PREVENTION OF MOTHER
TO
CHILD TRANSMISSION
GUIDELINE

Foreword

Considering the spread of HIV infection among women of the reproductive age, mother – to- child transmission has become a great concern in the area of HIV prevention and health services.

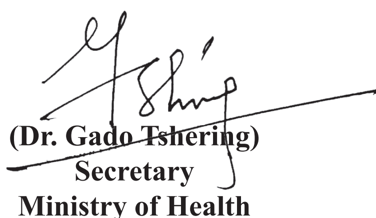
The first mother-to-child transmission in Bhutan was reported in the year 2002. Seven cases have now been officially documented. This covers nearly 9% of the total HIV infection in Bhutan. It is inevitable that more pregnant women will be affected in the coming years.

Mother to-child transmission of HIV is the most significant source of HIV infection in children below age of 10 years. Transmission can occur during pregnancy, delivery and after delivery through breast milk. In the absence of appropriate interventions infected child are likely to survive infancy. The extent of HIV infection among pregnant women is often used as an indicator of HIV penetration into the population at large.

The Royal Government has responded by adopting the prevention of mother to child transmission (PMTCT) as an integral part of the nation's response to the HIV/AIDS catastrophe. PMTCT will be a part of a wider response to HIV/AIDS, which includes expanding access to care and support for HIV infected mothers and their families, including treatment of opportunistic infections and accelerating access to treatment. PMTCT prevention should not stand in isolation, but it should be integrated to existing Health care infrastructures and Reproductive Health Services.

It gives me great pleasure to introduce the first edition of the National Manual for Prevention of Mother-to-child Transmission of HIV/AIDS. I look forward to seeing that every pregnant mother has access and utilizes the preventive services.

I commend the efforts of all those responsible for bringing out this comprehensive manual and that UNICEF for supporting their efforts.



(Dr. Gado Tshering)
Secretary
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Preface

HIV infection in pregnancy is associated with significant maternal morbidility. Infected children die early without interventions and uninfected children are left without parents. Society has to bear the loss of working people and the expense of looking after the orphans. Millions of children are infected from the maternal routes many of which could have been prevented. Combination of early diagnosis of infection, ART, Safer obstetric practice and infant feeding counseling and support can reduce the risk to less than 2%.

The first case of mother to child transmission was reported in Bhutan in 2002. However, the retrospective study shows that one of the earliest mothers – to- child transmissions could have taken place back in 1997, as one child was fourteen years old when detected with HIV infection in 2004. Thirteen children are recorded with HIV infection from their mothers by the end of 2008. This constitutes nearly 13 out of the total detected cases of 160.

The Royal Government of Bhutan is taking all the possible measures to reduce the risk of mother to child transmission in light of the effective and evidence based intervention available. The main goal of the PMTCT is to reduce HIV transmission through primary prevention in women and also prevent transmission from infected mothers to children and provide support and care to the infected and the affected families. All possible stages at which the maternal transmission of virus occurs is being addressed by adopting evidence based interventions. Efforts are being made for the early HIV detection and appropriate provision of available interventions for the prevention of mother to child transmission following the broad four prong approaches.

PMTCT program is an integrated component of the reproductive health of the mother and child. HIV test will be routinely offered in the antenatal clinics through opt-out approach. Free prophylactic ART will be provided to the HIV infected pregnant mothers. Breast feeding by the HIV infected mothers will not be recommended and mothers will be supported with the free infant formula. However, breast feeding in general population will be actively promoted as per the national breast feeding policy.

The PMTCT initiative is a newly implemented in a comprehensive manner. This is the first guideline for the PMTCT designed to guide the health workers. This guideline will remain dynamic to accommodate changes at regular intervals as per the changing policy approaches and evidences in the fast changing field of HIV/AIDS.

CHAPTER 1

Prevention of Mother to Child transmit of HIV

1.1. Overview of PMTCT

HIV infection in pregnancy is associated with significant maternal morbidity and mortality. Infected children die early without interventions and uninfected children are left without parents. Society has to bear the loss of working people and the expense of looking after the orphans.

1.2. Rationale for PMTCT

- More than 90%of the world's 2.5 million children living with HIV/AIDS were infected through PMTCT.
- Without interventions, rates of transmission are 25-45% in the developing countries.
- Combination of early diagnosis of infection, ART, safer obstetric practice and infant feeding counseling and support can reduce the risk to less than 2%.

1.3. Factors that will Increase the risk for HIV transmission

Pregnancy	Labour & Delivery	Breast feeding
High maternal viral load (new or advanced HIV/AIDS) Viral, Bacterial, or placental infection (e.g. Malaria) Sexually transmitted infections (STIs) Maternal malnutrition indirect cause)	High Maternal viral load (new or advanced HIV) Rupture of membranes more than 4 hours before labour begins Invasive delivery procedures that increase contact with mother's infected blood or body scalp monitoring) Chorioamnionitis (from untreated STI or other infection)	High Maternal viral load (new or advanced HIV/ AIDS Duration of breastfeeding parasitic Early mixed feeding (e.g. Food or fluids in addition to breast milk) Breast abscesses, nipple fissures, mastitis. Poor maternal nutritional status Oral disease in the baby (e.g. Thrush or sores.

1.4. Timing of prenatal Transmission

Without any interventions, there is difference of risk at various stages:

- During Pregnancy 5-10%
- Intrapartum 10-20%
- Postpartum period 10-20%

1.5. Effect of pregnancy on HIV-disease progression

All studies so far have not shown pregnancy to have any effect on the progression of HIV disease. Reports from developing countries, however, suggest that progression accelerates with pregnancy but it is difficult to interpret such reports because the sample sizes are small and the studies are subject to selection bias related to the indications for testing.

1.6. Effect of HIV on pregnancy outcomes

Controversies about the outcomes of pregnancy in HIV-infected women still exist. In rich countries, reports do not suggest an increase in the frequency of preterm birth, low birth weight babies, intrauterine growth retardation and stillbirths in comparison with similar groups of HIV-infected women from poor countries, with advanced HIV infections being associated with the highest neonatal death rates. The theory of a syndrome of malformation- related with HIV infection has not been proven. Similarly, no studies have indicated that there is an increase in the frequency of birth defects related to HIV infection. Is not an indication for termination of pregnancy?

1.7. Situation of mother to child transmission of HIV in Bhutan

The first case of mother to child transmission was reported in Bhutan in 2002. However, the retrospective study shows that one of the earliest mother-to-child transmissions could have taken place back in 1997, as one child was already eight years old when detected with

HIV infection in 2004. Thirteen children are recorded with HIV infection from their mothers as of February 2006. This constitutes nearly 9% out of the total detected cases of 160.

1.8. Approach for the PMTCT in Bhutan

The Royal Government of Bhutan is taking all the possible measures to reduce the risk of mother to child transmission in light of the effective and evidence based interventions available. Prevention of mother to child is focused adequately and resources are being mobilized to strengthen this intervention within the over all frame work of HIV prevention and control. All stages at which the maternal transmission of virus occurs is being addressed by adopting useful interventions. Efforts are being made for the early HIV detection and appropriate provision of available interventions for the prevention of mother to child transmission. HIV test will be routinely offered in the antenatal clinics through opt-out approach. Free prophylactic ART will be provided to the HIV infected pregnant mothers in addition to other care and support services. Breast feeding will not be recommended in HIV infected mothers. They will be supported with the free infant formula. However, breast feeding in general population will be actively promoted as per the national breast feeding policy.

a. Goal for PMTCT

Reduce HIV transmission through primary prevention in women and men, prevent transmission from infected mothers to children, and provide support and care to the infected and the affected families.

b. Objectives of PMTCT

I. Early detection of HIV infection in pregnant mothers through routine offer of HIV test to all pregnant women in health facilities during ANC, delivery and PNC.

II. Reduce HIV transmission by recommending formula feed options in infants born to HIV infected women.

III. Provision of ARV and/or OI prophylaxis in HIV positive pregnant women.

IV. Increase access for effective family planning services for HIV infected couples.

V. Improve quality of lives of HIV infected parents and the child.

c. Key components of PMTCT program

I. Offer of routine VCT for HIV in pregnant women

II. Provision of ART both for HIV positive mothers during pregnancy and delivery.

III. Practice safe obstetric intervention

IV. Recommend no breast feed and support with free formula feed

V. Follow up care for the infant including ART

VI. Family planning counseling and referral services

VII. Referral for care and support of positive mothers and infants

VIII. HIV testing of the baby at eighteen months.

d. Support for health workers in health care settings to provide PMTCT includes:

I. Specific training and supervision

II. Ensuring availability of necessary supplies

III. Focus on infection control and practice of universal precautions

IV. Making links between antenatal care (ANC), obstetric care, postnatal care, family planning, care and support

V. Ensure availability of post-exposure prophylaxis (PEP) to treat incidents of occupational exposure of HIV.

1.9. PMTCT strategy to follow up the "Four Prong Approach".

PMTCT strategy in Bhutan will be guided by the comprehensive for prong approach adopted by UN. The approaches are mentioned below:

Primary Prevention of HIV/AIDS in Women (and Men)	Prevention of Unwanted pregnancy in HIV-infected women	Intervention for prevention of PMTCT from HIV-Infected Women	Care and support for HIV infected infants & Women
Promotion of safe sexual behavior by : Promotion and provision of condoms Behavior change communication for Individuals, partners, families, communities, and youth. Prevention and treatment of sexually transmitted diseases. VCT and premarital counseling and testing.	Offering VCT to pregnant women Offering safe, FP to HIV-infected women.	Comprehensive MCH services VCT ARV prophylaxis Counseling and support for safe infant feeding. Optional obstetric practices.	Postpartum care for months (Including family planning) Postpartum care for infants (including identification, treatment of, and palliative care for condition) Social support for families and communities affected by HIV/AIDS, especially orphans and vulnerable children.

1.10. Integration of PMTCT services:

PMTCT service will be integrated and offerd with the present system of MCH services.

i. During the first ANC visits, mothers will be provided group information and group counseling or information on an individual basis.

