

# **Guidelines for the Prevention of Mother to Child Transmission (PMTCT) of HIV**

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## Foreword for Prevention of Parent to Child Transmission (PPTCT) Guideline

This guideline is developed for preventing HIV transmission in pregnant women, mothers, and their children. It is referred as a guideline for the prevention of parent to child transmission or simply the PPTCT guideline. This document provides guidance to maximize the benefits, reduce risk of resistance and failure of effective PPTCT interventions. It acts as the gateway for HIV prevention, treatment, care and support services for the whole family.

As a new born, every child has the right to life, and healthy livelihood. Preventing HIV infection in women protects themselves, their partners and children. As with almost every disease condition, the cost of treating HIV is higher than the prevention of its transmission. Our main focus is thus, on preventing the transmission of HIV.

In many countries, mother-to-child transmission has been almost completely eliminated as a result of effective voluntary testing and counseling services. It is imperative that we do our best to help our next generation reduce the risk of HIV by providing guidelines for its effective prevention, treatment and care.

Finally, it is important to consider all the emotional and social factors that might affect women suffering from HIV; as disclosing her status to the community might stigmatize her and her children, depriving their rights as human beings.



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## Abbreviations:

3TC	Lamivudine
AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Zidovudine
CCHDC	Center for Community Health and Disease Control
CHTC	Couples HIV Testing and Counseling
DNA	Deoxyribonucleic Acid
d4T	Stavudine
EBF	Exclusive Breastfeeding
eMTCT	Elimination of mother-to-child transmission of HIV
EFV	Efavirenz
EID	Early Infant Diagnosis (of HIV)
EPI	Expanded Programme on Immunisation
ERF	Exclusive Replacement Feeding
FP	Family Planning services
FSW	Female Sex Worker
FTC	Emtricitabine
HIV	Human Immunodeficiency virus
IEC	Information Education and Communication
IGMH	Indira Gandhi Memorial Hospital
KAP	Key Affected Populations
LPV/r	Lopinovir/ritonavir
MDGs	Millennium Development Goals
MNCH	Maternal Newborn and Child Health
MSM	Men who have Sex with Men
MTCT	Mother-to-Child Transmission of HIV
NAP	National AIDS Programme
NGO	Non Government Organisation
NVP	Nevirapine
OI	Opportunistic Infection
PCR	Polymerase Chain Reaction
PMTCT	Prevention of Mother-to-Child Transmission of HIV
PPTCT	Prevention of Parent-to-Child Transmission of HIV
PWID	People Who Inject Drugs
RF	Replacement Feeding
RTI	Reproductive Tract Infection
sdNVP	Single-Dose Nevirapine

SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
SW	Sex Worker
TB	Tuberculosis
TDF	Tenofovir
ULN	Upper limit of normal
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
WHO	World Health Organisation



# 1 Introduction

Rationale for the prevention  
of HIV infection in infants

## Section 1 - Introduction

The aim of this guideline is to help health professionals involved in Prevention of Mother to Child Transmission (PMTCT) activities offer quality services for all HIV infected mothers and their children, i.e. to use the most effective, evidence-based PMTCT interventions, to maximize the benefits, reduce risk of resistance and reduce failure of PMTCT interventions.

PMTCT services include primary HIV prevention among women and their spouses/partners, routine HIV testing and counseling, prevention of unwanted pregnancies among women living with HIV, antiretroviral (ARV) treatment and prophylaxis for mothers and children, safer delivery practices, counseling and support for safer infant feeding practices, long term follow-up care for mother and child and family planning. Pregnant women should receive pre-test HIV information at their first antenatal visit or as soon as possible thereafter. Without interventions the overall risk of MTCT is approximately 20-45%. The diagnosis of HIV infection in adults is established by detecting HIV antibodies using simple rapid tests administered according to the

protocols specified in the national HIV programme.

In Maldives, management and implementation PMTCT services is the responsibility of the Maldives PMTCT team, a multidisciplinary team of health professionals. The structure of the team is given in figure 1 below.

**Figure 1: The Maldives PMTCT Team**

- Gynaecologist
- Paediatrician
- Physician
- Reproductive Health Clinic representative
- NAP /CCHDC representative
- Reproductive Health programme/CCHDC representative

The objectives of these guidelines are to provide:

- an overview of PMTCT of HIV and its prevention;
- an overview of the 4 prongs of PMTCT;
- Recommendations for ART and ARV prophylaxis to HIV positive pregnant mothers, and ARV prophylaxis for infants;
- Recommendations on infant feeding for HIV positive mothers.

## Rationale for the prevention of HIV infection in infants

HIV prevention is important because every child has a right to live. Preventing HIV transmission from HIV infected women to their children may prevent premature death. Preventing HIV transmission to children is also more cost-effective than treating and caring for children infected with HIV, even in low prevalence countries. PMTCT may further assist in reducing HIV transmission by reducing stigma and discrimination through improving access to information, counseling and testing and provide an opportunity to reach and prevent HIV infections in young women. Steps taken to prevent paediatric HIV also have important benefits for maternal, newborn and child health (MNCH), and sexual and reproductive health (SRH).

Globally, the elimination of mother-to-child transmission of HIV (eMTCT) is now feasible, with the possibility of an "AIDS-free generation". Following an international heads-of-agency meeting in June 2010, there is now a strong global commitment to the overall goal of eMTCT, with the goal of eliminating new paediatric HIV infections by 2015 positioned within the broader vision of

improved HIV-free survival, MNCH, and SRH. It is also agreed that the elimination agenda should be linked to the global commitment to achieving the 2015 Millennium Development Goals (MDGs), as the success of elimination of MTCT is directly linked to the health of the mother and the child.

