

Guidelines for the Management of HIV infection in Pregnancy in Sri Lanka



**National STD/AIDS
Control Programme**

June 2008



**THE
WORLD
BANK**

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for the Management of HIV
infection in Pregnancy in
Sri Lanka



National STD/AIDS Control Programme
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Director's Message

Despite the dramatic advances made worldwide in understanding the natural history of HIV infection and the development of effective antiretroviral therapies, the AIDS epidemic continues to grow. The HIV/AIDS epidemic began in Asia in the late 1980s, considerably later than in Africa, but the epidemic has already spread rapidly in some countries. Overall in Asia, an estimated 4.9 million people were living with HIV in 2007, including the 440000 people who became newly infected in the past year. In this background Sri Lanka still remains a country with a low prevalence of HIV.

Sexual transmission of HIV is the main mode of transmission among the reported cases in the country. Parenteral transfusion has been kept to a minimal with the blood safety policy adopted at the beginning of the epidemic. Perinatal transmission account for 4%. The male to female ratio is narrowing and growing numbers of women living with HIV/AIDS is a dominant feature observed in Sri Lanka. The low maternal and infant mortality rates, increased life expectancy at birth, high immunization coverage, are some of the health indices which reflect the efficiency of the excellent health system delivery services that is available in the country. It is timely that prevention of parent to child transmission services are addressed through the available health system infrastructure and other multi sectoral channels. A strategy for prevention of parent to child transmission (PPTCT) has been developed in order to save babies from HIV/AIDS and prevent the occurrence of new infections among men and women in the reproductive age group and also to provide optimal services to HIV positive women.

Pregnancy and motherhood are among the most important gender roles fulfilled by women throughout the world. It is unfortunate that HIV/AIDS has emerged as a strong challenge for some women to achieve this goal. The guidelines for management of HIV infection in pregnancy has been prepared to assist health care workers to provide optimal services to women living with HIV.

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Director
National STD/AIDS Control Programme
Sri Lanka

2008

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Abbreviations and Accronyms

AIDS	Acquired immunodeficiency syndrome
ALT	Alanine aminotransaminase
ART	Antiretroviral therapy
ARV	Anti retroviral (drugs)
AST	Aspartate aminotransferase
d4T	Stavudine
ddI	Didanosine
EFV	Efavirenz
HIV	Human immunodeficiency virus
MTCT	Mother –to-child transmission
NRTI	Nucleoside reverse transcriptase inhibitor
NNRTI	Non- nucleoside reverse transcriptase inhibitor
NSACP	National STD/AIDS Control Programme
NVP	Nevirapine
PCP	Pneumocystis jiroveci pneumonia
PCR	Polymerase chain reaction
PPTCT	Prevention of parent to child transmission (of HIV)
STI	Sexually transmitted Infections
TDF	Tenofovir disoproxil fumarate

The human immunodeficiency virus (HIV) pandemic is one of the most serious social, health and development challenges the world faces today. Worldwide, UNAIDS estimates that in 2007 there were about 2.5 million children under 15 years living with HIV, and about 330,000 children died of AIDS. The majority of them were infected through mother to child transmission (MTCT) of HIV ¹.

Most children living with HIV acquire the infection through mother-to-child transmission (MTCT) which can occur during pregnancy, labour and delivery or during breastfeeding. In the absence of any intervention the risk of such transmission is 15-30% in non-breastfeeding populations. Breast feeding by an infected mother increases the risk by 5-20% to a total of 20-45%. The risk of MTCT can be reduced to under 2% by interventions that include antiretroviral therapy given to women during pregnancy and labour and to the infant in the first weeks of life, pre labour elective caesarean section and complete avoidance of breastfeeding ².

WHO promotes a comprehensive strategic approach to the prevention of HIV infection in infants and young children, consisting of four prongs; ²

1. Primary prevention of HIV infection;
2. Prevention of unintended pregnancies among women living with HIV;
3. Prevention of HIV transmission from mothers living with HIV to their infants;
4. Care, treatment and support for mothers living with HIV, their children and families.

In countries with a very low prevalence of HIV infection such as Sri Lanka, the most effective approach to preventing parent to child transmission (PPTCT) is through primary prevention among men and women in the reproductive age group. In Sri Lanka, HIV and sexually transmitted infections (STI) prevention activities are being conducted with migrant workers, women in sex work, drug users, prisoners, and men in the workplace. They are also entry point for PPTCT which provide opportunities to contribute to prevention of HIV infection in children. The message that HIV can pass to children can be a strong motivation for men to change behaviours that put them at risk of HIV and to learn their HIV status. Men who are HIV positive can be counseled about mother to child transmission (MTCT) and their wives provided with interventions to prevent MTCT. When a woman is the first in an HIV positive couple to learn her HIV status she may be blamed for the infection. This approach avoids women being stigmatized in this manner and can protect the uninfected partners of HIV positive men from becoming infected.

Maternal and child health (MCH) services provide a unique opportunity to reach women who may be vulnerable to HIV infection with information about prevention, referral for counselling and testing and other services. Integrating PPTCT strategies with MCH services from preconception stage onwards would strengthen the existing services. Another advantage of integration is the opportunity it provides for reaching the expectant father. Women are more susceptible to HIV infection during pregnancy and post-partum. There is often a period of sexual abstinence between couples during pregnancy and postpartum and men may be more likely to seek outside partners during this time. If they become infected with HIV they will be highly infectious as the post-infection peak in viral load is high when they resume sex with their wife. At this time the risk of MTCT is very high. Involving the

expectant father would raise awareness among men about MTCT of HIV and encourage personal risk assessment and attendance for counseling and HIV testing.

In addition to the focus on primary prevention it is important to provide optimal reproductive health care to women, men and couples who know they are HIV positive. HIV positive women and couples should have access to non-judgmental and non-coercive counselling and to appropriate contraception if they want to avoid pregnancy. Pregnant women living with HIV require either ARV treatment or ARV prophylaxis for PMTCT, co-trimoxazole prophylaxis, screening for and treatment of tuberculosis (TB) & STI infection, protection from malaria, counseling and care relating to nutrition, psychosocial support, safer delivery care and counseling and support for safer infant feeding.

These guidelines outline the care that should be offered at STD clinics, antenatal and postnatal clinics and obstetric wards. They include recommendations for the use of antiretroviral (ARV) drugs in pregnant women for their own health and for preventing HIV infection to the infant, safer delivery and infant feeding practices.

We hope that these guidelines will provide obstetricians, venereologists, paediatricians, midwives and counsellors with the evidence-based information they need to provide consistent and effective care, treatment and support to HIV positive women, their husbands and families.

Because this is a rapidly changing field the guidelines will need to be updated as new evidence becomes available.

1. Antenatal care (when the mother presents to an obstetric hospital clinic)

When an HIV positive pregnant woman is seen in the antenatal clinic she should be given the same services that other mothers are given. Good quality antenatal care and support are important for HIV positive pregnant women to reduce the risk of MTCT of HIV for the sake of both mother and child. The head of the unit would identify an appropriate person (eg Senior Registrar/Senior Nursing Officer) to be the link person for further care.

- If the pregnant woman has already been assessed at the STD Clinic review the findings, test reports, and management plan.
- If not at the first antenatal visit or when HIV is first diagnosed the woman, and her husband (if she agrees), should be referred to the STD Clinic for appropriate assessment and management of her HIV infection, and for a decision about ARV prophylaxis or treatment.
- The mother should follow routine antenatal clinic visits and assessments and be seen by the VOG at 12 weeks, 20 weeks, 32 weeks and 36 weeks.
- Ensure privacy and confidentiality during consultations and reassure the woman that her care will be kept confidential. Document history, examination and test findings and the management plan and explain to the woman who the information will be shared with.
- Check whether the woman has had appropriate antenatal investigations including serology, syphilis haemoglobin, blood grouping and Rhesus factor. Do not repeat these if already performed at the STD clinic/MOH clinic.
- Assess foetal growth: do amniotic fluid index and Doppler studies as indicated
- Perform an ultrasound during the first trimester to confirm gestational age and to guide potential timing of elective caesarean section, if needed, since elective caesarean delivery for prevention of perinatal HIV transmission should be performed at 38weeks gestation (see page 7).
- Avoid invasive procedures such as amniocentesis.
- Ensure that she receives iron and folate supplementation and tetanus toxoid immunizations, as for HIV negative pregnant women.
- Provide advice about danger signs in pregnancy and advise early care seeking for complications such as bleeding, fever, swelling, headaches and abdominal pain.
- Review the plan for ARV prophylaxis or treatment (see page 14). Ensure that the woman understands the plan and counsel her in relation to adherence. At each clinic visit check for adherence to therapy
- Discuss and document a plan for safer delivery care (see page 7).

- Counsel the woman and assist her to make informed and appropriate infant feeding choices (see page 27).
- Discuss the benefits of using condoms during pregnancy to prevent re-infection with a different virus strain and counsel the woman/couple in a non-coercive and non-judgmental way about post partum contraception (see page 25).
- Review the latest CD4 count report and baseline investigations. If Viral load testing is available check the level which would help to guide the mode of delivery

2. Safer delivery care for HIV positive women

Plan for delivery

Plan and discuss the mode of delivery with the pregnant woman (and her husband if possible) during antenatal care.

All known HIV positive women should have an individualised, regularly updated, plan of care which summarises mutually agreed obstetric/HIV management for each woman, including the drug regimen and recommended mode of delivery.

