



Republic of Namibia

Ministry of Health and Social Services

Guidelines for the Prevention of Mother-to-Child Transmission of HIV

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Preface

Approximately 90% of HIV infection among children is acquired through mother to child transmission of HIV (MTCT). Transmission from an HIV-positive pregnant woman to her child can occur during pregnancy, labour and delivery, or through breastfeeding. The World Health Organization estimates that the risk of transmission ranges from 15 to 30% in non-breastfeeding populations and from 20 to 45% in breastfeeding populations. Without intervention, most HIV infected children eventually die during infancy and early childhood.

Effective prevention of mother to child transmission of HIV (PMTCT) efforts can drastically reduce paediatric HIV infection. PMTCT also serves as an entry point to care, treatment and support for HIV infected women and their exposed children and families. In developed countries, effective PMTCT strategies have reduced the risk of transmission of HIV infection to less than 2% by interventions that include: a) antiretroviral (ARV) prophylaxis given to women during pregnancy and labour, and to the infant in the first weeks of life; b) safe obstetrical practices that include elective Caesarean Section delivery (prior to the onset of labour and rupture of membranes); and c) complete avoidance of breastfeeding.

Namibia's first PMTCT guidelines of 2004 were based on the use of single dose nevirapine given to the mother at the onset of labour and a single dose given to the infant between 12 to 72 hours after delivery. In 2006, WHO released guidelines that recommended the use of combination regimens to improve efficacy of prevention. To this end, it has become necessary to revise Namibia's first edition of the PMTCT guidelines to include the use of more efficacious regimens for PMTCT.

WHO Member States attending the UN summit in September 2005 reaffirmed their commitment to fully implement all goals contained in the 2001 United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Declaration of Commitment, which include reducing the proportion of infants infected with HIV by 50% by 2010. In December 2005, the Prevention of Mother to Child Transmission (PMTCT) High Level Global Partners Forum in Abuja, Nigeria, issued a Call to Action "Towards an HIV and AIDS Free Generation". The Call to Action expresses the political will and commitment of national governments and stakeholders to work together towards the goal of eliminating HIV infection in infants and young children, which will lead to a worldwide HIV/AIDS free generation. The implication of this commitment is that governments, with support from development partners, must accelerate the provision of PMTCT services, including use of more efficacious regimens for PMTCT, and furthermore, establish efficient monitoring and evaluation systems for tracking progress in the elimination of HIV transmission to infants and young children.

In March 2002, we introduced PMTCT services in the Katutura and Oshakati State hospitals. Since then the services have been rolled out to all 35 hospitals and 153 health centres and clinics out of the 335 public health facilities. This is indeed an excellent achievement. However, the effectiveness of the PMTCT programme depends on ensuring that the highest possible proportion of pregnant women attending antenatal care services are counselled and tested for HIV, and that ARV prophylaxis is provided to all those women found to be HIV positive, as well as to their HIV exposed newborn babies. To achieve this, the number of health workers with adequate counselling skills needs to be increased. HIV testing and counselling need to be offered routinely to pregnant women in ANC with option to 'opt-out' for those who refuse the test. Involvement of partners and family, as well as community support are also very important determinants of the success of PMTCT. Family members should support the expectant mother to receive counselling and testing in order to protect the unborn child. Studies elsewhere, and experiences in some regions in Namibia, have shown that most women actually desire testing in order to protect their babies, but unfortunately often fear the stigma and rejection if they were to test positive. To increase the counselling capacity and psychosocial support rendered to pregnant HIV positive women, the Ministry introduced the community counsellor cadre to assist health care workers with meeting the huge demand for counselling. In order to improve responsiveness to our clients, the Ministry has, together with the Namibia Institute of Pathology (NIP), introduced HIV rapid testing providing same day results. This has considerably reduced the waiting time for results and increased the proportion of pregnant women who receive their results and are post-test counselled.

As indicated in these guidelines, wherever possible, HIV-positive pregnant women who have a CD4 count equal to or less than 250 cells/mm³ or who have WHO clinical stage 3 or 4 disease should receive highly active ARV therapy (HAART), as treatment of their own disease: this lowers their viral load and therefore reduces the risk of MTCT. HAART in this case is for life and should be continued even after delivery.

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In these revised guidelines, the recommended ARV regimen for preventing MTCT in women who do not yet need HAART, has been changed to antepartum AZT from 28 weeks of pregnancy or as soon as possible thereafter, single dose NVP and AZT/3TC at the onset of labour and single dose NVP to the baby after delivery, and further postpartum AZT and 3TC for seven days to both the mother and her infant. The regimen will be discontinued after childbirth. All health professionals caring for pregnant women should undergo PMTCT training to be able to implement these guidelines in a competent manner.

A critical component of PMTCT is the provision of intensive counselling on infant feeding options in the context of HIV. All pregnant women should be counselled on the importance of breastfeeding regardless of their HIV status. Breastfeeding is still the best feeding option for mothers who are HIV-negative, or for those who do not know their HIV status. Even though the efficacy of ARVs for PMTCT is reduced by breastfeeding, it is neither acceptable nor safe for the majority of HIV infected women to use replacement feeding. Culturally, it is expected for a woman to breastfeed and if she does not do this, the woman may be stigmatised. Where water and sanitation is inadequate, babies who are not breastfed may die from diarrhoea and malnutrition due to improper preparation of replacement feeding. An HIV infected woman should thus receive counselling on infant feeding options to enable her to make an informed choice about the method of infant feeding best for her specific situation. Feeding options for HIV-positive mothers are described in detail in these guidelines.

The development of these comprehensive PMTCT Guidelines was made possible through the collaboration of many individuals, agencies and organisations. The Ministry of Health and Social Services wishes to recognise the contributions of the Departments of Obstetrics and Gynaecology and Paediatrics of the Windhoek Central and Katutura Hospitals, the Directorates of Primary Health Care Services and Special Programmes and Tertiary Health Care and Clinical Support Services, I-TECH, DED, GTZ, the Franco-Namibia Co-operation, UNICEF, USAID, FHI and the Centres for Disease Control and Prevention. These guidelines are to be utilised both in the public and private sectors. I urge all doctors, nurses, and other health professionals to familiarise themselves with the contents so as to be able to make well informed and effective contribution towards our goal to ensure an HIV/AIDS free generation.




Mr. K. Kahuure
Permanent Secretary

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List of abbreviations

AFASS	-	Acceptable Feasible Affordable Safe and Sustainable
AFB	-	Acid Fast Bacilli
AIDS	-	Acquired immune deficiency syndrome
ALT	-	Alanine amino transferase
ANC	-	Antenatal care
AROM	-	Artificial rupture of membranes
ART	-	Anti-retroviral therapy
ARV	-	Anti-retroviral
BCG	-	Bacille Calmette Guérin (TB Vaccine)
BD	-	Twice daily
CDC	-	Communicable Disease Clinic
CHCT	-	Couples HIV Counselling and Testing
CMV	-	Cytomegalovirus
CS	-	Caesarean Section
CTX	-	Cotrimoxazole
DBS	-	Dried Blood Spot
DCC	-	District Coordinating Committee
DED	-	Deutscher Entwicklungsdienst (German Development Service)
DNA	-	Deoxyribonucleic acid
EBF	-	Exclusive breastfeeding
ECV	-	External cephalic version
EFV	-	Efavirenz
ELISA	-	Enzyme Linked Immunosorbent Assay
FBC	-	Full blood count
FHI	-	Family Health International
FIL	-	Feedback Inhibitor of Lactation
FY	-	Financial Year/Fiscal Year
GI	-	Gastro-intestinal
GTZ	-	Gesellschaft fuer Technische Zusammenarbeit (German Technical Cooperation)
HAART	-	Highly active anti-retroviral therapy
Hb	-	Haemoglobin
HBsAg	-	Hepatitis B surface Antigen
HBV	-	Hepatitis B virus
HCT	-	HIV Counselling and Testing
HIS	-	Health Information System
HIV	-	Human Immunodeficiency Virus
HIVQUAL	-	HIV quality of care
HPV	-	Human Papilloma Virus
HW	-	Health worker
ICU	-	Intensive care unit
IM	-	Intramuscular
IMCI	-	Integrated Management of Childhood Illnesses
IMR	-	Infant Mortality Rate
IPT	-	Isoniazid Preventive Therapy
I-TECH	-	International Training and Education Centre on HIV
IUCD	-	Intrauterine contraceptive device

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IV	-	Intravenous
KJ	-	Kilo joule
L&D	-	Labour and delivery
M&E	-	Monitoring and evaluation
MCPDM	-	Management Committee on Patient Care and Disease Management
MoHSS	-	Ministry of Health and Social Services
MTCT	-	Mother to Child Transmission of HIV
NGO	-	Non-Governmental Organisation
NIP	-	Namibia Institute of Pathology
NRTI	-	Nucleoside reverse transcriptase inhibitor
NNRTI	-	Non-nucleoside reverse transcriptase inhibitor
ORS	-	Oral rehydration solution/salts
PCP	-	Pneumocystis Carinii (Jiroveci) pneumonia
PCR	-	Polymerase chain reaction
PHC	-	Primary Health Care
PI	-	Protease Inhibitor
PLWHA	-	People living with HIV/AIDS
PML	-	Progressive multifocal leukoencephalopathy
PMTCT	-	Prevention of Mother-to-Child Transmission of HIV
PNC	-	Postnatal care
Po	-	Per os
QID	-	Four times per day
RACOC	-	Regional AIDS Coordinating Committee
RF	-	Replacement feeding
Rh	-	Rhesus
RHCT	-	Routine HIV Counselling and Testing
RMT	-	Regional Management Team
RNA	-	Ribonucleic acid
RoM	-	Rupture of membranes
RPR	-	Rapid Plasma Reagin
RT	-	Rapid testing
SD	-	Single dose
STIs	-	Sexually Transmitted Infections
TAC	-	Technical Advisory Committee
TB	-	Tuberculosis
TBA	-	Traditional Birth Attendant
TDS	-	Three times per day
TOT	-	Training of Trainers
ULN	-	Upper limit of normal
UN	-	United Nations
UNAIDS	-	Joint United Nations Programme on AIDS
UNGASS	-	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	-	United Nations Children's Fund
USAID	-	United States Agency for International Development
VCT	-	Voluntary Counselling and Testing
VDRL	-	Venereal Disease Research Laboratory
WBC	-	White blood count
WHO	-	World Health Organization

Acronyms of medicines

3TC	-	Lamivudine
ABC	-	Abacavir
ATV	-	Atazanavir
AZT	-	Zidovudine
CTX	-	Cotrimoxazole
D4T	-	Stavudine
ddC	-	Zalcitabine
Ddl	-	Didanosine
DLV	-	Delavirdine
DRV	-	Darunavir
EFV	-	Efavirenz
FPV	-	Fosamprenavir
IDV	-	Indinavir
IDV/r	-	Indinavir + Ritonavir
LPV	-	Lopinavir
LPV/r	-	Lopinavir + Ritonavir
NFV	-	Nelfinavir
NVP	-	Nevirapine
RTV	-	Ritonavir
SQV (hgc)	-	Saquinavir, hard gel
SQV (sgc)	-	Saquinavir, soft gel
SQV/r	-	Saquinavir + Ritonavir
T-20	-	Enfuvirtide
TDF	-	Tenofovir
TPV	-	Tipranavir
ZDV	-	Zidovudine

Chapter 1: Introduction

1.1 Situation of HIV infection in women and children

The world estimates of HIV infections have been reviewed recently. In 2007, UNAIDS estimated that 33.2 million people were living with HIV/AIDS worldwide; of these 15.4 million were women. In many regions of the world more women than men are at risk of HIV infection, with 50% of all new daily infections in Sub-Saharan Africa being in women. Children account for more than 12% of all new infections, and globally 2.5 million children less than 15 years of age were living with HIV in 2007. About 1,200 children under the age of 15 years become infected with HIV daily (UNAIDS/WHO, 2007). Without appropriate care and treatment, more than 50% of newly infected children will die before their second birthday.

Table 1: Global summary of the AIDS epidemic November 2007

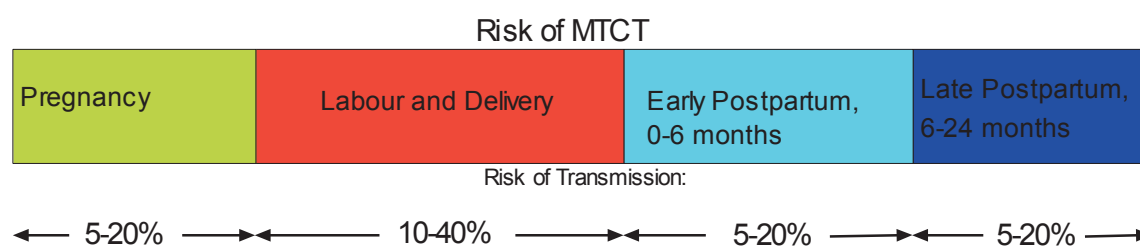
Number of people living with HIV in 2007	Total 33.2 million (30.6–36.1 million)
	Adults 30.8 million (28.2–33.6 million)
	Women 15.4 million (13.9–16.6 million)
	Children under 15 years 2.5 million (2.2–2.6 million)
People newly infected with HIV in 2007	Total 2.5 million (1.8–4.1 million)
	Adults 2.1 million (1.4–3.6 million)
	Children under 15 years 420 000 (350 000–540 000)
AIDS deaths in 2007	Total 2.1 million(1.9–2.4 million)
	Adults 1.7 million (1.6–2.1 million)
	Children under 15 years 330 000 (310 000–380 000)

UNAIDS 2007

In Namibia, according to the National Sentinel Serosurvey, the prevalence of HIV among pregnant women has increased from 4.2% in 1992 to 19.9% in 2006. The estimated number of pregnant women in 2006 was 64,134. Given the ANC HIV prevalence rate of (19.9%), an estimated 12,634 pregnant women were therefore infected with HIV. Without any intervention it is estimated that about a third, or 4,211 babies born to these mothers, would have been infected with HIV.

Most children living with HIV acquire the infection through Mother to Child Transmission (MTCT). In the absence of interventions, the risk of MTCT ranges from 15-30% in non-breastfeeding populations. In breastfeeding populations, such as in Namibia, the risk increases to 20-45%.

Figure 1: Risk of mother-to-child transmission of HIV during different stages of pregnancy



(Adapted from Bertolli et al., *Estimating the timing of mother-to-child transmission of human immunodeficiency virus in a breast-feeding population in Kinshasa, Zaire*. J Infect Dis. 1996 Oct. 174(4): 722-6.)

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More than 90% of paediatric HIV infection occurs through MTCT, which can occur during pregnancy, labour and delivery, or through breastfeeding. The greatest risk of transmission is during labour and delivery, due to the increased exposure of the newborn to HIV-contaminated blood and body fluids. In addition, prolonged breastfeeding increases the risk of HIV transmission (fig. 1). Higher viral load ($\geq 10,000$ copies/ml), lower CD4 count ($< 400 \times 10^6/l$), rupture of amniotic membranes more than 4 hours before delivery and breastfeeding all double the risk of MTCT (table 2). Vaginal delivery, prematurity, low birth weight and genital tract infection are some additional factors that may further increase the risk. Invasive procedures such as amniocentesis, use of foetal blood sampling and foetal scalp monitoring should be avoided as they too increase the risk of transmission (see Table 2).

Table 2: Factors increasing or affecting mother-to-child transmission of HIV

Obstetrical	Maternal	Foetus/New-born	Viral
<ul style="list-style-type: none"> • Episiotomy • Invasive monitoring • Instrumental Delivery • Rupture of Membranes (RoM) > 4 hours • Antepartum and intrapartum haemorrhage • Amniocentesis 	<ul style="list-style-type: none"> • High viral load • Low CD4 count • Advanced HIV disease • Poor nutrition • Breast condition • STIs • New HIV Infection • Illicit substance abuse 	<ul style="list-style-type: none"> • Prematurity • Multiple births • Breastfeeding • Mixed feeding • Immature gastrointestinal tract • Genetic factors • Immature immune system 	<ul style="list-style-type: none"> • Viral sub-type • Viral resistance

1.2 Current status of the PMTCT programme in Namibia

In March 2002, the Ministry of Health and Social Services introduced PMTCT services in the Katutura and Oshakati State hospitals. Since then, the services have been rolled out to all the 35 state and subsidised/church hospitals and to 153 health facilities and clinics in the public sector. In FY 2006/2007, 92% of the women starting ANC had an HIV test. Seventy nine percent (79%) of the pregnant women who delivered knew their HIV status, and of all HIV positive mothers who delivered, 64% took ARV prophylaxis.

Rapid testing for HIV has been introduced in most of the health facilities and this has increased the number of women enrolled into the PMTCT programme. A total number of 59 sites started rapid testing during Financial Year (FY) 2006/07, bringing the total number of sites rolled out to 74 since July 2005.