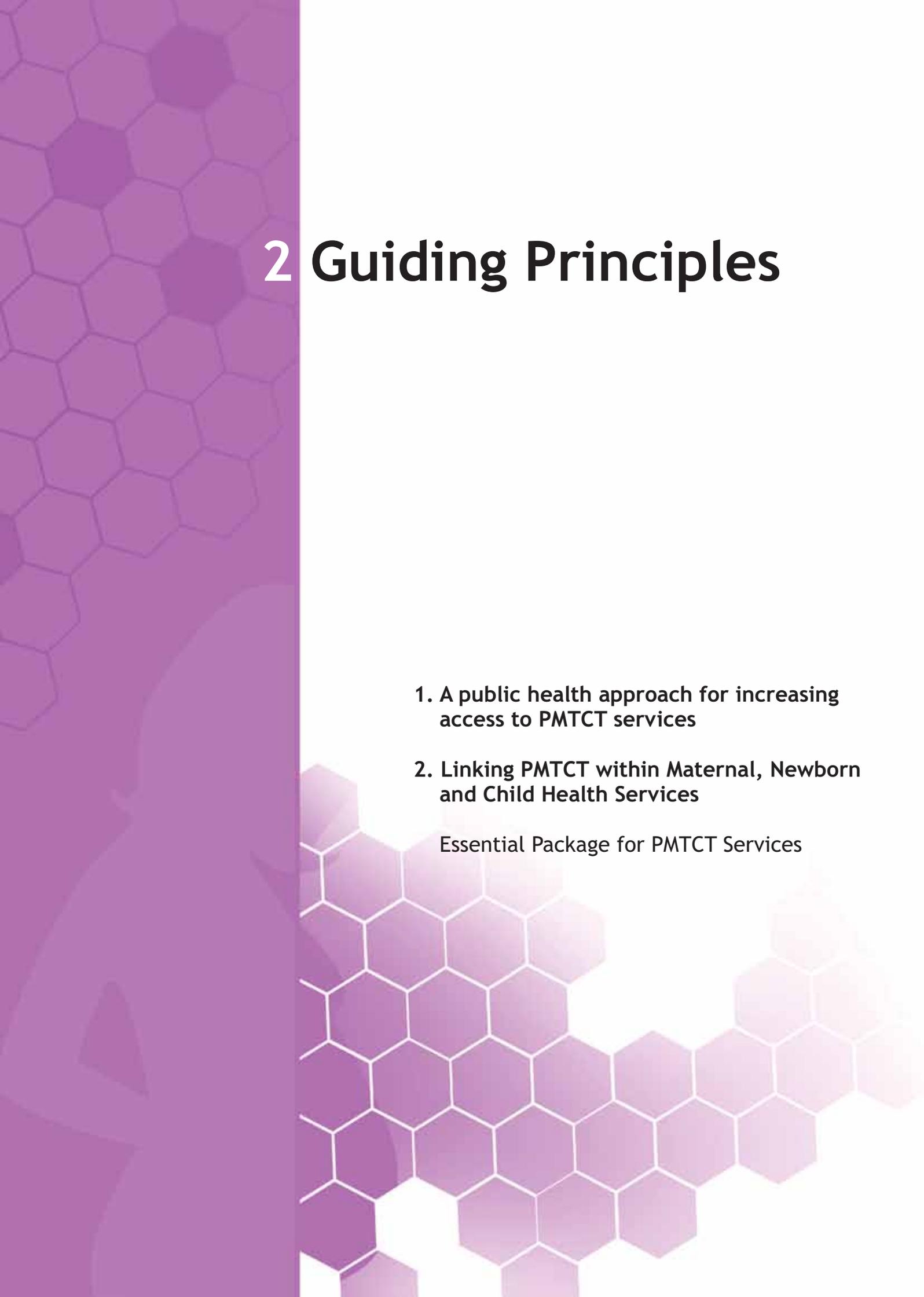
The global elimination initiative was endorsed at the regional level by the Asia Pacific United Nations PPTCT Task Force, which developed a Conceptual Framework and Monitoring and Evaluation Guide with two main goals:

- Eliminate new paediatric HIV infections and congenital syphilis; and
- Improve maternal and child health and survival in the context of HIV/STI.

The Maldives national guidelines, which are consistent with the global and regional ePMTCT goals, thus serve not only to help achieve the goal of providing good quality PMTCT services for all HIV infected mothers and their children, but they will have other important benefits for the population as a whole in strengthening of MNCH and SRH.

The guidelines incorporate approaches to PMTCT programming that have been shown to be most effective in achievement of the goals described above. In particular, two recent global guidelines are relevant, consisting of the *Programmatic Update on use of Antiretroviral Drugs for treating pregnant women and preventing HIV Infection in infants*, and the *Guidance on Couples HIV Testing and Counseling*, both published by WHO in April 2012. The *Programmatic Update* builds on recent evidence showing that ART initiation during pregnancy is both safe for mother and child and effective in terms of clinical outcomes and cost. The *Guidance on Couples Testing* is based on strong evidence that that couples who test for HIV together and mutually disclose their status can support each other, if one or both partners are HIV-positive, to access and adhere to ART and interventions to prevent mother-to-child transmission (PMTCT) of HIV. Increasing male involvement in primary prevention of HIV in women is also included, as an operational research priority, in the Conceptual Framework developed by the regional PPTCT Task Force.

An additional consideration, following from the need for an increased focus on couples in order to improve effectiveness of PMTCT programmes, is the importance of linking PMTCT to key affected populations (KAP). In the context of the situation in Maldives, where HIV prevalence is low, but with high behavioral risks for transmission associated with sex workers (SW), men who have sex with men (MSM) and people who inject drugs (PWID), there are important programmatic and financial reasons for strengthening the focus of PMTCT on linkages to KAPs. The regional Conceptual Framework recognizes the need for development of strategies to increase utilization of MNCH services by women from key affected populations. In addition, however, it is also necessary to increase access to prevention and treatment of the female partners of PWID and MSM, in recognition of the fact that many MSM are also engaged in heterosexual relationships.



## 2 Guiding Principles

1. A public health approach for increasing access to PMTCT services
2. Linking PMTCT within Maternal, Newborn and Child Health Services

Essential Package for PMTCT Services

## Section 2 - Guiding Principles

### **1. A public health approach for increasing access to PMTCT services**

Starting HIV prevention programmes among children and youth is an important approach from the strategic and programmatic points of view. The main goal is to offer evidence-based quality services, keeping a balance between the standards of best clinical evidence and the available resources and constraints at national level. PMTCT should provide ARV therapy for HIV infected pregnant women and their infants and effective prophylactic

treatment for those who do not yet require such therapy.

In this public health approach, which harmonizes with the guidelines issued by WHO in 2010 and 2012 on the use of ARV drugs for treating pregnant women and preventing HIV infection in infants, PMTCT programmes are built around standardized regimens and simplified approaches suitable for the majority of women.

### **2. Linking PMTCT within Maternal, Newborn and Child Health Services**

The aim of linking PMTCT within Maternal and Child Health Services is to ensure that women

(1) Have greater access to high-quality antenatal, labor, delivery and postpartum care, including counseling and support for

infant feeding, and (2) Use existing services more frequently and earlier in pregnancy. The following are key interventions in the linkage of PMTCT with MNCH services:

## Essential Package for PMTCT Services

- Routine offer of HIV counseling/information and testing to all pregnant women attending antenatal care, with “opt out” options;
- Involvement of the partner/spouse and family in order to ensure a family-approach, including offering HIV testing to the partner/spouse;
- Provide appropriate ART or ARV prophylaxis regimens to the women based on the medical assessment, CD4 count and clinical staging;
- Strengthened obstetric services;
- Provide other appropriate diagnosis and treatments such as for STI/RTI, TB, opportunistic infections (OI) and nutrition counselling;
- Provide psychosocial support for HIV-positive pregnant women;
- Provide counselling and support for safe infant feeding practices;
- Provide antiretroviral prophylaxis and cotrimoxazole to infants;
- Integrate follow up of HIV-exposed infants into routine healthcare services;
- Ensure early infant diagnosis (EID) using HIV-DNA PCR at 6 weeks of age as per the national diagnostic protocol for infants and children;
- Strengthen community follow up and outreach through local community networks to support HIV-positive pregnant women and their family;
- Family planning/SRH services (including counselling) for women living with HIV.

# 3 Four prongs in PMTCT

## 3.1 - PRONG 1 - Primary prevention of HIV infection among women of childbearing age

- A. Awareness programmes or campaigns
- B. Strengthening of VCT services
- C. Promotion of condom use

## 3.2 - PRONG 2 - Prevent unintended pregnancies among women living with HIV

## 3.3 - PRONG 3 - Prevent HIV transmission from women living with HIV to their infants

- Eligibility for ART or ARV prophylaxis
- The deciding criteria

## 3.4 - PRONG 4 - Provide care, support and treatment to women living with HIV, their children and families

## Section 3 – Four prongs in PMTCT

While the main goal of PMTCT is to prevent HIV transmission from women living with HIV to their infants, effective MTCT interventions must employ a comprehensive approach that includes, in addition to a focus on the pregnant women, primary prevention among parents, prevention of unintended pregnancies among women living with HIV, and post-natal care, support and treatment. In line with international standards for a comprehensive HIV prevention strategy, these elements are the basis for the “four prongs”, which are integral in preventing HIV transmission among women and children:

- *Prong 1:* Primary prevention of HIV, especially among women of childbearing age and their partners/spouses;
- *Prong 2:* Prevent unintended pregnancies among women living with HIV;
- *Prong 3:* Prevent HIV transmission from women living with HIV to their infants;
- *Prong 4:* Provide care, support and treatment to women living with HIV, their children and their families.

