# Fourth Edition NATIONAL GUDDELNES

**Prevention of Mother-to-Child Transmission of HIV in Nepal** 





Government of Nepal Ministry of Health and Population **National Centre for AIDS and STD Control** Kathmandu, Nepal **March 2011** 



# NATIONAL GUIDELINES

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TEKU KATHMANDU, NEPAL

#### Foreword

Date : .....

Ref. No .....

Prevention of HIV infection is a priority for the Government of Nepal. Even though our reported overall prevalence rate remains well under 1%, major efforts will be needed to bring about the virtual elimination of paediatric HIV by 2015 as endorsed by UNAIDS. More than one in every five reported cases of HIV infection is among female partners of HIV positive men, and 96% of these are women of child bearing age. Prevention of mother-to-child transmission (PMTCT) of HIV is therefore an important part of our *National HIV and AIDS Strategy*.

In 2010, the World Health Organization (WHO) released a set of four new recommendations for resource-limited settings. One for ART in adults, another for ART in infants and children, a third on the prevention of mother to child transmission (PMTCT) of HIV and a final guideline on infant feeding for HIV-exposed infants. These guidelines call for expanding the group of PLHIV who require life-long ART to include all of those in WHO Clinical Stages 3 or 4 and all adults with CD4 <350 cells/ml. In addition, PMTCT choices have changed to include early and stronger regimens for prophylaxis for women who do not yet require ART for their own health. For the first time, we have evidence and guidance on safer infant breastfeeding while either the mother or baby takes antiretroviral medications to prevent HIV transmission. Due to the accumulated evidence and guided by WHO, Nepal has committed to improving the PMTCT programme through implementation of these guidelines.

Additionally, in a more "concentrated" epidemic like ours, to avoid unplanned or unintended pregnancies among PLHIV, both broad-based and targeted interventions for HIV prevention are needed. We must integrate the "HIV dimension" soundly into our core package of maternal, neonatal and child health interventions at the community level, and we must identify the "family planning dimension" of every contact with PLHIV.

This 4<sup>th</sup> Edition of our *National Guidelines on PMTCT* in Nepal responds to the principal recommendations of the set of WHO guidelines in addition to the 2009 National PMTCT Review findings. At the same time, it draws on the latest international evidence for the successful management of pregnancies affected by HIV. It is, in fact, one of the first documents of its type to integrate policy and clinical guidance at a national level on the implementation of all four components of the United Nations comprehensive approach to PMTCT – i.e. primary prevention of HIV among women of childbearing age; prevention of un-intended pregnancies among women living with HIV; prevention of HIV transmission from a women living with HIV to her infant; and provision of appropriate care, treatment and support to women living with HIV, their children and their families.

These *Guidelines* will ultimately be accompanied by a pocket handbook for the prevention and treatment of paediatric HIV infection in Nepal. This will be a condensed version of PMTCT, Paediatric HIV and Infant Feeding guidelines with key clinical information to use during day-to-day encounters with pregnant women and children infected with or exposed to HIV.

We thank all those who contributed their expertise and experience to this 4<sup>th</sup> Edition of the national PMTCT *Guidelines* specially Dr. Hemant Chandra Ojha, SMO for leading the team from NCASC. Regular reviews and updates of the *Guidelines* will help us to continue to incorporate evolving international experience, strategies and approaches to PMTCT into our practice.

**Dr KK Rai,** MBBS, MD GP, MPH Director National Centre for AIDS and STD Control

Stop AIDS, Keep the Promise.

### **TABLE OF CONTENTS**

Foreword	i
Table of contents	iii
Acknowledgements	v
Acronyms and Abbreviations	viii
PMTCT of HIV in Nepal — Quick Reference Guide	x
Purpose and Intended Readership of these Guidelines	xiv
Chapter 1: Background Information	1
1.1 HIV Infection in Nepal	1
1.2 HIV Prevention in Mothers and Young Children	3
1.3 Introduction of PMTCT Services in Nepal	6
1.4 Current National PMTCT Strategies	7
1.5 Further Reading	7
Chapter 2: Primary Prevention of HIV in Women of Reproductive Age	9
2.1 Strategic Overview	9
2.2 Integrating Prevention with existing Sexual and Reproductive Health Services	and MCH 11
2.3 Priority Actions	13
2.4 Further Reading	14
<b>Chapter 3: Strengthening HIV Detection in Pregnancy through Counse</b>	lling
and Testing	15
3.1 Overview	15
3.2 Guiding Principles for VCT in Antenatal Settings	17
3.3 Pre-Test Information and Counselling	19
3.4 HIV Testing	22
3.5 Post-Test Information and Counselling	23
3.6 Testing Women of Unknown HIV Status in Labour	25
3.7 Quality Assurance for Counselling Services	
3.8 Priority Actions	
3.9 Further Reading	
<b>Chapter 4: Prevention of Unintended Pregnancies in HIV-Infected Wom</b>	en 27
4.1 Strategic Overview	27
4.2 Reproductive Decision-Making for PLHIV	27
4.3 Contraceptive Methods for PLHIV	29
4.4 Termination of Pregnancy	36
4.5 Special Considerations for Discordant Couples	36
4.6 Priority Actions	37
4.7 Further Reading	38



#### Chapter 5: Prevention of HIV Transmission from HIV Infected Mothers

to their Infants	49
5.1 Strategic Overview	49
5.2 Assessment of Women found to be infected with HIV during Pregnancy	44
5.3 Life-long ART for pregnant or lactating women requiring it for their own health .	45
5.4 Antiretroviral Prophylaxis to Prevent HIV Infection in Infants of Women not ye requiring Life-long ART	∍t 47
5.5 Neonatal Prophylaxis	48
5.6 Laboratory Monitoring of life-long ART or triple ARV prophylaxis	49
5.7 Special Situations in Pregnant or Lactating HIV-infected Women	49
5.8 Community based PMTCT5	52
5.9 Implementing Safer Delivery Practices	53
5.10 Summary of Strategic Steps and Priorities	55
5.11 Further Reading	57
Chapter 6: Counselling and Support on Infant Feeding Methods	59
6.1 Strategic Overview	59
6.2 Recommendations for Infant and Young Child Feeding	64
6.3 Counselling on Feeding of HIV-exposed Infants	66
6.4 Transition from Breast to Replacement Feeding	67
6.5 Feeding the HIV infected child	68
6.6 Feeding Infants of HIV-negative Mothers or Mothers with unknown status	68
6.7 Summary of Strategic Priorities	69
6.8 Further Reading	70
Chapter 7: Provision of Care, Treatment and Support to HIV-Infected Parents,	
Infants and Families	71
7.1 Strategic Overview	71
7.2 Treatment, Care, and Support of the Mother with HIV Infection	72
7.3 Assessment, Care, Antiretroviral Treatment and Support of Infants and	
Young Children Exposed to HIV	76
7.4 Further Reading	76
Chapter 8: Site requirements 7	77
8.1 Sites offering Full PMTCT Services and Support	77
8.2 Community Based PMTCT Services and Support	78
Chapter 9: PMTCT Programme Monitoring 7	79
9.1 Overview of Monitoring and Evaluation	79
9.2 Monitoring and Evaluation of the PMTCT Programme	79
9.3 PMTCT Programme Performance Indicators	80
9.4 Further Reading	83

### **Acknowledgements**

This fourth edition of the *National Guidelines for Prevention of Mother-to-Child Transmission of HIV in Nepal* builds on the first edition of the national *PMTCT Guidelines* (2005), the second and third editions (2008) and the WHO guidelines: Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infections in Infants: Recommendations for a public health approach (2010). It also follows WHO Guidelines on HIV and Infant Feeding: Principles and recommendations for infant feeding in the context of HIV and a summary of evidence (2010).