Universal Infection Control measures, properly applied, provide adequate protection for staff. Routine incorporation of universal precautions in service delivery is crucial to mitigate occupational risk and reduce fear of blood bourn infections on the part of the health care workers.

All ward staff should be aware of the need for confidentiality in relation to the patient's HIV status. On the basis of shared confidentiality staff members could be informed of the HIV status of the woman only on a "need to know" basis.

When the woman is admitted for delivery the identified link person would support the mother during her stay in the hospital

If normal vaginal delivery is planned

Normal vaginal delivery may be planned for a primigravida or multigravida without obstetric complications who has been on ARV treatment or prophylaxis and has an undetectable viral load (< 50 copies/mm³).³

When admitted for delivery carry out the following with the objective of preventing intrapartum complications such as prolonged labour, foetal distress, shoulder dystocia and to avoid an emergency caesarean section.

- Check the expected date of delivery
- Confirm normal growth of the foetus and exclude anomalies
- Check whether prescribed ARV drugs have been taken and what is prescribed during labour and post partum
- Head should be presenting and well engaged.
- Foetal size should be estimated to be under 3 kgs and the pelvis should be judged as adequate beyond doubts.

- Check whether the cervix is effaced and dilated and await spontaneous onset of labour

At delivery:

- To reduce the risks of infection to the mother try to minimize cervical examinations. Observe aseptic techniques throughout labour.
- ART prescribed to be given during labour should be given according to the ART plan
- Administer prophylactic antibiotics in women with CD4 counts of less than 200/ml; where there are signs of AIDS or severe immune deficiency; or rupture of membranes for more than 4 hours.
- Avoid early rupture of membranes. Prolonged rupture of membranes, especially for more than four hours, increases the risk of MTCT of HIV.^{4 5} Artificial rupture of membranes increases the risk of infection of the placental membranes.⁶ It is an unnecessary procedure unless there is an important reason to speed up delivery.
- Avoid prolonged obstructed labor by monitoring labor carefully and intervening appropriately when labor is prolonged (ie, augmentation of labor through oxytocin⁷ or caesarean section). Plot the course of labor on a partogram to determine whether labor is progressing normally. The objective is to prevent intrapartum emergencies such as prolonged labour, fetal distress, shoulder dystocia and to avoid emergency caesarean section.
- Avoid unnecessary episiotomy. Studies of the influences on MTCT have not been large enough to determine whether episiotomy is an important factor. Episiotomy increases the chance that the baby will be exposed to maternal blood. Studies show that routine episiotomy does not improve outcomes for the baby or the mother. Yet it is common for episiotomies to be carried out routinely. Only perform an episiotomy when there is a good reason, such as delay in the second stage of labour.
- Avoid use of forceps or other instruments to assist delivery if possible
- Do not apply a foetal scalp electrode or undertake foetal scalp blood sampling.^{2,4}

If elective caesarean section is planned:

- Explain to the patient about the reason for the caesarean section and obtain informed consent.
- For HIV uninfected pregnant population it is recommended that PLCS be performed at 39 weeks to reduce the frequency of transient tachypnea of the newborn seen in babies delivered by PLCS. However, in the HIV positive women, for whom delivery by caesarean section has been decided it is suggested that this be performed at 38 weeks to avoid the potential risk of pre mature labour or membrane rupture the frequency of which will necessarily increase towards term.
- When patient is admitted notify the Hospital Director, in charge theatre sister, consultant anaesthetist, and head of the intensive care unit
- Pre medication and preparation as usual
- Epidural analgesia is not contraindicated in delivery care of HIV infected women
- Continue ARV regimen as recommended. If necessary seek advice from STD team.
- Give antibiotic prophylaxis ^{8*}:

* a Cochrane review observed that post-partum morbidity, including minor (febrile morbidity, urinary tract infection) and major morbidity (endometritis, thromboembolism) was higher after elective caesarean than vaginal delivery

Caesarean section

Caesarean section *before* labour begins and *before* membranes have ruptured allows the baby to avoid contact with the mother's blood and cervical secretions. Summary results from observational studies, and a randomised controlled trial, have shown that pre labour elective caesarean section (PLCS) can reduce the risk of MTCT of HIV by 50 to 66% ⁹.

However if the woman has been on ARV treatment and has a very low viral load there is negligible additional reduction in MTCT risk with a caesarean section ⁴.

Caesarean section *after* labor and/or *after* ruptured membranes was associated with a risk of transmission similar to that associated with vaginal delivery. Emergency caesarean section may be needed for obstetric emergencies.

An elective caesarean section at 38 weeks of gestation is recommended as the mode of delivery when maternal viral load is unknown or is detectable at > 50 copies per ml.⁴ A decision for elective caesarean section must take into account the possibility of maternal morbidity and mortality, the availability of safe operating facilities, the potential increased service commitments and the accessibility of maternal services for the woman in future pregnancies.

Malpresentations

If the woman has a breech presentation it is safer for her to have an elective caesarean section than external cephalic version and a vaginal delivery. However if for some reason it is not possible for her to have a caesarean section, external cephalic version should be performed because the obstetric risk and the risk of MTCT is likely to be less than undergoing a breech vaginal delivery.¹⁰

3. Care for the baby

- Clean the eyes of the baby with saline at delivery of the head.
- Clamp the cord as soon as possible to minimise the risk of maternal fetal microtransfusions.
- Cover the umbilical cord with a swab when cutting to prevent blood spurting.
- Avoid suctioning the infant's mouth and pharynx, which may cause trauma to the mucus membranes.
- Towel dry the baby and bath as soon as possible.
- Clean the baby's skin thoroughly before any infusions or injections.

4. Minimize the risk of postpartum haemorrhage by :

- Actively managing the third stage of labor
- Giving ergometrine immediately after delivery
- Using controlled cord traction
- Performing uterine massage
- Repair any genital tears
- Carefully removing all products of conception



Antenatal care (primary health care antenatal clinic)

When an HIV positive pregnant woman is seen in the antenatal clinic she should be given the same services that other mothers are given. Ensure privacy and confidentiality during consultations and reassure the woman that her care will be kept confidential. Sharing of information with other staff members should be done only on "need to know" basis. Since the PHM will be providing routine post partum home care, she could be informed by the MOH of the mother's HIV status with the assurance that confidentiality would be maintained.

- Medical officer of Health (MOH) should check whether she has attended the STD clinic. If the woman has already been assessed at the STD Clinic review the findings, test reports, and management plan.
- If not at the first antenatal visit or when HIV is first diagnosed the woman, and her husband (if she agrees), should be referred to the STD Clinic for appropriate assessment and management of her HIV infection, and for a decision about ARV prophylaxis or treatment.
- Check whether she has been seen by the VOG at 12 weeks, 20 weeks, 32 weeks and 36 weeks.
- Check whether the woman has had appropriate antenatal tests including syphilis serology, haemoglobin, blood grouping and Rhesus factor. Do not repeat these if already performed at the STD clinic.
- Check the management plan made by the obstetrician and venereologist and assist in the management plan.

HIV positive women/couples should receive optimal management by a team including an obstetrician, a venereologist, a midwife, a paediatrician and a counsellor, who may be the midwife, or a staff nurse. Good coordination, confidential communication and shared responsibility are very important.

A pregnant woman may learn of her positive HIV status during pregnancy and referred to the STD Clinic for assessment and management of her HIV infection. On the other hand an HIV positive woman under the care of the STD clinic can become pregnant. HIV positive women should be assessed for her current status and prepare a management plan. She should be referred for antenatal care and the management plan should be sent to the obstetrician under confidential cover. Inform the obstetrician when the management plan is updated or changed.

All known HIV positive women should have an individualised, regularly updated, plan of care which summarises mutually agreed obstetric/HIV management for each woman, including the drug regimen and recommended mode of delivery. In all cases, management in pregnancy, including ARV prophylaxis or treatment, should be seen as only a part of the continuum of care for the mother, father and their child.

Ideally, HIV positive pregnant women (with their husband, if the woman agrees) will be assessed initially at the STD clinic at 12-14 weeks gestation. A consultation at 24 weeks is essential for mothers who do not yet need ARV treatment for their own health but require ARV prophylaxis to prevent transmission to the child.

Ensure privacy and confidentiality when taking a history and examination and assure the woman/couple that the consultation will remain confidential.

1. Clinica assessment & Laboratory tests

History,

- Check whether the woman has already attended for antenatal care and encourage regular attendance at antenatal visits.
- Check their understanding of HIV/ AIDS infection, especially routes of transmission, natural history and how to prevent further spread of HIV. Check for and correct any misconceptions.
- Ask about health and well-being of other children. May need to counsel on the need to check the HIV status of the children
- Ask about whether and to whom the woman/couple have disclosed their status. This has important implications for the management of the pregnancy and interventions to prevent MTCT.
- Obtain routine data including medical, obstetric and psychosocial history.
- Ask about symptoms and signs of HIV infection: fever, loss of weight, cough, diarrhoea, rashes, weakness, fatigue, neurological and psychological problems, including memory loss and depression, and gynaecological and urinary symptoms. Ask about symptoms and signs of tuberculosis (TB) and sexually transmitted infections (STIs). Ask about any problems during the pregnancy.

- Document medications, including medicines to treat symptoms, prophylaxis or treatment for opportunistic infections, and antiretroviral treatment. Ask about any ayurvedic treatment and complementary therapies.
- Ask about any allergies.