Modeling of MTCT HIV transmission demonstrates clearly the important contribution that interventions addressing each of these elements can make, in particular those that focus on Prong 1 and Prong 2, to the elimination of paediatric HIV. Further, modeling demonstrates that unless PMTCT activities address all four prongs, there will be a failure to achieve the goal of eMTCT.

In the Maldives context, being a low-prevalence country with certain sections of the population having high-risk behavior for HIV transmission, it is very important that attention is given to all four prongs, especially Prongs 1 and 2. A particular focus on key affected women and girls, that is female sex workers, women who are using or injecting drugs, and intimate partners of men at risk, will greatly increase the effectiveness of the PMTCT programme, and reduce the cost burden from more expensive interventions under prongs 3 and 4.

### 3.1 - PRONG 1 - Primary prevention of HIV infection among women of childbearing age

HIV infection in the mother has serious adverse effects on the fetus. HIV infected pregnant women have increased rates of spontaneous abortion, low birth weight babies, stillbirths, preterm labor, premature rupture of membranes, other sexually transmitted diseases, pneumonia, and urinary tract infections. Most transmission during pregnancy occurs in the third trimester. The placenta plays a protective role, but transmission can occur if the placenta is infected or if the mother has a very high viral load associated with recent infection or advanced immunodeficiency.

The goal of this primary prevention is to prevent the HIV infection among women at the reproductive age. Primary prevention of HIV among women and men can be achieved by:

- A. Increasing the awareness of HIV transmission from mother to infants;
- B. Improving the access to voluntary counseling and testing (VCT) for the general population and particularly for key affected populations;
- C. Improving condom promotion / distribution.

#### A. Awareness programmes or campaigns

Awareness programmes should be designed specifically for the target population. The following guidance is useful when designing and conducting educational or awareness programmes:

Awareness programmes for groups with high risk behavior (e.g. sex workers, people who inject drugs and men who have sex with men)

In the Maldives context, particular focus is needed on activities with women and girls who are members of groups with high-risk behavior or are intimate partners of people in these groups. They include female sex workers, women who are using or injecting drugs, and intimate partners of men at risk.

- When developing a target message for a vulnerable group the messages should be specific for each group, e.g. messages targeted for female sex workers (FSW) could refer to healthy sexual life;
- As a general rule, the message needs to be tailored for each group's needs and make it as simple as possible. All the terms used should be understandable by the majority of members of the target groups;

- IEC material should include information on how to access testing and treatment;
- The appeal, such as using appropriate images is also important, and should be appropriate for the target group;
- The most effective way to transmit the information for groups with high-risk behavior is usually through face-to-face discussion. Often this is best achieved through peer-based approaches, or by NGO and community organizations, through outreach activities or drop-in centres. If the decision is made to launch a national campaign and to spread the messages through other channels then it is important to explore the best channel to use, in order to avoid the possibility of inadvertently increasing stigma and discrimination;
- Several effective models exist for identification of women at greatest risk of transmission of HIV to their infants in concentrated epidemic scenarios such as Maldives. One of these is the District Model Approach, which has been implemented successfully in Pakistan, Cambodia and Vietnam. The District model includes the following elements:
  - Build capacity of District Headquarter Hospitals to identify and refer suspected HIV positive cases from Urology, Dermatology, TB and Paediatrics and to provide Prevention of Parent to Child Transmission (PPTCT) services;
  - Identify female spouses at risk through men registered in the Government HIV treatment and care centres;
  - Identify women at risk for HIV in districts with a concentration of HIV positive persons, through public outreach cadres of female health workers using risk criteria regarding history of blood transfusions in self or spouse, spouse working abroad and injecting drugs; and women at risk for HIV in districts with a sizeable population of injecting drug users through NGOs serving IDUs;
  - Refer women meeting risk criteria either directly to NGOs, HIV treatment and care centers or “Family health Outreach” at rural health centre level in each district where women are given iron and vitamin supplements and are offered voluntary counseling and testing;
  - Ensure children are tested for HIV if relevant and offered paediatric AIDS care if HIV positive; and families affected by HIV and AIDS are provided community home based care (CHBC) and other support services.

Consideration could be given to developing this approach as an “atoll-based” model, given that not all atolls rank the same in terms of risk behavior, and within an atoll not all people need HIV testing and/or other HIV-related services.

### Awareness programmes for the *general population*

As a complement to awareness programmes with KAPs, the country's enabling environment needs to be strengthened through awareness programmes, in order to increase the understanding of the general population, reduce stigma and discrimination and enhance prevention behavior.

- The messages need to be simple, easy to understand, culturally acceptable and appropriate;
- Educational material should contain information regarding the available services in the community or at the national level;
- The materials should be developed in collaboration with public health sector, NGOs involved in the area, and communication experts. Religious and community leaders should be involved especially when they are principal pillars in their community. It may be useful to link messages with religious information;
- IEC materials may include: leaflets, booklets, flyers, posters, promotion materials (such as pens, mouse pads, jackets, notebooks, caps, and t-shirts), films, as well as phone text messages, social media and other ICT approaches;
- IEC materials should contain images that convey messages even to illiterate persons and foreigners living in Maldives, who are at higher risk of acquiring infectious diseases in general. These should be displayed in visible places that are culturally appropriate, e.g. waiting areas, clinics, cinemas, etc;
- Mass media messages can be transmitted through TV, radio, newspapers, and magazines. Formative research and focus group discussions looking at popularity and relevance of specific channels, timings of advertisements, etc. need to be conducted at the national level;
- Small group information sessions in workplaces, educational institutions, NGOs, etc. could be used.

### Awareness programmes for the *health sector*

- IEC materials should be developed in accordance with medical aspects of the HIV infection;
- Training courses should be conducted for all medical personnel, especially for those involved in MNCH and PMTCT;
- Implementing universal infection control practices;
- Implementation of mandatory blood screening for HIV for health care providers;
- Rational use of blood and blood products to minimize the risk exposure, with strict adherence to Universal Precautions;
- Improving STI diagnosis by screening, case management and treatment.

### **B. Strengthening of VCT services**

HIV testing is the entry point to a range of other key HIV-related services, including PMTCT and ART. For this reason promotion of HIV VCT is important, in particular among those with high-risk behavior, or who are vulnerable to HIV transmission. VCT campaigns can increase awareness and make people more conscious about their HIV status. All materials developed should contain the VCT Centre address and contact details. VCT Campaigns must provide people with accurate information and give them the opportunity to make informed choices.

VCT Centers should be client-friendly and free of stigmatization. Integration of HIV testing with other blood screening (e.g. Hepatitis B, C) may reduce the stigma associated with HIV infection. More

specific/outreach activities promoting VCT for HIV among key affected populations need to be in place. Service delivery points can be located in health facilities, specially designed stand-alone sites, and mobile, outreach, community- and home-based settings. As recommended by WHO, in areas with concentrated HIV epidemics among PWID, consideration should be given to provision of HIV testing and counseling in: harm- reduction services; primary care services for PWID; opioid substitution therapy (OST) and other drug dependence treatment services; STI services; other health services for risk populations (sex workers, MSM, prisoners/residents of compulsory drug treatment centres); and tuberculosis (TB) services.