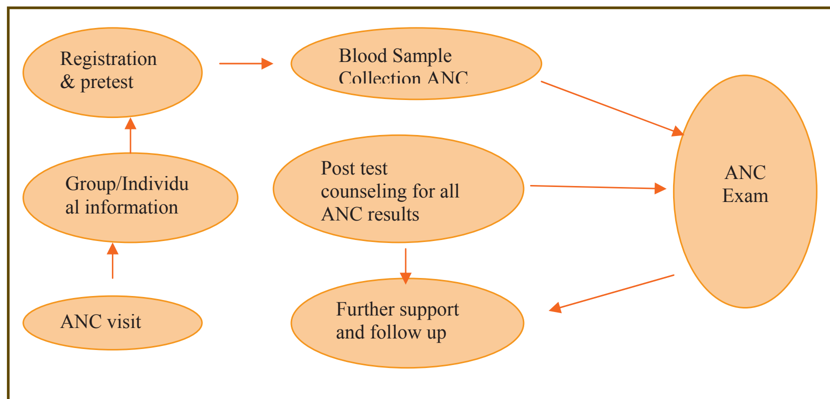
ii. At the registration, the mother will offered test for HIV.

iii. HIV test will be done along with other ANC test for the mothers who have consented

iv. Post test counseling will be offered for all the ANC tests and not for HIV test along.

v. ANC is conducted after pretest counseling/collection of blood samples.

The services delivery of the PMTCT services is shown in the following flow chart 1.



CHAPTER 2:

Voluntary Counseling and Testing in PMTCT

2.1 Policy guidance for testing in pregnant mothers

"Knowing the HIV status of the pregnant women is the prevention of MTCT". Therefore, the first step in the MTCT program is to encourage pregnant women to know their HIV status.

Testing procedure will follow the policy directives for testing of HIV in pregnant mother which states:

- All pregnant mothers attending the antenatal clinics will clinics will be offered HIV test as part of the route test.
- Pregnant mothers have the right to refuse the test. They will not be forced to under go HIV test. Mothers undergoing test will be purely on voluntary basis.
- "opt-out Strategy" will be adopted for HIV test for pregnant mothers.

2.2 Opt out Strategy in the PMTCT

Under this strategy pregnant women are offered counseling and testing as a part of the routine antenatal screening tests. They are tested for HIV unless they specifically decline or do not consent for the test.

Opt out strategy has the following benefit:

- Opt-out testing helps normalize HIV testing and makes the test a standard ANC component.
- It is likely to increase the number of women who are tested for HIV.
- Health worker must adhere to the guiding principles of counseling and testing informed consent, confidentiality, and the provision of the post-test services).

The women will be given the opportunity to decline the test should she choose to do so. The opt-out approach emphasizes that HIV testing is an expected part of ANC. However, testing is still voluntary under the opt-out approach: the woman has the right to refuse testing.

2.3 Where and when to offer routine VCT for the PMTCT

- Antenatal/MCH during the first visit or later when a woman is ready.
- Delivery Room (un-booked cases)
- Postnatal/immunization clinic (un-booked and home delivery)

2.4 Basic minimum information that should be given before opt out strategy for HIV testing:

Information should be provided before offering HIV test. In order that meaning of offer of HIV test is understood in the right sense, give time in sharing following information:

1. Basic information on HIV/AIDS, transmission, prevention, window period.
2. High light on the transmission in HIV positive pregnant mothers and the risk of transmission.
3. Availability of services of HIV test and interventions if found positive.
4. Inform that HIV test is part of the routine pregnancy screening tests like HB % urine test, etc but they can refuse HIV test if they do not wish to do.
5. However, tell them that HIV test is important and is strongly recommended that all pregnant women be tested because women can pass HIV to her baby.

6. Reiterate that if a woman has HIV, she will be offered medicines for her health and to reduce the risk of passing HIV to her baby.

7. Services are available for her and her family

2.5 Small group sessions/individual session

General information will be provided to groups/individual in the form of health education talks. The pretest counseling for group session includes

- Basic facts about HIV infection and AIDS including window period
- Risk reduction approaches (consistent condom use and demonstration)
- The benefit and potential issues related to testing
- HIV testing procedures and procedures for result provision
- Clarifying the meaning of the offered PMTCT interventions, including the meaning of ARV therapy and its benefits for pregnant mother and unborn baby and feeding options.
- Discussion about sharing of HIV test results with health care workers including the confidentiality offered to the clients
- Sharing HIV status with partner and /or family or friends
- Information on referral for related health care and social support
- Discussion on comprehensive family options, particularly condom for dual protection for unintended pregnancy and HIV and STI prevention in future. Health staffs shall support and encourage women to be tested at the initial visit because many women begin ANC late in pregnancy or are seen only once before delivery.

2.6 Pregnant women declining Test:

- Counselor/ Health worker must be non judgmental on pregnant mothers who declined the test.
- The health worker shall identify the problem and solve issues that are preventing women from accepting testing.
- Each woman will be reassured that declining an HIV test will not affect her access to ANC or related services.
- She will also be informed that if she changes her mind, an HIV test can be provided during a later visit.

2.7 Voluntary Counseling and Testing in PMTCT

Counseling should be performed by person trained on basic HIV counseling and prevention of mother to child transmission.

a. Confidentiality in VCT

Strict confidentiality must be observed regarding information shared by the pregnant mother, of their HIV test results, identity of the pregnant mothers and their spouses or the partners undergoing the test. All records must be protected and kept confidential. Proper coding and decoding system will be used in order to strengthen the confidentiality procedures.

b. Informed consent

In the context of PMTCT, written informed consent is not required. Clear and accurate information about implication and benefits of HIV testing will be given, to ensure that the patient understands she has the right and the opportunity to decline. The staffs must ensure that the following elements are understood by the client:

- The purpose and benefits of services
- The counseling and testing process
- The client's choice to testing decision

c. Pre-test group information and counseling

In busy ANC settings, instead of keeping clients waiting for the information, components of pre test counseling could be provided in a group setting. Providing pre-test information helps prepare women and their partners to understand the counseling and testing process. Basic information about HIV/AIDS will be offered. Printed materials, videos, presentations, and role-playing exercises shall be used to present content in a group setting.

Individual counseling will be provided again during the initial and subsequent ANC visit.

2.8 Individual pre-test counseling

After the group pretest counseling, individual pre-test counseling is provided for women. Individual pre-test counseling is considered to be the most effective strategy. It is most suitable to discuss issues specific to individual on an individual counseling. Each woman is further counseled individual and in private.

The counselor in the individual pre-test counseling session:

- Assesses if the information provided in the group session has been absorbed.
- Answers any remaining questions.
- Discussion the options for enrolment in the MTCT intervention:
  - To test and receive the results in person
  - To be counseled at a subsequent visit if she so decides.
  - To not take part in the interventions (no further counseling and testing.

2.9 Couple counseling

The women's partner's HIV status is a critical part of the family's decision making framework. Involving the partner in the HIV test related counseling can help ensure that he is supportive of his partner's dilemmas. Strategies for increasing partner's involvement might include providing ANC women with a card to take home to partners inviting them to "father's health checks" or couples information sessions.

- Clients coming for HIV/AIDS counseling will be encouraged, but not forced, to come with their partners.
- Counseling male partners of pregnant women provides and opportunity to encourage men to practices safer sex by using condoms and by limiting the number of partners.
- During counseling, healthcare workers can emphasize the man's responsibility for protecting the health of his wife or partner and their family.
- Testing both partners together as a couple may reduce the likelihood that the woman will be "blamed" for bringing HIV infection into the family
- Identifying discordant couples during counseling one partner is HIV-negative and the other one is HIV positive) will provide the opportunity to discuss safer sex practice.

2.10 HIV Testing

The HIV testing will follow the National VCT guideline for counseling and testing. A serial rapid testing mechanism will be used. A positive rapid test result is confirmed by a different rapid test. If the results of the two tests differ, a third rapid test will be used.

- If a woman gives informed consents to HIV testing, make sure she understands the consequence of a positive result.
- IF the first test is negative, the woman is considered HIV-negative.

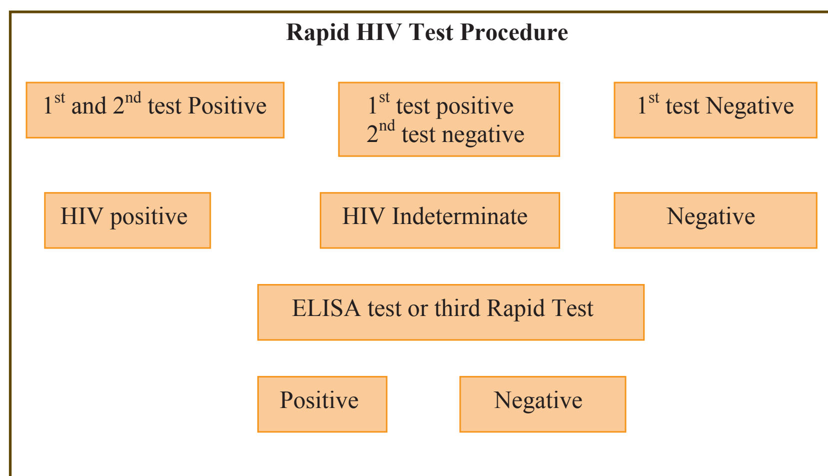
- If the first rapid test is positive, a second rapid test is done on a second sample using a different rapid test.
- If both tests are positive, the women is HIV-Positive
- If the first test is positive and the second test is negative the woman is HIV indeterminate. In this case a new blood sample must be sent for re-testing by the ELISA technique if facilities are available and if not do a third rapid test. (Follow Guideline on HIV testing)

a. Who should be trained to do the test?

For wider coverage and to expand the availability and accessibility of VCT services, various health staffs (doctors, midwifes, nurses, laboratory technicians and other qualified professional staff) could potentially become involved in HIV testing procedures using rapid test. In order to qualify for testing, person must undergo a training course on the testing procedures.

The test could be conducted in the antenatal clinic itself or at the laboratory in the hospital where ever it is feasible.

Flow chart 2: Algorithm of Rapid HIV Test



b. Lab Reporting of the HIV Test to the Counselor

Standardized and uniform reporting mechanisms maintaining confidentiality should be followed.

After the test has been performed, the midwife or laboratory assistant enters the results in the ANC – HIV Blood Test Register. A written result is given to the post test counselor. The register is kept confidential and always remains on site.

2.11 HIV Post Test Counseling

This is a good time to clarify with client that the information provided in the beginning of the pretest counseling session.

