Delivery**

<table>
<thead>
<tr>
<th>5.1 Any service interruption?</th>
<th>If yes, why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2 Community referral</td>
<td></td>
</tr>
<tr>
<td>5.2.1 Is there any community referral card in the facility?</td>
<td></td>
</tr>
<tr>
<td>5.2.2 Is the community team actively functioning?</td>
<td></td>
</tr>
<tr>
<td>5.2.3 Regular meeting, community conversation, house visit etc.</td>
<td></td>
</tr>
<tr>
<td>5.2.4 Any other?</td>
<td></td>
</tr>
<tr>
<td>6. Sustainable Supply mgmt. system: Essential equipment and supplies</td>
<td>If no, why?</td>
</tr>
<tr>
<td>6.1 Antiretroviral drugs</td>
<td>Expiry date</td>
</tr>
<tr>
<td>AZT + NVP Syrup in labor ward</td>
<td></td>
</tr>
<tr>
<td>TDF+3TC+DTG (combined) at ANC/Labor ward and pharmacy</td>
<td></td>
</tr>
<tr>
<td>ARV drug stock balance update</td>
<td></td>
</tr>
<tr>
<td>6.2 Laboratory Supplies</td>
<td></td>
</tr>
<tr>
<td>HIV Screening Test Kit</td>
<td></td>
</tr>
<tr>
<td>HIV Confirmatory Test Kit</td>
<td></td>
</tr>
<tr>
<td>HIV Tie Breaker Test Kit</td>
<td></td>
</tr>
<tr>
<td>DBS testing kits</td>
<td></td>
</tr>
<tr>
<td>DNA-PCR reagents</td>
<td></td>
</tr>
<tr>
<td>6.3 IP Supplies</td>
<td></td>
</tr>
<tr>
<td>Gloves</td>
<td></td>
</tr>
<tr>
<td>Aprons</td>
<td></td>
</tr>
<tr>
<td>Goggles</td>
<td></td>
</tr>
<tr>
<td>Autoclaves</td>
<td></td>
</tr>
<tr>
<td>Sharp containers</td>
<td></td>
</tr>
<tr>
<td>6.4 Basic Obstetric Care Supplies/equip</td>
<td></td>
</tr>
<tr>
<td>Delivery couches</td>
<td></td>
</tr>
<tr>
<td>Delivery sets</td>
<td></td>
</tr>
<tr>
<td>Oxytocin</td>
<td></td>
</tr>
<tr>
<td>7. Job Aids and IEC Materials</td>
<td></td>
</tr>
<tr>
<td>PMTCT updated guideline available</td>
<td>Yes No If no, why?</td>
</tr>
<tr>
<td>PMTCT brochures/leaflets</td>
<td></td>
</tr>
<tr>
<td>EID job aids available</td>
<td></td>
</tr>
<tr>
<td>Birth preparedness checklist</td>
<td>If yes, frequency per week</td>
</tr>
<tr>
<td>Health education sessions on PMTCT conducted</td>
<td></td>
</tr>
<tr>
<td>Presence of monthly group education schedule</td>
<td></td>
</tr>
<tr>
<td>8. Available PMTCT Related Formats and register</td>
<td>If no, why?</td>
</tr>
<tr>
<td>Integrated/PMTCT/RMNCAH register</td>
<td></td>
</tr>
<tr>
<td>ANC/L&amp;D/PNC register</td>
<td></td>
</tr>
<tr>
<td>Lab logbook (EID)</td>
<td></td>
</tr>
<tr>
<td>Lab referral slips</td>
<td></td>
</tr>
<tr>
<td>Referral linkage slips</td>
<td></td>
</tr>
<tr>
<td>ANC-PMTCT appointment book</td>
<td></td>
</tr>
<tr>
<td>Monthly summary reporting format (HMIS)</td>
<td></td>
</tr>
<tr>
<td>PMTCT cohort report format</td>
<td></td>
</tr>
<tr>
<td>9. Management support</td>
<td>If no, why?</td>
</tr>
<tr>
<td>Is there a functional management team?</td>
<td></td>
</tr>
</tbody>
</table>