Clinical assessment

When the mother is referred to the STD clinic a clinical and immunological evaluation will be done to determine her HIV status. WHO clinical staging criteria (annex-1) will be used for this purpose.

General examination. Pay attention to:

- weight (maternal weight should be monitored and nutritional supplementation advised when necessary)
- pallor
- shortness of breath and tachypnoea
- fever
- generalized lymphadenopathy
- Look in the mouth. Oral manifestations of HIV infection are common and pregnant women are more vulnerable to dental and oral problems. You may find opportunistic infections, including: oral candidiasis, ulcers, which may be herpetic, aphthous or bacterial, viral warts. You may find specific manifestations, such as Kaposi sarcoma or oral hairy leukoplakia. You may also find a number of non-specific conditions, such as: severe dental caries, dental abscesses, gingivitis, lip depigmentation and coated tongue.
- Examine the skin. Skin rashes are an important feature of HIV related illness. Skin manifestations may be due to neoplastic disease, especially Kaposi sarcoma, or they may be of an inflammatory nature. These include drug reactions, and dermatoses such as seborrhoeic dermatitis and psoriasis. Generalised dry and itchy skin is a common problem in HIV infection. Acquired ichthyosis is common, especially on the legs. Infections affecting the skin include pruritic papular eruption, herpes simplex, herpes zoster, bacterial infections and folliculitis from yeasts such as *Pytyrosporum orbiculare* and *Penicillium marneffeii*.
- Ophthalmoscopy : check for miliary tuberculosis or CMV retinitis
- Examine the chest for signs of TB or other chest infections.
- Examine the abdomen for enlarged liver, spleen, and any other swellings. Determine the size of the uterus, if palpable.

Other tests and examination

- Genital examination
 - Screen for other STI. Genital infections in particular ulcerative disease are associated with sexual transmission of HIV. Chorioamnionitis is associated with chlamydia, gonorrhoea infections and bacterial vaginosis. Chorioamnionitis may lead to premature rupture of membranes with the possibility of premature birth. Chorioamnionitis, premature rupture of membranes and premature birth have all been

associated with mother to child transmission of HIV. Detection and treatment of STI/RTI are important to reduce the risk of transmitting infection to the neonate during delivery³.

When a **speculum examination** is permitted check for

- Gonococcal and chlamydia infection
- Vaginal candida infection (note whether it is recurring in future examinations)
- Bacterial vaginosis
- Trichomoniasis

When required partner notification and treatment should take place where indicated to avoid re-infection.

- Pap smear for cytology. An association between CIN, cervical cancer and HIV related immunosuppression has been known for many years. If an abnormality is detected refer to the Visiting Obstetrician and Gynaecologist (VOG) for colposcopy. If CIN is present at colposcopy the colposcopy should be repeated on one or two occasions during pregnancy to ensure there are no signs of invasive cancer developing. Usually if any abnormality is detected treatment is deferred until six weeks post partum unless invasive cancer is suspected when biopsies are required. Irrespective of HIV status it is prudent to do these in the operating theatre since bleeding may be brisk³.

Laboratory tests

Check whether the following tests have been conducted, and if not, explain and request them:

- syphilis serology (VDRL and TPPA)
- haemoglobin (anaemia is more common in HIV positive women and may need to be corrected before commencing on antiretroviral drugs)
- blood group and Rhesus factor
- complete blood count
- liver function tests
- urea and creatinine

Immunological assessment

CD4 cell count :

The baseline CD4 cell count should be assessed at the initial visit and at least every three months during the pregnancy. The results should be conveyed to the obstetrician.

Viral load :

If viral load testing is available, measure baseline viral load at the initial visit. Viral load should be measured again 2-6 weeks after initiating or changing antiretroviral therapy⁴. It should then be measured monthly until undetectable levels are reached and then at least every two months. The recommended viral load monitoring in pregnancy is more frequent than in non-pregnant individuals because of the need to lower viral load as rapidly as possible to reduce the risk of MTCT.

If viral load is used to help decide mode of delivery it should be assessed at 34 -36 weeks gestation. The viral load result should be communicated to the obstetrician by 36 weeks so that a decision could be made regarding the mode of delivery.

HIV viral load testing is not recommended as a determining factor when deciding whether to use ARV drugs for prevention of MTCT.

Screen for other infections

- hepatitis B and C
- toxoplasma
- cytomegalovirus infection
- herpes simplex infection

2. Anti retroviral therapy(ART) :

Based on clinical and immunological evaluation determine her HIV stage using WHO clinical staging criteria (annex -1).

Asymptomatic women who do not require ART for their own health should be offered prophylaxis and those who need ART for maternal HIV status should be offered combination ART as per SL guidelines (A Guide to Anti Retroviral Therapy. National STD/AIDS Control Programme Sri Lanka 2005).

Develop an ART plan for the mother and initiate therapy. The management plan with ART drugs should be sent to the Obstetrician.

3. Prophylaxis for opportunistic infections

Cotrimoxazole

The World Health Organization (WHO) recommends the use of cotrimoxazole for HIV-infected individuals with CD4 cell counts below 350 cells/mm³, including pregnant women at any clinical stage, since benefits to women's health outweigh the risks of birth defects. Cotrimoxazole (fixed dose combination of sulfamethoxazole and trimethoprim) is a broad spectrum antimicrobial agent that targets a range of aerobic gram positive and gram negative organisms, fungi and protozoa. Cotrimoxazole prophylaxis prevents the opportunistic infections *Pneumocystis jirovecii* pneumonia (PcP) and toxoplasmosis and improves maternal health for HIV positive women.¹¹ Improvements in birth outcomes with reductions in chorioamnionitis, prematurity and neonatal mortality have been observed following the introduction of routine co-trimoxazole prophylaxis¹² for women living with HIV who had CD4 cell counts <200 cells per mm.³

The risk to the fetus of maternal sulphonamide administration in the third trimester is outweighed by the risk to maternal health of PcP. Kernicterus has not been reported where the drug was not also used in the neonatal period.

- If already on co-trimoxazole prophylaxis continue through pregnancy. Check for drug adherence.
- If not, begin daily dose of one single-strength tablets (400mg sulfamethoxazole and 80mg trimethoprim) to women with CD4 cell count <200 cells per mm.³

4. Treatment for opportunistic infections:

If treatment is necessary, it should be used in pregnancy, depending on the clinical stage of the patient. Treatment regimens should follow local guidelines. When treatment options are available, those with the lowest risk to the fetus should be used.

The obstetrician should be informed of the initial assessment giving the clinical and, immunological status of the patient and the ART plan. Thereafter the obstetrician should be informed of the progress especially in relation to clinical status, CD4 level and if available the viral load. A close and a regular liaison with the obstetric unit is required for successful management.

Document management plan

Ensure that the history, examination, test results, and ART management plan are all clearly documented so that this information is available to the obstetrician /anaesthetist.

There are a number of mechanisms through which ARV drugs can reduce MTCT of HIV. One important mechanism is by decreasing maternal viral replication and reducing antepartum maternal viral load in the blood and genital secretions, thereby reducing the possibility of passage of virus to the infant and protecting the infant from exposure to HIV. ARV drugs which cross the placenta also provide pre exposure infant prophylaxis resulting in adequate systemic drug levels in the infant at a time when exposure to maternal genital tract virus may take place during passage through the birth canal. Administration of drugs to the infant after birth provides post exposure infant prophylaxis. This would protect against cell free or cell associated virus that might have obtained access to the foetal/infant systemic circulation through maternal-foetal transfusion during uterine contractions occurring in labour, or through systemic dissemination of the virus swallowed by the infant during passage through the birth canal. Therefore for prevention of MTCT combined antepartum, intrapartum, and infant ARV prophylaxis are recommended.

Although data are insufficient to support or refute the teratogenic risk of ARV drugs when administered in the first 10 weeks of gestation, information to date does not support major teratogenic effects with the majority of ARV drugs. However, certain drugs are of more concern than others, for example, Efavirenz should be avoided particularly in the first trimester^{2,3,4}. ZDV should be included in the antenatal ARV regimen unless there is severe toxicity or documented resistance.

Anti Retroviral therapy are given for two purposes:

1. When pregnant women are well and do not yet need treatment for their own HIV illness, ARV drugs are given during pregnancy as **prophylaxis** to protect the baby. Combination antepartum ARV regimens are more effective than single-drug regimens in reducing MTCT of HIV.
2. Women with HIV related immune deficiency should receive potent combination ARV regimens during pregnancy as **treatment** for their HIV illness. When indicated, ARV treatment will improve the health of the mother by reducing the viral load and thereby also decrease the risk of mother to child HIV transmission.

Care providers may have to address two scenarios:

- Some women may need initiation of ARV during pregnancy
- Some women may be already receiving ARV treatment at the time they became pregnant

ARV prophylaxis is recommended for all pregnant women who do not require ARV treatment for their own HIV illness regardless of the CD4 count or viral load².

Adapted from WHO recommendations for management of HIV women in pregnancy the recommended regimen for Sri Lanka is given below. During counseling discuss the recommended regimen with the patient. Explain the importance of adherence and follow up at the STD clinic in addition to the visits to the antenatal clinic.