### C. Promotion of condom use

Condom promotion should be incorporated in an age-appropriate, gender and culturally sensitive manner as a method of protection for sexually active persons. In the Maldives context, particular focus is needed on key affected women and girls, that is female sex workers, women who are using or injecting drugs, and intimate partners of men at risk.

Information on condoms is usually tailored to individuals, and should be simple and very clear. Prevention messages need to reemphasize the role of condoms in PMTCT by preventing the transmission from spouses or other sexual partners to women. Similarly to VCT services, more specific interventions

should be in place for KAP, in particular female sex workers, women who are using or injecting drugs, and intimate partners of men at risk. There is considerable experience in this area in the Asian region, using a range of interventions to increase condom use, including peer outreach and structural interventions such as the 100% condom use programme (CUP), which have been successfully expanded and implemented in Cambodia, Viet Nam, Mongolia and China, and have contributed to containing the epidemic among FSWs. In addition to stimulating condom use, second-generation intervention programmes with SWs should emphasize the meaningful involvement of SWs and empowerment of the community.

### 3.2 - PRONG 2 - Prevent unintended pregnancies among women living with HIV

Preventing unintended pregnancies among women living with HIV is essential for improving the lives of women and children, and eliminating mother-to-child transmission of HIV. Women living with HIV, like all women, have the right to make decisions on matters concerning their personal life. However, given the challenges that their HIV positive status may present for the health and economic

well-being of themselves and their families, it is important that women are able to make informed decisions on planning whether or not to have children, how many children they want and when. The professionals that work with these women have an ethical and professional responsibility to support them in their decisions.

In addition to the family planning information and services that all women need, women living with HIV may need strengthened or additional information and services in specific areas. To meet these needs, strengthened or additional information, counseling, and services are required on:

- Rights including reproductive rights;
- Drug interactions: between certain ARVs and hormonal contraceptives;
- Contraceptives;
- Treatment for infertility: women living with HIV may be more likely to have difficulty getting pregnant as a consequence of either her own reduced fertility or that of her partner;
- STIs: people living with HIV may be at greater risk, specifically for human papilloma virus (HPV), syphilis, and genital herpes;
- Serodiscordance: lowering the risk of HIV infection to serodiscordant partner, if intending to get pregnant;
- Potential risk to the woman's health if she becomes pregnant, especially if her CD4 count is low.

With these considerations in mind, the objectives of the second prong of PMTCT are:

- To create awareness of HIV transmission and complications in children infected during pregnancy or at birth;

- To increase availability/access to contraceptive options and promote informed family planning for HIV positive women;
- To create a supportive environment in which the HIV positive women can make voluntary, safe and informed choices.

Strengthening of Family Planning (FP) services can be achieved through the following measures:

- Training of FP workers. In order to provide a tailored FP service for women living with HIV it is necessary to train FP workers to provide them with the information that HIV positive women need. FP workers have to learn about contraceptive needs of infected women, about counseling skills and provide safe and appropriate Family Planning choices;
- Integrate FP services as part of ANC and PNC;
- Ensure that referral policy and procedures are in place for both services. Women have to be referred to one or other service in accordance with their needs and risks identified by a counselor (see annex for The Maldives PMTCT system for identifying points of referral);

- Strengthen the role of community-based organizations. Using peer educators from the community it will be easier for people to understand the importance of FP services and the needs of HIV infected women. From the financial point of view, this intervention can be cost effective. Using the people from community can reduce the costs for transportation, accommodation and from the salary point of view;
- Train health care providers in Family Planning services in relation to HIV;
- National PMTCT policy should include promotion of a "couple oriented setting" for all medical and social services, linked with FP and ANC. Couples and partners, including those in antenatal settings and individuals with known HIV status, should be offered voluntary HIV testing and counseling with support for mutual disclosure. A range of actions can be taken to promote couple HIV testing and counseling (CHTC). These include:
  - Increase awareness of the benefits of and demand for CHTC in ANC;
  - Integrate CHTC into existing HIV services;
  - Address barriers and constraints to CHTC in ANC services and make services couple-friendly;
  - Increase male involvement, including making services male-friendly;
  - Provide/strengthen links between ANC and HIV care and treatment, and other services, such as RH and STIs;
  - Sensitize providers and the public;
  - Form private/public partnerships, e.g. with religious groups;
  - Find CHTC champions.
- Promote through the various media, work place campaigns and other channels increased male involvement and the role of boys and men in increasing access to health-related services (including HIV services) for their families;
- Strengthen religious leadership for PMTCT through involving religious leaders from the community as well as from the higher administrative levels to improve the acceptance of preventive measures.

### 3.3 - PRONG 3 - Prevent HIV transmission from women living with HIV to their infants

The aim of improving the quality of MNCH services and integrating a set of key interventions to prevent MTCT into these services is to ensure that women (i) have greater access to high-quality antenatal, labour, delivery and postpartum care, including counseling and support for infant feeding, and (ii) use existing services more frequently and earlier in pregnancy than is currently the case.

Therefore, a set of key interventions to prevent MTCT should be implemented as an integral component of essential MNCH services. HIV testing and counseling as the pivotal component of programmes to prevent MTCT of HIV is essential for identifying women who can benefit from ART and care either immediately or later, or benefit from interventions to prevent HIV infection in their infants. In Maldives, the offer of HIV screening is mandatory for all antenatal clinic attendees.

Once the HIV sero-status is established, it is important that a woman's clinical stage and her CD4 cell count are assessed in order to determine her eligibility for ART. This is important as the CD4 cell counts form a critical link between antenatal care and ART services, especially for asymptomatic women. To ensure that all

pregnant women who require ART are identified, efforts should be made to include the CD4 cell count measurement in the essential package of care for pregnant women.

During pregnancy, women living with HIV require,

- a. Either ART or ARV prophylaxis for PMTCT (depending on whether they have indications for ART);
- b. Cotrimoxazole prophylaxis (if they are eligible);
- c. Screening for and treatment of TB infection;
- d. Counseling and care relating to nutrition and psychosocial support;
- e. MNCH services need to pay particular attention to safer delivery practices and counseling and support on infant feeding for women living with HIV ( Prong 4).

A woman living with HIV may experience many emotional and social problems that affect her health and well-being. These can include concerns about disclosing her HIV status and difficulties in coping with uncertainty about the HIV status of her child. Thus, in addition to short and long-term medical care, women attending MNCH services may require psychosocial support.

Based on the initial evaluation of the pregnant women clinically and immunologically, there could be two main scenarios

- A. Pregnant women living with HIV who need treatment for their own health;
- B. ARV prophylaxis for all pregnant women living with HIV who do not need treatment for their own health.

**Eligibility for ART or ARV prophylaxis – The deciding criteria**

The eligibility for the ART should be established using the National guidelines

for use of ART in Maldives (December 2011). As per the Table 1 below, all HIV-infected pregnant women with CD4 count less than 350cells/mm<sup>3</sup> or in WHO clinical stage 3 or 4 (irrespective of CD4 cell count) should be given triple drug ART. In case CD4 testing is not available, and the woman is in clinical stage 1 or 2, ARV prophylaxis should be initiated.