The HIV status of infants born to HIV positive mothers can now be detected as early as 6 weeks after birth through the use of HIV Deoxyribonucleic Acid (DNA) Polymerase Chain Reaction (PCR) test. HIV DNA PCR testing was introduced by the Ministry of Health and Social Services (MoHSS) in collaboration with partners towards the end of 2005.

The PCR test can reliably and accurately detect HIV DNA on a dried blood spot (DBS) specimen. HIV DNA PCR improves early infant diagnosis of HIV and should lead to early referral of HIV infected infants for appropriate care and treatment. This reduces the morbidity and mortality of HIV positive infants/children. Without any intervention, 30% of HIV infected children will die in the first year of life and 50% would be dead by their second birthday.

1.3 PMTCT specific objectives, strategies and activities

1.3.1 Specific objectives

The following specific objectives guide Namibia's PMTCT Programme:

- 90 % of HIV positive pregnant women, their children and partners, have access to PMTCT services and receive a complete course of ARV prophylaxis to prevent mother to child transmission of HIV
- Mother to Child Transmission of HIV (MTCT) is reduced from 30% to 15% (by 50%) by 2010

1.3.2 PMTCT Strategies

The main strategies to be implemented in order to achieve the above specific objectives are:

- Primary prevention of HIV/AIDS in women of reproductive age

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- Prevention of unintended pregnancies in HIV-infected women
- Prevention of mother-to-child transmission through the use of antiretroviral (ARV) medicines and safe obstetric practices
- Provision of comprehensive care to HIV infected women, their partners, and their families (PMTCT plus)

1.3.2.1 Primary Prevention of HIV

Primary prevention of HIV and other sexually transmitted infections remains an important intervention towards Namibia's overall goal to achieve an HIV/AIDS free generation. The following three programmes/services represent the main approaches to reduce HIV incidence:

A. Behavioural change communication

Preventing HIV infection and other STIs in women will contribute significantly to the prevention of HIV transmission to infants and young children. Health workers should educate their clients and community to change sexual behaviour. Abstinence, faithfulness and the use of condoms must be encouraged, as these will contribute to the reduction of HIV transmission and other STIs in the general population.

B. HIV counseling and testing (HCT) services

Knowing one's HIV status may prepare one to make an informed decision about whether or not to become pregnant. This in turn plays a pivotal role in the prevention of mother to child transmission of HIV. Health workers should encourage the general population, particularly women of reproductive age, to make use of HCT services. Women who test HIV negative should be encouraged to remain negative. Primary prevention services particularly during pregnancy and lactation must be made readily available, since any new HIV infection during these stages greatly increases the risk of MTCT.

C. Treatment of Sexually Transmitted Infections

The most common Sexually Transmitted Infections (STIs) in our society are chancroid, chlamydia, gonorrhoea, syphilis, trichomonas vaginalis, genital herpes, genital warts (Human Papilloma Virus) and granuloma inguinale. Health workers should screen and treat STIs through the syndromic approach and encourage sexual partners to come for treatment. See the 1999 MoHSS Guidelines on Syndromic Management of STIs.

1.3.2.2. Prevention of Unintended Pregnancies in HIV positive women

HIV positive women have to cope with a variety of challenges related to their health, their social and economic outlook and their personal future. An unintended pregnancy may add considerable further challenges. Prevention of unintended pregnancies by way of effective and appropriate family planning methods is therefore an important service that should be offered at all health care delivery points.

A. Family planning services

Family planning is a key strategy to reducing the number of babies born to HIV positive women. Making an informed choice about contraceptive use involves recognition and acknowledgement of different methods, their effectiveness against pregnancy and the need to prevent STIs/HIV. Health workers should provide family planning services at Antenatal Care (ANC), ART sites, maternity and Postnatal Care (PNC) clinics, as well as in Under 5 clinics.

The health worker should encourage clients to use dual family planning methods i.e. use of condoms in addition to another contraceptive method. The dual method is particularly important for anyone who is sexually active, but is not planning to be pregnant.

B. Contraceptive considerations when female patients are on ARV therapy

Current WHO guidance gives women with HIV a choice of many methods (WHO 2004). Having HIV/AIDS, or using ARVs poses no limitations on use of hormonal methods such as oral contraceptive pills (OCs), injectable contraceptives and implants. While there is some theoretical concern that ARVs might reduce the effectiveness of combined oral contraceptives (COCs), women taking ARVs can still generally use COCs. See more details in WHO family planning medical eligibility criteria, 2004.

In general, if a woman using ARVs wants to use COCs, she can be given a formulation with at least 30µg of estrogen, counseled about the importance of taking COCs every day at the same time (without missing pills), and encouraged to use condoms consistently. Correct and consistent condom use would help to make up for any decrease in effectiveness of the oral contraceptives, prevent STIs, as well as help to protect an uninfected sexual partner.

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Most women with HIV, including those on ART, can have an IUCD inserted if they are clinically well. An IUCD should be avoided in women with AIDS who are not on ARVs or in those on ARVs who are not clinically well. Tubal ligation can also be offered to women who no longer want to have children.

Suitable contraceptive methods for women on HAART:

- Barrier methods (female and male condoms)
- Depot progestogen injection (Medroxyprogesterone acetate or Norethisterone enantate)
- Combined oral contraceptives
- Emergency contraception
- Sterilization/bilateral tubal ligation

In addition, vasectomy can be offered to the male partners of HIV positive women.

1.3.2.3. Prevention of mother-to-child transmission of HIV through ARV prophylaxis

A number of clinical trials in Sub-Saharan Africa have demonstrated the efficacy of various short-course ARV prophylactic regimens for PMTCT. These regimens are discontinued after childbirth for women who do not as yet meet eligibility criteria for ART.

ARV prophylaxis for PMTCT started in Namibia in 2002 with single dose nevirapine (SD NVP) given to both the mother and the newborn baby. However, research has shown that combination regimens reduce the risk of MTCT even more (WHO 2006). In designing a new regimen for PMTCT for Namibia, important considerations of simplicity of use, potential toxicity and cost have been taken into account, while at the same time moving towards a more efficacious regimen. Details related to the new regimen are discussed in Chapter 4.

1.3.2.4. Provision of comprehensive care, treatment and support for mothers living with HIV, their children and families (PMTCT plus)

PMTCT plus refers to the provision of care, treatment and support for the HIV infected woman, her exposed child, including her infected children from other pregnancies, as well as for her sexual partner. Women living with HIV/AIDS who have recently given birth need to be offered comprehensive care through continuum of care services for the whole family.

PMTCT plus is a comprehensive model that offers treatment with antiretroviral medicines to those in need, but also encompasses family planning and reproductive health services, nutritional support, counselling and supportive care and treatment of other diseases such as malaria and tuberculosis. It is important that the PMTCT plus approach is integrated into the formal health service.

1.4 Package of services for PMTCT

Comprehensive PMTCT services include the following elements:

- Essential ANC services, including routine offer of HIV testing and counseling, to the pregnant woman and her partner;
- Clinical and immunological assessment of the HIV positive women and referral for HAART for those eligible;
- Referral for pre-HAART registration for all HIV infected pregnant women;
- Provision of ARV prophylaxis for PMTCT to both mother and infant;
- Counseling and support on maternal nutrition and infant feeding;
- Treatment of malaria and provision of IPT in affected areas;
- Screening, prevention and treatment of TB;
- Screening, prevention and management of STIs;
- Cotrimoxazole and isoniazid prophylaxis to both mothers and infants;
- Counseling and support on reproductive health choices (including family planning, screening for cervical cancer, etc.);
- Care of the HIV exposed infant including early infant diagnosis of HIV and cotrimoxazole prophylaxis;
- Linkage of the HIV positive mother and her partner and children to care, treatment and support.

1.5 Benefits of PMTCT

PMTCT provides several benefits at the societal, household and individual levels:

- i. Decreases the burden on the household and health system, by decreasing the number of HIV infected children;
- ii. Reduces suffering from HIV/AIDS in children and those affected;
- iii. Provides an entry point to early and comprehensive HIV/AIDS care, including ARV therapy for the mother, partner and child;
- iv. Counselling, testing, access to ARV therapy and community sensitisation contributes to the reduction of stigma in society;
- v. Promotes behaviour change, e.g. use of dual methods of family planning, improved attendance for antenatal care, improved infant feeding practices;
- vi. Provides opportunity to plan for the future, e.g. choosing safe infant feeding options;
- vii. Implementation of the PMTCT programme affords an opportunity to improve the health services and strengthen the health infrastructure

1.6 Key activities for PMTCT programme strengthening

The release of this 2nd Edition of Namibia's PMTCT Guidelines is an important step in enhancing the effectiveness of the PMTCT Programme. A number of strategies will be implemented in the coming years to further strengthen the programme as follows:

- Ensure the rollout of PMTCT services to all health facilities providing ANC services;
- Provide PMTCT sites with essential equipment and supplies;
- Establish and/or strengthen linkages between PMTCT sites and community based support groups, including Traditional Birth Attendants;
- Conduct social mobilization activities in all regions, especially in low performing areas, in order to increase awareness and utilization of PMTCT services;
- Build capacity of health workers at operational level to provide quality PMTCT services;
- Build capacity of programme managers at all levels to manage and support the implementation of the PMTCT programme;
- Strengthen PMTCT data management systems at all levels;
- Strengthen the monitoring and evaluation system of the PMTCT programme at all levels.

1.7 Purpose of the PMTCT guidelines

The purpose of these revised guidelines is:

- i. To provide the basis for a national standard of care to prevent mother-to-child transmission of HIV in all health facilities
- ii. To sensitise health service providers and other stakeholders involved in PMTCT about issues that are important to the success of the programme
- iii. To promote the importance of PMTCT services and networking amongst all those involved in the care of pregnant women and family members
- iv. To equip health workers with essential knowledge and skills on counselling, infant feeding, obstetric care and ARV medicines
- v. To mobilise community support and participation for the successful implementation of the programme

Chapter 2: Routine HIV testing and counselling

2.1 HIV testing and counselling

Routine HIV Testing and Counselling (RHTC) is the cornerstone of all interventions to reduce mother-to-child transmission (MTCT) of HIV. In the PMTCT programme, pre-test, post-test and on-going counselling should be offered to all pregnant women, postpartum women, their partners and families.

Routine HIV testing and counselling in the antenatal clinic is different from Voluntary Counselling and Testing (VCT) in several aspects. In VCT, the client seeks the service for the specific purpose of learning their HIV sero-status and to receive counselling regarding the results as well as other information about HIV infection and AIDS. In the ANC, the pregnant woman is seeking medical care to ensure the health of her baby and herself. HIV testing and counselling is at best a secondary purpose for seeking care and is initiated by the health care provider (provider initiated). **Therefore, HIV testing and counselling in the antenatal clinic should be provided to all pregnant women as part of a routine comprehensive package of care.**

Health workers in all health facilities should provide information and support to pregnant women regarding their HIV status. The aim must be to de-stigmatize HIV testing.

Box 1: Benefits of Routine HIV Testing and Counselling in ANC Services

- Making testing and counselling a routine ANC service for all pregnant women and their partners can help reduce the stigma associated with both VCT and HIV infection.
- Knowing one's HIV status helps the client to access PMTCT services
- Testing and counselling services offered at ANC clinics may be more acceptable to pregnant women than those offered at VCT centres that serve both men and women.
- Testing and counselling services based in ANC clinics can reach a very high percentage of pregnant women.
- Pregnant women can receive ongoing counselling when they come for follow-up visits to ANC clinics and get answers to different HIV-related questions at various stages of the pregnancy.
- Offering testing and counselling during ANC within the clinic/health centre/hospital will help to integrate HIV/AIDS programmes with other forms of health care, such as treatment of STIs and other infections, nutrition support, and family planning.
- Testing and counselling during ANC at the clinic/health centre/hospital can help to ensure that women who are found to be HIV positive are referred for other interventions (treatment of STIs, TB and opportunistic infection prophylaxis, ARV prophylaxis, nutrition and infant feeding counselling and family planning).
- Women who are found to be HIV-negative can (and should) be encouraged to remain negative by practising safer sex.

Adapted from Preble and Piwoz, 2001

2.2 Testing for HIV infection

The only way to know whether or not one is infected with HIV is to take an HIV test. In PMTCT the purpose of HIV testing is to determine the sero-status of pregnant women, their partners and children. HIV testing should be performed routinely in ANC with the option to "opt-out". **It is important to note that results are needed in a timely manner in order to effectively intervene.**

Tests commonly used for HIV diagnosis are:

- Enzyme-Linked Immunosorbent Assay (ELISA)
- Rapid HIV Test

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ELISA is highly sensitive and was widely used in PMTCT and VCT before the introduction of rapid testing but it requires more expensive infrastructure, trained personnel and batch testing. The turnaround time for ELISA tests leads to a delay in availability of HIV test results.

On the other hand, rapid HIV tests are accurate, simple to perform and provide results immediately. For this reason, the rapid HIV test is now the first choice for routine testing.

Furthermore, for a pregnant woman arriving late in pregnancy, early in labour or immediately postpartum, the rapid test is the only option to get an HIV test result in time to intervene effectively for PMTCT. For more information on HIV tests, see the VCT guidelines.

2.2.1 HIV testing and counselling in labour ward

Health facilities providing labour and delivery services must at all times provide access to rapid testing for HIV and should put in place procedures to ensure that staff are prepared to provide counselling for HIV testing and to perform rapid testing for HIV. If the woman should test positive, there is a window of opportunity to minimise risk of HIV transmission as both the baby and the mother can then be offered ARV prophylaxis. In addition, the mother can be given counselling and support for a safe infant feeding option, and be referred for care and treatment.

2.2.2 HIV testing and counselling during the post-natal period

Women who have not been tested in pregnancy or in labour, should receive counselling and be offered rapid HIV testing in the immediate postpartum period, with the option to refuse testing. If the mother is found to be HIV positive, the newborn can be started immediately on ARV prophylaxis. Within the prescribed 72 hours after delivery, there is still a window of opportunity to offer PMTCT interventions that include ARV prophylaxis to the baby and counselling on safe infant feeding options.

2.3 Flow of services rendered at the ANC clinic

Step 1: Pre-test information sharing for all pregnant women visiting the clinic for the first time

The following topics can be covered in a group counselling session:

- Personal hygiene
- Maternal nutrition and negative effects of alcohol and smoking
- Prevention and treatment of STIs
- Prevention and treatment of TB and other opportunistic diseases
- Information on HIV transmission and prevention
- Routine testing and counselling for HIV
- Sharing results with partners
- ARV medicines for PMTCT and for therapy
- Newborn baby care and infant feeding options
- Warning signs of pregnancy complications

Step 2: Routine clinical and physical assessment

After a group counselling session, each client will see the health worker individually. The nurse will carry out the following activities:

- Registration and history taking
- Take all the baseline parameters
- Perform physical examination
- Individually review and clarify issues discussed during the group information session
- Conduct the HIV test if client agrees (**Pregnant women who “opt-out” should not be tested**)
- Draw blood for routine investigations i.e. blood group and Rhesus determination, Hepatitis B surface antigen, Hb, RPR and HIV test, (rapid test is preferred but HIV ELISA can be performed if RT is not available)
- Provide routine iron, folic acid and multivitamin supplements and Tetanus toxoid vaccination
- Provide routine prophylactic treatment for malaria in areas where malaria is common (see Appendix VIII)

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Step 3: Post-Test counselling

This session depends on whether the test result is negative or positive. Both the women who test positive, as well as those who test negative, need dedicated post-test counselling relevant to their specific situation:

1. Post-test counselling if HIV-negative:

- Inform the client about the meaning of a negative test as well as the 'window period'
- Retest at 36 weeks for women who were negative in early pregnancy
- Discuss risks of couples having discordant HIV results and review disclosure plans
- Provide counselling on primary prevention of HIV infection and on the importance of remaining negative. Counsel the client on the development of an individual risk reduction plan to remain negative and on the need to use condoms
- Encourage HIV-negative women to breastfeed exclusively for the first 6 months in order to promote good health and nutrition for their infants
- Review other aspects of pregnancy care and self-care (nutrition, hygiene, malaria, immunisations, etc.)
- Schedule next visit for routine ANC

NB: All women who test HIV negative should receive prevention messages to enable them to remain negative and should be offered a retest in the third trimester (\pm 36 weeks)

2. Post-test counselling if HIV positive

HIV-infected women need counselling on the following topics

A. The meaning of positive results (having HIV infection)

- Coping with feelings of shock and loss
- Difference between HIV and AIDS
- Infection prevention and care
- PMTCT through ongoing care and ARV medicines for the mother and baby
- Living positively

B. Disclosure

- Discuss whom to tell the result. Nearly all people who learn their HIV results disclose these results to someone else
- Discuss couple discordance and the importance of having partner(s) tested. Since HIV is a sexually transmitted infection, it is especially important for their partners also to be counselled and tested, as the partner may or may not be infected
- Discuss support systems at home and in the community
- Discuss return visit or referral for couple or partner to VCT
- Discuss safer sex: abstinence, being faithful to partner of known HIV status and condom use to prevent re-infection and protect partner(s)

C. PMTCT interventions

General information should be given about PMTCT interventions at each visit

- Explain the need for additional clinical evaluation and laboratory tests to check if she is eligible for HAART, cotrimoxazole preventive therapy (CPT) and/or TB-Isoniazid Preventive therapy (IPT)
- Explain the ARV prophylaxis regimen for mother and baby. Refer to chapter 4 of this guideline
- Encourage the mother to deliver at a health facility and to bring the baby immediately to the health facility in the event that she delivers at home

D. Nutrition for mother and infant

Explain the following aspects of nutrition to the mother:

- The importance of eating a variety of locally available foods from the different food groups
- Benefits and risks of replacement feeding for HIV-exposed infants

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- Acceptability, feasibility, affordability, sustainability and safety of replacement feeding
- Benefits and risk of breastfeeding in MTCT
- Exclusive breastfeeding for six months and abrupt stopping
- The risks of mixed feeding in HIV transmission

E. Issues on reproductive health choices

- Information about making decisions on whether or not to have children
- Information on contraceptive options
- Medicine interactions between antiretrovirals and contraceptives

F. Support groups

Link the women and family members to local AIDS support groups (NGOs, community based organisations, church organisations, home based care groups and people living with HIV). Health institutions should collaborate with these organizations. Linking HIV-positive women and family members to these groups is important for:

- Reducing fear, ignorance and stigma surrounding HIV
- Facilitating counselling support on an ongoing basis and beyond the ANC visits
- Reducing the potential for domestic violence
- Stimulating a community response in those living positively with HIV/AIDS
- Contributing to an environment supportive of safer sexual behaviour

G. Planning for the future

HIV infection is a chronic condition that requires careful planning for the future. Therefore the health worker should inform the client of the following:

- The need for ongoing HIV care, opportunistic infection prevention and treatment
- The life long increased risk of tuberculosis and the importance of early diagnosis and treatment
- Referral to the closest ART clinic
- The criteria to start ARV therapy and the benefits and risks involved
- Importance of medicine adherence

2.4 Couples HIV counselling and testing (CHCT)

Couples HIV Counselling and Testing is a model that facilitates the development of a shared vision between the two partners in a relationship. This shared vision is one where the couple accepts the reality of HIV in their lives and is empowered to prevent the acquisition and transmission of HIV. The aim is for them to share their support and compassion for each other.