In addition the document also draws on the following core documents:

- WHO. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access: recommendations for a public health approach (2006).
- WHO, UNFPA, UNAIDS, IPPF. Sexual and Reproductive Health and HIV/AIDS: A Framework for Priority Linkages (2005).
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### **Acronyms and Abbreviations**

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal clinic
ART	Antiretroviral therapy
ARV	Antiretroviral
BCG	Bacille Calmette Guerin (tuberculosis) vaccine
СВО	Community based organisation
CHBC	Community Home Based Care
CT&S	Care, treatment and support
DACC	District AIDS Coordinating Committee
DBS	Dried blood spot
DHO	District Health Office
DHS	Demographic and Health Survey
DOTS	Directly observed treatment short-course (for tuberculosis)
DPHO	District Public Health Office
ECP	Emergency contraceptive pill
EFV	Efavirenz
ELISA	Enzyme linked immunosorbent assay
EQAS	External quality assurance system
FBC	Full blood count
FBO	Faith based organization
FCHV	Female Community Health Volunteer
FHI	Family Health International
FSW	Female sex worker
HIV	Human immunodeficiency virus
IDU	Injecting drug user
IEC	Information, education, and communication
IMCI	Integrated management of childhood illness
IUD	Intra-uterine contraceptive device
LFTs	Liver function tests
LPV/r	Ritonavir-boosted lopinavir
M&E	Monitoring and evaluation
MAC	Mycobacterium avium complex
MARP	Most at-risk population
MCH	Maternal and child health
MCHW	Maternal and Child Health Worker
MMR	Maternal mortality rate

MOHP	Ministry of Health and Population
MSM	Men who have sex with men
MTCT	Mother-to-child transmission
N-9	Nonoxynol-9 (spermicide)
NCASC	National Centre for AIDS and STD control
NGO	Non-government organisation
NHEICC	National Health Education, Information and Communications Centre
NHTC	National Health Training Centre
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
OCP	Oral contraceptive pill
OI	Opportunistic infection
OST	Opiate substitution therapy
PCP	Pneumocystis jiroveci (formerly known as P carinii) pneumonia
PCR	Polymerase chain reaction
PHC	Primary health care
PI	Protease inhibitor
PITC	Provider-initiated testing and counselling
PLHA	People living with and affected by HIV and AIDS
PMTCT	Prevention of mother-to-child transmission
QA	Quality assurance
RHCC	Reproductive Health Coordinating Committee
sdNVP	Single-dose nevirapine
SRH	Sexual and reproductive health
STI	Sexually transmissible infection
ТВ	Tuberculosis
TDF	Tenofivir disoproxil fumarate
TMP-SMX	Trimethoprim-sulfamethoxazole (cotrimoxazole)
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
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
VHW	Village Health Worker
VL	Viral Load
WHO	World Health Organization
ZDV	Zidovudine (also known as azidothymidine; AZT)

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### **Prevention of Mother-to-Child Transmission** of **HIV in Nepal- Quick Reference Guide**

Mother-to-child transmission is the most common and important source of HIV infection in children.

Transmission risk is greatest during **labour** and delivery, but can also occur during pregnancy or through breast feeding.

Since 1998, there has been a steady increase in the number of women and girls infected with HIV in Nepal, among whom 90% are of child bearing age (15-49 years).

#### Key Facts

- The National Centre for AIDS and STD Control estimated that, by 2006, more than one in every five reported cases of HIV infection in Nepal were among female partners of HIV positive men
- Without any intervention, up to 30% of children of HIV positive mothers will themselves be born infected with HIV
- In exclusively breast fed infants, the risk increases by another 4–5% after 6 months without ARVs.
- Babies who receive mixed feeding (i.e. both breast and formula) have a much higher risk of HIV transmission: the cumulative risk is about 42–45% after two years of continuous breast and complementary feeding
- Without access to clean water and sanitation, formula feeding exposes infants to a much higher risk of diarrhoea and acute respiratory infection than in breast fed infants; overall mortality rates are increased compared to breast fed babies
- The MOHP provides free ARV drugs to prevent infection in the baby during pregnancy, labour, delivery and breastfeeding
- Early Infant Diagnosis using DNA PCR technology is becoming available in Nepal. All babies should be referred at 6 weeks of age for first HIV test. In addition, all babies should have Antibody screening at 9 months of age with referral of those who are antibody positive for DNA PCR testing. 18 month confirmatory tests should be obtained for all HIV-exposed babies.

### Consequences of HIV infection in infants and children

The consequences of HIV infection and AIDS in young children are serious.

Without treatment, about one-third of infected children will die before their first birthday, and

about half will die by 2 years of age; survival to 5 years of age is uncommon.

This is compounded by the social impact on children orphaned as a result of parental HIV infection.

## What can be done to prevent transmission of HIV infection to infants and young children?

To prevent HIV among infants and children, a comprehensive four-element strategy is needed.

This comprehensive approach requires a set of key interventions to be implemented as part of the core package of maternal, neonatal and child health services.

#### Comprehensive Four-Pronged Strategy for PMTCT of HIV

- 1. Prevent HIV infection among women of childbearing age;
- 2. Prevent unintended pregnancies among women living with HIV;
- 3. Prevent HIV transmission from infected mothers to their infants:
- a) antiretroviral prophylaxis for mother and baby
- b) safer delivery practices
- c) safer infant feeding choices;
- 4. Provide appropriate treatment, care and support to women living with HIV and their children and families.

### Prevention of HIV among women of childbearing age

The most effective way of preventing children being born infected with HIV is to protect women against HIV infection.

- Identify the "HIV element" all clinical contacts.
- Educate women and their male partners about HIV prevention.
- Provide (or refer for) STI screening and treatment and voluntary, confidential HIV counselling and testing (VCT).
- Help women plan or avoid pregnancies, and promote the use of condoms as "dual protection" against both pregnancy and HIV/STIs.

#### **Involvement of the male partner**

A woman's partner plays a critical role in determining her risk of HIV infection – especially if he is at risk of acquiring HIV infection himself. Male partners of both HIV positive AND HIV negative women, who are at risk of HIV should be offered VCT. If he is HIVinfected, VCT offers a chance to practise positive prevention and seek important HIV related health care, benefiting the entire family.

Regardless of his HIV status, he also has an important role in the family's decision-making processes. Involving him in HIV-related VCT and antenatal care can help ensure that he is supportive of the woman's choices related to HIV, pregnancy, infant feeding and family planning.