Clinical scenarios

Scenario-1: HIV infected pregnant women not on ART but require ARV prophylaxis solely to prevent perinatal HIV transmission

Recommended Regimen : Zidovudine + Lamivudine + Nevirapine (ZDV + 3TC+ sd NVP) Regimen

Antepartum:	Commence ZDV at 28 weeks of gestation or as soon as possible thereafter. Dose: ZDV 300mg oral twice a day until delivery
Partum:	On the day planned for elective caesarean section or when active labour begins if a vaginal delivery is planned the following tablets are given : ZDV 300 mg + 150mg 3TC oral one tablet (this combination comes as a single tablet) twice a day Plus One single oral tablet of NVP 200 mg The drugs can be given until at least four hours before surgery with 15ml of water.
Post partum:	ZDV 300mg+150mg 3TC oral one tablet should be given twice a day for 7 days (tail dose to prevent resistance developing to NVP)
To the newborn:	NVP syrup in a single dose: 2mg/Kg immediately after birth (if not, within 12 hours after delivery) plus ZDV syrup 4mg/kg/day, twice a day for 1 week (first dose should be given 8-12 hours of birth and thereafter every 12 hours) ¹

Notes :

- If the woman receives at least 4 weeks of ZDV during pregnancy, omission of the NVP single dose to the mother may be considered. However, the NVP dose to the baby should be given immediately at birth and ZDV syrup given 4 weeks instead of 1 week to the neonate. If the NVP dose is not given to the mother she does not require intrapartum ZDV+3TC and the post partum tail. Mother should continue only intrapartum oral ZDV 300 mg every 3 hours.²
- If the woman receives less than 4 weeks of ZDV during pregnancy, give 4 weeks instead of 1 week of ZDV to the infant.²
- Long-term ZDV can result in anemia. Women with mild anemia have not had problems taking ZDV prophylaxis during pregnancy. But if anemia is severe (Hb <7g/dl) start on a non zidovudine containing regimen and treat for anemia. Alternatively the antenatal component of prophylaxis could be avoided and women receive only ARV prophylaxis beginning in labour. This will not however, be as efficacious for preventing MTCT.²

Alternative regimen

ZDV + sd NVP Regimen

Antepartum:	Commence ZDV at 28 weeks of gestation or as soon as possible thereafter. Dose: ZDV 300mg oral twice a day until delivery
Partum:	As active labour begins give NVP Dose: oral NVP 200mg in a single dose No post partum dose for the mother
To the newborn:	NVP syrup in a single dose: 2mg/Kg immediately after birth (if not, within 12 hours after delivery) plus ZDV syrup 4mg/kg/day twice a day for 4 weeks (first dose should be given 8-12 hours after birth and thereafter every 12 hours)

This regimen is simpler than the first choice regimen but there is a risk of viral resistance developing to ZDV with the possibility of a sub-optimal viral response if NNRTI-ARV treatment is needed by the mother within six months of childbirth.

Both these short term prophylactic ARV regimens have reduced MTCT to about 2% in studies when mothers do not breastfeed.

If only NVP is available then give the following:

Partum:	As active labour begins give NVP Dose : oral NVP 200mg in a single dose
To the newborn:	NVP syrup in a single dose: 2mg/Kg immediately after birth (if not, within 12 hours after delivery)

This regimen is also simple and cheap but it is less effective than the regimens above (about 50% in the absence of breastfeeding) and there is a risk of viral resistance developing to ZDV with the possibility of a sub-optimal viral response if NNRTI-ARV treatment is needed by the mother within six months of childbirth.

Scenario-2: When delivery has occurred and the HIV positive mother has not received any ARV prophylaxis

Recommended regimen

To the newborn:	Sd-NVP 2 mgs/Kg oral suspension immediately after birth (within 12 hours) + AZT 4 mg/kg twice a day for 4 weeks
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Alternative regimen

To the newborn:	Sd-NVP 2 mgs/Kg oral suspension immediately after birth (within 12 hours) + AZT 4 mg/kg twice a day for 1 week
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Minimum regimen

To the newborn:	Sd-NVP 2 mgs/Kg oral suspension immediately after birth (within 12 hours)
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Scenario-3: When a HIV positive pregnant woman presents in labour and has not taken any ARV during ante partum period

- Check whether she has taken any ARV drugs during pregnancy for prophylaxis or treatment. If she is already on combination ARV treatment she should continue her usual doses.
- Evaluate the patient to see if she is in active labour and whether the membranes have ruptured. If she is not in active labour wait until active labour begins or membranes rupture before starting ARV prophylaxis.
- If she has not been on ARV treatment or prophylaxis during pregnancy and is in active labour or presents with ruptured membranes start ARV prophylaxis.
- Use the partograph to check that labour is progressing normally but also to alert when labour is not progressing within safe parameters. Minimise vaginal examinations.

Regimen 1: ZDV +3TC + NVP Regimen:

Partum:	As active labour begins give ZDV + 3TC (Combination tablet) oral every 12 hours and NVP 200mg oral in a single dose
Post partum:	ZDV 300mg+150mg 3TC orally every 12 hours for 7 days (tail dose)
To the newborn:	NVP syrup in a single dose: 2mg/Kg between 2-72 hours of birth Plus ZDV syrup 4mg/kg/day twice a day for 4 weeks (first dose should be given 8-12 hours of birth and thereafter every 12 hours)

Regimen 2: ZDV +NVP Regimen

Partum:	As active labour begins give ZDV 600 mg oral once and NVP 200mg oral in a single dose
To the newborn:	NVP syrup in a single dose: 2mg/Kg between 2-72 hours of birth plus ZDV syrup 4mg/kg/day twice a day for 4 weeks (first dose should be given 8-12 hours of birth and thereafter every 12 hours)

If only NVP is available then give the following:

Partum:	As active labour begins give NVP 200mg oral in a single dose
To the newborn:	NVP syrup in a single dose: 2mg/Kg between 2-72 hours of birth

If the patient presents with ruptured membranes:

She should be given the NVP dose immediately and ZDV + 3TC oral every 12 hours and continue for 7 days post partum.

To the newborn:

NVP syrup in a single dose: 2mg/Kg between 2-72 hours of birth
plus

ZDV syrup 4mg/kg/day twice a day for 4 weeks (first dose should be given 8-12 hours of birth and thereafter every 12 hours)

False labour or mistaken rupture of membranes:

The patient is evaluated and if found not to be in true labour, with membranes not ruptured, wait until she is in active labour. If the mother has been taking ARV drugs check what regimen she has been taking. If she has been on the antepartum ZDV regimen from 28 weeks, commence ZDV + 3TC oral every 12 hours and give the single dose NVP when active labour begins.

If she has already taken NVP, she should be given another tablet of NVP or if rupture of membranes occurs more than 24 hours after the initial dose. Continue ZDV +3TC for 7 days post partum.

To the newborn:

NVP syrup in a single dose: 2mg/Kg between 2-72 hours of birth
plus

ZDV syrup 4mg/kg/day twice a day for 4 weeks (first dose should be given 8-12 hours of birth and thereafter every 12 hours)

Nevirapine in labour

Woman can be given NVP in all stages of labour. It is only too late to give NVP if the delivery is imminent (the head is crowning).

Discontinuation of prophylaxis

When the mother has been given ZDV+3TC solely for prophylaxis it should be discontinued post-natally after 7 days. ARV treatment could be restarted with standard treatment regimens in the future when national criteria for initiation of treatment are met.

Special considerations

Premature infants

Premature infants require different ZDV doses to full term infants.

Infants < 36 weeks of gestation - 2mg/kg per dose orally every 12 hours

Use of ARV drugs other than ZDV cannot be recommended in premature infants due to lack of dose and safety data.

Nevirapine for neonates

General rule

If the baby weighs 2kg or more (>2000g): Give 0.6ml (6mg)

If a baby weighs less than 2 kg : Give 0.2ml/kg ie 2mg/kg

Nevirapine dosage for infants

Weight in Kg	NVP delivered at 50mg/ml oral suspension
	Dose/ml
1.5-1.7	0.3
1.8-2.2	0.4
2.3-2.7	0.5
2.8-3.2	0.6
3.3-3.7	0.7
3.8-4.2	0.8
4.3-4.5	0.9

If the baby vomits within one hour of NVP a second dose of NVP should be given and the baby is observed for another hour. A third dose of NVP should not be given.

Combination with more than 2 drugs

In some countries asymptomatic women who do not require ART for their own health is treated with a short-term antiretroviral therapy (START) commencing in the 2nd trimester with combination regimens with the intention to achieve undetectable viral loads of < 50 copies per ml prior to delivery. The optimal time to commence START is unclear but ideally this should be between 20-28 weeks and commencing prior to fetal viability (24 weeks) may be prudent^{3,4}.

At present it is recommended that this should contain ZDV and 3TC unless there are any contraindications. It is also recommended that this regimen should contain a boosted protease inhibitor (PI). In Sri Lanka due to limited availability of PI this regimen is not used.

Scenario-4: HIV positive pregnant women not on ARV and who need ARV treatment for their own health (initiation during pregnancy)

For women who require initiation of ARV treatment for their own health, treatment should be started as soon as possible, although this can usually be deferred until after the first trimester. If the potential benefits of treatment to the mother outweighs the potential foetal risks treatment can be started even in the first trimester. Pregnancy should not preclude the use of optimal therapeutic regimens.

The table given below guides the initiation of therapy when CD4 counts are available and not available.