The clients should get her test result as soon as test result is ready. All HIV test results, whether positive or negative, must be given in person. The initial post-test counseling session are provided to each patient separately in privacy with complete visual and auditory barriers, so that others cannot see or hear.

a. Negative test result

A negative result on an HIV antibody test means that a woman is not infected with HIV. Post-test counseling provides on opportunity for a woman who is HIV – negative to learn how to protect herself and her infant from HIV infection. Post-test counseling those who test negative for HIV – provides women with a powerful incentive to adopt safer sex practices, discuss family planning, understand the issue of discordance, and encourage partner testing.

Components of post test counseling for women testing HIV-negative

- Communicate with the client that the test result is ready now
- Provide test results clearly and simple which show her test results
- Review the meaning of test result and discuss window period if she is in most recent risk exposure. Explain client if there is no significant risk in the previous 3 months. Then no repeated test is required unless the client has a later exposure to HIV. If there is recent risk exposure revealed at the time of post test counseling a specific date to be fix up for retesting. Repeat test at 3 monthly intervals till delivery if partner is positive or if belongs to high risk group.
- Discuss and negotiate a specific, concrete risk reduction plan (skills of condoms use condom use demonstration as necessary and supply of condom for dual protection)
- Inform sero negative women that about the implication of acquiring HIV during pregnancy and breast feeding.
- Discuss test result disclosure for partner and partner testing for HIV testing.

b. Positive test result

A woman who tests HIV-positive is infected with HIV. The healthcare worker must remain non-judgetmaental, supportive, and

confident through out the counseling process. Because women may present late in pregnancy or only attend ANC once, key PMTCT messages will need to be provided during the post-test counseling session. Also during the post-test counseling session, the healthcare worker should encourage the woman who is HIV-positive to attend subsequent ANC visits. During those visits, key PMTCT messages can be reinforced and follow-up counseling provided. Referral for HIV treatment, Care, and Support is necessary.

Main Components of post-test counseling for women testing HIV-positive

- Inform client that the test results are ready
- Provide test result clearly and explore client's understanding of test result.
- Discuss the meaning of the test result and provide time to acknowledge test result.
- Determine whether she understands the meaning of the result and let her talk about her feelings.
- Give enough time for emotional expression of clients with positive report (Crying, Anger, No response, Denial)
- Talk about her immediate concerns.
- Inform her about essential PMTCT issues. Discuss benefits of ARV therapy and infant feeding options and its transmission rate should be discussed carefully.
- Discuss disclosure and partner testing. Discuss possible approaches to disclosure of test result in most MTCT intervention almost impossible to keep their status confidential due to need for on going follow and treatment.
- Encourage her to attend subsequent ANC visits and the importance of delivering in a PMTCT facility.

2.12 Disclosure of HIV status to partner and family

During the initial post-test counseling session, the counselor and the HIV positive mother should begin the discussion about disclosure as this may help to:

- Encourage the partner(s) to be HIV tested
- Prevent the transmission of HIV to her partner(s)
- Access PMTCT interventions.
- Receive support from her partner(s) and family when accessing PMTCT and HIV treatment, care and support services.

It is important to respect the women's choice regarding the timing and process of disclosure. A woman may perceive disadvantages in disclosing her HIV diagnosis. In some communities, women who are HIV-infective and their families may face stigmatization. If the woman has indicated her partners and family may react negatively to her HIV status, the counselor can help the women problem-solve and build skills to use when she discloses her HIV status. A written consent should be sought from the women before discloses of her HIV positive status to her spouse/partner/family members.

2.13 Counseling & testing for women of unknown HIV status in labour & delivery

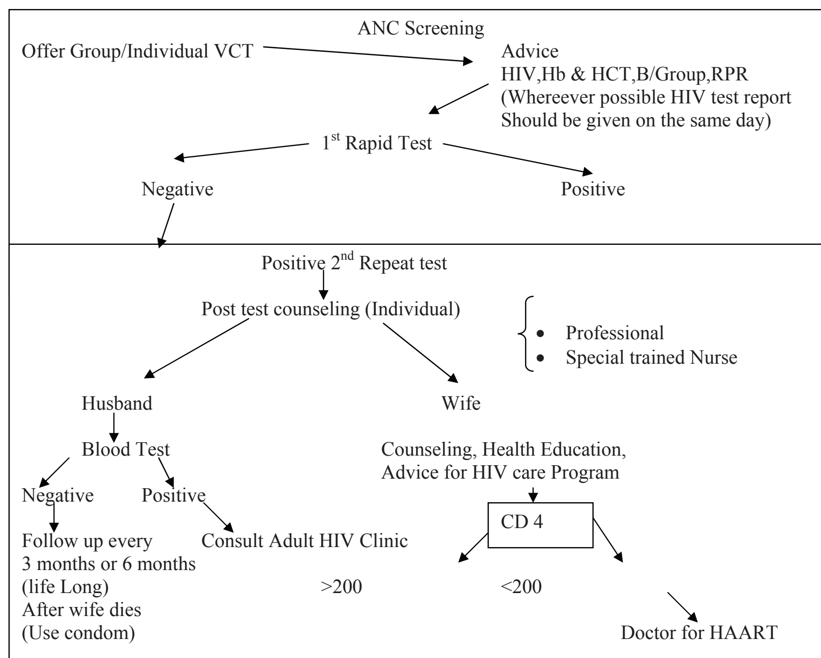
If women have not been tested during ANC or did not attend ANC, and comes to the health service at the time of labour with unknown HIV status, it is recommended that the opt-out approach to testing be used during labour and that post-test counseling provide after delivery. In these circumstances, in some cases it will be possible to provide ARV prophylaxis to the mother and the infant, and in other cases it will only be possible to provide ARV prophylaxis to the infant.

2.14.2008 Quality Assurance for counseling services

It is essential that the quality of both testing and counseling can be

assured with appropriate monitoring and evaluation as a key and planned component of interventions. Counselors and other health care providers involved in MTCT interventions sites must have adequate training, onsite coaching and technical support with supportive supervision to ensure the quality of services.

Flow Chart 3: Summary of VCT



CHAPTER 3:

Antenatal Care for HIV infected pregnant mothers

Antenatal interventions can reduce the risk of MTCT. Good maternal health care helps women with HIV infection stay healthy, longer and care for their children better. Early ANC booking is a key component to a successful PMTCT program.

ANC for women infected with HIV includes the basic services recommended for all pregnant women. However, obstetric and medical care will be expanded to address the specific needs of women infected with HIV. After HIV status is known, mother can be evaluated for ARV eligibility and offered the ARV treatment and offered the ARV treatment and prophylaxis.

Women of unknown HIV status should be made aware that testing is available. She should be counseled for testing.

3.1 Key elements of ANC for PMTCT

- Health information and education on HIV/AIDS and STIs Transmission and prevention.
- Interventions to reduce MTCT and provision of ARV.
- Education about safer sex practices and use of condoms.
- HIV counseling and testing
- Partner HIV counseling and testing.
- Infant-feeding counseling and support.
- Diagnosis and treatment of sexually transmitted infections (STIs)

3.2 Anti-retroviral therapy in pregnancy

ARV has been shown to be very effective in improving the quality and length of lives in HIV infected people. It also reduces the risk

of transmission from pregnant mother to her child. Pregnancy is not being regarded as a barrier to using the ART. ART is provided for two main reasons during pregnancy.

i. For prevention of MTCT (Therapy Usually discontinued at, or soon after delivery)

ii. For treatment of Maternal health (treatment continued indefinitely)

Most transmissions of HIV occur during the last 2 weeks of pregnancy, in labor and during delivery. Highest risks of transmission are seen among pregnant women with low immunity (low CD4 count), with increased number of HIV virus in the blood (high viral load) and primary infection occurring during pregnancy.

This is the reason for starting ART from 28 weeks onwards to cover the high risk time period (National Guideline on clinical management of HIV/AIDS). ART will increase the maternal immunity and reduce the number of HIV virus in the mother's blood and these in turn reduce the risk of transmission of HIV virus to her child.

a. Prophylaxis of HAART

Pregnant women who are not ill and have high immunity (CD4 count > 200) with HIV infection are to be given prophylaxis of ART. This will help reduce risk of mother-to-child transmission of HIV. Anti-retroviral therapy is to be commenced at 28 weeks onwards and continued intrapartum (according to the national guideline of HIV/AIDS Management). The timing will be influenced by the risk of preterm delivery. For instance, women with a multiple pregnancy or a history of previous preterm birth should receive ART earlier in order to achieve an undetectable plasma viral load by the time of delivery. Anti-retroviral therapy for mother after delivery should be discontinued after 1 week, excluding Neverapine.

b. HAART for symptomatic woman.

Women with advanced HIV should be treated with a HAART regimen. All these patients should be referred to regional referral hospitals for proper assessment and starting HAART.

- Pregnant women with symptoms and with CD4 below 200, therapeutic HAART is indicated any time in pregnancy. However, try to delay HAART for beyond 12 weeks of pregnancy in patients whose CD4 count is below 200cells/ mm3, as this period is highly sensitive to any drugs for organogenesis.
- For women who are severely ill, initiate HAART as soon a possible based on clinical grounds.

c. Medical contraindication to starting HAART regimen

- Several neutrocytopenia,
- Severe anemia,
- Thrombocytopenia
- Severe renal disease
- Hepatic insufficiency may preclude the use of HAART.

Other diagnostic evaluation must be done to find out any reversible etiology. The above conditions must be corrected before HAART can be used. If no other cause is found, an urgent referral must be made for expect consultation before the use of HAART. Co-infection TB and HIV in pregnancy also needs expect consultation.

d. General consideration for HAART for PMTCT

A base line CD4 count is also done and pregnant women is assessed the requirement of ARV. The requirement of ARV is determined by following factors.

- The gestational period of at least 28 weeks pregnancy is considered for provision of ARV prophylaxis only when HAART therapy is not indicated.

- Delay HAART for at least 12 weeks of pregnancy in patients whose CD4 count is below 200 cell/mm3, as it is medical emergency.
- For women who are severely ill, initiate HAART with a combination of AZT/3TC/NVP, earlier than 12 weeks.

e. Mandatory laboratory Investigations

Initially following tests must be done before starting the ARV prophylaxis:

- A base line CD4 count
- Hb,Hct
- White blood count
- Neutrophil count
- SGOT (AST),SGPT(ALT),RFT
- Hepatitis B and C
- If Hb<7.5 gm% and or neutrophil count is <750 cells/cu mm ZDV is not given immediately. Anemia should be corrected. And other infection should be taken care first.