**Table 1: Eligibility Criteria for initiating ART or ARV prophylaxis in HIV infected pregnant women based on D4 cell count and WHO clinical stage**

WHO Clinical Stage	CD4 cell count not available	CD4 cell count available	
		CD4 count equal or less than 350cells/mm <sup>3</sup>	CD4 count more than 350cells/mm <sup>3</sup>
Stage 1	Provide ARV prophylaxis	Provide ART	Provide ARV prophylaxis
Stage 2	Provide ARV prophylaxis	Provide ART	Provide ARV prophylaxis
Stage 3	Provide ART	Provide ART	Provide ART
Stage 4	Provide ART	Provide ART	Provide ART

**A. HIV infected pregnant mother who is eligible for ART:**

Pregnant women living with HIV who need treatment for their own health should start receiving the appropriate ART regimen as soon as they become eligible – as per Table 2 below, thereby giving utmost importance to health of the woman, while keeping in mind the possible side effects and monitor for them.

**Table 2: ART recommendations for eligible HIV positive mother and Infant Prophylaxis**

MOTHER	<p>Choose any one regimen from following regimens:</p> <ul style="list-style-type: none"> <li>• AZT + 3TC + NVP</li> <li>• AZT + 3TC+ EFV*</li> <li>• TDF + 3TC (or FTC) + NVP</li> <li>• TDF + 3TC (or FTC) + EFV*</li> </ul> <p>*EFV is now considered safe to be administered during first trimester of pregnancy (see WHO Technical Update June 2012)</p>
INFANT (irrespective of the mode of infant feeding)	Daily NVP or twice daily AZT from birth until 4 to 6 weeks of age

**B. HIV pregnant women who are eligible for ARV prophylaxis**

In cases where the HIV-infected pregnant women do not need ART for their own health, it is recommended that an effective ARV prophylaxis should be started as early as possible after 14 weeks of gestation (second trimester) – details are in Table 3 below. In the unlikely case (as Maldives has high ANC enrollments) of the woman is presenting for ANC late in pregnancy, or diagnosed as HIV positive in labour or at delivery, the ARV prophylaxis should be started as soon as possible.

**Table 3: ARV -Prophylaxis options recommended for HIV infected pregnant women who do not need treatment for their own health**

Option : Maternal AZT	
MOTHER	<p>Antepartum twice daily AZT starting from as early as 14 weeks gestation and continued during pregnancy. At onset of labour, sd-NVP and initiation of twice daily AZT+3TC for 7 days postpartum</p> <p>(Note: If maternal AZT was provided for more than 4 weeks antenatally, omission of the sd-NVP and AZT+3TC tail can be considered; in this case, continue maternal AZT during labour and stop at delivery)</p>
INFANT	<p><i>Infants receiving replacement feeding only</i> Daily NVP or twice-daily AZT from birth until 4 to 6 weeks of age.</p>

Note:

In PMTCT three treatment options are available, where, the country will decide at the policy level, with consultation with national programme managers and treating physicians and medical experts. Maldives has chosen **Option B**.

In addition to pregnant women living with HIV, initiation of ART or ARV prophylaxis should also be considered in special cases, such as women who are using drugs or women with co-infections (HIV-TB or HIV-Hepatitis B/C). In the epidemiological context of Maldives these are not unlikely cases.

### **Women using drugs**

Health-care providers should ask pregnant women about current and past alcohol and injecting or other drug use. A comprehensive package of nine interventions for the prevention, treatment and care of HIV among PWID is needed, including targeting co-morbidities such as hepatitis and TB

In general, the same recommendations for ART or ARV prophylaxis for pregnant women living with HIV apply to those who are also PWID. For pregnant women already on or starting ART, drug interactions may be a concern. Interactions between methadone and ARV drugs are the same in pregnant women as in other patients. Drug interactions may result in decreased methadone levels or

raised ARV levels, increasing the risk of methadone withdrawal or ARV-related side-effects. NNRTIs significantly decrease the methadone level and can precipitate withdrawal symptoms. If a pregnant woman receives an NNRTI-based intervention the dose of methadone should be increased and the woman should be monitored closely. The use of methadone is sufficient to prevent withdrawal symptoms in opioid-dependent women presenting around labour.

The neonatal withdrawal syndrome comprises the signs and symptoms exhibited by newborn infants cut off abruptly after prolonged exposure to drugs during pregnancy. The syndrome occurs in about 60% of neonates who have been exposed to these drugs, usually during the first 48–72 hours of life, although methadone withdrawal can occur up to 2 weeks after birth. Health-care providers should ensure that all newborn infants of women living with HIV who are IDUs are provided with appropriate neonatal withdrawal syndrome management care in accordance with national guidelines.

### **Women with TB**

The risk of active TB is approximately 10 times higher in HIV-infected pregnant women than in HIV-uninfected women and has been reported to account for about 15% of maternal mortality in some settings. TB in pregnant women is also associated with prematurity, low birth weight, and perinatal tuberculosis. All HIV-infected women should be assessed for TB at each visit, and those presenting with a cough, fever, night sweats and weight loss should be evaluated for TB and started on TB treatment when indicated.

In accordance with the recommendations for HIV/TB co-infection, HIV-infected pregnant women with active TB should start ART, irrespective of the CD4 cell count. The TB treatment should be started first, and followed by ART as soon as clinically possible (within 8 weeks after the start of TB treatment). Drug interactions between rifampicin and some of the antiretroviral drugs (i.e. the boosted protease inhibitors) complicate simultaneous treatment of the two diseases. As for all adults, EFV is the preferred NNRTI for HIV/TB co-infected pregnant women (starting after the first

trimester). For those HIV/TB co-infected women not able to tolerate EFV, an NVP-based regimen or a triple NRTI regimen (e.g. AZT + 3TC + ABC or AZT + 3TC + TDF) can be used. In the presence of rifampicin, no lead-in dose of NVP is required.

### **Women with Hepatitis B/C**

ART should be started in all pregnant women co-infected with HIV and HBV when treatment is required for the HBV infection irrespective of the CD4 cell count or the WHO clinical stage. Co-infected pregnant women requiring ART and HBV treatment should receive a regimen containing TDF and 3TC (or FTC). These recommendations are the same as those for all adults.

An elevation in hepatic enzymes following the initiation of ART may occur in HIV/HBV-co-infected women. For this reason pregnant women with HIV/HBV co-infection should be counseled about signs and symptoms of liver toxicity. When co-infected pregnant women do not require HBV treatment, ART or ARV prophylaxis should follow the general recommendation for HIV-infected pregnant women. However, it is