Recommendations for initiating ARV treatment in pregnant women based on clinical stage and availability of immunological markers

WHO clinical stage *	CD4 testing not available	CD4 testing available
1	In the absence of CD4 cell testing, asymptomatic patients who are HIV infected should not be treated.	Treat if CD4 cell count <200 cell/mm ³
2	A total lymphocyte count of < 1200 /mm ³ can be substituted for the CD4 count when the latter is unavailable and HIV related symptoms exist	Treat if CD4 cell count <200 cell/mm ³
3	Treat	Treat if CD4 cell count <350 cell/mm ³
4	Treat	Treat irrespective of CD4 cell count

* refer annex-1 for WHO Clinical Staging

Start treatment using ART recommended in the country guidelines (A Guide to Anti Retroviral Therapy, National STD/AIDS Control Programme, Sri Lanka 2005), taking into account ARV safety and efficacy data available in pregnancy: that is, potent combination ARV treatment, generally consisting of two nucleoside reverse transcriptase inhibitors (NRTI) plus a non-nucleoside reverse transcriptase inhibitors (NNRTI) or protease inhibitors (PI) with continuation of treatment post partum.

Consideration should be given to safety and efficacy data available in pregnancy. ZDV and 3TC as the nucleoside backbone is usually recommended in combination with a NNRTI or PI ⁴.

ARV treatment with the full regimen should continue during labour and infants born to women receiving ARV treatment should be given single dose NVP at birth plus ZDV for 1 week.

If an HIV infected woman with indications for treatment is first seen very late in pregnancy (beyond 36-38 weeks of pregnancy) and treatment cannot be initiated prior to delivery, the prophylaxis regimen as given in scenario:1 should be given to mother and infant. Plan to initiate ARV treatment for the woman as soon as possible.¹³

It is recommended that ZDV should be a component of the antenatal ARV treatment regimen, but there may be circumstances, such as the occurrence of severe ZDV-related toxicity, when this is not possible. Long-term ZDV may result in anaemia. Start women with severe anemia (Hb < 7 g/dl) on a non-ZDV-containing regimen. Anemia has to be investigated and corrected.¹³

Start women with severe anemia (Hb < 7 g/dl) on a non-ZDV-containing regimen. Anemia has to be investigated and corrected¹³.

NVP is avoided in women with CD counts > 250 cells/mm³ as there is an increased risk of developing symptomatic, skin rash or hepatotoxicity which can be severe, life threatening and in some cases fatal. If NVP is used, frequent and careful monitoring of transaminase levels particularly during the first 18 weeks of treatment is required⁴. NVP should be stopped in all women who develop signs and symptoms of hepatitis and Grade 3 and 4 skin rash. Transaminase levels (ALT & AST) should be checked in all women who develop a skin rash while receiving NVP (refer annex-2).

Efavirenz (EFV) should be avoided during the first trimester.

Do not prescribe a combination of d4T and ddI during pregnancy because of the potential for lactic acidosis with prolonged use⁴.

Tenofovir (TDF) should be used as a component of maternal combination regimen only after careful consideration of alternatives as data is limited on use in pregnancy and there is concern regarding potential fetal bone effects and nephrotoxicity¹³.

Scenario-5: HIV positive pregnant women who are currently receiving ARV treatment (conceive while on ARV treatment).

Women who become pregnant while receiving ART for their own HIV status should continue treatment during pregnancy. Counsel women (and their husbands, if appropriate) about the benefits and potential risks of continuing ARV treatment during the pregnancy. Stopping treatment will result in an increase in viral load, with decline in immune status and disease progression, and increase in risk of MTCT of HIV. Emphasize that treatment should be continued during pregnancy, and postnatally, whether or not the mother decides to breastfeed.

ARV treatment with the full regimen should continue during labour and infants born to women receiving ARV treatment should be given single dose NVP at birth plus ZDV for 1 week.

Efavirenz (EFV) should be avoided during the first trimester. If on EFV the preferred drug as a substitution is NVP or Indinavir boosted with ritonavir. Lopinavir / ritonavir is also recommended as an alternative regimen. Pharmacokinetic data indicate that when NVP is substituted for EFV, women should immediately commence NVP at 200mg twice a day, as the escalation dosing of NVP is associated with sub therapeutic NVP levels. Some experts are of the view that if women on EFV present in the second or third trimester, EFV could be continued given that the high risk exposure has already occurred.

Pregnant women who are receiving regimens containing NVP should continue therapy regardless of CD4 count. Although hepatotoxicity is a concern when initiating NVP with a CD4 count > 250 cells/mm³, an increased risk of hepatotoxicity has not been seen in women who continue NVP based combination therapy and has achieved an increase in the immune status.

It is recommended that ZDV should be a component of the antenatal ARV treatment regimen, but women already receiving an ARV regimen which does not contain ZDV, but who have achieved undetectable viral levels, could continue the non-ZDV containing regimen.

Women receiving TDF are recommended to continue the regimen during pregnancy. The benefits of continuing treatment are likely to exceed the risks to the foetus from a potential association between TDF and abnormal bone development.

Scenario 6: HIV infected pregnant women with tuberculosis

HIV pregnant women with active tuberculosis, especially smear positive pulmonary tuberculosis should be treated for tuberculosis. The optimum time to initiate ARV treatment depends on the CD4 cell counts, tolerance of tuberculosis treatment and other clinical factors. With careful clinical management women with HIV associated tuberculosis can receive ARV treatment at the same time as tuberculosis treatment. When EFV based regimens are initiated, the future possibility of pregnancy should be considered, and EFV should only be used if effective contraception can be ensured postpartum. NVP-containing regimens can be initiated during the rifampicin-free continuation phase of tuberculosis treatment¹³.

Women presenting in late pregnancy with tuberculosis could be given the short course ARV prophylaxis as described in clinical scenario 1.

Post-natal care (includes care in the institution and the field)

- Physical assessment in the postpartum period should follow routine guidelines. Examine women within 12 hours following delivery.
- Be aware of signs of infection following delivery. Like uninfected women, HIV positive women are also vulnerable to infection following delivery and retained blood and placental tissues. Postpartum uterine infection is a common and potentially life-threatening condition, and early detection and effective treatment are important measures to prevent complications.
- Monitor for secondary postpartum haemorrhage
- Manage infected tears or episiotomy
- Refer women who have urinary incontinence or vaginal prolapse
- When they are discharged from the healthcare facility women should be advised to return to the clinic or inform the PHM if they notice symptoms such as fever, lower abdominal pain, burning with urination, foul smelling discharge, abnormal bleeding, cough, shortness of breath, calf pain (increasing on walking), diarrhea, unusual / abnormal behaviour
- Give the mother information on care of the perineum and breasts. Women living with HIV require special care to reduce breast engorgement, mitigate pain and avoid mastitis
- Women who choose to breast feed should be counseled to avoid breast engorgement which could lead to mastitis, since inflammation is associated with increased risk of HIV transmission. She should be advised to seek immediate medical care if breast engorgement is associated with fever and pain
- Instruct her about the safe disposal of lochia and blood-stained sanitary wear or other potential infectious materials.
- If contraception has not been discussed before delivery it should be done during the early postpartum period

HIV positive women and men should be empowered to take informed choices relating to their reproductive lives, free of coercion. When selecting a family planning method, when only one partner is HIV positive the potential risk of transmitting HIV to the uninfected partner as well as the possibility of infection with other STI should be taken into account. When both partners are living with HIV, possible re-infection with other HIV strains has to be considered.

The same contraceptive options which are available to uninfected couples are available to HIV infected couples. Most methods are considered to be safe and effective for HIV infected women.

WHO publications indicate that there are no restrictions on the use of **hormonal contraception** by HIV positive women who are not on ART. However, use of OCP containing high dose oestrogen is recommended when women are on ART. Rifampicine used in tuberculosis treatment may decrease the effectiveness of oral contraceptives. Long-acting injectables (DMPA) can be safely used in all HIV positive women including those on ART.¹⁴

IUD can be used in case of HIV infection, except for women with AIDS and not on antiretroviral therapy.¹⁴

Female sterilization or male sterilization is often the most commonly used family planning method in developing countries.

Emergency contraception can help to prevent unintended pregnancies. It should not be used as a substitute to regular contraception. Women on ART should be given double the normal dose, ie 2 tablets within 72 hours and 2 tablets 24 hours later.

Protection against both unintended pregnancy and STI is referred to as "dual protection". Condoms are the mainstay of dual protection, alone or in combination with another method.

- Introduce yourself and put them at their ease.
- Encourage the woman to bring her husband for contraception counselling as they may need long term contraception.
- Discuss their thoughts about having more children.
- Ensure that they have the information they need about their own future prognosis, availability of HIV treatment, and risk of transmission of HIV to the baby in future pregnancies.
- Listen carefully to the couples' views. Correct any factual misunderstandings.
- If the husband is HIV negative emphasize the importance of using condoms to protect him from HIV infection.