National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a counselor support group?</td>
<td></td>
</tr>
<tr>
<td>Is there CQI team (multidisciplinary team)?</td>
<td></td>
</tr>
<tr>
<td>How regular is the MDT conduct their function?</td>
<td></td>
</tr>
<tr>
<td>Is there clinical and systemic mentoring conducted?</td>
<td></td>
</tr>
<tr>
<td>10. HMIS/Health management information system- M&amp;E</td>
<td>If no, why?</td>
</tr>
<tr>
<td>Completeness of the report and registration</td>
<td></td>
</tr>
<tr>
<td>Is cohort follow-up report done quarterly?</td>
<td></td>
</tr>
<tr>
<td>Analysis and use of data at facility level</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Best Practice/initiative</td>
<td>If no, why?</td>
</tr>
<tr>
<td>Any innovative experience/initiative practiced or documented?</td>
<td></td>
</tr>
<tr>
<td>Service uptake in the last quarter</td>
<td></td>
</tr>
<tr>
<td># of ANC:</td>
<td></td>
</tr>
<tr>
<td># of ANC/HTC:</td>
<td></td>
</tr>
<tr>
<td># of ANC/VDRL:</td>
<td></td>
</tr>
<tr>
<td># of ANC /VDRL reactive:</td>
<td># of HIV pos. mothers on FDC:</td>
</tr>
<tr>
<td># of male partner tested and know their status: /VDRL</td>
<td></td>
</tr>
<tr>
<td># of HIV Pos. ANC + Laboring + Lactating mothers:</td>
<td># of</td>
</tr>
<tr>
<td># of HIV pos. mothers on FDC:</td>
<td></td>
</tr>
<tr>
<td># of HEI’s DBS done:</td>
<td></td>
</tr>
<tr>
<td># Infants HIV positive:</td>
<td></td>
</tr>
<tr>
<td>............ing mothers:</td>
<td># HIV Pos. Women (on ART/ on pre ART/ room under follow up in RM-NCAH) and are on Family planning:</td>
</tr>
</tbody>
</table>

How are the kits and supplies stored?

________________________________________________________________________

Please comment on the supply chain management:

________________________________________________________________________

Priority challenges identified:

________________________________________________________________________
Actions taken and support provided by facilitator during site visit:

__________________________________________________________________________________________

General comment and suggestions:

__________________________________________________________________________________________

Comments of the supervisee:

__________________________________________________________________________________________

Signature of the supervisee:

__________________________________________________________________________________________

Signature of the supervisor/team leader

__________________________________________________________________________________________
### Annex I: Mother Baby Pair Cohort Register

#### Health Centre /Clinic/Hospital PMTCT Register

<table>
<thead>
<tr>
<th>Region</th>
<th>Zone/Subcity/Woreda</th>
<th>Health Facility Name</th>
<th>Begin Date</th>
<th>End Date</th>
</tr>
</thead>
</table>

National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus
**Annex J. Definitions of Data Elements**