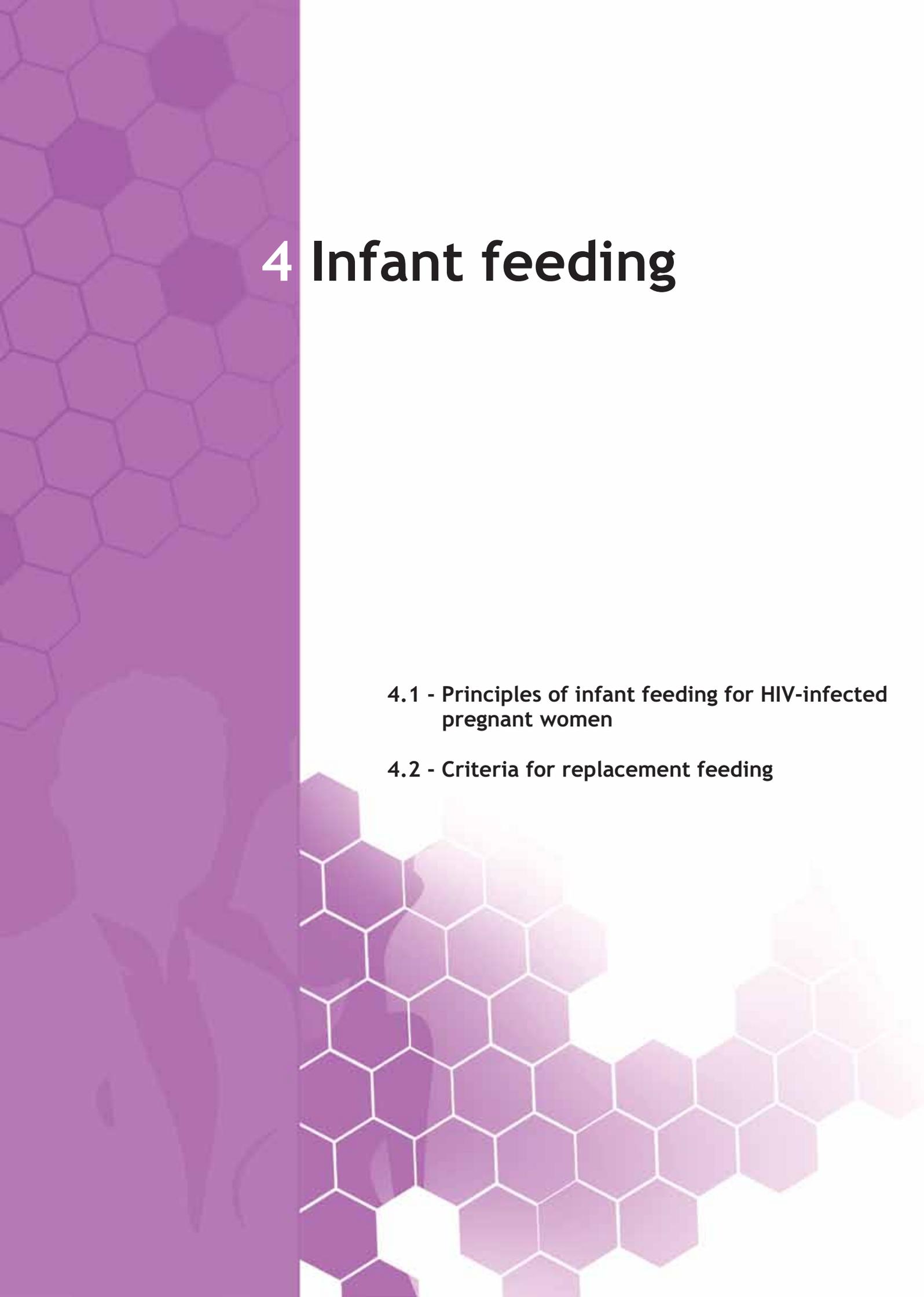
important to note that in HIV/HBV-co-infected pregnant women who do not require treatment of HBV and also do not require lifelong ART for their own health, hepatic flares may occur with the use of maternal triple ARV for prophylaxis of MTCT (option B) when the triple ARVs are stopped. Option A (maternal AZT (i) Anti-HBV therapy should be considered for all women co-infected with HIV and hepatitis B virus with any evidence of liver disease and extended infant prophylaxis), which

does not contain drugs with anti-HBV activity, may therefore be preferred if HBV treatment is not needed and lifelong ART is not planned.

Co-infection with HIV and HBV or HCV is common among PWID. Hence, all women living with HIV who are recognized to be PWID should routinely be offered testing for hepatitis B and hepatitis C infections and monitored according to WHO guidelines.

### **3.4. PRONG 4 – Provide care, support and treatment to women living with HIV, their children and families**

At present, VCT counseling trainees, including a doctor at central level and the assigned health worker at peripheral (atoll level), are assigned the task of providing psychosocial support to women living with HIV and their families. Specific social and economic needs may be addressed by involving or referring the family to the Ministry of Gender and Human Rights. It is important to have a mechanism to maintain strict confidentiality of the person's HIV status when such referral sare made.



# 4 Infant feeding

**4.1 - Principles of infant feeding for HIV-infected pregnant women**

**4.2 - Criteria for replacement feeding**

## Section 4 - Infant feeding

The infant feeding guidelines for HIV-exposed and infected infants aged 0 to 6 months are aimed at preventing HIV

infection from mother to child through breastfeeding and ensuring that the infant's nutritional requirements are met.

### Recommendations for infant feeding in HIV exposed and infected infants < 6 months of age

- Exclusive formula feeding for the first 6 months of life. In Maldives, HIV positive mothers are more likely to be drug users, so it is important to reduce the additional health risk to the infant from ingestion of drugs through breastfeeding;
- Formula milk will be provided to all infants of HIV positive mothers who cannot afford it for the first 6 months of life;
- These mothers should be taught and trained adequately on how to give feeds using appropriate hygiene measures. They also should be provided with adequate counseling;
- Monitoring infant feeding practices is very important and should be done regularly.

### 4.1 Principles of infant feeding for HIV-infected pregnant women

1. All HIV positive pregnant women should have **PMTCT interventions provided early in pregnancy** as far as possible. The interventions include either maternal or infant ARV prophylaxis during the duration of breastfeeding;
2. **Breastfeeding is not recommended** for babies of HIV positive mothers in Maldives. It is estimated that 15% of infants may be infected with HIV through breastfeeding. Also, in Maldives, HIV positive mothers are more likely to be drug users;
3. The six criteria for replacement feeding given below should be fulfilled, that is, it must be acceptable, feasible, affordable, sustainable and safe (AFASS);
4. Mixed feeding should not be practiced;
5. Breastfeeding may be given following the individual parents' informed decision;
6. In the case where parents decide to breastfeed, exclusive breastfeeding should be done for at least 6 months, after which complementary feeding

- may be introduced gradually, irrespective of whether the infant is diagnosed HIV negative or positive by early infant diagnosis;
7. Either mother or infant should be receiving ARV prophylaxis or ART during the whole duration of breastfeeding. ARV prophylaxis should continue for one week after the breastfeeding has fully stopped;
  8. For breastfeeding infants diagnosed HIV negative, breastfeeding should be continued until 12 months of age;
  9. For breastfeeding infants diagnosed HIV positive, ART should be started and breastfeeding should be continued till 2 years of age;
  10. Breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided;
  11. Abrupt stopping of breastfeeding should NOT be done. Mothers who decide to stop breastfeeding should stop gradually over one month;
  12. Monitoring of infant feeding practices is very important and should be done regularly until weaning;
  13. In cases where mothers are drug users, consideration should be given to identification of another caregiver who can be counselled and trained in how to feed the baby, in order to ensure continuity of care should the mother be unable to adequately care for the child herself. (this includes caretakers working at facilities such as Kudakudhinge Hiyaa at villingili)

## 4.2 Criteria for replacement feeding

**ALL** of the following conditions should be met for HIV infected mother to give replacement feeding:

1. Safe water and sanitation are assured at the household level and in the community;
2. The mother, or other caregiver can reliably afford to provide sufficient replacement feeding (milk), to support normal growth and development of the infant (in the case where a family cannot afford formula feeding, the state will provide formula for the first 6 months of life);
3. The mother or caregiver can prepare it frequently enough in a clean manner so that it is safe and carries a low risk of diarrhea and malnutrition;
4. The mother or caregiver can, in the first six months exclusively give replacement feeding;
5. The family is supportive of this practice;
6. The mother or caregiver can access health care that offers comprehensive child health services.

# Annexures

## **Annexure 1**

**Protocol for ANC clients if found positive for HIV antibody while tested for HIV**

## **Annexure 2**

**Components of the PMTCT of HIV programme**

## Annexures

### **Annexure 1: Protocol for ANC clients if found positive for HIV antibody while tested for HIV**

#### **Informed Consent**

All persons tested for HIV should undergo the procedure only following their informed consent. This involves:

- Providing pre-test information on the purpose of testing (Prevention of mother to child HIV transmission) and on the treatment;
- Ensuring availability of counseling support once the result is known;
- Counseling should ensure understanding;
- All relevant staff involved in the procedure should respect the individuals autonomy;
- Confidentiality should be maintained and post-test support service through counseling should be offered.