### Family planning for couples living with HIV

To avoid unintended, unplanned pregnancies among HIV positive women, careful reproductive health and family planning counselling is essential for all people living with HIV.

Identify the "family planning element" in every clinical contact with PLHIV, and ensure strong links with STI and TB programmes and services for most at-risk populations (MARPs).

Male (or female) condoms are the only contraceptive method that can provide "dual protection" against STIs and HIV, and are therefore most commonly recommended where one or both partners is infected with HIV.

Many other contraceptive methods are also suitable for women infected with HIV (e.g. pills, injectable contraception, implants). Used correctly, they are more effective for pregnancy prevention than condoms but provide no protection at all against HIV or STIs. (See Section 4.3 of the *PMTCT Guidelines* for more detail on contraception for HIV infected women and those on ART).

Couples should be free to make informed family planning choices, without coercion, and should have access to quality services to implement their choices.

If one partner is infected with HIV and the other is not, the correct and consistent use of condoms is the only method to effectively prevent HIV transmission to the uninfected partner. Condoms should be used even when another method is chosen to prevent pregnancy. (Section 4.5 of the *PMTCT Guidelines* describes approaches to managing discordant couples – i.e. where one partner is infected with HIV and the other is not).

If pregnancy occurs, offer all essential antenatal care as well as PMTCT interventions.

#### **Timing of Principal PMTCT Interventions**

Intervention	Antenatal	Labour and Delivery	Postnatal
Life long ART during pregnancy	✓	✓	√
Triple ARV prophylaxis for mother	<b>√</b>	✓	$\checkmark$
Interventions during delivery that are known to prevent MTCT	(discuss)	√	
ARV prophylaxis for infant	(discuss)		$\checkmark$
Counselling and support for safer infant feeding	(discuss)		$\checkmark$
Provision of (or referral to) prevention and care, treatment a nd support services for women infected with HIV, their infants and their families	~		~
Provision of (or referral to) prevention and support services for women who test negative to help them stay uninfected Encourage testing of high risk partners.	✓	√	√

#### When to commence full life-long ART

Initiate antiretroviral therapy (ART) in any pregnant woman with:

- WHO Stage 4 disease, irrespective of CD4
- WHO Stage 3 disease, irrespective of CD4
- WHO Stage 1 or 2 disease with CD4 < 350</li>

The standard ART regimen in pregnancy is

ZDV + 3TC + NVP or ZDV +3TC + EFV

Pregnant women with indications for ART should begin it as soon as possible in pregnancy. Do not start EFV in first trimester and ensure postpartum family planning for those on EFV.

To avoid transfer of drug-resistant strains of HIV, counsel couples about continued condom use.

#### Recommended First-Line Life-long ART Regimen for treating Pregnant Women, and Prophylactic Regimen for Infants

Recipient	Timing	ARV(s)
Mother	Start ASAP in	ZDV 300mg twice a day + 3TC 150mg twice a day
pregnancy and continue throughout		+ NVP 200mg once a day for 14 days
		If no reaction, continue ZDV + 3TC and increase NVP to 200mg twice a day after 14 days
Baby	pregnancy,	OR
labour and delivery and postpartum, for life	ZDV 300mg twice a day + 3TC 150mg twice a day	
	+ EFV 600mg once daily	
	life	Do not start EFV in first trimester. Ensure postpartum contraception if woman is taking EFV.
	Neonatal	Infant NVP once daily for 6 weeks.
		NVP dose is:
		10 mg (1.0 mL) if birth weight is <2.5 kg
		15 mg (1.5 mL) is birth weight is ≥2.5 kg
		First dose should be given as soon as possible after birth and continued until 6 weeks of life.

Precautions and alternative regimens are discussed in Section 5.7 of the PMTCT Guidelines.

#### Antiretroviral prophylaxis for mother and baby (Triple ARVs)

The risk of HIV transmission to the baby can be reduced to less than 5% (or more) including the breastfeeding period, if the mother takes ARVs during the antenatal period beginning at 14 weeks or as soon as possible thereafter, through delivery and the first postpartum year, until 1 week after the complete cessation of breastfeeding (at about 12 months postpartum). In addition, safer delivery practices should be implemented and babies should take daily NVP syrup for the first 6 weeks of life.

### Triple ARV Prophylaxis Protocol for mothers not yet requiring life-long ART –

HIV-infected pregnant women should begin one of the following triple ARV regimens from 14 weeks of pregnancy or as soon as possible thereafter, including 2<sup>nd</sup> and 3<sup>rd</sup> trimesters of pregnancy, during labour and delivery and during the first postpartum year, for breastfeeding prophylaxis. She should take three ARVs until 1 week after complete breastfeeding cessation.

Three ARVs are needed, avoiding the use of NVP due to potential for serious hepatic reactions in this group with high CD4 counts.

If the mother is given an EFV containing regimen, EFV should be stopped 1 week after the cessation of all breastfeeding and a "tail" of ZDV + 3TC is given for an additional week, to prevent NNRTI resistance (due to the long halflife of EFV). Contraception must be assured.

All babies receive NVP daily for the first 6 weeks of life, regardless of the type or duration of maternal ARVs.

For babies of mothers who start ARVs postpartum, consult paediatric HIV specialists for decisions regarding infant NVP prophylaxis duration.



#### **Triple ARV PMTCT Prophylaxis for Mother and Baby**

Recipient	Timing	ARV(s)
Mother	Start from14 wks of pregnancy, in labour/ delivery or in the first year postpartum. Continue throughout pregnancy, labour and delivery and the first year postpartum.	ZDV 300mg twice a day + 3TC 150mg twice a day + EFV 600mg once a day OR ZDV 300mg twice a day + 3TC 150mg + ABC 300mg all twice daily OR ZDV 300mg twice a day + 3TC + LPV/r 400/100mg all twice daily
Baby	Infant	Infant NVP once daily for 6 weeks. NVP dose is: 10 mg (1.0 mL) if birth weight is <2.5 kg 15 mg (1.5 mL) is birth weight is ≥2.5 kg First dose should be given as soon as possible after birth and continued for the first 6 weeks of life.

#### **Special situations**

#### Anaemia –

ZDV may cause anaemia and neutropenia. Investigate for and treat any underlying causes of severe anaemia or neutropenia. Tenofovir (TDF) should replace ZDV when Hb is <7.5g/ dL

### HIV-Infected Women in Labour who have not received Antenatal ARVs –

If a woman arrives in labour and is found to be HIV-infected and not taking any ARVs, she should be given triple ARV prophylaxis immediately. If her Hb is later found to be <7.5g/ dL substitute TDF for ZDV.

### HIV-infected women delivering in settings without full PMTCT ARVs available

If an HIV-infected woman is not yet taking ARVs and delivers in a setting without full ARVs (or at home), the mother can receive one NVP tablet (200mg) at the onset of labour or as soon as possible in the first stage and the baby should start infant daily NVP and continue for 6 weeks. The mother then needs immediate referral to the closest ART centre to start ARVs for the prevention of breast milk transmission and/or life-long ART (depending on her status). Community health workers or FCHVs can assist with NVP or mothers can self-administer take-home dose.