CHCT is based on four important concepts:

- Counsellors should focus on solutions – not problems
- Counsellors must assist in diffusing blame and tension
- Counsellors should focus on the present and the future
- Remember, the past is in the past and cannot be changed

Importance of CHCT

- The couple is a partnership of two people and forms the core of the family (“our family” “our life”)
- The couple is the backbone of the community
- HIV/AIDS is a disease that affects the family, the community and the society
- To contend with HIV and plan for their future, both partners must know their HIV status
- Couple HIV services enhance opportunities to prevent mother-to-child transmission of HIV
- Individual testing leads to assumptions about the other partner’s HIV status

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- Rates of disclosure are very low if individuals are tested separately
- In countries with high HIV prevalence, it is not uncommon for one partner to be HIV infected and the other uninfected – meaning that they are HIV sero-discordant, or simply “discordant.”
- Many individuals and couples have the misconception that discordance is not possible
- Couples can remain discordant for a long time – even more than 10 years
- Discordant couples are not entirely protected by remaining faithful
- Transmission risk is highest in steady discordant relationships. As many as 80% of couples in whom both partners are HIV positive share exactly the same virus strain
- Before knowing their HIV status, most discordant couples do not use condoms; however, CHCT has been shown to increase condom use
- In many cases, partners are already discordant when they enter a relationship. Thus discordance is NOT a sure sign of infidelity
- Sometimes a couple becomes discordant due to outside partners or other exposures to HIV

Advantages of CHCT

- Environment in CHCT is safe for couples to discuss their risk concerns. Counsellors and health workers are trained to create a secure and supportive environment for the couple
- Partners hear information and messages together, enhancing the likelihood of a shared or common understanding
- The CHCT session provides an opportunity to ease tension and diffuse blame
- Counselling messages are based on the results of both individuals
- The individual is not burdened with the need to disclose results to his or her partner or having to persuade the partner to be tested
- Counselling facilitates the communication and cooperation required for risk reduction
- Treatment and care decisions can be made together
- Couples can engage in decision-making for the future

2.5 Possible strategies for male involvement in PMTCT

Poor male involvement still remains one of the main challenges to the successful implementation of the PMTCT programme. In order to improve male involvement the following strategies are suggested:

- Encourage women to bring their partners at each visit
- Women who come with partners to the clinic should be attended to first
- Send the pregnant woman with an invitation letter to her partner, requesting him to attend a counselling session (see Appendix V)
- Use male health workers, community counsellors or men in their respective communities to promote male involvement by raising awareness and educating communities through meetings, seminars etc
- Use male clients who have undergone counselling at the antenatal clinic as peer educators and initiate male friendly activities at the facility

Chapter 3: Routine care during pregnancy, labour, delivery, and post-natal period for HIV-positive women

3.1 Management of known HIV-positive woman during pregnancy

3.1.1. Nutrition for HIV-positive pregnant women

All HIV-infected patients need information on a healthy diet and nutritional support. Pregnant women should be encouraged to eat food from all the different food groups (see the table below). Eating a variety of foods ensures that the body gets all the nutrients that it needs. Later in pregnancy when women have difficulties eating a full meal at any one time, frequent eating of smaller portions and healthy snacks are good options. Good nutrition in the mother will ensure a well-nourished foetus and infant and improves breast milk production.

In addition, the consumption of alcohol is to be stopped during pregnancy. Similarly pregnant women should preferably not smoke at all.

Table 3: Food groups and types of foods

Food groups	Main Nutrients	Types of food
Cereals	Carbohydrates	Maize, mahangu, rice, wheat, bread, sorghum, oats
Meat, fish, chicken, milk, milk products and legumes	Proteins	Nuts, meats, fish, eggs, soya beans, peas, lentils, beans, milk, Omaere, Oshikandela, yoghurt, cheese
Fruit and vegetables	Vitamins and Minerals	Dark green leafy vegetables, yellow and orange fruits, pumpkins, carrots, avocados and tomatoes
Fats and sugars	Fats and simple carbohydrates	Margarine, butter and cooking oil, sugar

Source: Food and nutrition guidelines of Namibia (MoHSS, 2000)

The health worker should inform the client that they should:

- Eat food that is well cooked and not contaminated
- Never leave raw or cooked meat, poultry, fish and shellfish outside a refrigerator for more than 1 hour
- Not keep uncooked meat in contact with other foodstuff
- Wash knives and all the other cooking utensils after contact with uncooked foodstuff
- Store raw food separately from cooked food
- Not drink water directly from lakes, ponds and rivers, due to the risk of acquiring various water-borne diseases, for example giardiasis, cryptosporidiosis and others

3.1.2. Routine antenatal care

When a woman who is known to be HIV-positive becomes pregnant, or is diagnosed as being HIV-positive during pregnancy, her obstetric and medical care will need to be modified and strengthened. All routine ANC supplies and vaccinations, for example iron, multivitamins, folic acid and tetanus toxoid should be provided. Sexually transmitted infections should be treated according to the syndromic approach.

Procedures such as amniocentesis, external cephalic version (ECV), foetal scalp blood sampling and other invasive procedures should be avoided because they carry an increased risk of HIV transmission to the foetus.

Clinical evaluation for opportunistic infections

At the initial and subsequent visits, the health worker should screen the patient and look for HIV/AIDS related signs and symptoms. The health worker should also determine the WHO clinical stage (Appendix IV) and manage or refer accordingly. The following are some of the signs and symptoms of opportunistic infections:

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- Persistent diarrhoea
- Fever and cough
- Respiratory infections
- Oral candidiasis
- Lymphadenopathy
- Herpes zoster
- Other skin conditions
- Poor weight gain, weight loss or wasting in pregnancy

TB and bacterial respiratory infections are common in HIV-positive individuals. All HIV infected pregnant women should be screened for active TB and evaluated if they have any of the following signs and symptoms: cough, fever, weight loss and/or night sweats and loss of appetite. After excluding active TB disease, Isoniazid Preventive Therapy (IPT) should be initiated.

Laboratory investigations for HIV-positive pregnant women

All HIV positive pregnant women should have the routine tests as carried out in all other pregnant women. In addition, CD4 count and the Hepatitis B surface antigen tests should be performed if they have not been done previously as a baseline.

- If the CD4 count is less than 250×10^6 cells/L, the pregnant woman should be referred to the ART clinic for evaluation and ART treatment. NB: Initiating ART at a higher CD4 threshold is under consideration by the Technical Advisory Committee of MoHSS. Revisions to the WHO recommendations on ART for resource limited settings will help to set the new CD4 threshold.
- If the CD4 is less than 300×10^6 cells/L, provide cotrimoxazole prophylaxis
- If the HBsAg is positive, the baby should be given the Hepatitis B immunoglobulin (HBIG), and Hepatitis B vaccination should be initiated within 12 hours of birth.

Follow-up for HIV positive pregnant women

HIV infected pregnant women with CD4 more than 250×10^6 cells/L who are asymptomatic need to be followed-up in ANC and be monitored for signs and symptoms of disease progression. In addition, they should be referred for pre-HAART registration.

- Repeat CD4 count every 3 months
- Pregnant women with CD4 less than 250×10^6 cells/L or WHO stage 3 or 4 should be referred to the ART clinic for HAART as a matter of urgency
- Prevention of opportunistic diseases and infections are important priorities for care at all stages of HIV disease
- The importance of not having unprotected sex must be emphasized during pregnancy. If a pregnant woman becomes re-infected with HIV then the risk of transmission to the foetus is greatly increased. She should thus be counseled to use condoms consistently.
- HIV-positive pregnant women and their partners should be encouraged to attend ANC together (see 2.4 on CHCT). If the partner is also positive, he should be referred to the ART clinic. When possible the HIV follow-up of the pregnant woman and her partner should be done simultaneously. Repeated counselling sessions will support the couple to make informed and shared decisions on various important issues, including the method of infant feeding.

A woman living with HIV may have difficulty disclosing to her partner and other family members. In addition, she may experience uncertainty about her health and the health of her unborn child. She thus needs ongoing counselling and psychosocial support.

Prophylactic treatment for HIV positive pregnant women

Prophylaxis in HIV-positive pregnant women may include:

- Ferrous fumarate (200mg) and Folic Acid (100 micrograms) tablets (pregamol)
- Multivitamin supplementation
- Tetanus toxoid immunisation
- Intermittent presumptive treatment for malaria during first and second pregnancies for women living in Namibia's malaria endemic regions. See Appendix VIII for the details of the prophylactic doses of Pyrimethamine-Sulphadoxine.
- Pregnant women should be encouraged to sleep under impregnated mosquito nets in malarious areas
- Cotrimoxazole prophylaxis after the first trimester if her CD4 is below 300×10^6 cells/L or she is WHO clinical stage 3 or 4 disease

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- Isoniazid preventive therapy (TB-IPT) is effective in preventing TB disease in persons who have been infected with tuberculosis bacilli (also called secondary chemoprophylaxis). It is therefore recommended for all HIV-infected pregnant women as long as there is no evidence of active TB and they have not received TB-IPT before.

Who should get TB-IPT	Who should not get TB-IPT
Pregnant HIV infected woman with:	Any HIV infected pregnant woman with any of the following signs or symptoms.
<ul style="list-style-type: none"> • No fever • No cough • No night sweats • No significant lymphadenopathy • No active liver disease (jaundice) <p style="text-align: center;">and</p> Has not received IPT before or TB treatment in the previous year	<ul style="list-style-type: none"> • Loss of weight • Fever • Cough • Night sweats • Lymphadenopathy • Liver disease (jaundice) • TB treatment in the previous year

NB: Isoniazid is safe to administer during pregnancy and breastfeeding.

3.2 Management of the HIV positive woman during labour and delivery

3.2.1. Universal precautions

Women with HIV infection should not be isolated from other women in labour. Universal precautions should be used by health workers on all women in labour irrespective of their HIV status.

Box 2: Universal precautions to follow in dealing with all patients.

- *Wash hands with soap and water after contact with blood and body fluids.*
- *Reduce needle prick injuries, do not recap needles.*
- *Wear gloves during operations and delivery or any invasive procedures.*
- *Cover your own broken skin or open wounds.*
- *Wear impermeable (disposable) plastic apron when conducting delivery.*
- *Wear eye shields/goggles during operations and deliveries.*

3.2.2. Specific intrapartum interventions

Management of labour in all known HIV positive women

General

- Confirm the HIV status of all women who are admitted to the labour ward by checking in the Antenatal health passport and/or by asking the woman whether she has been tested for HIV infection. If HIV status is not indicated in the passport, offer an HIV test
- Use the partogram to monitor the progress of labour in order to reduce the risk of prolonged labour in all women
- Emotional support during labour is important for all women, and may be even more crucial for an HIV-positive woman who is concerned about her condition and the risk of transmission to the child

During normal vaginal deliveries

- Clean vagina with chlorhexidine 0.25% solution
- Wipe the birth canal with gauze or cotton wool, soaked in chlorhexidine solution after every vaginal examination
- Minimise the number of vaginal examinations
- Where induction of labour is indicated, membranes should be left intact for as long as possible because prolonged rupture of membranes is associated with increased risk of HIV transmission
- Artificial rupture of membranes (AROM) should be reserved for women with foetal distress or abnormal progress
- Episiotomies should be used only for specific obstetric indications
- Avoid instrumental deliveries: if the second stage is prolonged, rather perform Caesarean Section
- If Caesarean Section (CS) is considered, apply universal precautions

Use of Elective Caesarean Section for PMTCT

Elective Caesarian Section performed at 38 weeks, before the onset of labour and rupture of membranes, has established efficacy in reducing mother to child transmission of HIV when the viral load is high: greater than 1000c/ml. However, performing Caesarian Section for PMTCT should take into account the risk/benefit ratio. If performed in non-ideal situations, Caesarian Section is associated with increased risk of complications such as wound infections, endometritis and even deaths. It should of course be offered to any HIV positive woman when a standard obstetric indication(s) for Caesarean section is present.

3.2.3. ARV prophylaxis for HIV-positive women in labour.

ARV medicines are effective in reducing transmission of HIV from the mother to the baby when used appropriately. In Chapter 4, the different clinical scenarios and recommendations for use of ARV medicines in pregnancy are described.

3.3 Management of women with unknown HIV status during labour and delivery or postpartum

It is common for women with unknown HIV status, such as unbooked cases, to present to the health facility in active labour. In such cases the health worker should:

- Counsel the mother about the need to know her HIV status
- Offer the test, and if she agrees perform HIV rapid testing as it is critical to know the result immediately. She and her baby can still benefit from ARV prophylaxis, if she is found to be HIV positive
- When the test results are known and she is positive, give ARV prophylaxis and counsel on infant feeding options.

3.4 Care of HIV-positive women after delivery

- If postpartum infection is suspected, treat with antibiotics and refer
- Review and support the infant feeding option chosen
- Provide information on contraception options (refer to chapter 1)
- Women whose HIV status is not known, should be offered counselling and testing in the immediate postnatal period once the patient has been stabilised. This offers a window of opportunity to give ARV prophylaxis to the baby and counsel on infant feeding options
- Give date for six weeks follow-up visit to all mothers and emphasize the importance of this visit.
- Further counselling and support will be needed. Women and their partners should be referred to community-based organisations or other support groups available

3.5 Post-natal services for HIV infected women at six weeks

It is very important that the following services be provided at the postnatal clinic:

- Check parameters, including Hb
- Physical examination
- Prophylaxis with co-trimoxazole and TB-IPT for eligible clients
- Monitoring for signs and symptoms of HIV disease progression (Clinical staging and CD4 counts)
- Assessment of the nutritional status of the mother
- Reproductive health choices
- Pap smear
- Provide ongoing counselling on:
 - ⌚ Infant feeding
 - ⌚ Disclosure
 - ⌚ Safer sex
 - ⌚ Family Planning
 - ⌚ Positive living, including appropriate nutrition
 - ⌚ Care for her exposed infant (discussed in Chapter 5)

Chapter 4: Pharmaceutical interventions for HIV positive pregnant women and HIV exposed infants

4.1 Overview of antiretroviral medicines

There are essentially six types of ARV medicines

- 1. Nucleoside Analogue Reverse Transcriptase Inhibitors (NRTIs).** These medications inhibit the transcription of viral RNA into DNA, which is necessary for replication of the virus. The class includes zidovudine (AZT), lamivudine (3TC), didanosine (ddI), stavudine (D4T), abacavir (ABC) and emtricitabine (FTC). The nucleotide analogue tenofovir (TDF) is also included in this class.
- 2. Non-Nucleoside Analogue Reverse Transcriptase Inhibitors (NNRTIs).** These medications are of a chemically different class from NRTIs, but also inhibit transcription of viral RNA into DNA. The class includes nevirapine (NVP), efavirenz (EFV), delavirdine (DLV) and etravirine (ETR).
- 3. Protease inhibitors (PIs):** These act on the viral enzyme that cuts long chains of virally produced amino acids into smaller proteins. The class includes lopinavir (LPV), indinavir (IDV), nelfinavir (NFV), saquinavir (SQV), ritonavir (RTV), atazanavir (ATV), fosamprenavir (FPV), tipranavir (TPV) and darunavir (DRV).
- 4. Fusion inhibitors:** They block the virus from being able to merge with the host cell (i.e. CD4 cell) after binding. The only currently available fusion inhibitor is enfuvirtide (T-20).
- 5. Integrase inhibitors:** These medicines block the viral enzyme that incorporates the viral DNA into the human cell DNA. Raltegravir (RAL) is the only available integrase inhibitor.
- 6. CCR5 inhibitors:** These medicines block the CCR5 receptor site on the surface membrane of the CD4 cell, thereby preventing the virus from effectively binding to the host cell. The only available CCR5 inhibitor is maraviroc (MVC).