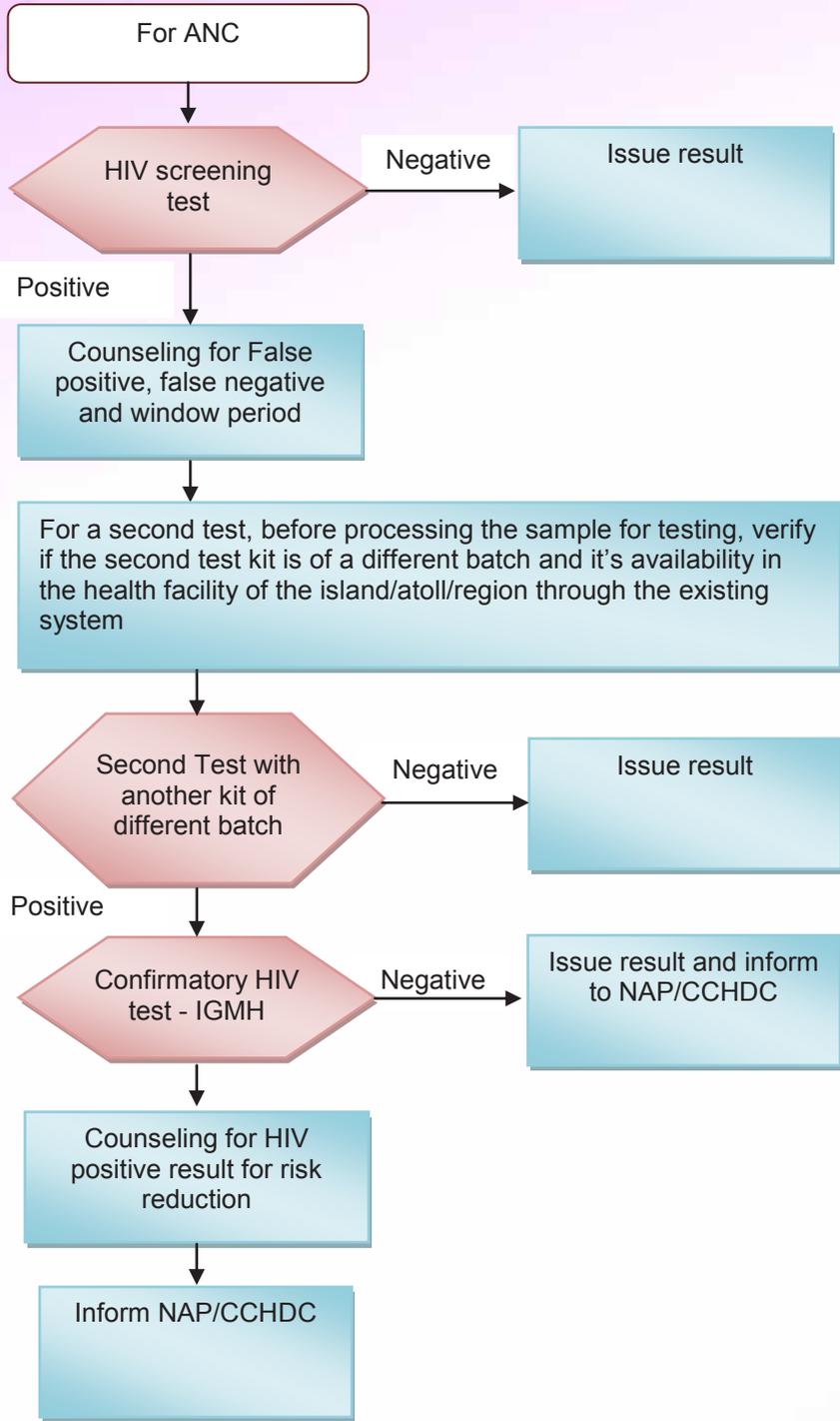
#### **HIV testing and protocol for reporting**

- All laboratories may collect blood for HIV testing only after confirmation of the identity of the individual to be tested by means of an official document bearing a photograph. If the individual is an infant the parent's identification may be used.

If the result of first test is negative, the HIV antibody test is reported as negative and results should be communicated to person tested on the same day. If the result of the testing shows sero positivity it can be

considered as a False Reactive and a confirmatory test is mandatory, to be done from IGMH before labeling the sample as HIV positive.

- If the first test result is positive, the sample is tested with a second test kit of a different batch number if it is available in the health facility of the island/atoll/region through the existing system. Before processing the sample for testing, it is important to verify that the second test kit from the health facility is of a different batch;
- Counseling should be given and the individual informed about false positive, false negative and window period before taking blood for the second time;
- If the second result is also positive, then a new sample has to be taken and send to IGMH for a confirmatory test.
- If the second test and confirmatory test are positive the result has to be submitted to the National AIDS Programme Manager (Center for Community Health and Disease Control) or the head of Center for Community Health and Disease Control/Ministry of Health with the information (Name, Age, Sex, and Address, date of birth and Identity Card number).



## Where HIV testing will take place in the Maldives

Not all laboratories in the Maldives can perform HIV testing and report results. They need to qualify and obtain a license to conduct HIV tests, and the license has to be renewed every two years. This is done by the Ministry of Health and Family as per the specifications in the protocol for licensing of labs for HIV testing 2005. Laboratories have been classified into three categories in the Maldives:

**Category I:** These are the referral laboratories at the central level and are authorized to perform Rapid Simple Assays, Supplemental Assays, ELISA Assays and Confirmatory Assays and report the test results to the individual tested for HIV.

**Category II:** These are clinical laboratories at Regional Hospitals and other health care institutes with both in and outpatient services. They can also perform Rapid Simple Assays and ELISA Assay and refer for confirmatory testing. Negative results can be communicated to the client.

**Category III:** These are the clinical laboratories at atoll Hospitals, Health Centers and all other health care facilities providing OPD services. They can perform Rapid Assays. Only negative results can be communicated to person tested, and the confirmation has to be obtained from higher centers before labeling a sample as positive for HIV antibodies.

Type of laboratory	Located at	Test performed	Results to be declared	
			Negative	Positive
Category I	Referral lab at Central level	Rapid/simple, supplemental assay, ELISA and Confirmatory tests	Yes	Yes
Category II	Regional and centers with both OPD and IPD services	Rapid/simple ELISA	Yes	Preliminary report; <b>refer sample for confirmation</b>
Category III	Atoll hospital health centers and facilities with OPD services	Rapid/Simple	Yes	No. Refer <b>person not sample</b> for confirmation

All laboratories can collect blood for HIV testing only after identification of the individual to be tested with an official document with a photograph (e.g. passport, driving license, National ID card). If the result of HIV testing shows sero positivity, this needs to be confirmed at the central level and any positive result has to be notified to the Center for Community Health and Disease Control through the identified reporting mechanism. Confidentiality of the results must be maintained at all levels and the results cannot be shared with anyone in any way that discloses the identity of the person. The disclosure of the test results can only be done to any other person or organization after a written and specific authorization of the individual tested. Sharing the positive results and notifying to CCHDC does not reflect a breach in confidentiality. The test report should always be given in labeled code, and not under the name of the individual who has been tested.