- If the husband is HIV positive, explain that although they both have HIV they could become infected with another strain of HIV and so it is sensible to use condoms to prevent pregnancy and infection.
- Discuss where they could obtain condoms. Demonstrate how to use condoms correctly. Let both members of the couple handle a condom. Provide them with condoms and an information leaflet.
- If they have decided that they want no more children, discuss vasectomy and female sterilization.
- If they are uncertain about having more children in future, explain that waiting at least 2 years after the last birth to become pregnant again is healthiest for mother and child. Discuss the need of a planned pregnancy.
- Discuss other temporary methods of contraception.
- Ask the woman if she has had infant feeding counselling and how she is planning to feed her baby. If she has not yet been counselled, counsel or refer for counselling.
- Explain that if not breastfeeding, she could get pregnant again as soon as 4 weeks after childbirth.
- If breastfeeding, explain that exclusive breastfeeding is very important for the health of her child and to prevent pregnancy. Breastfeeding will provide protection against pregnancy for up to 6 months but only if the mother is breastfeeding often, day and night, and giving no other food or liquids.
- Discuss about ARV and contraception use. Generally, antiretrovirals and contraceptives do not conflict, however:
 - Rifampicin (used for TB treatment) lowers effectiveness of contraceptive pills and implants. Other antibiotics do not have this problem.
 - Some antiretrovirals (protease inhibitors and NNRTI) *may* lower effectiveness of hormonal methods. This is not known for sure. (NRTI are not a concern.) Correct use of the method and use of condoms can make up for any decrease in contraceptive effectiveness.
 - Some women may have other medical conditions that affect choice of a method
- While breastfeeding non-hormonal methods such as condoms or IUD are suitable. The IUD can be inserted after 6 weeks.
- Progestogen-only methods can also be used while breastfeeding, starting 6 weeks after childbirth (long-acting DMPA injectables, subdermal implants).
- If not breastfeeding, she can use any method. She can start any progestogen-only methods immediately (the mini-pill, long-acting injectables, implants), or the oral combined contraception pill after 3 weeks.

Infants may escape MTCT of HIV during pregnancy and delivery but remain vulnerable to transmission through breastfeeding. The cumulative risk of postnatal transmission is 12%–16% with 18–24 months of breastfeeding. The risk of postnatal transmission is greatest in the first two months of breastfeeding. After that the risk of transmission continues throughout breastfeeding with a risk of between 0.6%–0.9% per month. On the other hand breastfeeding substantially reduces the risk of infant mortality from other infectious diseases and malnutrition on average by 4–6 fold in the first six months and close to twofold in the second six months of life¹⁵.

Influences on the risk of transmission through breastfeeding include:

- high maternal viral load
- HIV related illness
- mastitis and other breast problems
- long duration of breastfeeding
- mixed feeding (i.e. by adding other foods and liquids to the infant's diet in addition to breast milk) in the first months of life

The most appropriate infant feeding option for an HIV positive mother depends on her individual circumstances, including her health status and the local situation, the health services available and the counselling and support she is likely to receive.

When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV positive women is recommended by the WHO guidelines. If not Exclusive breastfeeding is recommended for HIV-infected women for the post natal first 6months.

However it should be noted that even when mothers are provided with infant formula and support, babies that are not breastfed are vulnerable when there are outbreaks of diarrhoeal disease, conflict or natural disasters.

- At six months, if replacement feeding is not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.
- Whatever the feeding decision, health services should follow-up all HIV-exposed infants, and continue to offer infant feeding counselling and support, particularly at key points when feeding decisions may be reconsidered, such as the time of early infant diagnosis and at six months of age.
- Breastfeeding mothers of infants and young children who are known to be HIV positive should be strongly encouraged to continue breastfeeding.
- Efforts should be made to protect, promote and support breastfeeding for all mothers and babies, and to actively support HIV positive mothers who choose

to exclusively breastfeed, and take measures to make replacement feeding safer for HIV positive mothers who choose that option.

A pregnant woman living with HIV needs help to decide how to feed her baby. In a counselling session on HIV and infant feeding the counsellor has three main tasks:

- to convey a large amount of information
- to help a mother to assess the risks for her baby in her own situation
- to give the mother confidence in her choices

During counselling the idea of weighing up risks can be difficult for a woman to understand. Her choice is not a simple one of deciding whether the risk of death for her baby is greater if she breastfeeds than if she does not. Her decision will be influenced by many factors. Some may tell the counsellor; some may keep private. It is therefore important that the woman makes the decision and not the counsellor.

A woman does not need to make all decisions about how she will feed her baby at the first counselling session. While she is pregnant she needs to decide whether she will breastfeed at all or not. But she does not need to decide when she will stop breastfeeding until later. She does not need information about safe weaning foods until the baby is older. However these points should be mentioned so that she understands that they are important points to ask about later.

Because there is a lot of information to give it is helpful to use a counselling checklist¹⁶. It is not easy to help mothers or couples reach decisions about the sensitive subject of infant feeding. Counsellors require adequate knowledge and skills

Early diagnosis of HIV infection in the infant is important. It reduces the anxiety of uncertainty for the parents, allows early, life-saving antiretroviral treatment for the child if infected, and assists in decisions about infant feeding.

The definitive diagnosis of HIV infection at any age requires diagnostic testing to confirm the presence of HIV infection. Antibody testing identifies HIV antibodies generated as part of the immune response to HIV infection. Diagnosis of HIV infection in infants is difficult because maternal HIV antibodies cross the placenta and so an HIV antibody test will be positive even if the child is not infected. Maternal antibodies disappear over time, with 74% of uninfected infants becoming antibody negative by 9 months of age and 96% by 12 months; all are negative by 18 months of age¹⁷. HIV exposed infants who have a positive antibody test result at 9 or 12 months of age are likely to be infected, but a definitive diagnosis of HIV infection using antibody testing can be made only at 18 months or later^{17, 18, 19}

To diagnose HIV infection definitively in children aged < 18 months, assays that detect the virus or its components are required. Diagnosis in children using HIV antibody tests is further complicated by the possibility of transmission through breastfeeding. HIV exposed infants who have a positive antibody test result at ages 9-18 months are considered at high risk of having HIV infection but a definitive diagnosis of HIV infection using antibody testing can be done only after 18 months of age in a non breast fed child. Children who are breastfed have an on going risk for acquiring HIV infection. Therefore HIV infection can be excluded only after breastfeeding is stopped for more than 6 weeks prior to the test^{17 18}

To diagnose HIV infection definitively in children <18 months of age assays that detect the virus or its components are required. The gold standard test for HIV infection in infancy is HIV-DNA-PCR on peripheral blood lymphocytes. If the test is negative at 6 weeks and 12 weeks of age and the baby is not breastfed at all the baby is not infected with HIV.²⁰

A positive virology test result in an infant 6 weeks of age or more who has never been breastfed or not been breastfed for the previous 6 weeks are considered HIV infected.¹⁸

Guidelines for diagnosis

- Examine the infant and assess the clinical status (annex-3). Clinical examination of the HIV exposed infant may show signs suggestive of HIV infection, including failure to thrive, generalized lymphadenopathy, hepatosplenomegaly, chronic dermatitis, oral candidiasis, and recurrent pneumonia or diarrhoea. Some babies may be HIV infected but asymptomatic.
- Since virologic tests are not available in Sri Lanka at present, test all infants of an HIV positive mother at 9 months using an ELISA.

1. Negative antibody test result

- The baby is likely to be not infected, if the child has not been breast-fed in the previous 6 weeks. Repeat at 12 months and still negative baby is uninfected. Stop co-trimoxazole prophylaxis and advise the mother not to put the baby to the breast¹⁸.
- If the child is breast-fed and the result is negative the child is probably uninfected but another test should be performed 6 weeks after the baby ceases breastfeeding. Continue co-trimoxazole prophylaxis. Repeat the test at 12 months if negative the infant is uninfected¹⁸. Stop co-trimoxazole prophylaxis. Counsel the mother to continue to breastfeed unless it is affordable, feasible, acceptable, safe, and sustainable to stop.

2. Positive antibody test result

- Reassure the parents that this does not mean that the child is definitely infected because there may still be maternal antibodies present. Test the child again at 12 months, and if still positive test again at 18 months. After 18 months if antibody test is positive that confirms the diagnosis of HIV infection in the child¹⁸.

3. HIV - DNA PCR test

If available test the child at 6 weeks.

- If test is positive infant is HIV infected. Refer to STD/HIV clinic. Continue cotrimoxazole prophylaxis. If breastfed, continue breastfeeding as long as possible. Confirm result with second PCR or confirm with antibody test at 18 months¹⁸. Start ARV treatment if indicated.
- If the child has not been breast-fed in the previous 6 weeks and the result is negative then the baby is not infected. Stop co-trimoxazole prophylaxis and advise the mother not to put the baby to the breast.
- If the child is breast-fed and the result is negative the child is probably uninfected but another test should be performed 6 weeks after the baby ceases breastfeeding¹⁸. Continue co-trimoxazole prophylaxis. Counsel the mother to continue to breastfeed unless it is affordable, feasible, acceptable, safe, and sustainable to stop.

4. Co-trimoxazole prophylaxis for the infant

Pneumocystis jiroveci pneumonia (PCP) has been identified as the leading cause of death in infants with HIV infection in many studies in all settings. The incidence peaks in the first six months of life. Co-trimoxazole is effective at preventing PCP and other infections¹¹.

- Because of difficulty in diagnosing HIV infection in infants, start co-trimoxazole prophylaxis for all HIV-exposed children born to mothers living with HIV at 4–6 weeks after birth. Continue until HIV infection has been excluded and the infant is no longer at risk of acquiring HIV through breastfeeding.
- Do not prescribe co-trimoxazole to children with a history of severe adverse reaction to co-trimoxazole or other sulfa drugs and children with glucose-6-phosphate dehydrogenase deficiency¹¹.