NB: Not all of these medications are currently available in Namibia. This is a comprehensive list of ARVs available on the international market at the time of printing and is given here for completeness.

4.2 Management of ARVs in pregnancy according to different clinical scenarios

Scenario 1: HIV infected pregnant women already on HAART during current pregnancy

HAART regimens in pregnant women achieve efficacy for PMTCT through significant reductions in maternal viral load. For women already receiving HAART and who become pregnant, continuation of HAART with a recommended regimen for pregnant women is the best option for mother and child. Not all HAART regimens, however, are safe or recommended in pregnant women.

All recommended regimens consist of two nucleosides and a potent third medicine to complement it. Because some patients will not tolerate the recommended first line therapy, clinicians providing HAART should be familiar with the various regimens. **The most widely used HAART regimens in pregnant women are:** zidovudine-lamivudine (AZT/3TC), with nevirapine (NVP), or lopinavir/ritonavir (LPV/r).

Note:

- While the combination of stavudine-didanosine (d4T/ddI) should never be prescribed, it is even more important that it is avoided in pregnant women due to the increased risk of lactic acidosis.

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- Efavirenz (EFV) should not be used in the first trimester of pregnancy due to the potential teratogenic effects on the foetus. Cases of neural tube defects have been reported in babies born to pregnant women exposed to efavirenz in the first trimester. For women who become pregnant and this is recognised during the first trimester, NVP should be substituted for EFV
- Women who cannot tolerate nevirapine (NVP) should be given lopinavir/ritonavir (LPV/r). If the pregnancy is identified during the second or third trimester, EFV could be continued given that the period of fetal organogenesis in the first trimester will have been completed.
- Women on HAART should be counselled about potential risks and benefits of continuing therapy during the first trimester. Discontinuing treatment during pregnancy has been associated with viral rebound and CD4 decline, and this increases the risk of MTCT and compromises the health of the mother. However, if therapy should be discontinued during the first trimester in a woman on an NNRTI based regimen, the recommendation is to stop the NNRTI first and then continue the two NRTI medications (e.g AZT/3TC or D4T/3TC) at their usual dosing for seven days to avoid functional monotherapy with the NNRTI, which has a very long half life. The same HAART regimen can then be restarted in the second trimester as long as the medicines are not contraindicated in pregnancy.

Consult a specialist physician if HAART in a pregnant woman needs to be substituted, switched or interrupted.

Scenario 2: HIV positive pregnant women who have not received prior antiretroviral therapy but need it for their own health

The use of HAART during pregnancy, when indicated, will improve the health of the mother and substantially decrease the risk of transmission of HIV to the infant. With more advanced disease, and higher viral loads, pregnant women who are eligible for HAART are at highest risk for MTCT and of developing NVP resistance following the use of sdNVP alone or in combination with AZT given as prophylaxis for PMTCT.

When a pregnant woman is severely ill and in need of HAART for her own health, treatment should be started as soon as possible even if she is in the first trimester of pregnancy. The potential risks to the foetus should be fully explained to the mother as well as the benefits to the mother herself and to her unborn baby. Where the pregnant woman is not very ill, treatment can be deferred to the second trimester.

Women with indications for HAART who present very late in pregnancy should be started on HAART irrespective of the gestational age of the pregnancy. If HAART cannot be started prior to delivery, ARV prophylaxis for PMTCT should be given as for scenario 3 and HAART started after delivery. Prior to initiation of therapy, assessment for medical contraindications to regimen must be done. For an HIV positive woman who has not yet received ARV therapy, follow Figure 2 to determine if she is eligible for HAART. If she does not qualify for HAART, she should receive an ARV prophylactic regimen for PMTCT.

Pregnant women should be started on HAART if they meet the following criteria:

- WHO stage 3 or 4 HIV disease irrespective of CD4 cell count
- WHO stage 1 or 2, with a CD4 cell count below 250/mm³
- Social criteria, which include the following
 - ~ Lived in a stable residence for the past 3 months
 - ~ Not abusing alcohol or other substances
 - ~ Have access to the ART Clinics for follow-up
 - ~ Are committed to long-term ARV therapy, adherence to treatment, practising safer sex, and allowing home visits if indicated
 - ~ Patient has identified someone at home, in the community, or at the workplace to serve as a therapy supporter **NB: Absence of a treatment supporter should not be a reason to deny treatment to any patient.**

The first-line regimen for HIV-positive pregnant women who do not have active TB and meet the eligibility criteria for HAART is zidovudine-lamivudine-nevirapine (AZT-3TC-NVP).

The HIV positive woman co-infected with TB will be discussed in section 4.4.1.

Guidelines for the Prevention of Mother-to-Child Transmission of HIV

The dosages for first-line HAART regimen in pregnant women are:

- i. Zidovudine (AZT) 300 mg twice daily. (Monitor haemoglobin levels)
- ii. Lamivudine (3TC) 150 mg twice daily
- iii. Nevirapine (NVP) 200 mg daily x 14 days, then 200mg twice daily. (Monitor alanine aminotransferase (ALT) levels)

ARVs should be continued as usual during labour and the postpartum period. Special attention should be made to watch for the following side effects:

- Nevirapine-related liver toxicity and skin rash; **Concerns about toxicity, including hepatitis, in women starting NVP containing regimens with a high CD4 count between 250 and 350 cells/mm³ exist and other options should be substituted if possible. If in the second trimester, EFV can be used instead. Alternatively, a triple NRTI regimen (AZT/3TC/ABC) or a PI-based regimen, could be used**
- Zidovudine (AZT) should not be used in women with Hb ≤ 7 g/dl. They should receive stavudine (d4T 30mg) twice daily as part of the HAART regimen, as well as appropriate management of underlying causes of anaemia.

Note: Stavudine (d4T 30mg) should be given only in the context of HAART and not as monotherapy from 28 weeks. Only AZT should be used as monotherapy from 28 weeks as ARV prophylaxis for PMTCT.

Scenario 3: HIV infected pregnant women who do not qualify for HAART but present at ANC

HIV positive pregnant women, who are not yet eligible for HAART on the basis of their disease status, should be offered ARV prophylaxis for PMTCT. These regimens reduce the risk of MTCT by lowering the viral load in the mother and offering post exposure prophylaxis to the baby.

There are concerns of resistance developing from using single dose nevirapine, and to decrease this risk, dual NRTI medicines, ('tail') of AZT/3TC, should be given postpartum to both the mother and the baby for seven days. Nevirapine has a long half life, and serum levels persist for up to 21 days even after a single dose, leading to functional monotherapy. Giving a 'tail' of AZT/3TC for seven days will effectively deliver 'triple therapy' for a short period, suppress viral replication and decrease the risk of resistance developing. Giving a longer 'tail' may induce resistance to 3TC.

- Antepartum:** AZT 300mg BD from 28 weeks or as soon as possible thereafter
- Only pregnant women living with HIV with Hb >7g/dl will receive AZT
 - If the Hb ≤ 7g/dl, focus on identifying the cause of anaemia and treat. Then once Hb is corrected, AZT can be started
 - Women on the AZT regimen will be seen at the ANC clinic every two weeks and will receive their supply during these visits
 - Hb will be monitored at the clinic at each visit. If the Hb falls below 7g/dl, AZT will be stopped. *See Figure 3 below for guidance on use of AZT in ANC in HIV positive pregnant women with anaemia*
 - AZT tablets will be counted at each visit (pill count method)

Intrapartum: AZT 300mg/3TC 150mg + Single Dose NVP 200mg at the onset of labor. If AZT is contra-indicated, administer sdNVP alone

Postpartum: AZT 300mg/3TC 150mg BD for 7 days for the mother
If mother's Hb is ≤7g/dl before delivery then do not administer AZT/3TC postpartum

Single Dose NVP 2mg/kg at 12-72 hours and AZT 4mg/kg + 3TC 2mg/kg BD for 7 days to the infant.

N.B. Sd NVP should be given at the onset of labour, at least 2 hours or more before delivery.

Scenario 4: HIV infected pregnant women who present at maternity ward and have not received any ARVs during their pregnancy.

Intrapartum: AZT 300mg/3TC 150mg + sdNVP 200mg at the onset of labor

Postpartum: AZT 300mg/3TC 150mg BD for 7 days for the mother
If mother's Hb \leq 7g/dl before delivery, do not administer AZT/3TC postpartum

Infant: sdNVP 2mg/kg at 12-72 hours and AZT 4mg/kg + 3TC 2mg/kg BD for 7 days
If the mother received single dose NVP less than 2 hours before delivery, treat according to scenario 5 below.

Scenario 5: Infants born to HIV infected mothers who received no ARV medicines during pregnancy or labour

- Newborns who present less than 24 hrs of age should receive a stat dose of Nevirapine syrup (2mg/kg) and a second dose at 48-72 hrs. In addition, the infant should be given AZT 4mg/kg + 3TC 2mg/kg BD for 7 days
- Newborns who present more than 24 hrs of age but less than 72 hours of age should receive a single dose of NVP syrup (2mg/kg) plus AZT 4mg/kg/3TC 2mg/kg BD for 7 days
- Newborns who present more than 72 hours of age do not benefit from PMTCT prophylaxis and should not receive any ARVs

See table 6 on page 34 for infant doses of ARV medicines

HIV positive pregnant women with anaemia

Anaemia is common in pregnant women and may be due to HIV, malaria, TB, hookworm infestation, low dietary intake of iron or folate and haemorrhage. Haemoglobin should be checked routinely in ANC and if anaemia is present, the underlying cause should be treated. Routine iron and folate supplementation is recommended for all pregnant women. See figure 3 on use of AZT prophylaxis in pregnant women with anemia.

Figure 2: Algorithm for use of HAART or ARV prophylaxis for PMTCT

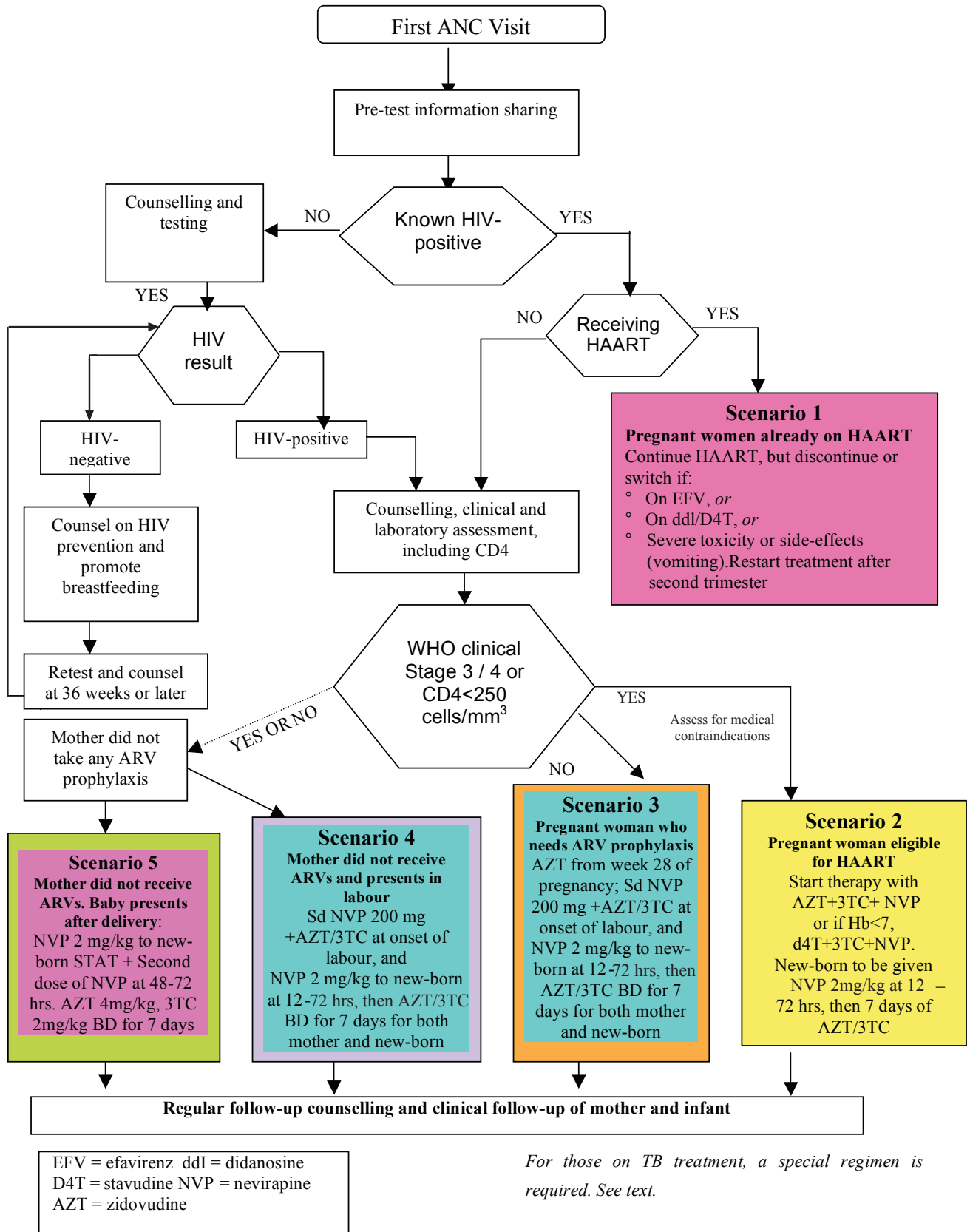
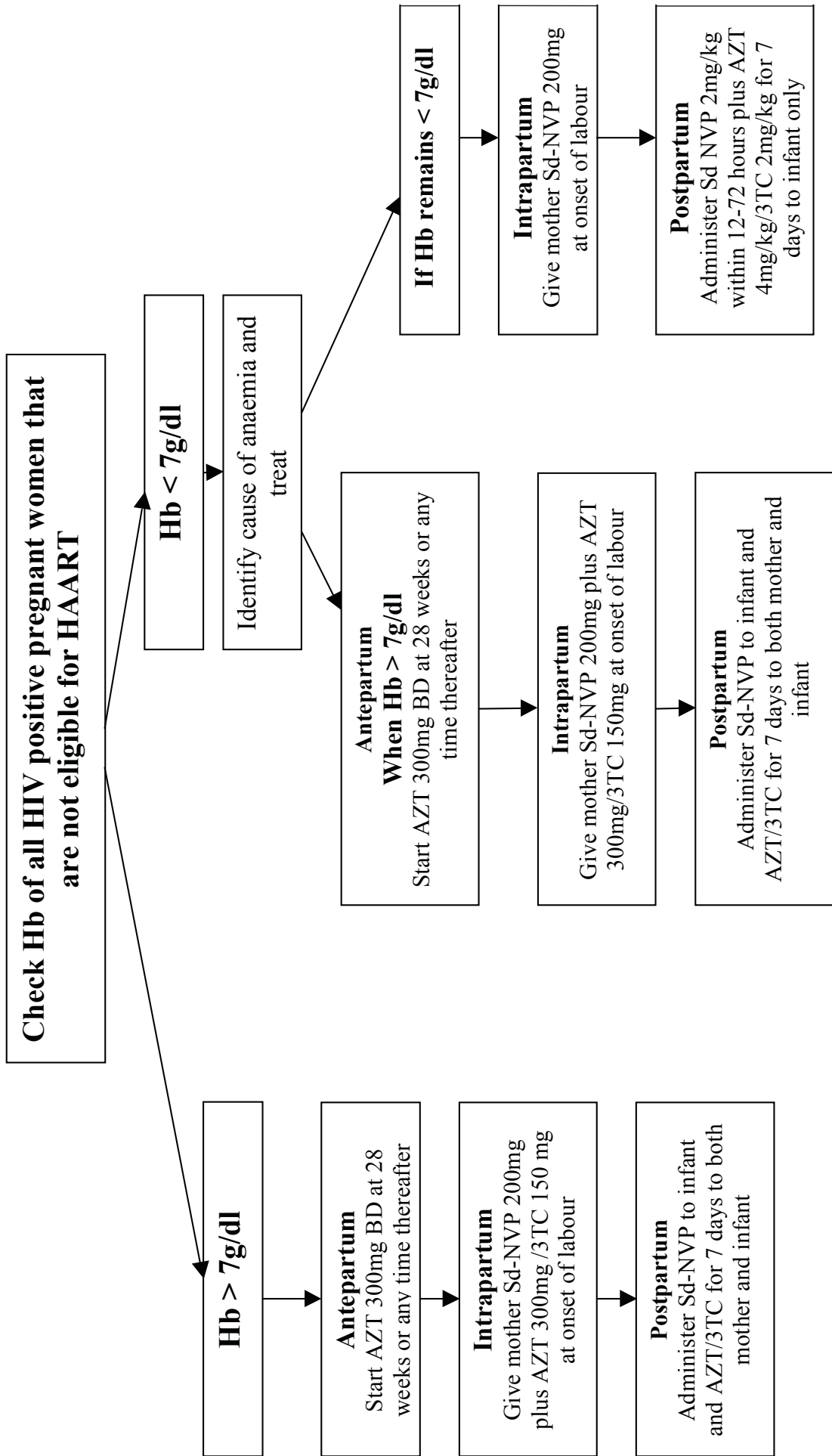


Figure 3: Algorithm for use of AZT in HIV Positive Pregnant Women Not Eligible for HAART



4.3 Clinical monitoring for pregnant women placed on HAART

4.3.1 Baseline clinical assessment

The baseline medical history should include

- Essential demographic characteristics
- Gestational age
- Past medical history including major illnesses, hospitalisations and surgeries
- Length of time since the diagnosis of HIV infection and if already on HAART
- Current medications
- Review of symptoms

The baseline physical examination should include: vital signs, weight, gestational age and height; and should detail any abnormalities of the:

- Eyes
- oropharynx
- lymph nodes
- lungs
- heart
- abdomen
- extremities
- nervous system
- genital tract

Once HAART has commenced, clinical monitoring must include follow-up visits at two, four, and six weeks after initiation and a minimum of every month thereafter for clinical and laboratory monitoring.