#### **Safer delivery practices**

Treat STIs and other signs of infection in the mother.

Allow normal delivery, but minimise both the duration of labour and obstetric interventions (including artificial rupture of the membranes and the frequency of vaginal examination).

If labour is not established quickly, augmentation of labour as per national obstetric guidelines should be initiated. If delivery is not imminent within four hours of rupture of the membranes or establishment of labour, seek advice from an obstetrician or physician skilled in managing HIV-affected pregnancies.

Minimise the risk of postpartum haemorrhage through active management of the third stage (i.e. oxytocin immediately after delivery, controlled cord traction and uterine massage).

Do not "milk" cord blood from the cord towards baby. Take great care with suction to avoid trauma of the baby's upper airway.

### Feeding infants born to HIV infected women

All health workers should promote exclusive breastfeeding from birth until 6 months of age, with continued breastfeeding until about 12 months of age. Complementary food should be added at 6 months. Adding maternal ARV prophylaxis to breastfeeding has made the practice much safer. Babies can now obtain the immunologic and nutritional benefits of breast milk, while having a very low risk of HIV infection. In Nepal where the custom is to breastfeed and replacement (formula) feeding is not safe, the overall risk to the baby from malnutrition, HIV and other infections can be minimised by **exclusively** breast feeding to 6 months of age. **Mixed feeding must be strictly avoided**. Any mother with a child under 12 months of age who tests HIV positive while breastfeeding, should begin ARVs either as triple ARV prophylaxis or as life-long ART. Extended infant NVP prophylaxis is another option in some cases.

### Transition from exclusive breast feeding to replacement feeding

In infants of HIV-infected mothers, transition to replacement feeding (where **all** breast milk is replaced with breast milk substitutes) should take place by about 12 months of age, if it is safe to do so. Baby should be gradually weaned over 1 month starting at about 11 months of age. Maternal ARV prophylaxis should continue until 1 week after all breastfeeding has stopped.

An open cup and spoon, rather than a bottle with a nipple (which is difficult to clean), should be used.

- Avoid recommencing breast feeding after completing the transition to replacement feeding
- Resist the temptation to breast feed at night or when the child needs comforting

### **Prophylaxis against PCP and other opportunistic infections**

Women who fulfil the following criteria should commence one double strength **cotrimoxazole** tablet (TMP-SMX 800/160mg) daily:

- WHO Stage 2, 3 or 4 disease, irrespective of CD4
- WHO Stage 1 disease with CD4 < 350

All HIV-exposed infants need cotrimoxazole prophylaxis beginning at 6 weeks of age and continuing until HIV-infection is excluded by appropriate testing and child has stopped breastfeeding for at least 6 weeks.

Prophylaxis for other OIs is summarised in Chapter 7 of the *PMTCT Guidelines*.

#### **Repeat HIV testing**

If a woman has a specific incident of known HIV exposure in the past 3 months, has known or ongoing risk for HIV, or has an STI and initially tested HIV negative, she should be offered repeat counselling and HIV testing in the third trimester of pregnancy.



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#### **Purpose and Intended Readership of these Guidelines**

The four-fold *purpose* of these *Guidelines* is:

- to guide managers, health staff and communities on suitable strategies for the prevention and detection of HIV in women and their families;
- to assist people living with HIV with their reproductive health choices (in particular, the avoidance of unplanned, unintended pregnancies);
- to assist clinical staff in making evidence based decisions about the most appropriate management of HIV infection in pregnant women and prevention of HIV infection in their unborn and newborn babies, in a range of clinical settings;
- to assist clinical staff, individuals and communities to strengthen approaches to the clinical care of PLHIV and their families.

The *target population* for the *Guidelines* includes pregnant and breastfeeding women infected with HIV, their unborn and newborn babies, their partners and families, and their communities.

The target *readership and end-users* of the *Guidelines* include policy makers, programme managers, clinical service providers and community leaders and members.

As medical knowledge in relation to HIV and PMTCT – especially regarding antiretroviral prophylaxis during pregnancy and infant feeding – is changing rapidly, these *Guidelines* will be **reviewed and**, **where necessary, updated every two years** (or sooner if important new evidence becomes available).



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### **1.1 HIV Infection in Nepal**

#### 1.1.1 Epidemiology

Since the first reported human immunodeficiency virus (HIV) infection in Nepal in 1988, a total of 16,262 individuals infected with HIV have been reported to the National Centre for AIDS and STD control (NCASC) (NCASC; August 2010 data).

The most recent population based estimates (NCASC, 2009) are that 63,528 adults and children are infected with HIV, reflecting an estimated prevalence of 0.39% in the adult population. During 2009, an estimated 4,701 adults and children died from Acquired Immune Deficiency (AIDS) related causes.

Almost 29% of all people living with HIV (PLHIV) in Nepal are women. *Among women, 90% of reported cases are of childbearing age* (15-49 years age group).

#### **1.1.2 Most At-Risk Populations**

Nepal is described as having a "concentrated" HIV epidemic, where the estimated prevalence of HIV infection in identified most at-risk populations (MARPs) – e.g. injecting drug users (IDUs)– consistently exceeds 5%.

Recent estimates are that 29% of all infections occur among seasonal labour migrants, 5% among clients of sex workers, and 28% among "low risk females" (NCASC, 2009; Figure 1.1).

#### Figure 1.1 HIV Infections Estimates 2009 by Population Sub-Group, Age and Sex

Population Sub-Groups	Total Population	Estimated HIV Infections	Share of Total HIV Infections (%)
IDU	28,439	2,524	4%
MSM	140,691	3,685	6%
FSW	32,137	590	1%
Clients FSW	727,421	5,703	9%
Migrants	1,485,499	17,101	27%
Remaining Male Population	6,839,077	18,861	29%
Remaining Female Population	7,488,215	15,154	24%
Total	16,741,479	63,617	100%

1

#### Figure 1.2

Distribution of Estimated HIV Infections by Sub-Population Group, 1980-2015



Source: NCASC, 2010

The estimated prevalence of HIV infection among people who inject drugs is 20.7% in Kathmandu and between 3.4% and 8.1% in other districts. Seroprevalence in people who inject drugs has dramatically dropped from a high of 68% in Kathmandu in 2002, to 52% in 2005 to 34.7% in 2007 and finally down to 20.7% in 2009.

Nearly one-quarter of women who sell sex in the eastern Terai are infected with either gonorrhoea, *Chlamydia* or both. The HIV prevalence among female sex workers (FSWs) in most districts is reported to be around 2%.

Among men who have sex with men (MSM), the prevalence of HIV in Kathmandu was estimated to be 2.6% in 2009.

The National HIV and AIDS Strategy, 2006-11 (see Section 1.1.4) notes a number of additional factors that contribute to vulnerability to HIV in Nepal: geographic and ethnic diversity; widespread poverty, inequality and illiteracy; recent civil conflict, political instability and population displacement; trafficking of girls and young women for both the domestic and international commercial sex trade; a varied level of knowledge about HIV transmission among MARPs and young people; and a low uptake of prevention and health services.

There are few data on the epidemic in rural areas of Nepal. An apparent growing rural epidemic (especially in the far-Western hill districts) is thought to be associated with migrant labourers returning from higher prevalence destinations.