3.3 Situations for initiating HAART prophylaxis or treatment.

Newly diagnosed HIV infected pregnant women without indication for the HAART:

For Mother:

- Start therapy from 28 weeks of pregnancy or as soon afterward as possible if presents later in pregnancy.
- AZT 300mg PO every 12 hours
- AZT 2mg/kg IV, then 1mg/kg hourly until delivery or AZT 600mg PO at onset of labor, then 300mg PO every three hours until delivery.

- NVP 200mg PO at onset of labor.

For Infant

- Single dose of NVP2mg/kg within 12 hours or at least before 72 hours after delivery.
- AZT 2mg/kg every 6 hours for 7 days.

Note: if the mother received AZT less than 4 weeks of AZT during pregnancy, extend AZT to 4 weeks to infants.

a. Newly diagnosed HIV infected pregnant women with indication for treatment (CD4<200):

Delay the HAART unit the first trimester (12 weeks) of pregnancy, however if, mother is severely ill, treatment should be initiated regardless of trimester. The following ART regimes are considered at different stages of pregnancy:

Delay the HAART unit the first trimester (12 weeks) of pregnancy, however if, mother is severely ill, treatment should be initiated regardless of trimester. The following ART regimes are considered at different stages of pregnancy:

Antepartum:

Start AZT+3TC+NVP after the first trimester or as soon as possible if presents later in pregnancy.

Intrapartum:

For the mother:

- NVP 200mg PO at onset of labor
- AZT 2mg/kg IV, then 1mg/kg hourly until delivery or AZT 600mg PO at onset of labor, then 300mg PO every three hours until delivery plus 3tc 150 mg PO at onset of labour and 150mg 12 hourly until delivery.

Note: if the mother received AZT less than 4 weeks of AZT or HAART during the pregnancy, extend AZT to 4 weeks to infants.

Postpartum:

Continue the same regime as taken during the ante partum period in the mother as the mother would require continuing with the treatment with HAART.

b. HIV infected women conceiving while on HAART.

Continue same therapeutic (AZT+3TC+NVP) during antepartum, intrapartum and postpartum period. Booster doses of the medicines are added intrapartum as per the regime.

Note: if the regime contains EFZ, discontinue it due to teratogenic effect.

Pregnant women diagnosed with HIV during the delivery:

- If there is time, rapid HIV antibody test is offered to the mother.
- If there is no time offer rapid test to the mother as soon as after the delivery.
- If test is positive, administer single dose NVP to the mother during the labour.
- If test positive and mother cannot receive single dose NVP, or receive NVP less than 2 hours before delivery. For the child initiate NVP within 72 hours of delivery and AZT for 4 weeks.

c. Women diagnosed with HIV after he delivery:

In this situation it is important to administer ART to the infant to reduce the risk of maternal transmission. The following strategies will be adopted:

For the child:

Within 72 hours of delivery: single dose NVP and AZT for 4 weeks after 72 hours: No ARV but follow up the child and plan HIV test at 18 months for the infant.

For the mother:

Do a CD4 count and assess the clinical problem of the mother.

Needing HAART, continue with the general regime of HAART (AZT+3TC+NVP) not needing HAART, future follow up and assessment.

3.4 how to dispense HAART

- A written instruction should be given with the dose of ART at 28 weeks gestation.
- The dispensing of ART with the onset of labour or rupture of membranes.
- At every visit (monthly) the staff should check that the patient:
- Has not lost her dose of ART.
- Know when and how to take ART.
- Knows to present in early labour or immediately after rupture of membranes.
- Has counseled about not to breast-feed her baby and how to give formula feeding.
- Inform that all the drugs in PMTCT are safe to be taken with any food. There is no drug food interaction.

3.5 Treatment and Prophylaxis for opportunistic infections.

Pregnant women with symptoms and or on HAART may need prophylaxis from other opportunistic infections (OIs). They will be treated as per the national guideline for clinical management of HIV/ AIDS.

Monitoring for ARV Drugs.

The cornerstone of monitoring is the viral loads but this facility at present is not available in Bhutan. We would use clinical findingd with CD4 count levels. CD4 Counts: treatment in the non-pregnant is generally indicated when the CD4 counts falls to<200. This guideline is also recommended for pregnant women.

Adherence: to therapy must be strictly monitored. Haphazard or intermittent therapy compliance leads to drug resistance.

PCP prophylaxis: is usually administered when the CD4 T-lymphocyte count is below <200. The first line treatment is cotrimoxazole (a folate antagonist) and this must be given with a folate supplement.

Pre-eclampsia: is more common among pregnant women treated with HAART compared with those not taking anti-retroviral therapy. However, the clinical presentation of pre- eclampsia and toxic effects of anti-retroviral therapy may overlap.

Lactic acidosis: is a recognized complication of certain HAART regimens and may mimic the symptoms and signs of pre-eclampsia. Maternal deaths have been reported. The presenting symptoms of lactic acidosis are often nonspecific but may include gastrointestinal disturbance, fatigue, fever and breathlessness.

Nevirapine Toxicity: women initiating nevirapine with CD4 +counts>250 cells/mm3, including pregnant women receiving antiretroviral drugs solely for prevention of transmission, have an increased risk of developing symptomatic, often rash-associated, neverapine-related hepatotoxicity, which can be severe, life-threatening.

Clinicians giving HAART with nevirapine during pregnancy should be aware of this potential complication and conduct frequent and careful monitoring of clinical symptoms for rashes and hepatic transaminases (i.e.. alanine aminotransferase, ALT and aspartate

aminotransferase, AST), particularly during the first 18 weeks o=f therapy.
It is recommend measuring serum transaminases at baseline, every 2 weeks for the first month, at least three monthly thereafter. Transaminase levels should be checked in all women who develop a rash while receiving nevirapine.
Hepatic toxicity has not been seen in women receiving single dose nevirapine during labor for prevention of perinatal transmission of HIV.

Some toxicity due to other drugs: include gastrointestinal disturbances, hepatotoxicity, rashes, glucose intolerance and diabetes.

The following investigation should be done to rule out the toxicities.

- Fasting blood sugar
- Renal function test
- Liver function test
- Complete blood count
- Serum electrolytes

(Refer guideline for clinical management of HIV/AIDS)

3.6 Special situations

a. Un-booked pregnancy

Given out low ANC coverage, some HIV infected pregnant women are expected to come very late for ANC and some may come directly with labor without ANC. There may not be facility for the CD4 count. So it is recommended that they should be offered HAART prophylaxis. Arrange to send for CD count and reassess the need for treatment HAART.

b. Fetal Lung induction

There is known contraindication to the use of short-trem steroids to promote fatal lung.

c. Unexpected emergency situations

As we have many women who present in labour without ANC or those on PMTCT program with emergency situations.

- APH (massive bleeding)
- Severe PIH (elevated blood pressure)
- Preterm labour
- Spontaneous Rupture of Memberance

In such situations, immediate safety of the mother and baby takes priority. These situations should be addressed as any other obstetric emergencies. Take precaution as much as possible to reduce the risk of transmission

CHAPTER 4:

Management in Labour and Delivery

4.1 HIV transmission during labor and delivery

Infants of HIV-infected mothers are at great risk of becoming infected with HIV during childbirth. During this single event, between 10 and 20 percent babies will become infected if no steps are taken to prevent the transmission. Many infants who acquire HIV during labor and delivery do so by sucking, imbibing, or aspirating maternal blood or cervical secretions that contain HIV. Others can acquire HIV through the mixing of fetal and maternal blood as the placenta separates. The durations of membrane rupture (>4 hours) and acute chorioamnionities (resulting from untreated STIs or other infections); and invasive delivery techniques that increase the baby's contact with the mother's blood have been associated with higher risk of MTCT during labor and delivery (WHO, 1999). Midwife and obstetrical practices are modified for the HIV-positive woman to reduce the risk of HIV transmission to the infant.

4.2 Mode of Delivery: Vaginal delivery

Although elective caesarean section (prior to labor) is of a better choice, it is not feasible to be routinely offered in all settings. Logistic and human resource constraints cannot make caesarean section to be available everywhere in Bhutan at this point of time. In addition, observational studies have reported very low rates of transmission among women taking proper ART who deliver vaginally with safer obstetric practices. Therefore HIV infected pregnant mothers, normal vaginal delivery adopting safer obstetric practices is recommended.

Caesarean section in HIV infected pregnant mothers will be performed only if there is other obstetric indication.

4.3 Facility Preparation

All health facilities in Bhutan catering for PMTCT should have:

- Appropriate equipment, test kits and supplies for HIV testing
- Essential drugs for PMTCT services
- Health education materials, condom supplies
- Supplies for infection prevention (universal precautions)
- Appropriate record keeping, monitoring and evaluation forms

a. An ideal core team for PMTCT should consist of:

- All obstetricians/ Midwife/ANM/AN/HA
- All pediatrician/nurse
- 1-2 trained counselors, according to the local case load
- 1-2 staff nurses
- One lab technician

b. Provision of safety gear necessities in the labour room and operation room:

- Safe delivery kits
- Disposable gowns
- Goggles
- Long rubber gloves
- Delivery bed with waterproof cover materials
- Rubber boots
- Sharp disposable containers.

c. Minimum criteria for Delivery areas to have:

- Continuous free flowing clean water Good lighting source/ alternatives
- Water proof Mattress covers
- Articles in place of all sizes
- Plastic apron, disposable gown, Disposable Mask with cap, Goggle, Long gloves, boots.
- Infections control procedures fully functional (Refer to National infection Prevention Guideline)
- Proper decontamination procedures
- Separate containers/water proof bags for soiled linens
- Proper disposal procedure and place of infective waste
- Provision for giving bath to baby

4.4 Precaution for all staff conducting delivery

- All staff must practice universal precaution strictly and treat all cases potentially infections.
- All Staff conducting deliveries must wear.
    - Mask and cap
    - Protective eye goggles
    - Plastic apron
    - Gown
    - Long boots/shoes covering all the feet (not sandal or slippers)
    - Always use gloves irrespective of HIV status in the labor room(long rubber gloves In very high risk cases)

4.5 General safe Practice Points for Management of Labor in HIV Positive

a. Use good infection prevention practices for all patient care.