Patients should be assessed by a trained member of staff at every visit. At each visit the health worker must assess for adherence to treatment and any new symptoms that may be related to medicine side effects, HIV disease progression or opportunistic infections.

4.3.2 Clinical monitoring for toxicities and effectiveness of ARVs in pregnant women

Patients should be informed about the symptoms of ARV medicine side effects/toxicities and should be educated regarding the need to seek care. Clinical evaluation of the effectiveness of ART is important. The basic parameters examined and documented should include:

- ~ the patient's perception of how she is doing on therapy
- ~ changes in body weight over the course of therapy/pregnancy
- ~ signs of immune reconstitution syndrome
- ~ HIV-related disease progression
- ~ signs of medicine toxicities
- ~ decrease in symptoms of HIV disease and an improvement in the quality of life

For further information on monitoring patients on HAART refer to the current MoHSS Guidelines for Anti-Retroviral Therapy, 2nd Edition, April 2007

4.3.3 Baseline laboratory assessment

Baseline laboratory assessment for confirmed HIV infected pregnant women prior to starting ARV therapy:

- CD4 count
- FBC
- RPR
- HBs Ag
- ALT
- Creatinine

Refer to Appendix III for the detailed schedule of Laboratory tests to be performed for each different HAART regimen.

4.4 Management of HIV positive pregnant women with concurrent diseases

4.4.1 Pregnant HIV positive women with active Tuberculosis

The major problems with giving TB and HAART medicines together are the high number of interactions and side effects from the medicines, as well as the very high pill burden. Pregnant women with TB disease should, if possible, complete their TB treatment prior to beginning HAART. The optimum time to start HAART will depend on CD4 cell count, tolerance of TB treatment and other clinical factors.

Table.4: Management of TB in HIV positive Patients

HIV/TB Disease Assessment	Management
CD4 >350cells/mm ³	<ul style="list-style-type: none"> Treat TB Monitor CD4 counts and reassess need for HAART after completion of TB treatment.
CD4 200-350 cells/mm ³ or Pulmonary TB	<ul style="list-style-type: none"> Treat TB Postpone HAART until after TB treatment
CD4 50-200 cells/mm ³ or extra-pulmonary TB	<ul style="list-style-type: none"> Start TB treatment Start HAART after 2 months of TB therapy If in 2nd trimester of pregnancy, use AZT/3TC + efavirenz If in 1st trimester, consider a triple NRTI regimen such as AZT/3TC + ABC. Consult a specialist.
CD4 <50 cells/mm ³	<ul style="list-style-type: none"> Start TB therapy. Evaluate at 2 weeks, Start HAART as soon as TB therapy is tolerated If in 2nd trimester of pregnancy use, AZT/3TC + efavirenz If in 1st trimester, consider a triple NRTI regimen such as AZT/3TC + ABC. Consult a specialist.

The recommendations for ARV prophylaxis for PMTCT should apply to women with TB/HIV co-infection who are not yet on HAART.

4.4.2 Hepatitis B Virus (HBV)

There is a high prevalence of HBV coinfection among Namibians with HIV. Among patients on HAART, liver disease is one of the most common complications due to hepatotoxicity of many HAART regimens as well as accelerated liver damage following immune reconstitution.

4.4.2.1 ARV medicines to use with HBV/HIV co-infection

Lamivudine and tenofovir have antiviral effect on HBV. Using these medicines together as part of a triple HAART regimen reduces the chance of the hepatitis virus developing resistance. The use of tenofovir is generally not recommended in pregnancy due to the risk of bone demineralization in the foetus. However, if a pregnant woman is already on a TDF/3TC based regimen, it is preferred that she continues this regimen, to prevent flaring up of HBV during pregnancy. Among the NNRTIs, efavirenz is the best tolerated in patients with HBV.

If in 1st trimester

First line: AZT/3TC/ABC

Alternative if patient cannot tolerate ABC due to hypersensitivity: use AZT/3TC/LPV/r provided ALT is less than 3 times the Upper Limit of Normal (ULN) and there is no clinical evidence of active hepatitis.

If the woman is still in the first trimester, cannot tolerate ABC, and has active hepatitis or ALT > 3 x ULN then consult with the specialist.

After 1st Trimester:

First Line: AZT/3TC/Efavirenz

4.4.3 Renal Failure

In patients with renal failure, dosages need to be adjusted for some medicines on the basis of creatinine clearance.

Table 5: Use of ARVs in patients with Renal Failure

No Dose Adjustment Needed	Dose Adjustment Needed
Abacavir	Lamivudine
Efavirenz	Didanosine
Nevirapine	Stavudine
Indinavir	Tenofovir
Lopinavir/ritonavir	Zidovudine
Nelfinavir	
Ritonavir	

Consult with a specialist physician before starting HAART in a patient with renal failure or when renal failure develops in a patient on HAART. Tenofovir can cause Fanconi Syndrome. This is asymptomatic and can be monitored by checking for proteinuria and elevated creatinine.

4.5 Specialist referral

In the following circumstances, consult a specialist:

- Failure of first line therapy
- Discordant couples considering having children
- Combined pathologies (hepatitis, renal failure, diabetes, neoplasia, etc.)
- Severe medicine toxicities
- Pregnant women receiving any other regimen than the recommended ones

4.6. Clinical management of the HIV-exposed newborn

4.6.1 Use of ARVs for PMTCT in Newborns

The newborn of an HIV-infected mother should receive single-dose Nevirapine 2 mg/kg between 12-72 hours after delivery if mother has received Nevirapine at least 2 hours before delivery. In addition, the baby will receive a tail of AZT/3TC BD for 7 days.

If an HIV-infected mother has not received Nevirapine more than two hours before delivery and the newborn presents at the health facility:

- less than 24 hours of age: the newborn should receive a stat dose of Nevirapine syrup and a second dose at 48-72 hours. In addition the infant should be given AZT/3TC for 7 days (AZT 4 mg/kg + 3TC 2 mg/kg every 12 hours).
- more than 24 hours of age but less than 72 hours of age: the newborn should receive Sd NVP (2mg/kg) plus AZT/3TC for 7 days (AZT 4mg/kg + 3TC 2mg/kg every 12 hours).
- more than 72 hours of age: the newborn will not benefit from PMTCT prophylaxis and should not receive any ARVs.

Table 6: Dosages of ARV suspension

WEIGHT	AZT (4MG/KG)	AZT SUSPENSION (10MG/ML)	3TC (2MG/KG)	3TC SUSPENSION (10MG/ML)	NVP (2MG/KG)	NVP SUSPENSION (10 MG/ML)
<1.5kg	6mg	0.6ml	3mg	0.3ml	3mg	0.3 ml
<2kg	8mg	0.8ml	4mg	0.4ml	4mg	0.4ml
2-3kg	8-12mg	0.8-1.2ml	4-6mg	0.4-0.6ml	4-6mg	0.6ml
3-4kg	12-16mg	1.2-1.6ml	6-8mg	0.6-0.8ml	6-8mg	0,8ml

Chapter 5: Management of the HIV-exposed infant

5.1 Immediate care and management of the newborn

- All babies should be handled with gloves, wiped with towel or surgical cloth and washed with water and gentle soap.
- Avoid suction in most newborns. If suction is required do it gently and use a mechanical suction unit (at a pressure below 100mmHg) or bulb suction.
- Cut the cord under the cover of lightly wrapped gauze.
- All babies, irrespective of their HIV status, should be kept warm after delivery.
- Skin to skin (chest to chest) contact between the mother and the baby should be established immediately after birth, even if the mother is not intending to breastfeed.
- Infant should receive 1% tetracycline eye ointment as prophylaxis against ophthalmia neonatorum.
- Vitamin K, BCG and polio immunisation should be given according to the recommendations for all newborns. *Injections should be given only after bathing.*
- Assessment of the newborn, including the measurement of the birth weight, length and head circumference should be done routinely.
- Where mothers are AFB sputum positive (have active TB and are on treatment), BCG vaccine should NOT be given to infants until they have completed 6 months of INH prophylaxis.
- Infants of mothers who are Hepatitis B surface Antigen positive (HBsAg) must receive Hepatitis B immunoglobulin and Hepatitis B vaccination within 12 hours of birth.
- Breastfeeding should commence at once if the mother has decided to breastfeed.
- As soon as possible after birth, show breastfeeding mothers correct positioning and attachment.
- Ensure that breastfeeding is on demand; rooming-in and night feeds must be practiced.
- If there is a problem with breastfeeding then the mother should stay in maternity ward until the problem is resolved.
- Advise mothers who opt for breast-feeding on the importance of exclusive breast feeding and the risks of mixed feeding.
- Reinforce need to exclusively breastfeed for 4 months followed by abrupt weaning, if breastfeeding option is chosen.
- Show mothers who are not breastfeeding how to prepare replacement feeding of their choice in private.
- Teach and show mothers how to express and feed breast milk or replacement milk by cup.
- Teach mothers about the dangers of using bottles, artificial teats, dummies and cups with spouts.

5.2 Infant feeding options

Health workers should continue to *protect, promote and support* breastfeeding as the best method of infant feeding. After birth the infant can still be infected with HIV through breastmilk. However evidence from studies in South Africa and other countries have shown that exclusive breastfeeding for four months with early cessation does not pose a significant risk of transmission of HIV.

5.2.1 Feeding recommendations for HIV negative women and women who do not know their status

The recommendation for HIV negative women and for those with unknown HIV status is to exclusively breastfeed for the first six months, and to continue breastfeeding to two years and beyond with introduction of adequate complementary foods from six months and optimal feeding for children up to five years. Health workers should assist mothers with appropriate breastfeeding techniques, the management of breastfeeding problems and discuss safer sex practices during the period of breastfeeding.

5.2.2 Feeding recommendations for HIV-positive women

Breastfeeding is normally the best way to feed an infant. Even if the mother is HIV positive she could still breastfeed exclusively for the first four months with early cessation. HIV infected women who choose not to breastfeed should be counselled on safe alternatives to breast milk. The risk of morbidity and mortality from giving replacement feeding in that context should be less than the potential risk of HIV transmission through infected breast milk.

Guidelines for the Prevention of Mother-to-Child Transmission of HIV

Following HIV counselling and testing and acceptance of an HIV positive result, the mother/couple should be counselled to choose one of the following feeding options as stated in the infant feeding policy:

- Exclusive breastfeeding for the first four months and early cessation, followed by replacement feeding.
- The mother should continue to exclusively breastfeed up to six months if replacement feeding is not acceptable, feasible, affordable, safe and sustainable (AFASS) at four months
- Exclusive replacement feeding using infant formula or modified cow's/goat's milk where they are acceptable, feasible, affordable, safe and sustainable in the home and community

There are risks such as diarrhoea, dehydration, respiratory and ear infections, malnutrition and death associated with using replacement milk in all situations. These are enhanced when conditions for giving replacement milk are not acceptable, feasible, affordable, safe and sustainable (AFASS).

If the mother is not able to breastfeed for any medical reason such as advanced HIV disease, severe pulmonary TB and breast cancer or if the baby is an orphan, formula milk should be prescribed until the infant is six months old. NB HIV positive status by itself is not a sufficient reason for which formula should be prescribed.

5.2.3 Exclusive replacement feeding

Replacement feeding is an option for feeding infants of HIV-positive mothers if it is acceptable, feasible, affordable, safe and sustainable. Even if there is no risk of postnatal HIV transmission to the infant with exclusive replacement feeding studies have shown no survival advantage in infants who are exclusively replacement fed versus those who are exclusively breastfed.

Infant formula is already modified to meet the infant's nutritional needs while cow's and goat's milk need to be modified for the first 6 months. The baby on exclusive replacement feeding also needs additional water and daily multivitamin and mineral supplements.

Always use a cup to feed the baby on replacement feeding. Avoid bottles, teats and dummies.

Important considerations before choosing replacement feeding

Acceptability: There are no social or cultural barriers to choosing replacement feeding and no fear of stigma or discrimination.

Feasibility: Breast-milk substitute can be correctly prepared by the mother or caregiver with adequate time, knowledge, skills, resources and support to feed the infant 8-12 times per 24 hours.

Affordability: After considering the cost for acquiring ingredients, fuel, clean water and necessary medical expenses resulting from unsafe preparation and feeding practices, the mother or caregiver is able to pay for procurement, preparation, storage and use of replacement milk. Costs involved with replacement feeding should not compromise the health and nutrition of the baby or the family.

Safety: The mother or caregiver acknowledges that replacement foods can be correctly and hygienically stored, prepared and fed to the infant. Hygiene includes using clean hands, cups and other utensils and not using bottles or teats, which are prone to bacterial contamination.

Sustainability: Availability of a continuous and uninterrupted supply of all ingredients and products needed for safe replacement feeding, for as long as the infant needs it, up to one year of age or longer. According to this concept, there is little risk that the formula will ever be unavailable or inaccessible.

The above five criteria are also known as the AFASS criteria.

NB: The mother should be advised on the following:

Exclusive replacement feeding is more difficult than exclusive breastfeeding. Therefore mothers should be counselled:

Guidelines for the Prevention of Mother-to-Child Transmission of HIV

- On the dangers of mixed feeding
- To hold baby during feeding and talk to him/her during feeding to promote bonding
- Not to store prepared feed in a thermos, flask/bottle, because this will help bacteria to multiply
- To always check the expiry date on the tin
- To store infant formula in a cool and dry place
- About the dangers of diarrhoea and how to treat dehydration with ORS

Modified cow's and goat's milk

Modified animal milk is another infant feeding option. In Namibia, fresh cow's and goat's milk may not always be available all year round. Fresh cow's or goat's milk is available in shops and supermarkets, and milk directly from the animal may be used. Modification of animal milk is more complicated than preparation of infant formula, which is already modified. The baby should also be given multi-vitamin and mineral supplements (including iron) to prevent micronutrient deficiency. After six months the baby can be given unmodified animal milk. See Appendix vii.

How to feed an infant by cup

Counsel the mother to:

- o Hold the infant sitting upright or semi-upright on her lap
- o Hold a small cup of milk to the infant's lips. The cup should rest lightly on the infant's lower lip and the edges of the cup should touch the outer part of the infant's upper lip
- o Tip the cup so that the milk just reaches the infant's lips. The infant becomes alert and opens his or her mouth and eyes
- o A low birth weight infant starts to take the milk into his or her mouth with the tongue
- o A full term or older infant sucks the milk and may spill some of it
- o DO NOT POUR the milk into the infant's mouth. Just hold the cup to his or her lips and let him take it himself
- o When the infant has had enough, he closes his mouth and will not take any more. If he has not taken the calculated amount, he may take more at the next feed or the mother may need to feed him more often
- o Measure intake over 24 hours – not just at each feed
- o Talk to the baby and look into his/her eyes to show love and care

5.2.4. Exclusive breastfeeding for four months with early cessation

An HIV positive mother may choose to breastfeed her baby if she considers it to be the best way of feeding. If the mother chooses to breastfeed, she should be educated about exclusive breastfeeding prior to delivery, and be provided with support and encouragement.