**INSTRUCTIONS FOR INTEGRATED MNCH/PMTCT REGISTER**

<table>
<thead>
<tr>
<th>Col.No</th>
<th>Data Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. N.</td>
<td></td>
<td>Sequential serial number in registration book, beginning with 1 for the first client in the cohort.</td>
</tr>
<tr>
<td>Mother’s name</td>
<td></td>
<td>Name of the mother</td>
</tr>
<tr>
<td>MRN</td>
<td></td>
<td>Write Unique individual identifier for mother used on medical Information folder, for HC and hospital.</td>
</tr>
<tr>
<td>ART unique ID number</td>
<td></td>
<td>Record the existing Unique ART number or assign one during initiation. A unique ART number should be assigned to clients initiated on ART at MNCH clinic. This includes: region number / facility type code / specific facility code / client assigned number. Region number: the following code numbers are used:</td>
</tr>
<tr>
<td></td>
<td>Tigray:- 01</td>
<td>SNNPR:- 07</td>
</tr>
<tr>
<td></td>
<td>Afar:- 02</td>
<td>Gambella :- 12</td>
</tr>
<tr>
<td></td>
<td>Amhara:- 03</td>
<td>Harar :- 13</td>
</tr>
<tr>
<td></td>
<td>Oromia:- 04</td>
<td>Addis Ababa :- 14</td>
</tr>
<tr>
<td></td>
<td>Somali:- 05</td>
<td>Dire Dawa :- 15</td>
</tr>
<tr>
<td></td>
<td>Benishangul Gummuz :- 06</td>
<td>Sidama :-</td>
</tr>
<tr>
<td></td>
<td>Facility type code: Hospital =08</td>
<td>Health Center = 09</td>
</tr>
<tr>
<td></td>
<td>Each HC / hospital in each region is coded with three digits starting from 001. These specific facility codes are assumed to be given by regions together with federal, which means it is pre coded and given to each facility centrally.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient assigned number: A 5 digit number unique within the facility; the first pregnant woman to start ART in the clinic will be given 00001.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Example Unique ART No. 01/08/001/00001</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Age of the woman in years, Document the clients age in the column,</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Booking Date</strong></td>
<td>Booking date is the first date for Maternal enrollment in PMTCT. If the mother starts ART in the PMTCT clinic in the same day, this date will be the same with ART start date. But for mothers who had already started ART, the booking date will be entered and as a result the date will be different from ART initiated date</td>
<td></td>
</tr>
<tr>
<td><strong>Newly diagnosed &amp; started on ART</strong></td>
<td>Write “1” for the women who are diagnosed and started on ART during ANC for the first time. Write “2” for the women who are diagnosed and started on ART during at L&amp;D for the first time. Write “3” for the women who are diagnosed and started on ART during PNC for the first time.</td>
<td></td>
</tr>
<tr>
<td><strong>Known HIV + write code (1=On ART at entry; 2=Not on ART)</strong></td>
<td>Write “1” for woman who was started on ART before PMTCT entry. Write “2” for known HIV + women was not started ART before PMTCT entry.</td>
<td></td>
</tr>
<tr>
<td><strong>LNMP</strong></td>
<td>Write the date (DD/MM/YY) of the last normal menstrual period.</td>
<td></td>
</tr>
<tr>
<td><strong>EDD</strong></td>
<td>Write the Expected date (DD/MM/YY) of delivery.</td>
<td></td>
</tr>
<tr>
<td><strong>Gestational age (GA) in weeks</strong></td>
<td>Write the gestational age (GA) in weeks.</td>
<td></td>
</tr>
<tr>
<td><strong>Ferrous Sulfate/ Folic Acid Provided (Y/N)</strong></td>
<td>Write “Y” if ferrous sulphate / folic acid is provided. Write “N” if ferrous sulphate / folic acid is not provided.</td>
<td></td>
</tr>
<tr>
<td><strong>Syphilis test result (R/NR/ND)</strong></td>
<td>Write “R” if the syphilis test result is Reactive. Write “N” if the syphilis test result is not Reactive. Write “ND” if syphilis test is not done.</td>
<td></td>
</tr>
<tr>
<td><strong>Selected Infant Feeding option (EBF, ERF, MF)</strong></td>
<td>Write “EBF” if the mother selects exclusive breast feeding. Write “ERF” if the mother selects exclusive replacement feeding. Write “MF” if the mother selects mixed feeding.</td>
<td></td>
</tr>
<tr>
<td><strong>Date of delivery</strong></td>
<td>Write the date the mother gave birth E.C. (DD/MM/YY)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex of Infant (M/F)</strong></td>
<td>Write “M” if the Infant is Male or Write “F” if the Infant is Female</td>
<td></td>
</tr>
</tbody>
</table>
| **Place of Delivery (write code)** | Write code for Place of Delivery  
1= same facility,  
2= another health facility  
3= home delivery. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery Outcome (LB,SB)</strong></td>
<td>Write “LB” if delivery outcome is Live Birth or Write “SB” if delivery outcome is Still birth.</td>
</tr>
<tr>
<td><strong>ART Taken During Labor (Y/N)</strong></td>
<td>Write “Y” if the woman took ART during delivery or “N” if the women didn’t take ART during delivery</td>
</tr>
<tr>