Use universal precautions, which include use of protection gear, safe use and disposal of sharps, sterilization of equipment, and safe disposal of sharps, sterilization of equipment, and safe disposal of contaminated materials.

b. ART

Women should continue their HAART regiment throughout labour and start ART for late comers.

c. Minimize internal examinations.

Perform cervical examination only when absolutely necessary and with appropriate clean technique.

d. Fetal Monitoring

Fetal monitoring should be performed according to normal standard, HIV infection per se is not an indication for continuous electronic fetal monitoring.

e. Avoid prolonged labour.

Consider using oxytocin to shorten labour when appropriate

Use non-invasive foetal monitoring to assess need for early intervention

Use a partograph to measure the progress of labours.

f. Avoid routine rupture of membranes unless necessary.

Studies have demonstrated doubling of risk of transmission after 4 hours and further 2% incremental increase in transmission risk for every hour of ruptured membranes up to 24 hours

g. Avoid unnecessary trauma during delivery.

Avoid invasive procedures, including scalp electrodes or scalp sampling

Avoid routine episiotomy

Minimize the use of forceps or vacuum extractors

h. Emergency cesarean

All emergency caesarean sections in HIV positive women should performed

- To avoid a prolonged labour and
- Prolonged rupture of membranes
- For the usual other obstetric reasons

i. Baby Management

Gently clean the mouth and nose at delivery of the head.

The cord should be clamped as early as possible after delivery. Cut cord under gauze cover to avoid splashing of blood.

The baby should be bathed with warm water and soap immediately after the birth including at caesarean section.

Avoid un-necessary suctioning of the neonate.

j. Minimize the risk of postpartum haemorrhage.

Actively manage the third stage of labour.

Give oxytocin immediately after the delivery.

Use controlled cord traction.

Perform uterine message.

Repair genital tract lacerations.

Carefully remove all products of conceptions.

k. Blood test

A maternal blood sample should be taken at delivery for D4 count, if facility to measure CD4 count is available.

l. Use safe transfusion practices.

Minimize the use of blood transfusion.

Use only blood screened for HIV and when available syphilis, and hepatitis B and C

m. Preterm rupture of membrane

If there is preterm rupture of membranes, with or without labour, the risk of HIV transmission should be set against the risk of preterm delivery. Preterm infants are more likely to be infected with HIV. This may be attributable to underlying chorioamnionitis or to increased susceptibility of preterm infants to HIV transmission, because of immature immune functions, incompetent mucosal barriers or reduced levels of acquired maternal antibody.

4.6 Management in labour room

a. women on ART from antenatal period

- Upon admission, the staff should inacqire if the woman took ART at home or check for the documents and the prescriptions for details.
- If the patients is found to be in labour or to have ruptured membranes and did not take the ART at home, she should be given ART immediately.

- In the case of false labour or mistaken rupture of membranes: send out the patient to wait for more active labour with instruction to take ART with the onset of stronger and more regular contractions or with rupture of membranes.

b. Women in true labour without rupture of membrane:

Wait for active labour and give another ART tablet if active labour or rupture of membrane occurs more than 24 hours after initials dose.

- In the case of emergency caesarean section, ART should have already been administered during labour. Women can be given ART should have already been administered during labour. Women can be given ART in all stages of labour. It is only too late to give ART if the baby is delivering imminently (the head is crowning).

4.7 Women whose HIV status is unknown and comes for Delivery

This group will usually include the following:

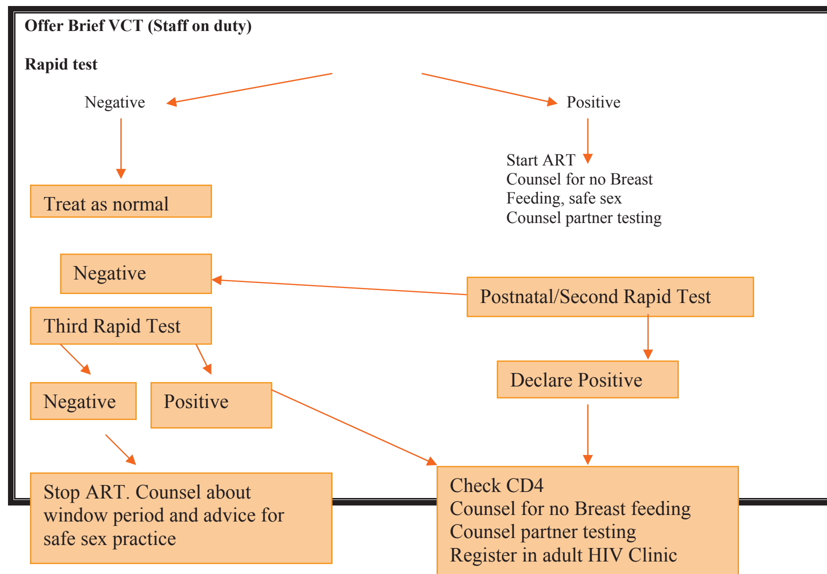
- Women with no or limited prenatal care
- Women who were not offered testing
- Women whose results are unavailable
- Women who declined testing previously

a. How to approach:

- Do brief VCT and get consent by labour staff
  - Offer rapid HIV testing with right to refuse.
  - Mention benefits of the HIV test and availability of ARVs and other services.
  - Describe the testing process

- Do rapid HIV Antibody test if she agrees
- Confirm the report and provide Post Test Counseling after delivery
- If negative, treat as normal
- If positive start ART and counsel for:
  - No breastfeeding
  - Need of baby testing
  - Family planning
  - Partner testing
  - Include her for subsequent counseling sessions.

Flow chart 4: Management of Un-booked cases coming in labour



4.8 Women coming with false labour

- Women should be put back on antenatal regime is she remains undelivered beyond 24 hours.
- Restart the intrapartum regime when she comes with true labour.

4.9 Immediate care of the Newborn

The immediate care of the newborn exposed to HIV follows standard practice. Regardless of the mother's HIV status, all infants are kept warm after birth and are handled with gloves until maternal blood and secretions have been washed off.

Immediate newborn care consists of the following:

- Maintain universal precautions throughout care and treatment.
- Wipe infant's mouth, eyes and nostrils with gauze when the head is delivered.
- Clamp cord immediately after birth, and avoid milking the cord. Cover the cord with gloved hand or gauze before cutting.
- Use suction only when meconium-stained liquid is present. Use either mechanical suction or bulb suction.
- No mouth to mouth resuscitation
- All babies should be given an immediate warm water bath with mild soap wearing protective gloves. Once the initial bath is given, then no need to wear gloves for handling the baby.
- If warm water bath is not feasible, then gently wipe the infant dry with a clean soft towel. Towel can be discarded or disinfected.

- Wear gloves when giving injections, and clean all injection sites with surgical spirits. Dispose of all needles according to facility policy.
- Administer Vitamin K

4.10 ART prophylaxis for the new born baby.

As a part of PMTCT, ART is given to the baby to reduce the risk of transmission of HIV from mother to baby in the following recommended doses.

- Single oral dose of NVP 2mg/kg within 12 hours or at least before 72 hours after delivery.
- AZT 2mg/kg orally every 6 hours for 7 days

Note: if the mother received less than 4 weeks of AZT during pregnancy, extend AZT to 4 weeks for the baby.

4.11 Prophylaxis to prevent first episode of opportunistic disease in infants

- All children born to HIV infected mothers should receive PCP prophylaxis irrespective of clinical evidence of HIV disease.
- Age to start – 6 weeks of age
- Give cotrimoxazole 6-8 mg/kg day as a single dose daily. (PCP) prophylaxis)
- Give till 12 months of age.
- After one year of age prophylaxis should be given if CD4 % is less than 15%
- Prophylaxis can be stopped at 9-12 months of age if HIV infection in the baby can be ruled out.

4.12 Immunization

Almost all the babies are asymptomatic at birth even if they have been infected with HIV from the mother. Hence the routine immunizations as per the national guidelines must be carried out.

4.13 Regular monitoring

Infant born to HIV-infected mother should be followed up regularly and monitored to ensure early intervention if symptoms develop.

Follow up visits:

- At age 6, 10 and 14 weeks on the occasion of routine immunizations
- At 6 weeks prophylaxis of PCP should be started.
- Thereafter once a month up to 1 year
- Every 3 month up to 1 year
- Every 3 months from 1 year to 5 years.

4.14 HIV Testing in Babies

As antibodies are transferred from the mother to baby in utero the baby may be falsely HIV positive. These antibodies persist in the baby fro 12 to 18 months. Thus, HIV testing has to be done at 18 months to definitely say whether the baby is infected or not.

HIV testing in infants and interpretations

Age	Test in months	Result	Inference	Follow up
9-12	Rapid	HIV-ve	Uninfected*	Graduated from PMTCT
->18	Antibody tests	HIV+ve	Infected	Retest after one month
		Negative	Uninfected*	No further testing needed*
		Positive	Infection Confirmed	Regular clinical follow up

*unless breast-feeding in ongoing or was stopped in the last three months.

However, when DNA-PCR facilities become available in future, we can definitely say whether the baby is infected or not by 4 months. We need to have two negative DNA –PCR test results done more than one month apart to declare that the baby is uninfected. However an antibody test is still done at 18 months to definitely say that the baby is uninfected.

CHAPTER 5:

Postpartum Management

5.1 Postpartum care to women infected with HIV

Health care workers should ensure that women who are infected with HIV and have given birth in a healthcare facility return for postpartum appointment or visit at home. Women who have given birth at home should be evaluated 1 week after the birth and again at 6 weeks. There after, counseling should be provided at interval one month to monitor on feeding issues, ART and clinical follow up.

Every visit should include:

- Assessment of general condition
- Check wound healing
- Monitor uterine involution
- Confirm cessation of postpartum bleeding
- HAART adherence if on treatment
- Infant-feeding counseling and support if required.
- Discuss on family planning practices

5.2 Sexual and Reproductive Health

- Discuss condom use as dual protection (against STIs, including HIV, and for family planning).
- Support the mother's choice of contraceptive method
- Discuss the importance of safer sex to prevent the spread of HIV and other STIs.
- Provide advice regarding early STI treatment, including symptom recognition and where to go for STI assessment and treatment.

- Answer any questions the women may have about safer sex behaviors.