Giving the baby any drinks, water or foods other than breast milk and use of pacifiers or dummies or artificial teats interferes with exclusive breastfeeding. In addition, it may cause gut infection and irritation that will make the baby more susceptible to HIV transmission and other infections.

How to help mothers achieve abrupt stopping (or early cessation) of breastfeeding

Stopping breastfeeding early reduces the risk of transmission of HIV by reducing the length of time the infant is exposed to the virus in breast milk.

Before a mother stops breastfeeding abruptly, she needs counselling about replacement feeding and support for her decision, as described in replacement feeding section. The health worker should show the mother how to prevent breast engorgement and how to transition from exclusive breastfeeding to replacement feeding.

How to help the mother's milk production stop without engorgement

Breast milk production is controlled by hormones secreted centrally as well as locally in the breast itself. If excess milk is left in the breast the Feedback Inhibitor of Lactation (FIL) stops the cells from secreting more milk and this helps protect the breast from being too full. Natural drying up of the milk takes a week or more; therefore, the mother needs to express just enough milk to keep her breasts

comfortable and healthy during this process. Stopping breastfeeding quickly can lead to engorgement, mastitis and, if left untreated, breast abscess formation.

Teach the mother to:

- Support the breast with a well supporting bra or a cloth to make her more comfortable
- Apply warm or cold compresses (whichever is more comfortable for her) to reduce swelling
- Express just enough milk to relieve discomfort. Be sure to stress that too much milk expression may stimulate milk production
- Prescribe an analgesic, such as ibuprofen or paracetamol to relieve the pain
- Pharmacological treatments such as stilboesterol, bromocriptine (Parlodol) and cabergoline that reduce milk supply have a limited role to play.

How to feed and care for a baby who is stopping breastfeeding

To abruptly stop breastfeeding can be very traumatic for the baby and the mother. The ideal way is to do it gradually but this may result in mixed feeding, which should be avoided.

The health worker should therefore teach the mother to:

- **Not mix breast milk and replacement milk.**
- Begin the transition by expressing breast milk and providing feeding by cup between regular feeds for the baby to get used to cup feeding
- Replace breastfeeding with cup feedings of expressed breast milk one feed at a time
- Once the baby has accepted all feeds of expressed breast milk with a cup, switch to exclusive replacement feedings by cup
- As the infant may seek comfort, mothers should be advised on alternative methods to comfort the baby, such as massaging, swaddling, carrying, rocking, singing, sleeping with and talking to the baby. Re-initiating lactation and resuming breast feeding should be discouraged as it increases the risk of HIV transmission.

5.2.5 If the mother has difficulty stopping at 4 months

If replacement feeding is not acceptable, feasible, affordable, safe or sustainable at 4 months, mothers should be advised to continue exclusive breastfeeding up to 6 months or until replacement feeding is feasible and safe. At 6 months, the infant can take unmodified animal milk with complementary foods.

5.2.6 Compliance with Exclusive Feeding Options and Dangers of Mixed Feeding

Important considerations for health workers:

- HIV transmission to the infant is higher with mixed feeding than with exclusive breastfeeding
- The introduction of any foods or liquids, even water, while the baby is taking breast milk can disrupt the developing gastrointestinal (GI) tract
- The irritation to the GI tract increases permeability, which allows foreign particles, including HIV, to pass through to the blood.
- Exclusive breastfeeding helps to maintain a healthy GI tract, which can then act as a protective barrier to infectious agents.

5.2.7 Introducing complementary feeding from 6 months

Health workers should counsel mothers to introduce solid foods at 6 months for both breastfed and replacement fed babies regardless of HIV exposure. The first food to be introduced is the household staple energy food. The consistency and frequency of solid food is very important. The food should be energy rich, i.e. prepared with cereal and enriched with oil, peanut butter, milk, eggs or beans. Increase the amount, consistency and frequency up to 5 times per day by 1 year of age.

5.2.8. Infant feeding considerations with DNA PCR testing

Counselling on infant feeding options prior to testing an infant using HIV DNA PCR should be given during pre-test counselling sessions to provide the mother/couple time to consider feasible and acceptable feeding options based on either test result. According to the algorithm for DNA PCR test below, both a negative or positive result requires further assessment to ensure the infant receives optimal nutrition.

Guidelines for the Prevention of Mother-to-Child Transmission of HIV

During pre-test counselling, discuss potential infant feeding choices based on test result:

- Negative result:
 - If breastfeeding, the baby is still at risk of being infected with HIV through breast milk. If replacement feeding still does not meet the AFASS criteria, counsel the mother to continue exclusive breastfeeding until replacement feeding is AFASS.
 - If replacement feeding, check that formula or milk is prepared correctly and enquire if the mother has a steady supply of replacement milk for the baby, at least until the baby is one year old. It is critical to stress that the mother gives NO breast milk at any time while she is giving replacement feeding to the baby.
- Positive result:
 - If breastfeeding, stress to continue giving only breast milk without any other foods, liquids or water until the baby is 6 months and then introduce adequate complementary foods with continued breastfeeding up to 2 years or beyond. The mother must continue safer sex practices to prevent her own re-infection, which could then be passed to the infant. Continued breastfeeding for the HIV-infected infant will help the infant stay healthy longer.
 - If replacement feeding, ensure that feeds are prepared correctly and that mother has a steady supply of replacement milk, until the baby is at least one year old.

5.3 PMTCT follow up of the mother-baby pair

- The first follow up is at 6 weeks for both mother and baby. At this time, the baby will undergo the HIV DNA PCR test and will be commenced on Cotrimoxazole prophylaxis.
- After that, the follow up dates are scheduled monthly.
- At each of the follow up visits, health workers should:
 - Assess the feeding option and assist
 - Stress the dangers of mixed feeding
 - Immunise the child
 - Monitor the growth of the child (weighing and plotting the weight on the child's health card)
 - Continue cotrimoxazole preventive therapy until infant is proven HIV negative
 - The infant on modified animal milk should receive multivitamin/mineral syrup
 - The mother/partner should be linked to the ART clinic

5.3.1 Prophylaxis for Opportunistic Infections

All HIV exposed infants should be seen at the first scheduled immunisation visit at 6 weeks and be offered the HIV DNA PCR test. Then monthly visits should be scheduled until HIV infection is excluded (refer the baby for regular child health interventions). If HIV positive, the infant should be referred to an ART site to start HAART.

Pneumocystis jiroveci (carinii) pneumonia (PCP) is the leading cause of HIV related mortality in infants. Co-trimoxazole prophylaxis and multivitamins should be started for all HIV exposed infants from 6 weeks. The child should be followed up monthly and evaluated for treatment, if HIV infected. Once the infant is confirmed HIV negative on DNA PCR, co-trimoxazole prophylaxis should be discontinued.

Table 7: Recommended doses of co-trimoxazole for PCP prophylaxis

Age	Co-trimoxazole dosage
Six weeks to five months	2.5 ml once daily
Six months to six years	5 ml once daily

Isoniazid Prophylaxis (IPT)

All children under 5 years of age, who are exposed to a TB patient that has a positive AFB sputum smear are eligible for Isoniazid preventive therapy (TB-IPT); Isoniazid 5mg/kg/day for 6 months. Active TB disease should be excluded first. This is especially important for all HIV-exposed and infected children.

For the management of ARV prophylaxis for PMTCT in HIV exposed infants, see chapter 4.

5.4 Diagnosis of HIV infection in children

5.4.1 Early infant diagnosis of HIV using diagnostic DNA PCR testing

As a result of the programme for the prevention of mother-to-child transmission (PMTCT), a large number of HIV-exposed infants are being identified who require HIV diagnosis and follow-up care. It is important to identify young infants with HIV infection early and to refer them for ART because of the high mortality from untreated HIV/AIDS. It is also important to promptly identify young infants who are not HIV-infected in order to reassure their parent(s), discharge them from costly follow-up, and measure the overall effectiveness of the PMTCT programme.

The polymerase chain reaction (PCR) test can reliably and accurately detect HIV DNA on a dried blood spot (DBS) specimen at an early age. This test detects the genetic material of HIV instead of anti-HIV antibodies, and therefore is not affected by the transplacental transfer of maternal anti-HIV antibodies, unlike the standard HIV serologic tests. If the PCR test is positive, then it means that the child is truly HIV-infected. If the PCR test is negative and there has been no breastfeeding for the previous 2 months, then it means that the child is truly HIV-negative. The algorithm for diagnostic DNA PCR testing is summarised in Figure 4.

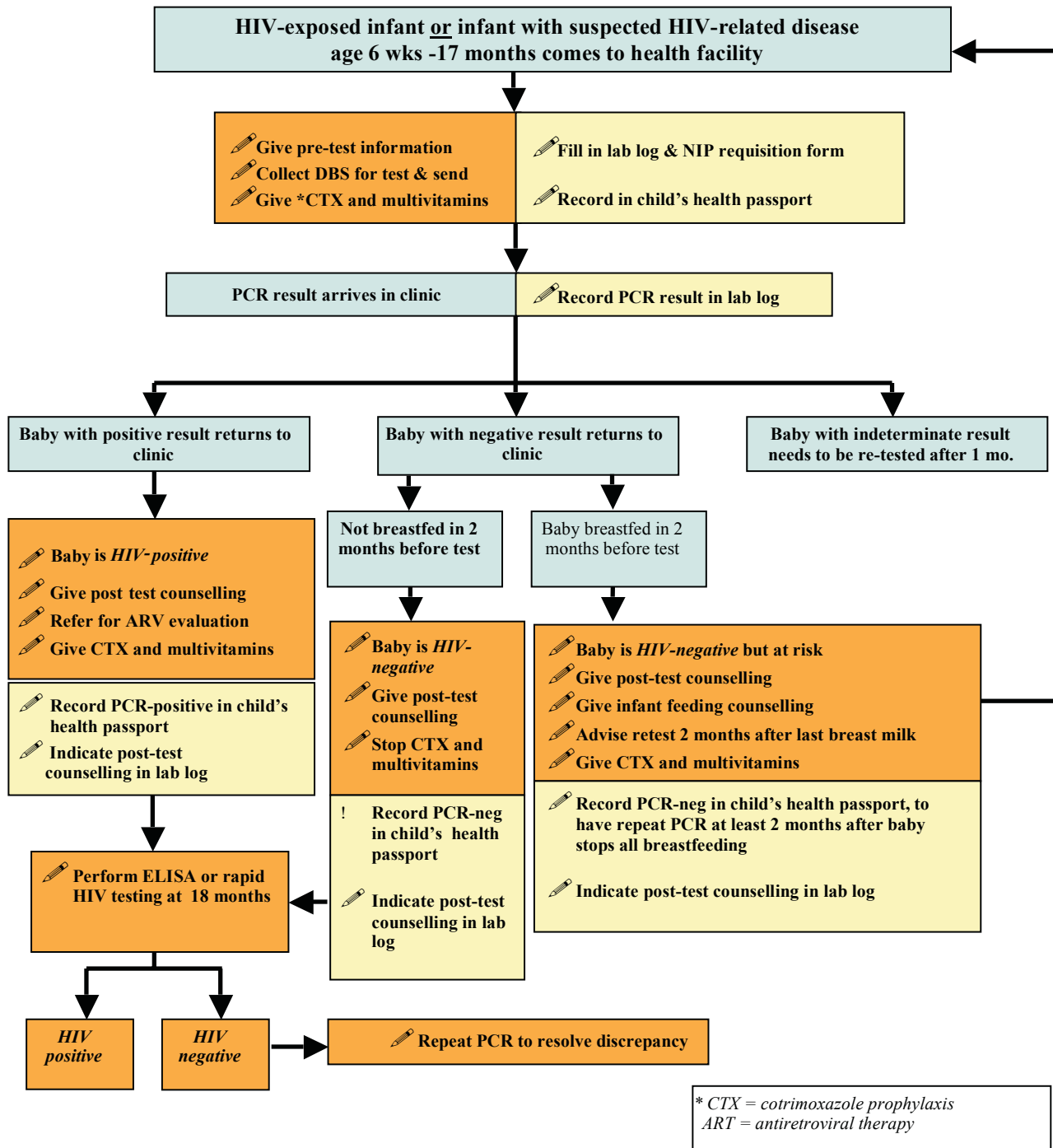
Parent(s) can be counselled and the infant managed as being HIV-positive if:

- HIV ELISA or rapid testing is positive at ≥ 18 months, regardless of symptoms, *or*
- HIV ELISA or rapid testing is positive at an earlier age, e.g. 12 months, and there are signs and symptoms suggestive of HIV/AIDS. The child still needs to be re-tested at 18 months to reconfirm their HIV status, *or*
- Diagnostic DNA PCR testing is positive at any age
- Infants who test positive by PCR, ELISA, or rapid test at an early age should be evaluated for ART as soon as possible due to the high mortality rate if treatment is delayed.
- It is recommended that children who test positive by ELISA, rapid test, or DNA PCR before 18 months of age should have ELISA or rapid testing repeated at 18 months of age.

The parent(s) can be counselled that their child is HIV-negative and the child discharged from HIV follow-up if:

- HIV ELISA or rapid test is negative at age 12 months or later and the child has not been breastfed in the preceding 3 months, *or*
- Diagnostic DNA PCR test is negative and the child has not been breastfed for the preceding 2 months.
- Until further notice, children who test negative by ELISA, rapid test, or DNA PCR test should repeat ELISA or rapid test at 18 months of age, to reconfirm their HIV status.

Figure 4: Ministry of Health and Social Services Algorithm for Early Infant Diagnosis of HIV infection Using DNA PCR



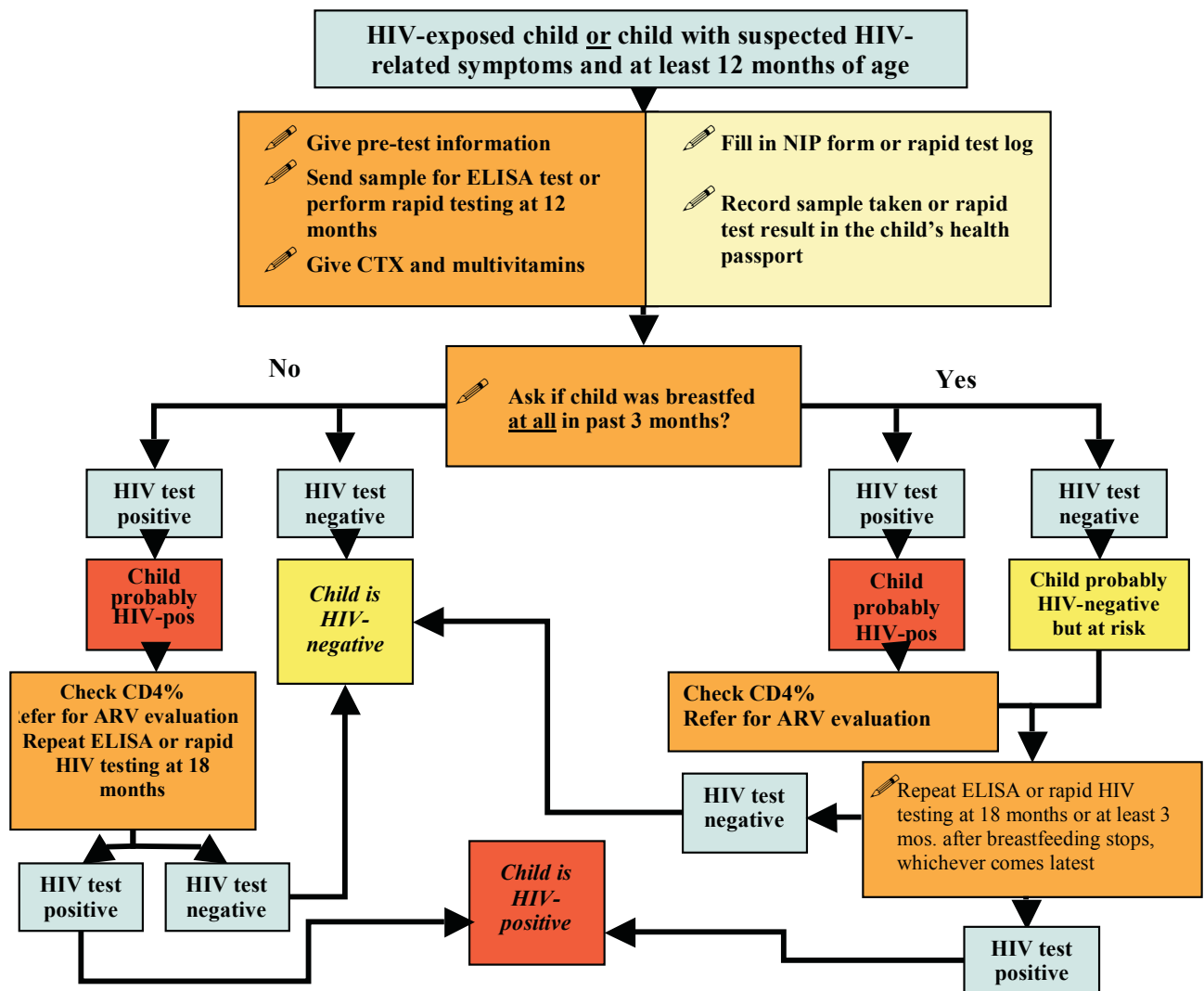
5.4.2 ELISA or rapid HIV testing

As with adults, either ELISA (enzyme-linked immunosorbent assay) or rapid HIV testing can be used in children – however, passively transferred maternal HIV antibodies may persist for up to 18 months. Therefore, to establish a definitive serological diagnosis of HIV infection in a child the test should be repeated at the age of 18 months. Children > 18 months old who have had prolonged breastfeeding would need to have a negative HIV test result at least 3 months after breastfeeding is discontinued to exclude HIV infection.