<td><strong>Infant Received ARV Prophylaxis (AZT + NVP for the 1st 6 weeks) &amp; (NVP only for the next 6 weeks) total 12 weeks (Y/N)</strong></td>
<td>Write “Y” Infant Received ARV Prophylaxis (AZT + NVP for the 1st 6 weeks) &amp; (NVP only for the next 6 weeks) total 12 weeks, I not write “N”</td>
</tr>
<tr>
<td><strong>Family Planning Counseled(Y/N)</strong></td>
<td>Write “Y” if the mother is counseled on family planning or “N” if the mother is not counseled on family planning.</td>
</tr>
<tr>
<td><strong>New acceptor (√)</strong></td>
<td>Tick (√) if client is new acceptor at the time of registration. A new acceptor is someone who has not received a contraceptive method from a recognized Provider before registration.*</td>
</tr>
</tbody>
</table>
| **Repeat acceptor (√)** | Tick (√) if client is repeat acceptor at the time of registration. 
A repeat acceptor is someone who is not a new acceptor; in other words, a repeat acceptor has received a contraceptive method from a recognized Provider before registration. |
<p>| <strong>Contraceptive provided (write abbreviation)</strong> | Write abbreviation of modern contraceptive methods a client chose. See the abbreviation on the register. |
| <strong>HIV testing accepted (√)</strong> | Tick (√) if the partner/husband accepts testing for HIV |
| <strong>Partner tested (P/N/ND)</strong> | Write “P” if test result is positive, Write “N” if the test result is negative, Write “ND” if partner test is not done. |
| <strong>Partner Target population Category write code</strong> | Write the selected from the following list of target population category. An individual should be assigned to only one category that best describes him/her. A= Female Commercial Sex workers , B= Long distance drivers, C= Mobile/Daily Laborers, D= Prisoners, E= OVC, F= Children of PLHIV, G= Partners of PLHIV, H= Other MARPS, I= General population |
| <strong>HIV Positive partner Linked to ART</strong> | Tick (√) if the partner is positive and linked to ART. |
| <strong>TB symptom screening (P/N/ND)</strong> | Write the mother’s TB symptom screening result as “P” for Positive, “N” for Negative and “ND” for test not done |
| <strong>Date INH prophylaxis started</strong> | Write the date as E.C(DD/MM/YY) INH prophylaxis is initiated. |
| <strong>Date TB Rx started/Unit TB Number</strong> | Write the date as E.C(DD/MM/YY) TB Rx is initiated on the upper row and unit TB Number in lower row. |
| <strong>Initial CD4 count(Value/ND)</strong> | Write initial mother’s CD4 count value as a baseline for newly enrolled mothers in PMTCT after initiating ART as soon as possible. For those mothers who are already on ART during enrollment, the most recent CD4 count value has to be documented or write ND if CD4 count is not done |
| <strong>WHO Clinical Stage</strong> | Write mother’s WHO clinical stage. |
| <strong>Maternal CPT started (Y/N)</strong> | Write “Y” if mother started CPT prophylaxis or Write “N” if mother didn’t start CPT prophylaxis. |
| <strong>Date ART initiated</strong> | Write ART start date on which ART was started and could be the same as booking date for those clients newly started ART. |
| <strong>Initial ART Regimen (write Code)</strong> | Write the code for the regimen that patient has started. This is found at the bottom of the ART register. |
| <strong>Infant’s MRN</strong> | Write the medical record number of the HIV exposed infant |
| <strong>Date of HEI enrollment to PMTCT</strong> | Write date of the HIV Exposed Infant (HEI) enrolled in PMTCT cohort |</p>
<table>
<thead>
<tr>
<th><strong>Infant Received NVP write code</strong>&lt;br&gt;(1=For 6 wks 2=For 12 wks 3=not provided)</th>
<th>Write “1” if the Infant Received NVP for 6 weeks.&lt;br&gt;Write “2” if the Infant Received NVP for 12 weeks.&lt;br&gt;Write “3” if the Infant is not provided NVP.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant Received NVP (DD/MM/YY)</strong></td>
<td>Write the date AZT + NVP was initiated as (DD/MM/YY)</td>
</tr>
<tr>
<td><strong>Infant feeding practice within the first 6 months (EBF/ERF/MF)</strong></td>
<td>Write “EBF” if exclusive breastfeeding; “ERF” if replacement feeding; “MF” if mixed feeding.&lt;br&gt;Provider should refer the patient follow up card, ask the mother “what, how did she feed her baby every time she comes for follow up (Complete this at 6th month of infant age) to document the status</td>
</tr>
<tr>
<td><strong>Age in wks Started CPT</strong></td>
<td>Write age in weeks when the infant initiated Cotrimoxazole prophylaxis.</td>
</tr>
<tr>
<td><strong>Age in months DNA/PCR test done (MM)</strong></td>
<td>Write age in months DNA/PCR test done.</td>
</tr>
<tr>
<td><strong>Result of DNA/PCR (P/N)</strong></td>
<td>Write “P” if positive or “N” if negative.</td>
</tr>
<tr>
<td><strong>Rapid HIV-AB test result (P/N)</strong></td>
<td>Write “P” if HIV-AB test result is positive or “N” if HIV-AB test result is negative</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Write important patient related issues not incorporated in the list of data elements.</td>
</tr>
</tbody>
</table>