#### **1.1.3 HIV Infection in Women and Children**

Mother-to-child transmission (MTCT) is by far the largest source of HIV infection in children in Nepal.

The HIV seroprevalence rate among pregnant women is estimated to be 0.2%. Based on this estimate, 1,228 (0.2%) of the 798,174 pregnancies each year may be expected to occur in HIV positive women. Based on an assumed vertical transmission rate of 25-45%, the annual birth cohort of potentially infected newborns would be 307-552.

It is estimated that there are 3,544 children living with HIV in Nepal. Of these, only 1,037 have been reported (NCASC, August 2010). This may be partially due to the lack of in country HIV diagnostic testing for those less than 18 months of and the fact that death from HIV in infancy and early childhood may be attributed to other causes.



#### **1.1.4 National HIV and AIDS Strategy**

The *National HIV and AIDS Strategy, 2006-11* places a strong emphasis on prevention (including through PMTCT) and universal access to care, treatment and support (CT&S).

It also emphasises strong linkages to the continuum of care for PLHIV.

The *Strategy* notes that HIV is more than a public health priority – it affects all aspects of society. Building an adequate response to the HIV epidemic will require a decentralised, multi-sectoral and interdisciplinary approach.

### **1.2** HIV Prevention in Mothers and Young Children

#### 1.2.1 Risk of Mother-to-Child Transmission

By the end of 2009, an estimated 2.5 million children under the age of 15 years worldwide were infected with HIV. An estimated 370,000 children are newly infected with HIV in 2009 and, among these, the overwhelming majority acquire the infection through MTCT.

MTCT of HIV can occur during pregnancy, labour, delivery or lactation. In the absence of any intervention, 15-30% of children born to non-breast feeding HIV positive mothers in developing countries will themselves become infected with HIV. Transmission is believed to be uncommon during early pregnancy, but the risk increases sharply in late pregnancy and during labour and delivery.

Breast feeding contributes further to the overall risk of vertical transmission, and transmission rates may reach 30-45% if breast feeding continues for 18 to 24 months.

Overall, about 15-20% of those children who acquire HIV infection from their mothers are infected during the antenatal period, 50% during delivery and 33% through breast feeding.

Table 1.1 summarises estimated rates of transmission during pregnancy and for differ-ent durations of breast feeding.

#### Table 1.1

#### Attributable Risk (%) of MTCT of HIV during Pregnancy, Labour and Delivery and Breast Feeding without intervention

Phase of Pregnancy or Duration of Breast Feeding	Transmission Rate
During pregnancy	5 - 10%
During labour and delivery	10 - 20%
During breast feeding	5 - 20%
Overall without breast feeding	15 - 30%
Overall with breast feeding to 6 months	25 - 35%
Overall with breast feeding to 18-24 months	30 - 45%

Source: de Cock et al, JAMA (2000)

Table 1.2 summarises the maternal and infant factors that may increase the risk of HIV transmission during pregnancy, labour, delivery and breast feeding.



The most important risk factor for MTCT is the amount of HIV virus in the mother's blood, known as the viral load. The risk of transmission to the infant is greatest when the viral load is high – which is often the case with recent HIV infection or advanced (World Health Organization [WHO] Stage 3 or 4) clinical disease.

Where viral load assays are not available, low CD4 T-cell counts are similarly associated with increased risk of antenatal and intrapartum transmission.

Pregnancy	Labour and Delivery	Infant Feeding
<ul> <li>High maternal viral load (new HIV infection or advanced clinical disease)</li> <li>Viral, bacterial or parasitic placental infection (e.g. malaria)</li> <li>Sexually transmissible infections (STI)</li> <li>Maternal malnutrition (indirect cause)</li> </ul>	<ul> <li>High maternal viral load (new HIV infection or advanced clinical disease)</li> <li>Rupture of membranes more than 4 hours before labour begins</li> <li>Invasive delivery procedures that increase contact with mother's infected blood or body fluids (e.g. episiotomy, fetal scalp monitoring)</li> <li>First infant in multiple birth</li> <li>Chorioamnionitis (e.g. from untreated STI or other infection)</li> </ul>	<ul> <li>High maternal viral load (new HIV infection or advanced clinical disease)</li> <li>Duration of breast feeding</li> <li>Mixed feeding (i.e. any food or fluids in addition to breast milk)</li> <li>Breast abscess, nipple fissures, mastitis</li> <li>Poor maternal nutritional status</li> <li>Oral disease in the baby (e.g. thrush or sores)</li> </ul>

### Table 1.2 Factors that may increase the risk of MTCT of HIV

After the onset of labour, transmission risk increases with the length of time the membranes have been ruptured. Higher risk of MTCT during labour and delivery is also associated with other causes of acute chorioamnionitis – e.g. resulting from untreated sexually transmissible infections (STIs) or other lower genital tract infections – and invasive delivery techniques that increase the baby's contact with the mother's blood.

Premature infants are more likely to become infected than full-term infants.

Duration of breast feeding is a key factor in postnatal transmission. Breast feeding without antiretroviral prophylaxis for 6 months increases the overall risk of MTCT by about 9% for women with established HIV infection, by 14% when follow-up is extended to 18 months, and by 16% at two years. (Breast feeding appears to have no detrimental effect on the mother's health).

The pattern of infant feeding also appears to affect the risk of postnatal transmission. Complete avoidance of breast feeding removes the risk of MTCT through lactation; however, an unsafe water supply or a family's inability to afford consistent formula feeding exposes the infant to risks of infectious diseases or malnutrition that may be greater than the risk of HIV infection.

# Several studies of infants followed up for between 6 and 15 months of age have now demonstrated that mixed breast and artificial feeding during the first 3-6 months of life is associated with a much higher risk of HIV transmission than when the child was exclusively breast fed.

Acute maternal HIV infection during lactation increases the overall risk of MTCT by 29%, demonstrating the *great importance of ongoing HIV prevention in HIV negative lactating women*.

Breast infection (especially mastitis) and cracked or bloody nipples are additional risk factors for transmission during lactation, but can be prevented by improved breast feeding techniques and probably account for only a small proportion of postnatal infections.

Sores or candidiasis in the infant's mouth may also facilitate infection occurring during breast feeding.

Pregnancy itself does not seem to have an effect on the clinical progression of HIV infection or AIDS. However, women infected with HIV are more likely to experience pregnancy-related complications, including premature labour and delivery.



Since the 2006 WHO PMTCT Guidelines were issued, important new evidence has emerged on the use of ARV prophylaxis to prevent MTCT, including during breastfeeding, on the optimal time for ART initiation for individuals who need treatment and on safe feeding practices for HIV-exposed infants. This has warranted new guidelines in settings such as Nepal. (WHO 2010 PMTCT Guidelines)

#### **1.2.2 Consequences of HIV Infection in Infants and Young Children**

Progression of HIV infection to clinical disease occurs more rapidly in children than in adults. An estimated one-third of infants infected with HIV will have died by the time they reach their first birthday, and half will have died before their second birthday.