The algorithm for HIV diagnosis using ELISA or rapid testing is outlined in Figure 5. In summary: using either ELISA or rapid HIV testing at 12 months of age or older, diagnosis of HIV infection may be excluded if the child's test is negative and there has been no breastfeeding in the past 3 months. If the child tests positive before 18 months, the test needs to be repeated at 18 months to exclude the possibility of persisting maternal antibodies. With the availability of HIV DNA PCR testing, the same child should have the status confirmed as early as possible. If ELISA or rapid testing is negative at 18 months, then the child is HIV-negative provided there has been

no breastfeeding in the last 3 months. ELISA or rapid HIV testing is also the recommended testing approach for the diagnosis of, or exclusion of, HIV infection in children older than 18 months.

Figure 5: Ministry of Health and Social Services algorithm for diagnosis of HIV infection in children using ELISA or rapid testing



Chapter 6: Programme management of PMTCT

6.1 Organisation and coordination

6.1.1 Levels of programme management

National level

At national level the PMTCT programme is located in the Family Health Division within the Directorate for Primary Health Care (PHC) Services. PMTCT is part of the Reproductive Health Programme. PMTCT activities are integrated into the Safe Motherhood and Newborn care section.

At national level the Technical Advisory Committee (TAC) provides technical advice to MOHSS on matters related to HIV/AIDS policies and guidelines. The Committee on Patient Care and Disease Management (MCPDM) is responsible for overseeing and coordinating the management of HIV/AIDS, TB and Malaria programmes in the country.

Regional level

At regional level the management of the PMTCT programme falls under the SHPA for Family Health. The MoHSS Regional Directorates and multi-sectoral Regional AIDS Coordinating Committees (RACOCs) are responsible for overall monitoring, guidance and support for the implementation of these programmes in a specific region

District level

The overall management of the PMTCT programme within a health district is the responsibility of the District Coordinating Committee (DCC). The DCC is responsible for planning the rollout of PMTCT services in the district. The DCC is tasked with identifying the health and social needs of the local communities and devising solutions to meet their needs. They are also responsible for planning of the health and social welfare services in their respective districts and regions. The District PHC Supervisor is responsible for supervising and supporting staff that provides PMTCT services in health facilities.

Operational level

At this level the nurse in charge of the facility oversees the provision of PMTCT services as well as ordering and control of ARV stock. She is also responsible for submitting monthly reports to the district office. Operational links between PMTCT services with welfare organizations and CBOs are important to provide post-partum care and support for mothers with HIV and their children.

6.2 Prerequisites for successful implementation

Successful implementation of the PMTCT program requires participation and collaboration of different stakeholders and programmes, especially Tuberculosis Control, ART, STI, Family Planning and Nutrition. In order for this programme to be successful, the following needs to be in place:

- Adequate number of health workers trained in PMTCT and VCT
- Availability of community counsellors, especially in high burden PMTCT sites
- Availability of HIV testing and counselling services, especially rapid testing
- Availability of ARVs for PMTCT prophylaxis
- Linkages with ART clinics and community support groups
- Regular technical supervision by programme managers at national, regional and district level, as well as by PMTCT Trainers

Human Resources

PMTCT is integrated into routine ANC care and should be provided by all nurses. Due to the increase in workload and clinical responsibilities that this entails, the MoHSS has introduced community counsellors to assist with counselling and rapid testing.

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Comprehensive PMTCT services require a multidisciplinary team that includes clinic nurses, midwives, counselors, social workers, pharmaceutical, obstetric and paediatric nursing staff and doctors complementing each other.

Training and human capacity development is critical for the development of adequate staff competencies, morale and motivation. Formal classroom-based training needs to be complemented with more on-site, and in-service training with a focus on skills development, local problem solving and on changing attitudes towards HIV.

Physical infrastructure

Health facilities should ensure adequate space and privacy to provide comprehensive PMTCT services, including space for rapid HIV testing and schedule 5/6 lockable cabinets for stocking ARV medicines.

6.3 Integration of PMTCT services into the outreach services

Outreach services provide a great opportunity to increase PMTCT coverage in the country and to reach remote communities. It is therefore important to integrate PMTCT into outreach services. Outreach services for VCT and PMTCT should be carried out at fixed points in the community. The following PMTCT services should be provided during outreach visits:

- Registration and history taking
- Measurement of all the baseline parameters
- Physical examination
- Review and clarification of issues discussed during the group information session
- Routine HIV testing and counselling of ANC clients
- Conduct rapid HIV test when available and if client agrees
- Draw blood for routine investigations (Rh, Hb, RPR etc) and include HIV test for ELISA if rapid test is not available
- Provide routine supplements (i.e. iron, folic acid and multivitamin)

6.4 Stock management of ARVs at clinics and health centres

6.4.1 Pre-requisites to stocking ARV medicines for PMTCT

Stock levels

The district pharmacy and district managers, together with the regional pharmacist, should determine stock levels of ARVs for PMTCT for each health facility. Maximum supply of 3 months and a minimum supply of 2 months should be stocked at the health facility based on the expected number of HIV positive pregnant women.

Schedule 7 registers for recording ARV stock

All receipts and issues of ARVs should be recorded in this book and a current running balance of stock on hand should be kept at all times. A separate page should be kept for each different ARV medicine.

Monthly reports must be submitted to the PHC supervisor and pharmaceutical services.

This monthly report will assist in determining appropriate stock levels of ARV medicines on an ongoing basis.

6.4.2. Ordering ARVs from District Pharmacy

- The officer in charge of the health facility will be responsible for ordering ARVs from the district pharmacy. Orders will be based on current stock levels and the agreed minimum and maximum stock levels.
- The pharmacy will also have records of what the agreed minimum and maximum stock levels should be for each item in each clinic.
- All orders for ARVs from clinics and health centres must be signed for by the officer in charge of the facility.
- All issues of ARVs from the district pharmacy must be recorded in their stock records, and the ARVs dispatched to the ordering facility together with documentation giving details of items ordered and supplied.

6.4.3. Receiving ARVs from District Pharmacy

As soon as stock of ARVs is received from the district pharmacy, the stock should be counted and placed in the lockable cabinet. The receipt must be recorded in the schedule 7 register and the new balance of stock on hand reflected.

6.4.4. Record Keeping for ARVs

Each issue of AZT, NVP or AZT/3TC must be immediately recorded in the appropriate page of the schedule 7 register. At the same time the balance of stock on hand should be adjusted and this should tally with the physical stock on hand in the lockable cabinet.

6.4.5. Supervision of ARV stock and records

Stock balances, record keeping as well as implementation of the PMTCT programme in general should be supervised by the PHC supervisor at least once a month.

The monthly PMTCT report should be scrutinised by the pharmacy to ensure that the appropriate ARV stock levels are being kept in each health facility

Once every three months, a member of the District pharmacy staff should supervise storage and record keeping and appropriate stock levels of the ARVs.

6.5 Promotion of PMTCT through communication strategies

Communication is a key component to empower individuals and communities to support behaviour change including the utilization of PMTCT services. Communication plays a vital role in increasing knowledge of mother to child transmission (MTCT) of HIV. Therefore, there is need to provide adequate information to women/families on safe pregnancy, delivery and newborn/infant care and to promote access to key services. There is also need to address beliefs and harmful community practices which place women at risk and affect their access to information, services and support.

Communication operates through three main strategies:

Programme communication (behaviour change communication) for changes in knowledge, attitude and practices of specific key social groups. Activities focus on strengthening programmes for women, their male partners, families and peers by developing their skills and confidence to challenge harmful practices. Health workers should use interpersonal communication and counselling skills to support women and their male partners. PMTCT and HIV messages should be disseminated through Maternal and Child Health services, including Family Planning, ANC, PNC, and Under 5 clinics.

Social mobilisation is important for wider participation and to generate ownership of PMTCT by community leaders and groups of people. Activities include raising awareness through campaigns or establishing support groups or strengthening links between groups. It is done through the use of community networks to encourage community support and action.

Advocacy is geared towards obtaining political will and community leadership commitment for PMTCT. Activities focus on developing new policies or laws to protect vulnerable individuals or increase their access to services. It may also include sourcing support from politicians and policy makers.

6.6 Monitoring, evaluation and reporting

6.6.1 Supportive supervision

Supervisors and PMTCT trainers at national, regional and district levels should provide regular supportive supervision to front-line staff. This will ensure provision of quality PMTCT services, boost staff morale and help prevent staff burn-out.

6.6.2 Monitoring and evaluation (M&E)

Monitoring means tracking the key elements of programme performance (inputs, activities and results) on a regular basis. Evaluation is the periodic assessment of the change in targeted results that can be attributed to the programme intervention; or the analysis of inputs and activities to determine their contribution to results. Monitoring and evaluation helps programme implementers to:

- Determine the extent to which the programme is reaching its targets
- Take timely corrective measures
- Make informed decisions regarding operations management and service delivery
- Ensure the most effective and efficient use of resources
- Evaluate the overall programme impact

6.6.3 PMTCT programme indicators

The indicators in the UNGASS M&E and the National Strategic Plan on HIV/AIDS in Namibia framework will help in monitoring progress. The following indicators can be used at national, regional and district levels, while some of them can also be used at facility level:

- Number and % of health facilities providing ANC services out of total number of health facilities
- Number and % of health facilities providing comprehensive PMTCT services out of total number of health facilities providing ANC services
- Number and % of pregnant women starting ANC out of estimated annual expected pregnancies
- Number and % of pregnant women pre-test counselled out of total antenatal first visits
- Number and % of pregnant women tested for HIV out of pregnant women pre-test counselled
- Number and % of pregnant women post-test counselled out of number of pregnant women tested
- Number and % of pregnant women tested HIV-positive out of total number of pregnant women tested
- Number and % of pregnant women receiving a complete course of antiretroviral prophylaxis to reduce the risk of MTCT out of the number of HIV positive pregnant women
- Number and % of CD4 tests done out of total HIV positive pregnant women
- Number and % of eligible pregnant women put on HAART out of the total number of HIV positive pregnant women meeting the eligibility criteria
- Number and % of HIV positive women who choose to exclusively breastfeed for 4-6 months out of the total number of HIV positive pregnant women
- Number and % of HIV positive women who choose replacement feeding out of the total number of HIV positive pregnant women
- Number and % of babies born to HIV positive mothers who received ARV prophylaxis out of all live births to HIV positive mothers
- Number and % of babies born to HIV positive mothers who test HIV positive out of all live births to HIV positive mothers
- Number and % of babies receiving Co-trimoxazole prophylaxis out of all live births to HIV positive mothers

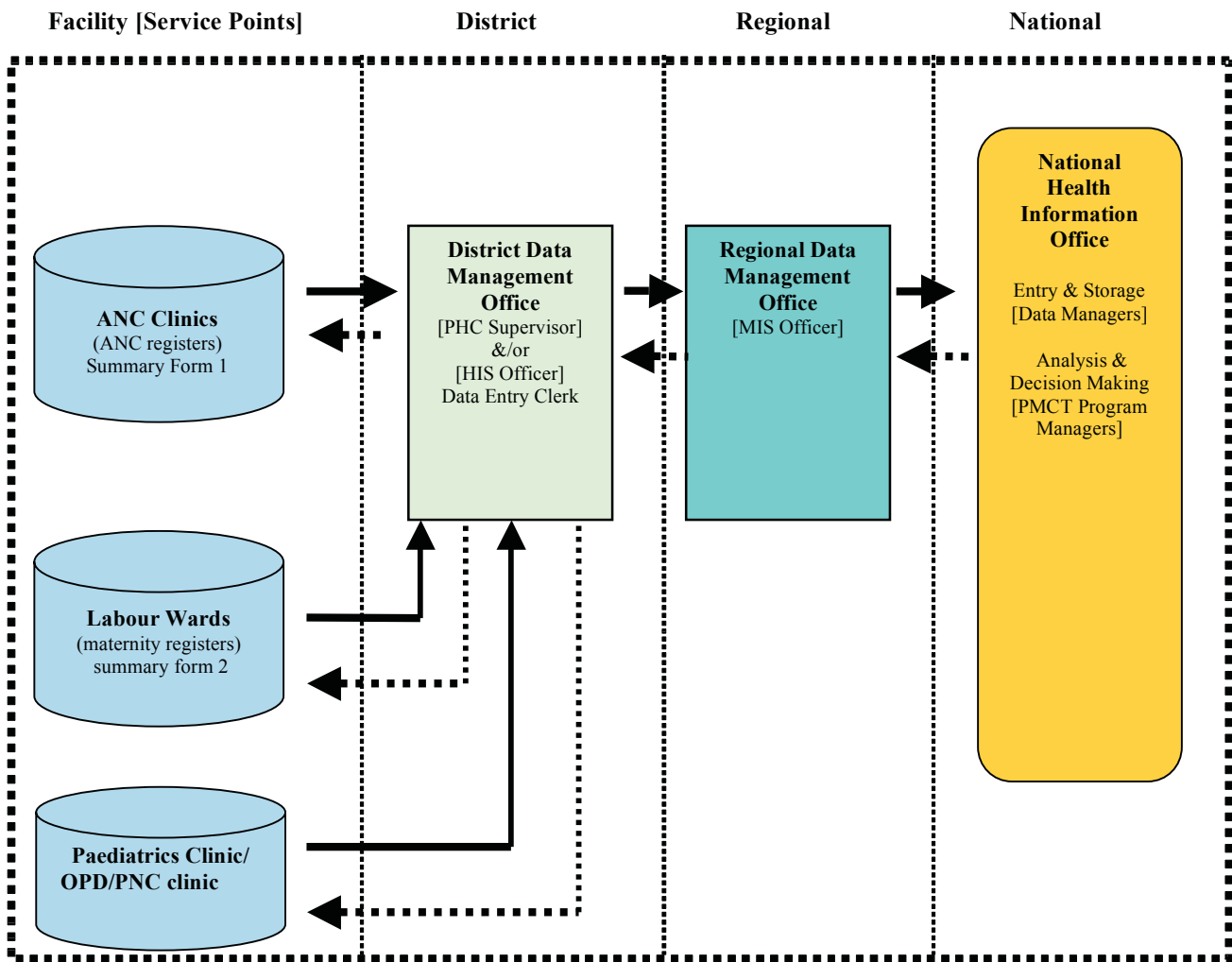
Accuracy and completeness of the ANC/Maternity Register and monthly summary forms should be ensured at all times.

6.6.4 PMTCT record-keeping and reporting

The PMTCT record-keeping and reporting system consists of the following elements:

- The Antenatal Clinic Register and the Maternity Register that have been revised and updated to include PMTCT information.
- Two facility-based Monthly Report Forms which are aggregated from the antenatal and maternity registers and submitted to the district HIS office.
- The computerised PMTCT database at the district, regional, and national level
- HIV DNA PCR Registers for Early Infant Diagnosis of HIV

Figure 6: PMTCT record keeping and reporting system



The following steps assist programme managers in optimizing the use of data:

- Collect good-quality data by completing ANC and labour and delivery registers accurately
- Compile monthly summary reports: Form 1 for ANC statistics and Form 2 for labour and delivery statistics.
- Identify the different end-users, and present and package the data according to their needs.
- Set up mechanisms for efficient data analysis and utilization at each level.
- Provide feedback to clinics and health centres, DCCs, RMTs as well as ART/PMTCT management committees.

Results of the analysis of routinely collected data will help the health staff to identify, in a timely manner, the problems occurring in their health facility regarding the above three dimensions of the intervention, namely availability of essential resources, utilisation of services and adherence. When problems are identified, managers and the health staff will rationally conduct analysis of the identified problems with stakeholders and plan for possible solutions.