Co-trimoxazole formulations and dosage for infants and children living with HIV or exposed to HIV (according to age)

Recommended daily dose	Suspension (5 mls of syrup 200 mgs / 40 mg)	Child tablet (100 / 20 mgs)	Single strength adult tablet (400 mgs / 80 mgs)	Double strength adult tablet (800mgs / 160 mgs)
< 6 months 100 mgs sulfamethoxazole / 20 mgs trimethoprim	2.5 mls	One tablet	_ tablet – possibly mixed with feeding (only if suspension not available)	-
6 months – 5 years 200 mgs sulfamethoxazole / 40 mgs trimethoprim	5 mls	Two tablets		
6 – 14 years 400 mgs sulfamethoxazole / 80 mgs trimethoprim	10 mls	Four tablets	One tablet	Half tablet
> 14 years 800 mgs sulfamethoxazole / 160 mgs trimethoprim			Two tablets	One tablet
Frequency once a day				

Co-trimoxazole formulations and dosage for infants and children living with HIV or exposed to HIV (according to weight)

Infant weight	Syrup dose (8mg/ml)	Adult tablet (TMP 80mg/SMX 400mg)
3-4.9kg	2ml daily	
5-6.9kg	3ml daily	
7-9.9kg	4ml daily	1 tablet
10-11.9kg	5ml daily	1 tablet
12-14.9kg	7ml daily	1 single-strength tablet



Management of HIV infection in children

Children diagnosed with HIV infection require clinical and immunological assessment to allow decisions about their need to start on ARV treatment and diagnosis of any opportunistic infections, including tuberculosis.

Experience in several settings has shown that with careful preparation, monitoring and support, children with HIV infection are able to benefit greatly from treatment with ARV. It is important to evaluate the response to ARV and manage any drug toxicity carefully.

Immune reconstitution inflammatory syndrome (IRIS) is a collection of signs and symptoms resulting from the ability to mount an immune response to antigens or organisms associated with immune recovery while on ART. It manifests as an unexpected deterioration of clinical status soon after starting ARV treatment and opportunistic infections may be unmasked, such as TB, hepatitis B and C, and cryptococcal disease. IRIS may require management with prednisone.

Monitoring for failure of first-line ARV treatment is important and some children will require a switch to second-line ARV drugs.

A clinical manual has been prepared by UNICEF Regional Office for South Asia that provides valuable guidance on these aspects of managing HIV infection in children.

The use of all potent medication is associated with side effects and toxicities and ARV medication is no exception. Some side effects & toxicities associated with ART are commoner during pregnancy.^{2,3,4,19,20.}

The rash associated with the use of NNRTI, NVP in particular is usually a mild toxicity that occurs shortly after the start of treatment. In a subset of patients, however, NNRTI-associated rashes are severe enough to warrant withdrawal of NNRTI. Another toxicity that often follow ART is hepatic toxicity.

Perinatal exposure

Long term side effects of perinatal exposure to ART can be considered in four main categories: teratogenic, carcinogenic, developmental and mitochondrial

Teratogenicity is most likely to be a problem with first trimester exposure to ART. All currently licensed antiretroviral therapies (except efavirenz which has recently been classified D) are classified either B or C for use in pregnancy.

NRTI drugs are known to induce mitochondrial dysfunction. Clinical disorders linked to mitochondrial toxicity include neuropathy, myopathy, cardiomyopathy, pancreatitis, hepatic steatosis and lactic acidosis. Among these disorders hepatic steatosis and lactic acidosis may have a female preponderance. These syndromes have similarities to rare but life threatening syndromes (HELLP syndrome) that occur during pregnancy, most often during the third trimester:

There are conflicting data regarding that mitochondrial dysfunction might develop in infants with in- utero exposure to NRTI drugs. Data at present are conflicting.

1. Zidovudine (ZDV)

ZDV is a nucleoside reverse transcriptase inhibitor (NRTI) that inhibits HIV-1 reverse transcription by acting as a DNA chain terminator. ZDV was the first antiretroviral drug approved for treatment of HIV infection.

Toxicity and side effects: reversible bone marrow toxicity (anaemia or leucopenia) is the major dose limiting toxicity of ZDV treatment.*Fatigue, rash, severe muscle pain and inflammation (myopathy), nausea, insomnia and headache are also associated with ZDV therapy. Side effects are generally more severe and frequent in patients with advanced disease. Enlarged fatty liver and lactic acidosis have been reported in patients taking ZDV. Patients with risk factors for liver disease should be followed very closely. Lactic acidosis should be considered when patients develop tachypnea, dyspnea or decreased bicarbonate levels.

Pregnancy & breast feeding

Category C.

Advocated for pregnant women beyond first trimester to prevent vertical transmission.

Infants exposed to zidovudine may exert a small but significant durable negative effect on hematopoiesis up to the age of 18 months. .

Drug interactions: bone marrow suppressive agents and cytotoxic agents dapsone, flucytosine, vincristine, vinblastin may increase the hematologic toxicity.

Ganciclovir : Using ganciclovir with ZDV increases the risk of hematologic toxicities and should be administered with caution

Stavudine (*d4T*) : should not be used with ZDV because of potential antagonism.

2. Lamivudine (3TC)

3TC is a nucleoside reverse transcriptase inhibitor (NRTI) that inhibits HIV-1 reverse transcription by acting as a DNA chain terminator. It crosses the placenta efficiently and is excreted in breast milk.

Toxicity and side effects: headache, nausea, malaise, fatigue, diarrhea, neuropathy, neutropenia and anemia have been reported.

Pregnancy & lactation
Category C.

Lamivudine is well tolerated and has pharmacokinetic properties similar to those of non-pregnant women.

3. Nevirapine (NVP)

Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that binds directly to HIV-1 reverse transcriptase, slowing the rate of viral DNA synthesis and thereby inhibiting viral replication. NVP is rapidly absorbed when given orally to adults, and has a long elimination half-life $t_{1/2}$ of approximately 40 hours. It is even longer in pregnancy (66 hours). NVP crosses the placenta efficiently after a single oral 200mg dose to the mother at the onset of labour. In infants median $t_{1/2}$ ranges from 45-72 hours for elimination of the maternal NVP and from 37-46 hours for the elimination of a single 2mg/kg neonatal dose.

Patients receiving NVP should be closely monitored for adverse effects. The most frequent adverse effect of NVP is skin rash which occurs in about 16% of individuals who start long-term therapy. The risk of skin rash from NVP is greatest during the first six weeks of treatment and diminishes thereafter. Most cases of rash are mild to moderate and either subside spontaneously or is manageable without discontinuation of therapy. Guidelines for management of the rash which have been developed based on clinical presentations and constitutional findings are given in annex-2.

Toxicity and side effects: NVP when given along with NRTI (eg ZDV, ddI, d4T) has been associated with hepatotoxicity. The most common laboratory abnormality observed during nevirapine therapy is an elevation of hepatic transaminase enzyme levels. Cases of overt hepatitis, some of them fatal, have also been associated with NVP and NRTI treatment. The majority of cases of hepatitis occurred within the first eight weeks of treatment. Patients should be intensively monitored during the first 12 weeks of initiation of therapy and frequently thereafter. NVP should be stopped and never readministered in patients with AST or ALT greater than twice the upper limit of normal when associated with hypersensitivity reactions or hepatitis.

When pregnant women require ART for their own health and if NVP is included in a long term ART regimen initiate as follows. The recommended dose is 200mg once daily for the first 14 days of therapy followed by the standard dose of 200mg twice daily. This "lead-in" period may reduce the incidence of drug related rash. NVP may be taken with or without food.

Resistance

NVP resistance emerges rapidly with universality when NVP is used as monotherapy or in sub optimal combinations.

Pregnancy & lactation

Category C.

Do not initiate NVP based HAART in women with a CD4 >250 due to hepatotoxicity. It does not apply to the single perinatal dose which is highly effective for preventing transmission.

4. Efavirenz (EFV)

EFV is a non-nucleoside reverse transcriptase inhibitor (NNRTI) binds to HIV-1 reverse transcriptase and inhibits its activity.

Toxicity and side effects : the most commonly reported adverse events are central nervous system related - dizziness, sleep disturbances, nightmares, hallucinations and confusion. Avoid in patients with a history of psychiatric symptoms or suicidal attempts. Grade 1 or 11 maculopapular skin eruptions have been reported. Most cases resolved when treatment was interrupted and did not recur when drug was resumed.

Elevated transaminase levels and lipid levels have been reported.

Teratogenic effects have been observed in primates at EFV exposures similar to those given in clinics, therefore EFV should be avoided in the first trimester of pregnancy.

Universal precautions are those which service providers need to follow in order to prevent the transmission of blood borne viruses to other individuals and to themselves. Since most HIV infected women in Sri Lanka may be asymptomatic carriers it is important to consider all body fluids as potentially HIV infected material. This avoids discrimination and ensures a high standard of practice. It is important to remember that the universal precautions are essentially reinforcement and strengthening of time tested routine infection control regimens in health care systems.

Aims of prevention

1. Direct contact
2. Cross infection

Prevent contact with the following body fluids of both mother & baby.

- Blood
- Vaginal discharge
- Serous exudates from ulcers/cuts
- Meconium

1. Protection from blood and other body fluids during deliveries

- Wash hands with soap and water before and after caring for the mother & baby and after changing linen
- Wear sterile gloves when touching blood, body fluids, mucus membranes, non intact skin, when performing vaginal examination, delivery, cord cutting, blood drawing, handling contaminate waste, cleaning instruments, cleaning blood and body fluid spills
- Wear long sterile gloves for manual removal of placenta
- Wear a plastic apron to protect from splashes
- If splashes of liquor is anticipated protect your eyes

Most HIV transmission to healthcare workers in healthcare settings is the result of skin puncture with contaminated needles or sharps. These injuries occur when sharps are recapped, cleaned or inappropriately discarded.