WHO has estimated that at least half of these deaths could be avoided through antibiotic prophylaxis against opportunistic infections (OI), and that the majority of deaths would be prevented if treatment for OIs and antiretroviral therapy (ART) were readily available.

The overall impact of HIV on children will depend on the course of the epidemic in women.

### **1.2.3 Comprehensive Prevention of HIV Infection in Mothers, Infants and Young Children**

In June 2001, the United Nations General Assembly Special Session (UNGASS) on HIV/ AIDS *Declaration of Commitment* undertook to reduce the proportion of infants infected with HIV by 20% by 2005, and by 50% by 2010, through:

- ensuring that 80% of pregnant women accessing antenatal care have information, counselling and other HIV prevention services available to them;
- increasing availability and access for HIV-infected women and babies to effective treatment, especially antiretroviral (ARV) prophylaxis, to reduce MTCT of HIV; and
- effective interventions for women infected with HIV, including voluntary confidential coun-selling and testing (VCT) and, where appropriate, breast milk substitutes and a continuum of care, treatment and support.

The current goal adopted by UNAIDS is the virtual elimination of Paediatric HIV by 2015. This is part of the "Three Zeros" approach which seeks to have "Zero New HIV infections".

To meet these targets, it is generally agreed that a four-pronged approach to PMTCT should be adopted. This is summarised in Table 1.3.

#### Table 1.3

#### Four-Pronged UN Strategy for PMTCT of HIV

Prevent HIV infection in women of reproductive age
 Prevent unintended pregnancy in HIV-positive women
 Prevent mother-to-child transmission of HIV by:

 providing antiretroviral therapy during pregnancy
 implementing safer delivery practices
 providing counselling and support on infant feeding methods

 Provide care, treatment and support to HIV-infected parents, infants and families

The first strategy (or "prong") focuses on primary prevention of HIV in women and their partners. If we can prevent women from becoming infected, the number of infected infants and children – as well as the number of children orphaned by AIDS – will also decrease.

The second strategy focuses on good access to reproductive health services for PLHIV. If a woman is already infected with HIV, regular counselling and provision of contraception can ensure

5

that unplanned pregnancy does not occur. If an HIV positive couple desire to become pregnant, careful pre-conception planning and appropriate interventions during pregnancy can reduce the risk of the baby being born infected.

If an infected woman becomes pregnant, the risk of transmission of HIV to her child can be reduced less than 5% (or even lower) using the approaches outlined in the third strategy – combination ARV prophylaxis from early in the pregnancy, and careful management of the delivery to reduce the exposure of the baby to maternal blood and secretions.

Pregnant women with advanced HIV infection require full, highly active ART for life, both to reduce the risk of AIDS related illness and to minimise the risk of MTCT.

In the absence of other interventions, elective caesarean section alone reduces the risk of transmission by approximately half. However, if ART is provided during pregnancy and labour, the potential benefit of caesarean section is reduced relative to its disadvantages (see also Section 5.10).

In resource limited settings, elective caesarean section may not be available or safe; refraining from breast feeding is often not safe, feasible or acceptable, and breast milk substitutes may not be available or affordable. Approaches to PMTCT have therefore begun to focus on the implementation realities in resource-constrained settings. And now with the additional tool of ARV prophylaxis for breastmilk transmission prevention, breastfeeding has become even safer for babies of HIV-infected mothers.

The fourth strategy focuses on linking PMTCT services with integrated, family-centred, primary and preventive care for PLHIV – clinical care and prevention, nutrition, family planning, counselling and other supportive care – as well as ongoing ART when indicated.

### **1.3** Introduction of PMTCT Services in Nepal

In February 2005, the NCASC initiated a pilot PMTCT programme in three hospitals; this was been extended to additional facilities. The National PMTCT Working Group and its partners including WHO, United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), Joint United Nations Programme on HIV/AIDS (UNAIDS) and United States Agency for International Development (USAID) / Family Health International (FHI) continue to provide active support to the programme.

In early 2007, the NCASC, UNICEF and other members of the Working Group undertook an operational *Review* of the pilot PMTCT programme.

The principal recommendations of the *Review* include:

- to integrate PMTCT activities with community based maternal and neonatal health services,
- to increase the involvement of Female Community Health Volunteers (FCHVs) and other community based health work-ers in "Prong 1" and "Prong 2" activi-ties, with a focus on MARPs and referral for "Prong 3" and "Prong 4" services,
- to involve local implementing partners (including District Health Offices [DHOs], District Public Health Offices [DPHOs] and civil society organisations) in managing and supporting PMTCT services, and
- to strengthen the role of the NCASC in overall programme management and governance.



### **1.4 Current National PMTCT Strategies**

#### 1.4.1 Targets

Consistent with the findings and recommendations of the *Review*, Section 4.6 of the *National HIV* and *AIDS Strategy*, 2006-11 seeks to *Expand and Strengthen the PMTCT Program* using a more decentralised, community-based model to improve coverage and access.

The over-arching targets were for the proportion of HIV positive pregnant women receiving a complete course of ARV prophylaxis to reduce the risk of MTCT to reach 80% by 2011. UNAIDS now implores all countries to seek to achieve virtual elimination of paediatric HIV by 2015.

#### 1.4.2 Strategies and Key Actions

These targets are to be reached through 6 strategic outcomes:

- 4.6.1 Reduced transmission of HIV infection to newborn
- 4.6.2 Increased decentralised coverage and access to PMTCT at district level in collaboration with private sectors, communities and non-government organisations (NGOs)
- 4.6.3 Increased health seeking behaviours among pregnant women and women of childbearing age and safe sexual practices
- 4.6.4 Increased knowledge, acceptance and demands for PMTCT programme among communities, families and targeted pregnant women.
- 4.6.5 Strengthened linkage between PMTCT services and HIV CT&S services to ensure that ART programme fast tracks women in PMTCT programmes into ARV treatment plans, followed by care and support services
- 4.6.6 Increased capacity of health service providers for effective management and delivery of PMTCT services

The *National Strategy* identifies a number of key actions that will be necessary at the national and community levels to achieve the above outcomes – these actions have been incorporated into these *Guidelines*.

### **1.5** Further Reading

WHO Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infections in Infants: Recommendations for a public health approach. World Health Organization Geneva. 2010

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7

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(available from <a href="http://www.unaids.org.np/publication/metadata.php?PublicationID=213">http://www.unaids.org.np/publication/metadata.php?PublicationID=213</a>).

UNAIDS Global Report on AIDS Epidemic 2010

### Primary Prevention of HIV in Women of Reproductive Age

### **2.1 Strategic Overview**

#### 2.1.1 Rationale

Well over 75% of all HIV infections are acquired sexually, or through transmission during pregnancy, labour, delivery or breastfeeding. The presence of non-HIV STIs in either or both partners increases the risk of sexual transmission of HIV.

It is important to note that HIV infection is not gender-neutral. Women are biologically at twice the risk of acquiring HIV infection as men, and their relative lack of decision-making power, education, and economic independence further amplify their risk. They are often vulnerable to coercive or transactional sex, and the expectation that they will care for younger siblings or ill relatives means they may not be able to go to school or work.