5.3 Related services for HIV treatment, care and support

The postpartum period is an ideal time to link the women who is HIV-infected to comprehensive care that will support her health, prevent complications, and improve her ability to live with HIV. A range of related services should be provided directly or by referral, including those lists below:

- Prevention and treatment of opportunistic infections
- ARV treatment when indicated and available
- Treatment of symptoms and palliative care
- Nutritional support
- Social and psychosocial support
- Home-based care
- Prevention and treatment of opportunistic infections
- Treatment and health education for opportunistic and other infections.

a. Antiretroviral treatment

Women initially followed up in PMTCT settings should be linked to treatment services for themselves and their families. ART treatment according to the National Guideline should be administered. If she was on HAART during pregnancy and delivery, it should be continued. The prophylaxis ART is stopped within seven days after delivery. Appropriate referral must be made for further monitoring and giving continued support to her.

b. Treatment of symptoms and palliative care

Postpartum women with HIV are subject to HIV symptoms that can limit participation in family and community activities. Healthcare interventions that focus on managing symptoms and relieving discomfort can improve a woman's quality. Simple management of common HIV symptoms, such as nausea, vomiting, fatigue and skin problems can ease discomfort. Assessment and management of more complex issues such as pain, weight loss and wasting resulting from disease progression can improve comport, function and emotional well-being.

c. Nutritional counseling, care and support

Often, people with HIV infection or AIDS have symptoms that make food preparation and eating difficult. Women receiving HIV-related medications require counseling on specific dietary practices and nutritional needs, in order to successfully manage side effects and avoid nutrition-related complications. Emphasize to women with HIV the importance of cleanliness during food preparation and storage. Counsel mothers on adequate nutrition, exercise, rest, good hygiene practices, and abstinence from harmful habits such as smoking, alcohol and drug abuse.

d. Social and psychosocial support

Because people with HIV face stigma in many communities, women who are HIV-infected often are reluctant to disclose their sero-status to partners, family, or friends

The following services shall be offered directly or by referral:

- Support to help the woman come to terms with her diagnosis and consider her options for disclosure
- Psychosocial support for the mother whose infant is exposed to HIV

- Community support, including referrals to community-based
- Peer group counseling and support from health agencies or NGOs
- Support and counsel to assist women who are HIV-infected and their partners with disclosure issues

e. Home based care

Home-based care provides services to women with HIV when hospital services are not easily accessible. Home based care is initiated only if there is a strong family support mechanism.

The advantages of home based care for patient s and families, and for communities and the healthcare system include:

- Care is provided in a familiar, supportive environment that allows for continued participation in family maters
- Travel expenses for poor families are reduced
- The local community can be slowly involved in caring, which may help counter myths and misconceptions.

5.4 Family Planning of all HIV positive mothers

FP information, counseling and services should be considered for every woman during antenatal care and again in the immediate postpartum period and must be discussed during every visit. HIV positive woman have the equal right as any other women to decide her family size, her reproductive rights and choice of family planning methods. But she must be educated about the risk of transmission, should she get pregnant again. The consequence of having children becoming orphaned at early developing ages should be communicated to the women.

HIV-infected mothers who do not breastfeed are deprived of protection from lactation amenorrhea. If they do not use appropriate

family planning methods, they may have a shorter interval between births and at increased risk of an early pregnancy. Therefore, it is important to ensure that she has access to appropriate contraceptives within six weeks of delivery.

There are no contraindications for an HIV-infected woman for using any of the available contraceptives. Women known to be infected with HIV may safely use IUDs if they have continued access to medical care and are in a stable, mutually monogamous relationship. However, women who are at risk of STIs, especially adolescents, should avoid using IUDs. Weighting all pros and cons, tubal ligation or vasectomy remains the best option. In future the second option will be subdermal implants. If the mother agrees, make arrangements for having the postpartum tubal ligation done before she discharged from the hospital or arrange a referral for this at the nearest hospital where these services exist.

If the mother is on oral pills, a back-up contraception should be given if she also takes other medications, such as rifampicin, or any anticonvulsant medication other than valproic acid; if she has severe diarrhea; or if she is taking a broad-spectrum antibiotic such as ampicillin or tetracycline.

Due to dual protection of condoms, HIV infected women must be counseled for correct and consistent use of condoms along with all other contraceptive methods both temporary and permanent methods. Condoms are recommended ever where both partners are infected.

5.5 Mothers leaving the health facility after delivery

- Examine and check that both mother and baby are fine.
- Early referrals should be made if there is any problem either with the mother or her baby.
- Ensure that the mother understands where she should get help for further monitoring and care.

- Make them understand the risk of breast feeding, and draw up the plan of feeding her infant.
- Send them with the formula milk for that would at least last for one month
- Get them to show you how to maintain cleanliness and prepare to feed the baby with formula milk.
- Inform about safer sexual practices and the need to have a reliable family planning method by 4th to 6th week postpartum, if she did not have tubal ligation at the facility. Counsel on use of condoms.
- Women who have breast engorgement may need breast milk suppression
  - Table Bromocryptine (2.5mg) B/D for 7 days
  - Or Tab Pyridoxine (100 mg_ B/D for 5 days
  - Advice to wear firm bra for few days.
- Women should have all her questions answered before she leaves the facility.
- If all remains well, the mother and child can be discharged on 3rd day with medications for baby and herself, if indicated.

CHAPTER 6:

HIV and Infant Feeding

Breastfeeding is associated with significant additional risk of HIV transmission from mother to child. The risk of transmission is about 20-35% with breastfeeding up to six months. These risk further increases to 30-40% if breastfeeding is continued to 24 months ARV prophylaxis does not provide long-term protection for the infant who is breastfeeding. There is increase risk of transmission with long duration of feeding and mixed feeding. From studies done in Bhutan, 89% of women practices mixed feeding. Mixed feeding has the highest risk of transmission of HIV. With intervention, the risk of transmission through breastfeeding will be reduced. In all developed countries breast feeding in HIV positive mothers is not recommended. The option to eliminate HIV risk through breast feeding and from more dangerous practice of mixed feeding is to completely substitute with other forms replacement feeding. However, replacement feeding. However, replacement feeding is also associated with increased morbidity and mortality in absence of clean environment, safe drinking water, presence of mix feeding and other factors in the developing countries like ours. Like anywhere, it is extremely difficult to strike balance between avoiding breastfeeding in HIV infected mothers to avoid HIV transmission versus preventing morbidity and morbidity and mortality in infants and young children due to unsafe replacement feeding. Although there are many strategies recommended by different agencies, Bhutan has formulated a policy for infant feeding of infants born to HIV positive mother to suit its own context.

6.1 Estimated risk and timing of MTCT of HIV in the absence of interventions.

Timing	Rates of transmission
During pregnancy	5-20%
During labour and delivery	10-15%
During brestfeeding	5-20%
Overall without breastfeeding	15-25%
Overall with breast feeding up to 6 months	20-35%
Overall with breast feeding up to 18 to 24 months	30-45%

6.2 Bhutan's Approach to infant and young child feeding.

The infant and young child feeding policy born to HIV infected mothers in Bhutan states that:

1. Breast feeding will not be recommended for the infants and young child born to HIV infected mother.
2. Such infants will be supported with the free formula milk for the first year of life, provided by the government.
3. The ministry of health will recommend a commercial infant formula preparation that fulfils the international Code of Marketing of Breast Milk Substitutes.
4. All possible environments will be created to make formula milk safe in order to reduce the mortality and morbidity related to unsafe formula feed.

6.3 Counseling and Support for formula feeding.

HIV infected woman should receive counseling and education on infant feeding during the antenatal visit. The pregnant mother should have decided about feeding her infant during the pregnancy.

However the issue has to be discussed again after the delivery. For unbooked cases, education and counseling must be provided in the labour room or during her postpartum visit.

- Educate the mother on the risk of HIV transmission through breast feeding.
- Inform on the higher risk of HIV transmission due to mix feeding.
- Make her understand the exclusive formula feeding can eliminate this risk of exposure and is promoted in the PMTCT program.
- Educate the mother regarding the relative risks and benefits of formula and breast feeding.
- Ensure that mothers understand the risk of HIV transmission through breast feeding and understand our government policy of no breast feeding to remove this risk. However, let her understand on the general benefit of the breast feeding in non infected women. Also discuss about the possible stigma and discrimination she may encounter by not breast feeding.
- When she is ready she can receive infant feeding counseling at a later date. She has to be orepared to give replacement feeding before her baby is born. She will need first, to watch a demonstration of how to prepare the feed and second to practice preparing the feed herself with a little supervision of an infant feeding counseling.

Mother should be asked to bring sups and spoons to their delivery. Promote cup and spoon feeding and not bottle feeding. Cups are easier to keep clean. The safety of the formula feed must be ensuring by following means:

- Health workers must teach how to mix the formula and sterilize the sups and the spoons, clean pots and use boiled water.

- Hospitals and BHUs should support with disposable cups and spoons for mothers who have brought their own cup and spoons.
- Health staffs should help the mother with first few feedings.
- Mothers should be told from where to get the formula feed, once they are discharged from health facility.
- Within a week of delivery she will need to prepare another feed with gentle supervision to make sure that she is able to make feeds adequately.
- If all is going well at one week, the next follow up check can be done at 6 weeks. If she is having some difficulty, follow up should be earlier.
- Follow up should also include counseling the mother on family planning or ensured that she is referred for family planning help.

6.4 Replacement Feeding

Replacement feeding by a woman who is HIV positive should never result in mixed feeding – that is breastfeeding at the same time as giving other forms of milk or food to a child. Otherwise the benefits of avoiding transmission through breastfeeding will be lost.

Commercial infant formula is:

- Regulated to meet nutritional specifications for infant feeding for the first months of life (as in codex Alimentations)
- Fortified with micronutrients, including iron.
- Usually based on modified cows milk, but other types are also available
- Usually available as a powder to be reconstituted with boiled water.

Feeding an infant for six months with commercial infant formula requires 20 kg of formula. After the first six months, an infant needs about 16 kg up to one year, if infant formula is continued in addition to complementary feeding.

6.5 Preparation of milk feeds

- Always use the marked cup or glass and spoon to measure water and the scoop to measure the formula powder.
- Wash your hands before preparing a feed.
- Bring the water to boil and then let it cool. Keep it covered while it cools
- Measure the formula powder into the marked glass of cup. Make the scoops level. Add a small amount of the cooled boiled water and stir. Fill the cup or glass to the mark with water. Stir well.
- Feed the baby using a cup
- Wash the utensils.