Appendices

Appendix I: Trend in HIV prevalence among pregnant women by sentinel site 1992-2006

Table 8: Trend in HIV prevalence ratio among pregnant women by sentinel site, 1992-2006

	1992	1994	1996	1998	2000	2002	2004	2006
Namibia	4.2%	8.4%	15.4%	17.4%	19.3%	22.0%	19.7%	19.9%
Katima Mulilo	14.0%	25.0%	24.0%	29.0%	33.0%	43.0%	42.0%	39.4%
Opuwo	3.0%	1.0%	4.0%	6.0%	7.0%	9.0%	9.0%	7.9%
Swakopmund	3.0%	7.0%	17.0%	15.0%	22.0%	16.0%	28.0%	17.3%
Grootfontein		9.0%				30.0%	28.0%	19.3%
Oshikuku					21.0%	27.0%	27.0%	22.4%
Walvis Bay				29.0%	28.0%	25.0%	26.0%	22.1%
Oshakati	4.0%	14.0%	22.0%	34.0%	28.0%	30.0%	25.0%	27.1%
Katutura Hospital	4.0%	7.0%	16.0%	23.0%	31.0%	27.0%	22.0%	21.1%
Onandjokwe		8.0%	17.0%	21.0%	23.0%	28.0%	22.0%	23.7%
Luderitz							22.0%	22.5%
Rundu		8.0%	8.0%	14.0%	14.0%	22.0%	21.0%	20.1%
Nankudu				13.0%	18.0%	16.0%	19.0%	13.9%
Engela		7.0%	18.0%	17.0%	23.0%	19.0%	19.0%	27.0%
Andara		2.0%	11.0%	16.0%	15.0%	21.0%	18.0%	22.7%
Otiwarongo	2.0%	9.0%		16.0%	18.0%	25.0%	17.0%	18.7%
Outapi						23.0%	17.0%	21.1%
Keetmanshoop	3.0%	8.0%		7.0%	17.0%	16.0%	16.0%	18.5%
Tsumeb						25.0%	16.0%	17.0%
Nyangana		6.0%	5.0%	10.0%	16.0%	22.0%	15.0%	10.2%
Rehoboth	3.0%				9.0%	10.0%	14.0%	13.9%
Gobabis	1.0%			9.0%	9.0%	13.0%	13.0%	7.9%
Outjo							12.0%	12.1%
Mariental					10.0%	12.0%	11.0%	10.2%
Windhoek Central							10.0%	9.1%
Omaruru/Usakos								16.0%
Okahandja								18.5%
Eenhana								21.4%
Okahao								22.5%
Karasburg								22.7%

Source: MOHSS.

This table shows the trend over time in the proportion of pregnant women who tested HIV-positive by sentinel survey site. HIV surveillance has been conducted in alternate years amongst pregnant women in Namibia since 1992 using the same standardized methodology. The number of sentinel sites was increased from 21 to 28 in 2006 to improve survey quality.

Appendix II: Testing for HIV infection in pregnancy

Types of HIV tests related to HIV

1. HIV antibody tests

Most commonly available HIV tests detect antibodies against HIV. They do not detect the virus itself. Detectable antibodies against HIV take from 1-3 months to develop after HIV infection occurs. This time period is known as the window period. HIV antibody tests are sometimes false positive, therefore the laboratory routinely confirms with a second antibody test.

2. ELISA tests (Enzyme Linked Immunosorbent Assay)

These are the most efficient tests for testing a large number of samples per day, but require laboratory facilities with expensive equipment, maintenance, staff and a reliable power supply. In Namibia, they are used for blood safety and diagnosis because they are very sensitive (false negative tests are rare). A positive ELISA test result needs to be confirmed with a second ELISA test using a different test kit, in order to diagnose HIV infection conclusively. ELISA tests are also used to run quality assurance programmes for rapid HIV tests.

3. Simple/rapid HIV tests

These tests utilise serum or a small sample of whole blood from a finger prick. Like ELISA, the rapid test determines whether there are HIV antibodies in a person's blood. They are a type of ELISA test built into an absorbent strip where the serum passes over a test and control line. They do not require special equipment or highly trained staff and they are as accurate as the routine ELISA tests. Simple/rapid tests will usually give results in less than 30 minutes and are easy to perform.

4. HIV antigen and viral test

These tests measure components of the virus itself and, in the case of HIV RNA PCR, can quantify the amount of the virus in the blood stream. These tests are useful for:

- Diagnosing HIV infection in the window period, before HIV antibodies are detectable
- Diagnosing HIV infection in infants. All infants have maternal antibodies present and so will test positive for HIV antibodies with ELISA or rapid test. Only those infected with HIV will have the virus itself detected by HIV DNA PCR

5. HIV RNA PCR

This is a good tool for measuring disease progression and response to therapy. The level of plasma HIV-1 RNA is clearly a useful indicator of the response to HAART in those on treatment. Currently a baseline viral load is not required for initiating therapy in Namibia. In fully adherent patients, viral load is likely to reach undetectable levels in 70-80% of the patients after 4 to 6 months of therapy. This is therefore an appropriate time to assess therapy effectiveness. See Appendix III for when to do viral load.

6. CD4+ lymphocyte count:

HIV targets lymphocytes having a receptor on their surface known as "CD4", destroys them, and thereby creates immunodeficiency. As the CD4 count progressively declines, immunodeficiency becomes progressively worse and opportunistic infections occur. A CD4 count is only performed on patients with HIV infection. Available in Namibia, the CD4 count is the best measure of immune function in a patient with HIV infection and is measured using flow cytometer equipment in the laboratory. CD4+ lymphocyte counts are one of the most useful and reliable ways of assessing whether an HIV-positive patient should start ART and they are also extremely important in the assessment of the effectiveness of ART. An increase of >100 CD4 cells/mm³ in the first 6-12 months is typically seen in an ART adherent patient. Higher elevations can be seen and the response often continues in subsequent years in individuals who are maximally virologically suppressed. Immunologic failure on therapy can also be assessed by CD4 counts.

Quality control for rapid testing (RT)

As with any laboratory test, quality control is also important to establish and maintain for rapid HIV testing. Such a programme will help to detect any substandard tests as a result of manufacturing errors, poor storage conditions, or user error. It is recommended that each facility performing rapid testing should:

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- ~ Ensure that any staff performing rapid HIV testing has been trained and certified by the NIP to perform the test.
- ~ Maintain a log book of rapid test results which lists date of the test, results for test 1 and test 2, any tie-breaker test results, any ELISA results if performed, comments and signature of the person who performed the test.
- ~ Collect 1 in every 10 sample and send to NIP for HIV ELISA testing in addition to performing a Rapid test on the same sample; to check for concordance.

Additional criteria for Quality Assurance for RT can be found in the Standard Operating Procedure Manual for RT.

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Appendix III: Clinical and laboratory monitoring by regimen

Table 9: First line regimens: clinical and laboratory monitoring by regimen : M = month Q = every

Zidovudine-lamivudine-nevirapine (AZT/3TC/NVP)	M 0.5	M 1	M 1.5	M 2	M 2.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	As clinically indicated
History and targeted physical exam	X		X			X	X	X	X	X		
HB	X		X			X	X		X		X	
ALT	X		X			X	X		X		X	
Creatinine							X		X		X	
CD4 count									X		X	
HIV-1 RNA viral load							X					X
Amylase												X
Labs to assess lactic acidosis												X
Pregnancy test												X

Stavudine-lamivudine-nevirapine (D4T/3TC/NVP)	M 0.5	M 1	M 1.5	M 2	M 2.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	As clinically indicated
History and targeted physical exam	X		X			X	X	X	X	X		
HB						X	X		X		X	
ALT	X		X			X	X		X		X	
Creatinine							X		X		X	
CD4 count									X		X	
HIV-1 RNA viral load							X					X
Amylase												X
Labs to assess lactic acidosis												X
Pregnancy test												X

Zidovudine-lamivudine-efavirenz (AZT/3TC/EFV)	M 0.5	M 1	M 1.5	M 2	M 2.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	As clinically indicated
History and targeted physical exam	X		X			X	X	X	X	X		
HB	X		X			X	X		X		X	
ALT							X		X		X	
Creatinine							X		X		X	
CD4 count									X		X	
HIV-1 RNA viral load							X					X
Amylase												X
Labs to assess lactic acidosis												X
Pregnancy test												X

M = month

Q = every

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Stavudine-lamivudine-efavirenz (D4T/3TC/EFV)	M 0.5	M 1	M 1.5	M 2	M 2.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	As clinically indicated
History and targeted physical exam	X		X			X	X	X	X	X		
HB							X		X		X	
ALT							X		X		X	
Creatinine							X		X		X	
CD4 count									X		X	
HIV-I RNA viral load							X					X
Amylase												X
Labs to assess lactic acidosis												X
Pregnancy test												X

Tenofovir-lamivudine-efavirenz (TDF/3TC/EFV)	M 0.5	M 1	M 1.5	M 2	M 2.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	As clinically indicated
History and targeted physical exam	X		X			X	X	X	X	X		
HB							X		X		X	
ALT							X		X		X	
Creatinine							X		X		X	
Urine dipstick for protein						X	X		X		X	
CD4 count									X		X	
HIV-I RNA viral load							X					X
Amylase												X
Labs to assess lactic acidosis												X
Pregnancy test												X

Table 10: Second line regimens: clinical and laboratory monitoring by regimen

Tenofovir-zidovudine- lamivudine-lopinavir-ritonavir (TDF/AZT/3TC/LPV/rtv)	M 0.5	M 1	M 1.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	Q 12M	As clinically indicated
History and targeted physical exam	X		X	X	X	X	X	X			
HB	X		X	X	X		X		X		
ALT				X	X		X		X		
Creatinine					X		X		X		
Urine dipstick for protein				X	X		X		X		
CD4 count							X		X		
Cholesterol/triglycerides							X			X	
HIV I RNA Viral load					X						X
Amylase											X
Labs to assess lactic acidosis											X
Pregnancy test											X

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Abacavir-didanosine-lopinavir-ritonavir (ABC/ddI/LPV/rvt)	M 0.5	M 1	M 1.5	M 3	M 6	M 9	M 12	Q 3M	Q 6M	Q 12M	As clinically indicated
History and targeted physical exam	X		X	X	X	X	X	X			
HB					X		X		X		
ALT				X	X		X		X		
Creatinine					X		X		X		
CD4 count							X		X		
Cholesterol triglycerides							X			X	
HIV RNA Viral load					X						X
Amylase											X
Labs to assess lactic acidosis											X
Pregnancy test											X

Table 11: Actions to take in case of abnormalities in laboratory parameters

ARV	Lab test	Result	Recommendation
Zidovudine (AZT)	HB	< 7.0 grams	Substitute D4T for AZT
	WBC	< 1,250 cells/mL	Substitute D4T for AZT
	Neutrophils	< 750 cells/mL	Substitute D4T for AZT
Nevirapine (NVP)	ALT	> 3x ULN with rash, hepatitis symptoms or jaundice	Substitute EFV for NVP
	ALT	> 5 - 10x ULN without symptoms	Substitute EFV for NVP
Stavudine (D4T) Zidovudine (AZT) Lamivudine (3TC) Didanosine (ddl)	Creatinine	> 150 micromols/L	Calculate creatinine clearance and adjust dose if needed
Tenofovir (TDF)	Creatinine	> 150 micromols/L	Substitute another NRTI for calculated creatinine clearance < 50 ml/min.
	Urine protein	≥2+ on dipstick	Substitute another NRTI; D4T or AZT.

See also discussion of hepatitis B virus and management of ALT abnormalities.

Appendix IV: WHO clinical staging of HIV disease in adults and adolescents

<p>Clinical Stage 1</p> <ul style="list-style-type: none"> • Asymptomatic • Persistent generalised lymphadenopathy
<p>Clinical Stage 2</p> <ul style="list-style-type: none"> • Unexplained^(a) moderate weight loss (under 10% of presumed or measured body weight)^(b) • Recurrent upper respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) • Herpes zoster • Angular cheilitis • Recurrent oral ulceration • Papular pruritic eruptions • Seborrhoeic dermatitis • Fungal nail infection
<p>Clinical Stage 3</p> <ul style="list-style-type: none"> • Unexplained^(a) severe weight loss (over 10% of presumed or measured body weight)^(b) • Unexplained^(a) chronic diarrhoea for longer than one month • Unexplained^(a) persistent fever (intermittent or constant for longer than one month) • Persistent oral candidiasis • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe bacterial infections (e.g., pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia, severe pelvic inflammatory disease) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Unexplained^(a) anaemia (below 8 g/dl), neutropenia (below $0.5 \times 10^9/L$) and/or chronic thrombocytopenia (below $50 \times 10^9/L$)
<p>Clinical Stage 4^(c)</p> <ul style="list-style-type: none"> • HIV wasting syndrome • Pneumocystis pneumonia • Recurrent bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital or anorectal 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 mycobacteria infection • Progressive multifocal leukoencephalopathy • Chronic cryptosporidiosis • Chronic isosporiasis • 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 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 take into consideration the expected weight gain of pregnancy.

Appendix V: Men's invitation letter to an Antenatal Clinic

Example: Men's Invitation Letter to an Antenatal Clinic

Date:

Name:

Address:

Dear Sir,

This letter is written to invite you to attend a meeting to discuss issues related to pregnancy. Since your partner is one of the pregnant women attending antenatal care in clinic/hospital; your participation in the discussion about how to take care of your pregnant partner, what to do during delivery and after delivery will be greatly appreciated.

This meeting will be facilitated by health workers in the maternity department of clinic/hospital.

The meeting will be on: Day Time

If you are not able to come on the above date, you are advised to accompany your partner the next time she comes to the clinic for follow-up, before she delivers.

Looking forward to meeting you.

Yours Sincerely,

Signature:

Maternity staff

Appendix VI: Preparation of infant formula

Mothers should be counselled to follow all the instructions given for preparation and mixing of the formula:

- Wash hands with clean water and soap before preparation.
- Use clean utensils washed in soap and water and kept covered.
- Boil water for 5 minutes and cool to room temperature before mixing.
- Make sure the water and the powder are correctly measured.
- Mix powder and water well.
- Prepare only one feed at a time.
- Use a cup to feed the baby, hold the baby close to foster bonding.
- Discard left over feed.

Appendix VII: How to modify cow's and goat's milk

Because cow's and goat's milk contain twice as much protein, about six times as many minerals, and less carbohydrate content than human milk, it must be modified so the infant can properly digest the milk. The baby should also be given daily multi-vitamin and mineral supplements to prevent micronutrient deficiency. Milk should be prepared one feed at a time and left over milk should be discarded.

Boil the milk after it is milked, cover and store in cool dry place.

1. Wash hands thoroughly with soap and water before preparation.
2. All utensils should be clean, washed in soap and water, boiled, and kept covered.
3. Boil water for 5 minutes and cool to room temperature before mixing.
4. Bring the milk to a rolling boil and cool it to room temperature.
5. Measure the correct amount of water, milk and sugar based on the infant's age as per Table 12.
6. Mix well in a clean container.
7. Use a cup to feed the baby, hold the baby close to foster bonding.
8. Discard leftover milk.

From six months onwards, the baby can be given full strength milk.

Minimum requirements for modified animal milk (in household measures – cups and spoons)

Table 12: Baby's minimum requirements using modified animal milk

Baby's Age	Dilution per feeding			Approximate number of feeds / day	Total volume / day	Total volume (L) / month
	Milk	Water	Sugar			
1 month	40ml	20ml	4g (slightly less than 1 teaspoon)	8 x 60ml	480ml	14.4 L
2 months	60ml	30ml	6g (1¼ teaspoon)	7 x 90ml	630ml	18.9 L
3 months	80ml	40ml	8g (slightly more than 1½ teaspoon)	6 x 120ml	720ml	21.6 L
4 months	80ml	40ml	8g (slightly more than 1½ teaspoon)	6 x 120ml	720ml	21.6 L
5 months	100ml	50ml	10g (2 full teaspoons)	6 x 150ml	900ml	27.0 L
6 months	100ml	50ml	10g (2 full teaspoons)	6 x 150ml	900ml	27.0 L
Total						130.5 L

Appendix VIII: Dosages for intermittent presumptive treatment (IPT) with sulphadoxine pyrimethamine and tetanus toxoid vaccination

Table 13: Schedule for intermittent presumptive treatment with Sulphadoxine Pyrimethamine

Gestation Period	26-28 weeks	34-36 weeks
Dosage	3 tablets	3 tablets

This regimen is beneficial in low to high transmission areas. Two doses of SP should be given after quickening and at least four weeks apart up to 36 weeks of pregnancy. SP should be provided to pregnant women in their 1st and 2nd pregnancies.

In areas where HIV prevalence is greater than 10%, a third dose of SP should be given four weeks after the second dose (38-40 weeks).

Tetanus Toxoid (TT) Vaccination

TT should be stored and transported between 0 and +8°C. Never freeze TT, because it gets damaged when frozen.

The following should apply for the administration of TT vaccine:

Age: Women between 15-49 years of age (or during pregnancy)

Dose: 0.5ml

Route: Intramuscular injection into the left or right upper arm

No. of doses: 5

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