**Right Side of the page**

| **Month “0” in the Right Page** | Month “0” in the Right Page is the initial month and year (MM/YY) that the mothers are enrolled in PMTCT service. This is the shared event for maternal cohort monitoring and analysis of the maternal outcome such as retention and viral load suppression as well as others.<br>Maternal enrolment to PMTCT cohort (MM, YY) is also the shared event for HEI PMTCT Cohort |

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National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus
<table>
<thead>
<tr>
<th>TO, TI, LTF</th>
<th>Write transfer out (TO), transfer in (TI) and lost to follow up (LTF) in the column and row (cell) corresponding to each client followed in the cohort when the situation takes place. –Fill out a formal TO format for clients who is transferring to other PMTCT and ART sites. Write TI for clients transferred out from other PMTCT sites and who came with formal TO. N.B. Clients coming from ART clinics are not considered as TI. These clients are considered as newly enrolled to PMTCT cohort for the purpose of the current pregnancy. Write LTF in the cell for mother miss their appointment for more than two months.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort follow up for the Maternal and HEI PMTCT cohort</td>
<td>Fill the status of mother and infant in each visit using the codes mentioned and write their sums every months at the bottom of each column. Write maternal viral load result at 3 months of ART initiation for newly started ART then put the result every 6 months in the lower row. If viral load is &lt;1,000 copies per ml, write undetectable; otherwise write detectable or &gt;1000 copies /ml. Cohort follow up for the Maternal and HEI PMTCT cohort</td>
</tr>
<tr>
<td>Arrows</td>
<td>For data elements related with “Maternal Status”, Put the total number of retained /alive &amp; On ART Put the total number of “LTF” Put the total number of “TO” Put the total number of mothers with detectable Viral load &gt;1000 copies Put the total number of mothers Malnourished Put the number of deaths. For data elements related with “Infant status”, Put the total number of infants Still on BF /Exposed Put the total number of positive infants “LTF” Put the total number of Discharged negative infants Put the total number of positive infants Put the total number of “TO” Put the number of infant died.</td>
</tr>
</tbody>
</table>
### Annex K.1 PMTCT Register for Health Center / Hospital Page 1

#### PMTCT Register for Health Centre/ Hospital

**Registration**

<table>
<thead>
<tr>
<th>S.N</th>
<th>Mother’s Name</th>
<th>ART unique ID Number</th>
<th>Age</th>
<th>ART Type</th>
<th>ANC</th>
<th>Delivery</th>
<th>HIV Care to be Filled when applicable</th>
<th>HIV Exposed Infant</th>
<th>Convinced on</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>LNMP</th>
<th>EDD</th>
<th>ANC Delivery</th>
<th>Infant  Received ARV Prophylaxis (AZT + NVP for the 1st 6 weeks) &amp; (NVP only for the next 6 weeks) total 12 weeks</th>
<th>Y/N</th>
<th>Family Planning Counseled</th>
<th>Y/N</th>
<th>New accept or (√)</th>
<th>Repeat accept or (√)</th>
<th>HIV Care to be Filled when applicable</th>
<th>HIV Exposed Infant</th>
<th>Convinced on</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>19</td>
<td>20</td>
<td>21</td>
<td>22</td>
<td>23</td>
<td>24</td>
<td>25</td>
<td>26</td>
<td>27</td>
</tr>
</tbody>
</table>

**Use Abbreviation For col. 24**

- Con=Condom
- OC=Oral contraceptive
- bP=Injectable
- Imp=Implant
- IUD=Intrauterine device
- Oth=Others

**Key ART regimen Code (36)**

- 1c = AZT-3TC-NVP
- 1d = AZT-3TC-EFV
- 1e = TDF-3TC-EFV
- 1f = TDF-FTC-NVP
- 1J = TDF-3TC-DTG
- Others, specify

**Targeted population category (27)**

- A. Female Commercial Sex workers
- B. Long distance drivers
- C. Mobile workers/daily laborers
- D. Prisoners
- E. OVC/Children of PLHIV
- F. Other MARPS
- G. General Population

**ART**

- Con=Condom
- Inj=Injectable
- Imp=Implant (Implanon, Jadelle, Sinoplant)
- IUD=Intrauterine device
- Oth=Others

**National Guideline for Prevention of MTCT HIV, Syphilis and Hepatitis B Virus**

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### PMTCT Register for Health Centre/ Hospital

<table>
<thead>
<tr>
<th>Client No.</th>
<th>Months 0-6</th>
<th>Months 7-12</th>
<th>Months 13-24</th>
<th>Months 25-30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td>6</td>
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<td>29</td>
<td>30</td>
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</tr>
</tbody>
</table>

#### Client RXs
- **AZT / NVP**
- **CPT**

#### Maternal PMTCT Cohort Outcomes
- # Retained/Alive & On ART
- # LTF for Lost to follow up of appointment
- # TO for Transferred Out
- # Viral load >1000 copy
- # Malnourished /< Standard BMI
- # D for Known Dead

#### HEI PMTCT Outcomes
- # LTF for Lost to Follow up of appointment
- # D for Died during negative infant tests after 6 months of age
- # D for Dead infant

#### Comments:
- Maternal Viral Load
- Infant Nutritional Status
- Infant Growth
- Infant Development
- Infant Clinical Status
- Infant Laboratory Results