**Window period:** While communicating the test results, particularly during post as well as the pre test counseling, it is important that the counselor identifies the risk factors and the possibility of the client being in the window period. This implies that, after the entry of the HIV into the body, there is a time interval from the

infection and to the appearance of the antibodies in the body. This time may vary from 2 weeks to 3 months. Hence, during this period, if a person is tested for HIV using antibody tests (the method normally used in VCTC), the result may be negative. However, there would be a need to retest after 3 months to confirm the HIV status.

### **Infection Control**

A breach in infection control practices can be a potential reason for transmission of infection from patients to health care workers. Hence, it is mandatory that the Universal Precautions are strictly followed in health care settings.

Staff working in the blood collection room and laboratory should observe simple precautions while handling blood and blood products. These include:

- Using gloves when handling blood samples;
- Using disposable needles and syringes for drawing blood;
- Practicing routine hand-washing before and after any contact with blood samples;
- Disposing of sharp instruments safely as per procedure, e.g. discard disposable syringes in a puncture-resistant container after disinfection with bleach solution. In areas where such work is undertaken a source of clean water should be maintained.

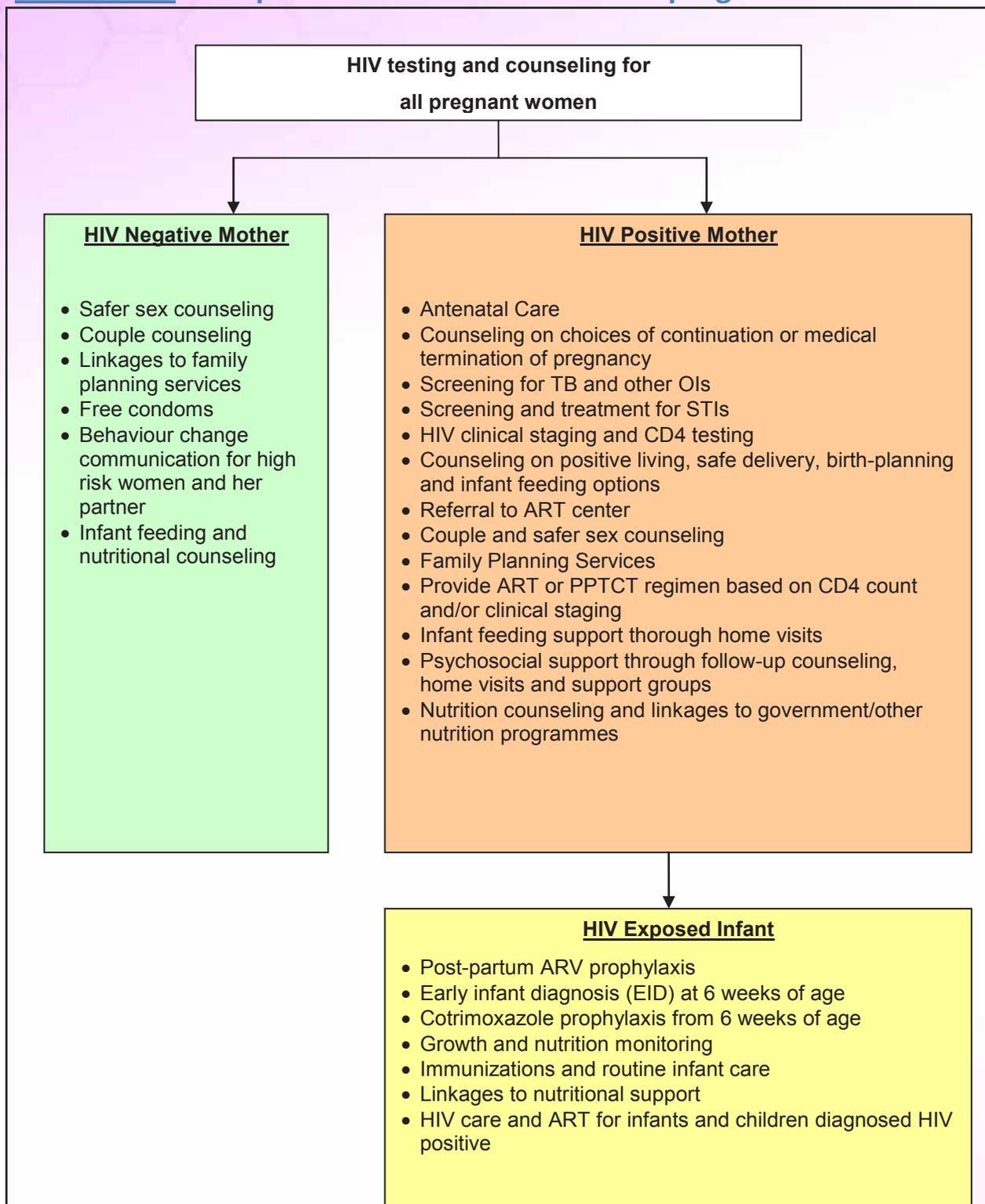
### ***Disinfection and Waste management***

The laboratory should adhere to disinfection and sterilization standards. All re-usable supplies and equipment should be disinfected by sterilization or washing with soap and bleach solution.

Hospital waste can be infective, hazardous, non-hazardous, pathological waste or clinical waste. It may be bio degradable or non biodegradable. It is advisable to use color-coded containers to dispose of waste material.

Disposable items such as gloves, syringes, IV bottles, catheters, etc. have to be shredded, cut or mutilated. This ensures that they are not recycled / reused. They have to be dipped in an effective chemical disinfectant for a sufficient amount of time or autoclaved or microwaved so that they are disinfected. A good disinfectant such as bleach/hypochlorite solution should be used. Liquid pathological waste such as blood, serum, etc. should be treated with a chemical disinfectant. The solution should then be treated with a reagent to neutralize it. This can then be flushed into the sewage system.

## Annexure 2: Components of the PMTCT of HIV programme



## Annexure 3: Three options for PMTCT programmes

<b>Table 1. Three options for PMTCT programmes</b>			
<b>Woman receives:</b>			
	<b>Treatment (for CD4 count ≤350 cells/mm<sup>3</sup>)</b>	<b>Prophylaxis (for CD4 count &gt;350 cells/mm<sup>3</sup>)</b>	<b>Infant receives:</b>
<b>Option A<sup>a</sup></b>	Triple ARVs starting as soon as diagnosed, <i>continued for life</i>	<i>Antepartum:</i> AZT starting as early as 14 weeks gestation  <i>Intrapartum:</i> at onset of labour, sdNVP and first dose of AZT/3TC  <i>Postpartum:</i> daily AZT/3TC through 7 days postpartum	Daily NVP from birth through 1 week beyond complete cessation of breastfeeding; or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks
<b>Option B<sup>a</sup></b>	<i>Same initial ARVs for both<sup>b</sup>:</i>		Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method
	Triple ARVs starting as soon as diagnosed, <i>continued for life</i>	Triple ARVs starting as early as 14 weeks gestation and <i>continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding</i>	
<b>Option B<sup>+</sup></b>	<i>Same for treatment and prophylaxis<sup>b</sup>:</i>		Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method
	Regardless of CD4 count, triple ARVs starting as soon as diagnosed, <sup>c</sup> <i>continued for life</i>		

Note: "Triple ARVs" refers to the use of one of the recommended 3-drug fully suppressive treatment options.

<sup>a</sup> Recommended in WHO 2010 PMTCT guidelines

<sup>b</sup> True only for EFV-based first-line ART; NVP-based ART not recommended for prophylaxis (CD4 >350)

<sup>c</sup> Formal recommendations for Option B+ have not been made, but presumably ART would start at diagnosis.

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