Early marriage adds to the risk of transmission, if sexual intercourse is traumatic.

Although most people interviewed for the 2006 *Demographic and Health Survey* (DHS) indicated that they would be willing to "take care of a family member with the AIDS virus" [*sic*] in their home, HIV-positive women are still more vulnerable to abuse or abandonment than women who are not infected.

Without addressing the many ways in which these circumstances contribute to women's increased vulnerability, PMTCT efforts (which, in Nepal, have traditionally focused on the perinatal and breast feeding periods) and HIV prevention will have limited success.

#### 2.1.2 Socioeconomic Context and Knowledge of HIV

The 2006 DHS highlights aspects of the socioeconomic context in Nepal that present both direct and indirect challenges to implementing the *National HIV and AIDS Strategy* and scaling up PMTCT, VCT services and the primary prevention of HIV.

#### Age –

Nepal's population is young, with 41% aged less than 15 years and 13% under five.

#### Gender and Economic Migration -

An estimated 31% of the population (35% in rural areas, 10% in urban areas) lives in poverty.

There are about 89 males for every 100 females, due mainly to the outward migration of men. In the 2006 DHS, more than one-third of households reported that at least one member had travelled away from the home in the 12 months before the survey – mostly men, mostly to other parts of Nepal or to India, and mostly for at least 6 of the last 12 months.

#### Literacy and Education -

The literacy rate is low (65% for males, 42.8% for females). Almost one-half of women and onequarter of men have never attended school.

#### Knowledge and Awareness of HIV Prevention Methods -

Only 55% of women and 77% of men know that the risk of becoming infected with HIV can be reduced by using condoms and limiting sex to one uninfected partner who has no other partners.

Among young people aged 15-24 years, 87% of females and 97% of males know where they can obtain condoms.



#### 2.1.3 Community Level Action

A comprehensive approach to preventing HIV infection in infants and young children must include community, health sector and other partners working together for the prevention of primary HIV infection in women.

The strategic approaches at different levels are summarised in Table 2.1.

### Table 2.1 Primary Prevention of HIV in Women of Reproductive Age Integrated Summary of Strategic Components

COMMUNITY	HEALTH FACILITY
<ul> <li>Increase awareness of HIV</li> <li>Mobilise community leaders</li> <li>Dispel local myths</li> <li>Mobilise, orientate, train and supervise FCHVs</li> <li>Establish partnerships and linkages to NGOs and community based organisations (CBOs)         <ul> <li>Community-based service organisations</li> <li>Community development NGOs and NGOs serving needs of MARPs (e.g. IDUs, CSWs, sexual minorities)</li> <li>Community based NGOs addressing the SRH needs of young people</li> <li>Faith-based initiatives and organisations</li> </ul> </li> <li>Employ prevention strategies</li> <li>Provide non-test dependent counselling and support</li> <li>Facilitate access to and utilisation of VCT</li> <li>Encourage involvement of male partners.</li> </ul>	<ul> <li>Encourage prevention</li> <li>Identify the "HIV element" in every clinical contact</li> <li>Promote dual protection</li> <li>Help women plan or avoid pregnancies</li> <li>Provide STI screening and treatment</li> <li>Offer or refer for VCT</li> <li>Provide pre- and post-test counselling and support</li> <li>Establish intra- and inter-sectoral partnerships and linkages         <ul> <li>Linkages between MCH and HIV services</li> <li>Linkages between Reproductive Health and HIV services</li> <li>Linkages with other health programmes for special needs: e.g. tuberculosis (TB), harm reduction for IDUs</li> </ul> </li> <li>Lobby and advocate with employer groups, NGOs, faith based organisations (EBOs) and CBOs</li> </ul>
DISTRICT	NATIONAL
<ul> <li>Coordination and management through multi-sectoral District AIDS Coordinating Committee (DACC)</li> <li>Inclusion of PMTCT on Reproductive Health Coordinating Committee (RHCC) agenda</li> <li>Facilitate intra- and inter-sectoral partnerships and linkages</li> <li>Integrated training for health care workers and community-based volunteers, including informing traditional birth attendants about the importance of early antenatal care and the principles of management of HIV positive pregnancies</li> <li>Resource mobilisation</li> <li>Monitoring and evaluation</li> </ul>	<ul> <li>Ongoing review of evidence, and policy and major strategy development</li> <li>Establish and implement national coordination mechanism</li> <li>Coordination at national level</li> <li>Training (curricula, standards and technical support)</li> <li>Resource mobilisation and harmonisation (human, financial)</li> <li>Development and sharing of knowledge and information through mass media (audio-visual) and print media targeting antenatal mothers</li> <li>Production of information, education, and communication (IEC) materials and messages</li> <li>Monitoring and evaluation</li> </ul>

This can best be achieved through education and community linkages supporting safer and more responsible sexual behaviour and practices, provision of condoms, and the early diagnosis and treatment of STIs.

This will reduce the number of mothers infected with HIV and, in turn, reduce the risk to their unborn or newborn children.

Community leaders, FCHVs, Village Health Workers (VHWs) and Maternal and Child Health Workers (MCHWs) have very important roles to play, and must be supported by health facility staff under the strategic direction of the DHO and DPHO.



# **2.2** Integrating Prevention with existing Sexual and Reproductive Health and MCH Services

#### 2.2.1 Reaching the "At-Risk" Mother and Baby

Many women at risk of HIV infection (whose children are therefore at risk for MTCT) do not look to hospitals for their health care needs and those of their children. If HIV prevention and PMTCT programmes only target hospital populations, they are likely to miss the "average" at-risk mother and baby – especially those living in remote rural or mountain settings.

A woman of unknown HIV status may be poor, young, a widow, not attending school, or the partner of a man working away from home who has HIV risk behaviours. She may have a history of STI or tuberculosis. She may have "transactional" sexual encounters to earn money to feed her family.

She is more likely to use existing community-based maternal and child health (MCH) and sexual and reproductive health (SRH) services, and can therefore be reached through those services. She may have attended antenatal clinic in the past (or for a current pregnancy), and she may have delivered previous babies at a rural health centre. She may breast feed her babies and bring them for regular well child care, and she may also seek advice on family planning.

Linking HIV prevention and PMTCT services with SRH also addresses the unmet need and rights of PLHIV and members of MARPs to these services. The majority of women living with HIV will be asymptomatic, and will therefore either not have been tested or will not be forthcoming about their HIV infection. Providing essential labour and delivery care (including safer delivery practices) will reduce MTCT, while better infection control through universal precautions (knowing that some women will be HIV positive) will improve the quality of maternity care for all women and their babies.

Adding HIV prevention to existing SRH services also provides greater support for "*dual protection*" – i.e. protection against unintended pregnancy <u>and</u> STIs (including HIV).

To maximize opportunities to prevent and reduce the risk of HIV infection for all mothers and babies, and to enhance programme effectiveness and efficiency, PMTCT services should be an integral component of all existing SRH and MCH services.

#### 2.2.2 A Special Focus on Young Women

The 2006 DHS tells us that a focus on youth – especially poorer and less educated young women – is particularly important for HIV prevention and PMTCT.