### Annex K.2. PMTCT Register for Health Center / Hospital Page 2

Cohort register (Right)  Year: ___________  Page 2
### Annex L – Follow up form (1)

**HIV CARE/ART FOLLOW-UP FORM MINISTRY OF HEALTH**

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Name:</th>
<th>Age ______ years (Months for Children &lt;5 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>M</td>
<td>F</td>
</tr>
<tr>
<td>Patient Card No</td>
<td>Unique ART No</td>
<td>Date confirmed HIV+ (Retesting):</td>
</tr>
</tbody>
</table>

**Type of HIV Test:** Rapid HIV tests DNA/PCR (for children) Client readiness: (date client is ready) | | |  |

**Height (Adult) in cm:** ______

<table>
<thead>
<tr>
<th>Follow up date</th>
<th>dd/mm/yy</th>
<th>Months on ART</th>
<th>Weight (Kg)</th>
<th>Edema +/-</th>
<th>BMI</th>
<th>MUAC for pregnant women or bedridden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert- MTD/ RB(1)</td>
<td></td>
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<tr>
<td>LF (LAM2)</td>
<td></td>
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<tr>
<td>Type of Co-Ca screening &amp; Treatment</td>
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<tr>
<td>Co-trimoxazole</td>
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<tr>
<td>Co-trimoxazole Preventive therapy</td>
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<tr>
<td>Co-trimoxazole Preventive therapy (Dispensed Dose)</td>
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<tr>
<td>Pregnancy status / FP method</td>
<td></td>
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<tr>
<td>Functional Status W,A,B</td>
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<tr>
<td>WHO Stage (1-4 / T1- T4</td>
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<tr>
<td>TB Screen - P/N Xpert-MTB/ RIF (1)</td>
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<td>TB Treatment/TB Prophylaxis</td>
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<tr>
<td>Dispense Dose TPT drugs (Dispensed Dose)</td>
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<tr>
<td>Patient adherence for TPT (G,F,P)</td>
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<td>Side effect for TPT drugs (see side effect at back 1-13)</td>
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<td>Cx Ca screening &amp; Treatment</td>
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<td>OIs/HIV related cancers</td>
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<td>VL result (copies/ml)</td>
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<td>Hgb.</td>
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<td>ALT/AST/Cr/CrAg</td>
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<td>Type of Cx Ca screening (0-7)</td>
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<td>Management of cervical lesions (0-5)</td>
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<td>Assess &amp; counsel for ARV Adherence</td>
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### HIV Care/ART Follow-up Form Ministry of Health

#### Client Information

**Name:**

**Age:**

**Gender:**

**ART Status:**

**Date of Birth:**

**Date of HIV Diagnosis:**

**ART Initiation Date:**

**Duration on ART:**

**CD4 Count at Initiation:**

**Current CD4 Count:**

**Weight at Initiation:**

**Current Weight:**

**BMI at Initiation:**

**Current BMI:**

**Blood Pressure:**

**Current Blood Pressure:**

**Hypertension Status:**

**Current Hypertension Status:**

**Current Medications:**

**Side Effects:**

**Reason for停药:**

** Vital Signs:**

**Current Vital Signs:**

**Other:**

#### TB Screening

- **TB Symptom:**
  - **Cough:**
  - **Fever:**
  - **Night sweats:**
  - **Weight loss:**
  - **History:**
  - **Pain:**
  - **Other:**