6.6 Amount of feeds needed for the child.

Most of the commercials infant formula is prepared by mixing one level scoop with 30 ml of water. However please read the instructions on the milk preparation before each use. The amount that is needed for each feed for babies is given below:

Approximate amount of formula needed per day

Age in months	Weight in kilos	Approx amount of formula per 24 hours	Approx number of feeds.
1	3	450 ml	8 * 60 ml
2	4	600 ml	7*90 ml
3	5	750 ml	6*120 ml
4	5+	750 ml	6*120 ml
5	6	900 ml	6*150 ml
6	6+	900 ml	6*150 ml

In the first two months of life advise the mother caretaker to feed at least 8 times in 24 hours. Therefore the number of feed may be decreased to 6 times in 24 hours.

6.7 Commercial infant formula requirements

The amount of milk that needs to be given for each baby at various age is given below. However should the mother ask for more she may be given as extra one or two tins provided it is documented that her baby is growing well.

Months	500g tins needed per month	450 g tins needed per month
First month	4 tins	5 tins
Second month	6 tins	6 tins
Third month	7 tins	8 tins
Fourth month	7 tins	8 tins
Fifth month	8 tins	8 tins
Sixth month	8 tins	9 tins
7-8 month	7 tins	8 tins
9 – 11 months	6 tins	6 tins

6.8 Monthly requirement of milk (approximately)

Age in months	Milk feeds per day	Cows milk, water and sugar to make home prepared formula per day	Commercial formula needed per month
1	450	300ml milk + 150 ml water + 30g sugar	4*500g tins
2	600	400ml milk + 200 ml water + 40g sugar	6*500g tins
3	750	500 ml milk + 250 ml water + 45g sugar	7*500g tins
4	750	500 ml milk + 250 ml water + 45g sugar	7*500g tins
5	900	600 ml milk + 300 ml water + 56g sugar	8*500g tins
6	900	600 ml milk + 300 ml water + 56g sugar	8*500g tins
Total for 6 months		92 liters of milk + 9 kg of sugar	40 * 500g (20 kg)

6.9 Method of feeding:

Cup feeding is the recommended method and mothers should be counseled regarding the benefits of cup feeding and harmful effects of bottle feeding. They should be taught how to cup feed the babies.

a) How to feed an infant with a Cup

- Hold the infant upright or semi-upright on your lap
- Hold the cup of milk to the infant's lips
- Tip the cup so that the milk just reaches the infant's lips. Rest the cup lightly on the infant's lower lip and the edges of the cup touch the outer part of the upper lip.
- The infant becomes alert and opens the mouth and eyes. A low birth weight baby sucks the milk, spelling some of it.

- Do not pour the milk into the infant's mouth. Just hold the cup to the infant's lips and let the infant take it.
- An infant who has had enough will close its mouth and take no more. If the infant has not taken the calculated amount, it will take more next time, or the mother needs to feed more often.
- Measure the infant's intake over 24 hours, not just at each feed, to calculate whether it is getting the right amount of milk.

b) Advantages of cup feeding.

- Cups are easily available in every household
- Cups are easy to clean
- Cup feeding is associated with less risks of diarrhea, ear infections and both decay
- A cup cannot be propped beside a baby. The caregiver has to hold the baby and pay attention. This ensures social contact during feeding and adult attention if the baby is having any difficulties.
- A cup does not need to be boiled, in the way that a bottle does
- Small and preterm babies can be cup fed as well as older babies.
- Spoon-feeding is acceptable. However it is slow for large amounts of milk. There is a risk that the caregiver may become tired and stop giving the feed before the baby has taken sufficient amount.
- Cups are less likely than bottles to be carried around for a long time, giving bacteria a long time to multiply.

c) Ways of comforting a baby.

- Babies who are not breastfed are at risk of not getting enough attention, so a special efforts needs to be made.
- Message, swaddling, carrying rocking, singing, or talking to the baby and sleeping with the baby can all help to comfort the baby.
- Sucking is very comforting the baby. He can such on his mother's forearm, a clean figure, or any part of the baby except the nipple. This ensures that he has contact with his mother.
- Do not use pacifiers as it does not make a substitute for contact with another person and also pacifiers carry the risk of infection thereby increasing the risk of a child having diarrhea, respiratory illnesses and thrush.

d) Check how the mother is feeding the child:

An infant under six months on formula feeds:

- Using a suitable type of milk
- Able to get enough the type of milk that she has decided to use;
- Measuring the ingredients correctly;
- Giving an appropriate volume and number of feeds;
- Preparing the feed cleanly and safely;
- Feeding it to the baby by cup
- Not breastfeeding;
- Giving no additional water;
- Teach again how to prepare and give feeds if there is any problem

e) Check the child's growth and health

- The baby's health, stools and any mouth sores;
- The baby's weight
- The child's development and care
- The child 's immunization
- Refer for treatment if necessary

f) Growth monitoring

- Should start as soon as possible after birth and continue until the child is no longer at risk of malnutrition. This is 2 years, and for some children it is 3-4 years.
- Infants should be weighted every month for the first year of life and then every 3 months thereafter.
- Weight more frequently if there is a growth problem.

6.10 mixing home modified animal milk using different milks (by volume)

For first six months:

Should the need arise to give any of the following milk then it needs to be prepared in the following formulations.

60 ml (one feeding for one month

Type of milk	Milk	Water	Sugar
Cow, goat	40 ml	20 ml	4 gm
Sheep, Buffalo	30 ml	30 ml	3 gm
Evaporate	16 ml	44 ml	4 gm
Powered full cream	5 gm	60 ml	4 gm

Note: Calculate according to make increasing amounts of feeds i.e. 90ml, 120 ml, 150 ml, after six months, animal milks do not require

any dilution. However special preparation is still required for fresh and powered milk:

- Fresh animals milk: boil the milk to kill any bacteria
- Powered or evaporated milk: Add clean water according to directions on the tin in order to make full strength.
- Processed/ pasteurized or UHT milk: no preparation needed.

6.11 Complementary feeding

Some valuable advice that needs to be given to the caretaker of HIV infected children regarding complementary feeding after the age of six months. Please note that these are in addition to the milk feed that is stated above.

Age	Texture	Frequency	Amount at each meal
From 6 months	Soft porridge, fruit well mashed vegetables	2 times per day	2-3 tablespoonfuls
7-8 months	Mashed foods	3 times per day	Increase gradually to 2/3 of a 250 ml cup.
9-11 months	Finely chopped or mashed foods, and foods that baby can pick up	3 meals plus one snack between meals	¾ of a 250 ml cup or bowl.
12-24 months	family foods, chopped or mashed if necessary meals	3 meals plus two snack between	A full 250 ml cup/ bowl

Note : These amounts are in addition to milk feeds.

6.12 Counseling visits

Mothers who are HIV-positive should receive infant-feeding counseling over the course of several sessions. At least one counseling session will take place during the antenatal period but not immediately after she learns her positive result.

Counsel her feeding techniques and other subject related to feeding during schedule monthly follow-up sessions whenever the mother brings the child to the clinic for well-baby checkups or immunizations. Additional sessions may be required during special high-risk periods, such as when the:

- Child is sick
- Mother returns to work
- Mother decides to change feeding methods

Networks and linkages will be strengthened with different programs under Ministry of Health such as Nutrtions Program, Reproductive Health Program, Emergency Obstetric Care Program and the Safe Motherhood programs for continued care and support referrals.

6.13 Postnatal Visits

During each postnatal visit, clinic staff will review information from the infant-feeding counseling session and focus on issues most relevant to the mother. Reinforcing essential and relevant information supports optimal infant nutrition, growth, and development while minimizing risks.

- Baby should get immunizations as any other baby according to the national immunization protocol.
- Subsequent visits recommended as follows:
  - At ages 6, 10, and 14 weeks
  - Once a month from 14 weeks to 1 year
  - Every 3 months from the ages of 1 to 2 year
  - Anytime the infant become ill or the mother

However, the frequency of follow up will be determined by the need of support services and counseling by the mother.

CHAPTER 7:

Care and support for Mothers and Families with HIV infection

7.1 Establishing Linkages

PMTCT needs multidisciplinary and multi-setectoral initiatives. It should be linked to the various sectors, organization groups through multisectoral collaborations for:

i. Ensuring support and promotion of PMTCT programs

ii. Complementing activities of the PMTCT

a. Ways to establish Linkages

Integrate PMTCT services into existing maternal and child health (MCH) services.

- MCH services are entry points for PMTCT and for the treatment, care, and support of women who are HIV-infected and their infants and other family members.
- PMTCT is integrated into MCH services through training (building human capacity) and program development.
- Caring for and treating families affected by HIV is a shared responsibility.
- All children born to women who are HIV-infected require close follow up and appropriate care.
- Village Health Workers may be encouraged to provide information on health promotion and disease prevention, as well as care and support services to these families.
- Specialists in HIV who care for women and children should provide consultation, antiretroviral treatment, and help with the ongoing management of HIV infection.

b. Linkages with other health programs for special needs

- Reproductive health program can look into the need for family planning, treatment of sexually transmitted infections (STIs), or assistance with substance abuse.
- Disease-specific programs, such as those for people with tuberculosis (TB) and malaria may benefit with HIV –infected. TB is a leading cause of mortality is persons infected with HIV on a global scale.
- National Nutrition Program can help with nutritional support programs for mothers and children are especially important for people living with HIV/AIDS.

c. Linkages to community-based service and positive net work

Linkages with community organizations ad groups should be established when community acceptance of HIV as chronic disease becomes better.

Other linkages among the infected people themselves such as self help group and peer educators could be explored.

Women infected with HIV may become involved in voluntary or paid HIV-related work, provide. Education, counseling, and often help with specific needs such as housing, transportation, food assistance, legal assistance and advice, and income-generating activities.

CHAPTER 8:

Safety and care in the work Place

8.1 Universal Precautions and creating a Safe Work Environment

Transmission of infectious agents in the healthcare setting can be prevented by suing infection control measures, including adherence to universal precautions, risk reduction in the obstetric setting, and ongoing education of employees in infections prevention. Infection control program can supplement the PMTCT activities.

a. Universal precautions

Universal precautions are practices designed to protect healthcare workers and patients from exposure to blood borne pathogens. Universal precautions should be practiced while handing with all patients, regardless of diagnosis.