Patient to patient transmission of HIV could be prevented by disinfecting or sterilizing equipment and devices used in invasive or percutaneous procedures.

The usual plan is for the mother to have an elective lower segment caesarean section at 38th week of gestation.

When a HIV positive mother presents in labour

Perform vaginal examinations only when absolutely necessary

Consider using oxytocin to shorten labour when appropriate

Use the partogram to measure the progress of labour (The partograph should be used to reassure that labour is progressing normally but also to alert them when labour is not progressing within safe parameters). However, vaginal examinations should be minimized.

Adopt the following :

- Minimise invasive procedures
- Have a delivery kit prepared with disposable items
- Prepare bed with washable bed sheets over a fully protective double lined rexine or plastic covered mattress
- Collect waste into a separate bin

- Use disposable needles, syringes, catheters and discard them into puncture resistant waterproof containers

Avoid routine episiotomy & other invasive procedures

Avoid routine rupture of membranes (Transmission rates increase about 2% for every 24 hours of the bag being ruptured. If the membranes rupture spontaneously, delivery should occur in less than 4 hours).

- Avoid routine episiotomy
- Avoid use of forceps and vacuum
- Avoid Artificial Rupture of Membranes

2. Care of the cord

- Use controlled cord traction
- Clamp the umbilical cord early and carefully (this procedure is thought to decrease the chance of maternal blood which contains HIV to cross over to the foetus)
- Cut the cord under cover of a lightly wrapped gauze swab to prevent blood spurting.
- Avoid unnecessary suctioning of the neonate with naso-gastric tubes unless there are signs of meconium.
- Mouth operated suction should be avoided
- Avoid other invasive procedures such as intra uterine scalp monitoring and sampling

3. Collection of blood samples from Infant

- Wear sterile gloves
- Use a needle and syringe to collect foetal blood.
- Avoid spilling blood on the outside of the specimen tube.
- Be sure the rubber stopper is securely fastened on the specimen tube to avoid spills. Label correctly.
- Put the tube into another plastic container lined with absorbing material and send to the lab

4. Actions to prevent needle stick injuries

- Keep a puncture resistant container for disposal of sharps (sharps bin)
- Use each needle and syringe only once
- After use do not recap, bend or break needles after use
- Avoid hand manipulations of needles
- Drop all disposable needles, plastic syringes, directly into the sharps bin without recapping
- Send for incineration when the bin is three-quarters full

5. Waste Management

soiled linen

Collect all soiled linen into a bag after it is used. Soiled linen should be soaked for 20 minutes in a 1% solution of bleaching powder and then washed with soap in hot water

Disinfectant material

- 0.5% Sodium hypochlorite to disinfect instruments (made by adding 90ml water to 10ml bleach containing 5% available chlorine)
- 10% Lysol
- 2.5% Povidone iodine
- 2% Glutaraldehyde

Cleaning of spillage of blood and other body fluids

- Absorb with material (paper towels, gauze, wadding)
- Pour 1% hypochlorite solution till it is well soaked. Leave for at least 10 minutes
- Remove the absorbent material as clinical material using heavy duty gloves
- Clean the area with detergent
- Discard gloves

Disposal of the placenta

Collect into plastic bag and incinerate or bury deep.

Dispose of infected waste , body fluids and tissue and disposable equipment by incineration, deep burying.

WHO CLINICAL STAGING OF HIV DISEASE AMONG ADULTS AND ADOLESCENTS

Clinical Stage 1

Asymptomatic
Persistent generalized lymphadenopathy

Clinical Stage 2

Unexplained^a moderate weight loss (<10% of presumed or measured body weight)^b
Recurrent upper respiratory tract infections (sinusitis, tonsillitis, otitis media and pharyngitis)
Herpes zoster
Angular cheilitis
Recurrent oral ulceration
Papular pruritic eruptions
Seborrhoeic dermatitis
Fungal nail infections

Clinical Stage 3

Unexplained^a severe weight loss (<10% of presumed or measured body weight)^b
Unexplained^a chronic diarrhoea for longer than one month
Unexplained^a persistent fever (above 37.5°C intermittent or constant for longer than one month)
Persistent oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis (current)
Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis or bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Unexplained^a anaemia (<8 g/dl), neutropaenia (<0.5 x 10⁹ per litre) and/or chronic thrombocytopaenia (<50 x 10⁹ per litre)

Clinical Stage 4^c

HIV wasting syndrome
Pneumocystis pneumonia
Recurrent bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or ano-rectal of more than one month's duration or visceral at any site)
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Extrapulmonary tuberculosis
Kaposi's sarcoma
Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacterial infection
Progressive multifocal leukoencephalopathy
Chronic cryptosporidiosis
Disseminated mycosis (coccidiomycosis or histoplasmosis)
Recurrent septicaemia (including non-typhoidal Salmonella)
Lymphoma (cerebral or B-cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy

- a** Unexplained refers to where the condition is not explained by other conditions.
- b** Assessment of body weight among pregnant woman needs to consider the expected weight gain of pregnancy.
- c** Some additional specific conditions can also be included in regional classification, such as the reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in the WHO Region of the Americas and penicilliosis in Asia.

Source: World Health Organization.

Annex-2

Management of NVP Rash

Rash description	Action with NVP
<p>Mild/moderate rash (may include pruritus)</p> <ul style="list-style-type: none"> • Erythema • Diffuse erythematous macular or maculopapular cutaneous eruption 	<p>Can continuing dosing without interruption</p> <ul style="list-style-type: none"> • If rash or other suspected nevirapine toxicity occur during lead-in, the dose should not be escalated until rash resolves • If nevirapine is interrupted for > 7days, reintroduce with 200mg / day lead-in
<p>Urticaria</p>	<p>As above; however, if nevirapine is interrupted, do not reintroduce</p>
<p>Severe rash</p> <ul style="list-style-type: none"> • Extensive erythematous or maculopapular rash or moist desquamation • Angioedema • Serum sickness –like reaction • Steven-Johnson Syndrome • Toxic epidermal necrolysis 	<p>Immediate and permanent discontinuation</p>
<p>Any rash with associated constitutional findings, such as</p> <ul style="list-style-type: none"> • Fever >39 C • Blistering • Oral lesions • Conjunctivitis • Significant elevations in LFT • Facial oedema • Myalgia /arthralgia • General malaise 	<p>Immediate and permanent discontinuation</p>
<p>Any rash with associated constitutional findings and organ dysfunction, such as</p> <ul style="list-style-type: none"> • Hepatitis • Granulocytopenia • Eosinophilia • Renal dysfunction 	<p>Immediate and permanent discontinuation</p>

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The recommended 14 day lead-in dose of 200mg/day nevirapine, prior to escalating to the maintenance dose of 200mg twice daily, has been shown to reduce the frequency of rash. If rash or other suspected nevirapine toxicity occurs during the lead-in period, the dose should not be escalated until symptoms resolve. Pre-emptive therapy with systemic corticosteroids is not recommended.

ANNEX 3.

WHO CLINICAL STAGING OF HIV DISEASE IN INFANTS AND CHILDREN

Clinical Stage 1

Asymptomatic
Persistent generalized lymphadenopathy

Clinical Stage 2

Unexplained^a persistent hepatosplenomegaly
Papular pruritic eruptions
Fungal nail infections
Angular cheilitis
Lineal gingival erythema
Extensive wart virus infection
Extensive molluscum contagiosum
Recurrent oral ulcerations
Unexplained^a persistent parotid enlargement
Herpes zoster
Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis or tonsillitis)

Clinical Stage 3

Unexplained^a moderate malnutrition or wasting not adequately responding to standard therapy
Unexplained^a persistent diarrhoea (14 days or more)
Unexplained^a persistent fever
(above 37.5° C intermittent or constant, for longer than one month)
Persistent oral candidiasis (after first 6-8 weeks of life)
Oral hairy leukoplakia
Acute necrotizing ulcerative gingivitis or periodontitis
Lymph node tuberculosis
Severe recurrent bacterial pneumonia
Symptomatic lymphoid interstitial pneumonitis
Chronic HIV - associated lung disease including bronchiectasis
Unexplained^a anaemia (<8 g/dl), neutropaenia (<0.5 x 10⁹ per litre) and/or chronic thrombocytopaenia (<50 x 10⁹ per litre)

Clinical Stage 4^b

Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy

Pneumocystis pneumonia

Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)

Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site)

Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)

Extrapulmonary tuberculosis

Kaposi's sarcoma

Cytomegalovirus infection (retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month)

Central nervous system toxoplasmosis (after one month of life)

Extrapulmonary cryptococcosis (including meningitis)

HIV encephalopathy

Disseminated mycosis (coccidiomycosis or histoplasmosis)

Disseminated non-tuberculous mycobacterial infection

Chronic cryptosporidiosis (with diarrhoea)

Chronic isosporiasis (with diarrhoea)

Chronic isosporiasis

HIV-associated tumours, including cerebral or B-cell non-Hodgkin lymphoma

Progressive multifocal leukoencephalopathy

Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy

- a. Unexplained refers to where the condition is not explained by other conditions.
- b. Some additional specific conditions can also be included in regional classifications, such as the reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in the WHO Region of the Americas, penicilliosis in Asia and HIV-associated rectovaginal fistula in Africa.

Source: World Health Organization.

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