**Pain Assessment:**

**History of TB:**

**Previous Treatment History:**

**Duration on TB Treatment:**

**Reason for Stop:**

**Current Tuberculosis Treatment:**

**Previous TB Treatment:**

**Duration on Previous Treatment:**

**Reason for Stop:**

#### TB Prevention Treatment

**Reason for TB Prevention Treatment:**

**Duration on TB Prevention Treatment:**

**Reason for Stop:**

**Current TB Prevention Treatment:**

**Reasons for Discontinuation:**

- **Side Effects:**
  - **Diarrhea:**
  - **Other:**

**Intensification:**

**Reason for Intensification:**

**Duration on Intensification:**

**Reasons for Stop:**

#### Antiretroviral Therapy

**Pre-ART:**

**ART Initiation:**

**ART Indication:**

**Reason for Start:**

**Duration on ART:**

**Reason for Stop:**

**Current ART Regimen:**

**Side Effects:**

**Reasons for Stop:**

#### Nutritional Status

**Estimated Body Weight:**

**Weight at Initiation:**

**BMI at Initiation:**

**BMI at Follow-up:**

**Percentage Change:**

**Recent Nutritional Assessment:**

**Recent Body Composition Assessment:**

**Recent Anthropometric Assessment:**

**Recent Feeding Observation:**

**Recent Growth Monitoring:**

**Recent Developmental Milestones:**

**Current Developmental Milestones:**

**Reasons for Delayed Development:**

**Recent Growth Plot:**

**Recent Developmental Milestones:**

**Recent Nutritional Status:**

**Recent Feeding Observation:**

**Recent Developmental Milestones:**

**Recent Growth Monitoring:**

#### Preventive Services

**Vaccinations:**

**Recent Vaccinations:**

**Other Preventive Services:**

**Recent Preventive Services:**

#### Obstetric Services

**Pregnancy History:**

**Current Pregnancy:**

**Recent Obstetric Services:**

**Recent Family Planning Services:**

**Recent Gynecologic Services:**

**Recent Preventive Services:**

#### Other Services

**Recent Services:**

**Recent Social Services:**

**Recent Other Services:**

#### Other Indicators

**Side Effects:**

**Reasons for Stop:**

**Other Indicators:**

**Recent Indicators:**

**Recent Other Indicators:**

#### Client Follow-up

- **Next Follow-up Date:**
  - **Reason for Stop:**
  - **Current Activities:**
  - **Other:**

#### Referrals

- **Referral History:**
  - **Referral Reason:**
  - **Referral Date:**
  - **Referral Outcome:**

### Other Information

**Recent Laboratory Assessments:**

**Recent Laboratory Testing:**

**Recent Laboratory Results:**

**Recent Laboratory Follow-up:**

**Recent Laboratory Notes:**

#### DISC Code

**Code:**

**Reason for Code:**

**Other:**

---

In the follow-up date, in 2nd column if one of the options below applies, use raw next to last to visit the enter to appropriate information:

- **TB:** Transfer out. **LST:** Lost most seen since 1 month. **MRT:** Missed to last follow-up for >3 months. **STOP:** When the clinician stop ART for different reason and patient is on follow-up. **DEAD:**
## Annex M – DNA PCR test logbook

DBS collection for DNA PCR test and TAT Logbook

**DBS (DNA PCR test) Logbook to be placed in ANC room**

<table>
<thead>
<tr>
<th>Region</th>
<th>Woreda</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Name of Health Facility: ____________________________________________

| S/N | Mother’s MN | Mother Name | Infant’s MN | Infant Name | Infant Date of Birth (DD/MM/YYYY) | Facility entry point (PMTCT, Nutrition, Pediatric Inpatient or OPD) | Date DNA-PCR requested (DD/MM/YYYY) | Result of testing (1- Disposed samples, 2- Repetition, 3- Invalid, 4- Other reason: provide clear reason) | Date DBS collected (DD/MM/YYYY) | Lab Name/ Lab ID | Date DBS sent to lab (DD/MM/YYYY) | SNR/ Hard copy | Date result received by caregiver (DD/MM/YYYY) | DNA PCR Result (Positive/ Negative/ Invalid) | Date infant linked to ART, if Positive (DD/MM/YYYY) | Date infant initiated ARV if Positive (DD/MM/YYYY) | Status of infant (Alive/Dead) | TAT<1 Month | TAT 1-3 Month | Name and signature of HW performing PMTCT/ANC | Remark |
|------|-------------|-------------|-------------|-------------|----------------------------------|---------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------|----------------------------------|----------------|----------------------------------|----------------|----------------------------------|-------------------------------|------------------------------------------------|----------------------------------|----------------|----------------|----------------------------------|---------|------------------|--------------------------|---------|
Annex N – Infant follow up card (1)

HIV Exposed Infant Follow up Card Legend

Date of enrollment: It is the date (dd/mm/yy) when the HEI is linked to & registered on the integrated MNCH/ PMTCT register (MBPC register), and enrollment shall be done as soon as after birth before discharge. HEI Code: Infant’s Full Name Initial/ Mother Full Name Initial/ Regional Code/ Facility Type/ Specific Facility Code/ Year/ Month/ Serial Number on integrated MNCH/PMTCT (MBP Cohort) Register and unique ART number of the mother: The national PMTCT guideline recommends provision of dual prophylaxis to all HEIs for 12 weeks.