Key components of universal precautions and infection control procedures include:

- Hand washing
- Safe handling and disposal of sharps
- Use of personal protective equipments
- Decontamination of equipment
- Safe disposal of infectious waste materials
- Safe environmental practices
- Cleaning, disinfection, and sterilization of all instruments used in invasive procedures reduce risk of patients –to-patients' transmission of infection.

8.2 Risk reduction in the obstetric setting

The potential for exposure to HIV-contaminated blood fluids is greatest during labour and delivery. In labour and delivery settings, healthcare workers should:

- Provide appropriate and sensitive care to all women regardless of HIV status.
- Work in a manner that ensures safety and reduces the risk of occupational exposure for themselves and their colleagues.

8.3 Ongoing education for employees in infections prevention

- Orient all staff, including peer and counselors, to the site's infections control policies
- Ensure that all workers who are routinely exposed to blood and body fluids (e.g. physicians, mid wives, nurse, and housekeeping personnel) receive preliminary and ongoing training on universal precaution procedures, safe handling of equipment and materials.
- Provide regular supervision to observe and assess safety practices and remedy deficiencies as needed.

8.4 Managing Occupational Exposure to HIV Infection

Post-exposure prophylaxis (Refer National guideline for the VCT) In spite of the practice of universal precaution, in healthcare settings, there exists occupational risk of becoming HIV-infected due to occupational exposure and injure at work place. Such exposure involves injuries from needles or sharps that have been used on a patient who is HIV-infected. Through the risk of occupational exposure is very low but it not non existent. The risk of HIV transmission from exposure to infected fluids or tissue is believed to be lower than from exposure to infected blood. The risk of transmission depends on the nature and the severity of the injury.

After occupational HIV exposure, a short-term course of ARV drugs may use to reduce the likelihood of infection, following the national guidelines for ARV therapy (2005). This is referred to a post-exposure prophylaxis (PEP), ans is a key part stragy of reducing staff exposure to infectious agents in the workplace. Drugs for PEP should be available on site 24 hours a day.

A proper VCT procedure should be followed in handing health staffs who are exposed through an occupational exposure maintaining strict confidentiality.

CHAPTER 9:

Monitoring and Evaluation

9.1 PMTCT Program Monitoring

Since PMTCT is a new area in Bhutan, operational research and careful monitoring and evaluation will be necessary to understand the costs, effectiveness, acceptability, and other characteristics of various packages of intervention, and to develop strong, evidence-based programming for MTCT prevention interventions and policies in the context of our country.

a. Why monitoring?

Monitoring is regular tracking of key program elements. Monitoring of the PMTCT programme will help to:

- Assess programme performance
- Detect and correct performance problems
- Make more efficient use of PMTCT programme resources

b. Why evaluation?

Evaluation is measuring the changes the changes in a situation resulting from an intervention. A formal evaluation of the PMTCT programme will demonstrate to what extent the programme contributed to changes in the indicators. Formal evaluations should be conducted intermittently to try to examine the ways in which the PMTCT programme is causing these changes.

9.2 PMTCT Programme Monitoring at the healthcare Facility Level

PMTCT programme monitoring should include all activities aimed at providing the full package of services for preventing mother-to-child transmission including:

- HIV counseling and testing for pregnant women

- ARV treatment and prophylaxis to prevent MTCT
- Counseling and support for safe infant-feeding practices
- Safe obstetric care
- Family planning counseling or referral
- Data on these activates are counseling or referral

Data on these activities are recorded at the healthcare facility, complied at a district level, and forwarded to the national level for aggregation.

Staff members will record the PMTCT services provided in standard ANC and maternity ward registers as part of routine MCH data collection. Periodic summary reports summarize register information for local program management and reporting.

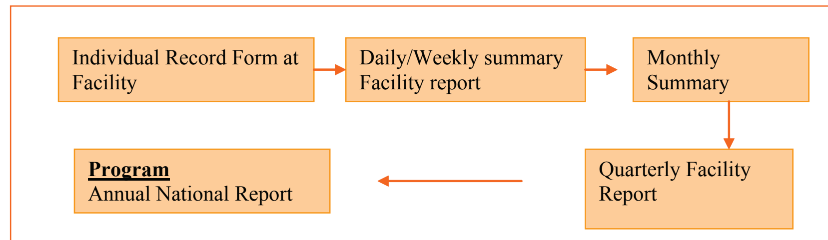
In every healthcare facility where PMTCT services are delivered, it is important to designated staff and outlines their responsibilities in the monitoring process.

Clear roles and responsibilities should be defined for staff involved in:

- Data collection
- General recommendation Analyses
- Reporting
- Dissemination
- Data use

9.3 Using monitoring information for intervention-related decision-making.

Monitoring information should be reviewed periodically to assess program performance and improve program procedures. Monitoring information is used for decision-making about the PMTCT programme at local, national, and levels.

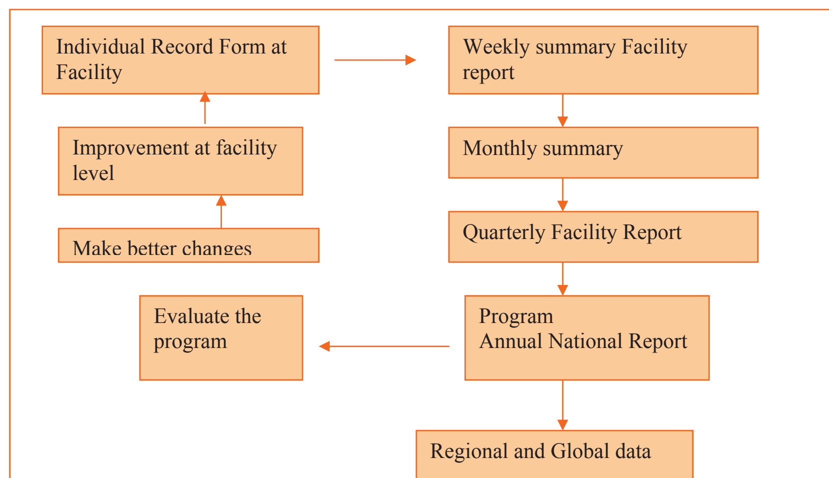


9.4 Some of PMTCT performance indicators

- Number of venues offering the full package of PMTCT services in the preceding 12 months
- Number of health care workers newly trained or retrained in full package during the preceding 12 months
- Percentage of pregnant women who have made at least one ANC visit and have been counseled at a PMTCT site in the preceding 12 months
- Percentage of pregnant women who have made at least one ANC visit and have accepted testing for HIV in the preceding 12 months
- Percentage of women making at least one ANC visit who are HIV-infected and who receive their test result and post-test counseling in the preceding 12 months
- Percentage of women who are HIV-infected who took a full course of ARVs for PMTCT in accordance with the national approved treatment protocoal in the preceding 12 months
- Percentage of infants who were HIV-exposed and received ARVs in accordance with the nationally approved treatment protocol in the preceding 12 months
- Percentage of HIV- positive infants born to HIV-infected women in the preceding 12 months
- Number of male partners who are HIV-tested in the preceding 12 months

- Percentage of women with unknown HIV status at delivery in the preceding 12 months
- Percentage of women with unknown HIV status who were tested during labour or after delivery in the preceding 12 months.

Flow chart 5: Summary of Monitoring and Evaluation



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Appendix i: Safety of HAART drugs used in PMTCT in Bhutan

Class of drugs	FDA Pregnancy Category	General Recommendation
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		Well studies and safe for use in Pregnancy used for HAART in substitute for those who cannot
• Zidovudine(AZT/ Retovir)	C	tolerate AZT All NRTIs can cause mitochondrial toxicity
• Lamivudine (3TC/ Epivir)	C	
• Stavudine(d4T/Zerit)	C	Short course is safe in pregnancy & delivery longer
Non-nucleoside Reverse Transcriptase Inhititors (NNRTIs)		use develops resistance by virus after 6 weeks Hepatotoxicity and rash if used with CD4 > 250.
• Neverapine (Viramune)	C	Should not be used in Pregnancy Neural Tube Defects reported if used in 1st trimester
• Efavirenz (Sustiva)	D	Not used for PMTCT only used for post-exposure prophylaxis
Protease Inhibitors (Pls) • Lopinavir + Ritonavir (Kaletra)	C	

Reference:

1. Prevention of mother-to-child transmission of HIV in Asia, Practical Guidance for programs, March 2002, Elizabeth A. Preble and Ellen G.Piwoz.
2. UNICEF (2003). Programme recommendations for the prevention of mother-to-child transmission of HIV. A practical guide for managers.
3. Report of the UN Asia-Pacific Regional Task force on PMTCT, UNICEF 2005
4. National guideline: PMTCT Nepal 2005
5. Antiretroviral Drugs for Treating Pregnant Women and preventing HIV Infection Infants guidelines on Care, Treatment and support for women Living with HIV/AIDS and their children in Resource –constrained Settings, WHO.
6. Prevention of Mother to Child Transmission of HIV, Full Protocol, HIV/AIDS Directorate, Department of Health Provincial Administration of the Western cape Drop Street, cape Town, South Africa
7. CDC: Public Health service Task Force Recommendations for use of antiretroviral Drugs in pregnant HIV-1 infected Women for Maternal Health and Interventions to Reduce Prenatal HIV-1 Transmission in United States, February 24, 2005
8. The MTCT-Plus Initiative, Mailman School of Public Health, Columbia University, New York USA.
9. Basic AIDS Counseling Guide, South African AIDS Training Program, Harare, Zimbabwe
10. Safety and Toxicity of individual Antiretroviral Agents in Pregnancy, the penal on clinical Practices for Treatment of HIV Infection, July, 2005.
11. Management of human immunodeficiency virus infection in pregnancy J, & D. Moodley, Best Practices & Research Clinical Obstetrics and Gynecology, Vol. 19, No. 2, PP 169-183, 2005.
12. Management of HIV in Pregnancy, RCOG Guideline No 39, April 2004
13. Women, Children, and HIV: resources for Prevention and Treatment, 3rd Edition, July 2004. University of California Collaboration Project.
14. National Guidelines for Management of Pediatric HIV/AIDS in Bhutan (Draft 2005)