<table>
<thead>
<tr>
<th>Date of Enrollment</th>
<th>Age</th>
<th>Anthropometric measurement</th>
<th>Developmental (Dev’t) Milestone = Red Flags</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter in Ethiopia Calendar (dd/mm/yy)</td>
<td>Enter current age of the infant in months on the day of visit</td>
<td>Wt: enter current weight of the infant in Kg</td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Lt: enter current length of the infant in cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enter date of Visit in Ethiopia Calendar in dd/mm/yy format</td>
<td>HC: enter current the head circumference in cm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Infant feeding practices:
For infant less 6 months:
“1” Infant is on exclusive Breastfeeding (EBF),
“2” Infant is on exclusive replacement Feeding (ERF),
“3” Infant is on mixed feeding (MF) Should be corrected immediately
For infant older than 6 months
“4” Infant is on breastfeeding and complementary feeding,
“5” Replacement feeds with complementary feeds
Breast condition – if mother breastfeeding “0” Normal
“1” Cracked nipple(s)
“2” Mastitis
“3” Breast Abscess
“4” Other (Specify)
“5” Not Applicable (for ERF mothers)

Abnormal findings of diagnosis that may suggest HIV infection (enter all appropriate findings)

<table>
<thead>
<tr>
<th>Growth Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotrimoxazole Prophylaxis</td>
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</tbody>
</table>

Cotrimoxazole Prophylaxis Adherence grading

<table>
<thead>
<tr>
<th>Adherence</th>
<th># of missed dose per month</th>
<th>% of missed/mon.</th>
</tr>
</thead>
<tbody>
<tr>
<td>G (good)</td>
<td>&lt; 3 doses</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>F (Fair)</td>
<td>5-8 doses</td>
<td>85-94%</td>
</tr>
<tr>
<td>P (Poor)</td>
<td>&gt; 9 doses</td>
<td>&lt;85%</td>
</tr>
</tbody>
</table>

Treatment given:
List drugs/medication given on each visit

HIV Test Done
“0” No test done
“1” Sample collected for DNA PCR
“2” DNA/PCR result “Negative” or “Not detected”
“3” DNA/PCR result “Positive” or Detected”
“4” Rapid antibody test result negative
“5” Rapid antibody test result positive

Conclusion

0= No Clinical or laboratory evidence of HIV
1= Clinical evidence of HIV
2= Laboratory evidence of HIV (DNA PCR/ Antibody tests)
3= Lost to follow up
4= Died

Decision

0= Continue Follow Up
1= Referred for Pediatric HIV care within facility
2= Referred Pediatric HIV care outside facility
3= Discharged Negative form care (HIV Free)
Annex O – Infant follow up card (2)

HIV-Exposed Infant Follow up Card

Facility Name: -------------------------- Infant’s MRN: -------------------------- Enter Enrollment date: / / DD / MM / YYYY (EC)

HEI Code: ............................................................... Infant referred from if referral ..........................................

Infant’s Name: -------------------------- Date of birth: ( / / ) Place of birth: ---- Age at enrollment: ( ) Birth Weight: ( gm.) Sex: M □ F □

Mother’s/Caretaker’s Name: Mother’s MRN: □ If “Caretaker” describe relationship

Parents Status: Mother? Alive /? Dead If alive mother is: enrolled in HIV/ART care/ Not enrolled in HIV ART care If “enrolled” Within the facility/ Out of the facility

ART (Specify regimen) __________________ Start date _____________ Unique ART No. of the mother: ______________________

Infant ARV Prophylaxis: NVP + AZT for 6 weeks and NVP only for additional 6 weeks □ None □

Father: HIV Status: □ Positive □ Negative □ Unknown □ Alive □ Dead □ if alive, enrolled in: □ HIV /ART care □ Not Enrolled in HIV/ART care

If on ART, Unique ART No. __________________________________________

Immunizations: (circle) BCG OPV (0) (1) (2) (3) Pentavalent (1) (2) (3) PCV (0) (1) (2) (3) Rota (0) (1) (2) Measles ( )

| Date of visit | Age | Anthropometric measurements | Growth pattern (0/1) | Dev’t milestones Red Flags (0/1) | Infant Feeding practice (1/2/3/4/5/6) | Mother’s Breast condition; if breast feeding (0/1/2/3/4/) | Abnormal findings or diagnosis that may suggest HIV infection (0/1/2/3/4/5/6/7/8/9) | Treatment/medication given for infant | Cotrimoxazole prophylaxis | HIV test/s Done (0/1/2/3/4/5/6) | Conclusion (0/1/2/3/4/5) | Decision (1,2,3) | Next visit date |
|---------------|-----|-----------------------------|---------------------|---------------------------------|-------------------------------------|---------------------------------------------|------------------------------------------------|-----------------------------------|---------------------|-----------------|----------------|----------------|---------------|---------------|
|               |     |                             |                     |                                 |                                     |                                             |                                                   |                                    |                     |                 |                 |                 |               |               |

Health Care provider referred the infant for HIV care/ART or discharged form follow up: Name -------------------------- Signature---------------- T e l. # ----------------Date / / DD / MM / YYYY (EC)
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