According to the DHS, the median age of first sex for women In Nepal is 17.2 years – this is the same as the median age of first marriage. Although the median age of giving birth to their first child is 19.9 years, almost a quarter of women have had their first baby by the time they are 18 years of age. Women with no education begin child bearing more than three years earlier than women who have completed secondary school.



#### Figure 2.1





Source: WHO, UNFPA, UNAIDS, IPPF. Sexual and Reproductive Health and HIV/ AIDS: A Framework for Priority Linkages (2005)

While some young people may be reached by integrating PMTCT into existing MCH and reproductive health programs, health service planners and health care workers should also explore other ways to reach young women and men with HIV and PMTCT information – in schools, at markets, at football matches and other sporting occasions, in the work place, and in youth-friendly clinics.

Where VCT is available, providers should pay extra attention to youth-friendly counselling content and approaches.

#### 2.2.3 Importance of Partner Involvement in PMTCT

Both mothers and fathers have an impact on transmission of HIV to the infant, since a woman's partner plays a critical role in the family's decision-making process.

Because of the much greater risk to the baby posed by acute maternal infection during pregnancy and breast feeding (see Section 1.2), it is of great importance to avoid HIV infection or detect undiagnosed HIV infection in the male partner. Finding discordant couples (in this case, where the woman is not infected with HIV but her male partner is HIV-positive; see also Section 4.5) should be a priority so that appropriate counselling can be provided. This can only happen if the male partners of uninfected women are also tested for HIV.

Regardless of the male partner's HIV status, involving him in non-test dependent or HIV testrelated counselling can help ensure that he is supportive of his partner's dilemmas and choices related to HIV, infant feeding and family planning.



### **2.3 Priority Actions**

There are a number of important first steps that need to be taken to strengthen and fully operationalise primary prevention.

#### 2.3.1 National

The *National Strategy* gives us clear guidance about moving towards a more decentralised, community-based model for PMTCT that is fully integrated with community health services.

The NCASC and the National Health Education, Information and Communications Centre (NHEICC) will support the production of IEC materials for behaviour change communication in clinical and community settings and via mass media outlets. IEC materials targeting young women and antenatal clinic (ANC) mothers should be included.

With inputs from the NCASC, the Family Health Division and the NHEICC, the National Health Training Centre (NHTC) will have the responsibility for developing, updating and disseminating training materials for health workers on primary prevention.

The NCASC will maintain and support national level surveillance and monitoring and evaluation (M&E) systems.

#### 2.3.2 District

The DHO and DPHO can work in partnership to coordinate and manage the work of community level health centres.

They should support the implementation of national guidelines on VCT, risk assessment, pre-test counselling and post-test counselling.

Their most important functions are to plan and support integrated training in HIV prevention and SRH, resource mobilisation, and establishing systems for M&E of primary prevention activities and the prevalence of HIV and STIs.<sup>1</sup>

#### 2.3.3 Health Facility

Health facility managers need to identify FCHVs, health educators, Community Home Based Care (CHBC) workers and other categories of health worker in their community who have the potential to become involved in primary HIV prevention and PMTCT counselling. The training and support needs of these workers needs to be assessed, training conducted and supervision provided.

Clinic staff and community health workers need to initiate health education and promotion on HIV and STI prevention and care, including safer sex practices, birth planning, optimal infant feeding and family planning (using both group and individual education strategies).

They should establish the supplies of reproductive health commodities that are needed and distribute male and female condoms.

They can develop outreach programmes for young people, and initiate antenatal, couple and/or partner counselling. Establishing partnerships with NGOs and other CBOs – especially those serving the needs of migrant workers and their families, IDUs, FSWs and other MARPs – is a very important aspect of every health facility's networking in the community.

To link prevention activities with good quality clinical care and supervision, they need to identify patient and specimen referral and transportation links for HIV VCT and syphilis and other STI screening.

#### 2.3.4 Community

We can begin by identifying, engaging and sensitising leaders about HIV as an issue of importance to their community, including for parents and families.

With the help and support of leaders, we need to stimulate awareness among men and women of reproductive age – and particularly young people – on basic facts about HIV and AIDS, behaviour change, pregnancy planning and PMTCT.



FCHVs and other categories of community based health worker and volunteer have an important role to play in dispelling misconceptions about HIV and stigma and discrimination associated with HIV infection, and stimulating community dialogue about HIV prevention, care, treatment and support.



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### Strengthening HIV Detection in Pregnancy through Counselling and Testing

### **3.1** Overview

#### 3.1.1 Role of HIV Counselling and Testing

Confidential voluntary counselling and testing provides an important link between programmes for HIV prevention, STI prevention and treatment, obstetric and neonatal care, and the detection and treatment of tuberculosis and other opportunistic infec-tions. By "normalising" HIV screening and awareness, it may also reduce stigma and discrimination against PLHIV.

It can promote and sustain behaviour change, and may play a role in improving the quality of life of PLHIV. It is both an entry point and a stimulus for ART access and systems of CT&S (Figure 3.1).

The scaling-up of PMTCT services should be directly linked to the expansion of VCT and SRH services. It is important that PMTCT and VCT services are coordinated and linked, and do not attempt to duplicate each other or evolve in parallel.

#### Figure 3.1:

VCT – An Important Entry Point for HIV Prevention, Treatment, Care and Support Services



Source: UNICEF Scaling Up VCT Services: Lessons Learned from Cambodia (2007)

#### 3.1.2 Client-Initiated Testing and Counselling

Traditionally, HIV testing and counselling has operated on a client-initiated basis – i.e. the individual presents to a health facility requesting a test for HIV infection or "for AIDS".

Under these circumstances, it is important to provide counselling and risk assessment, as well as to offer (or refer for) HIV testing according to the national *VCT Guidelines* and the standards summarised in Table 3.1.



#### Table 3.1: Minimum Standards for HIV Counselling and Testing

- 1) HIV counselling and testing should be voluntary. Individuals should have sufficient information, understanding and freedom of choice to be able to give informed consent to testing.
- 2) Pre-test information should describe the purpose and procedure of HIV testing and the treatment and support that are available after testing.
- 3) There should be appropriate post-test information counselling and/or referral.
- 4) There should be consistent commitment and ethical support to encourage partner participation and disclosure to significant others.
- 5) Persons whose test result is positive should receive counselling and referral to care support and treatment where available.
- 6) HIV test results and counselling records should be treated confidentially and only those health workers with a direct role in the management of patients should have access to this information.
- 7) Persons whose test results are negative should receive counselling to enable them to remain free of HIV.

Source: UNICEF (2007); adapted from WHO, UNAIDS and International HIV/AIDS Alliance, *Scaling-Up HIV Testing and Counselling Services: A Toolkit for Programme Managers* (2005)

#### 3.1.3 Non-Test Dependent Counselling and Risk Assessment

It will take time to establish comprehensive, decentralised antenatal counselling and testing services. Most districts of Nepal have a low prevalence of HIV or an epidemic that is concentrated among members of most-at-risk-populations (MARPs) (see Section 1.1.2) – consequently, most people will have a low risk of exposure to HIV.

Health care providers therefore do not necessarily need to recommend HIV testing to everyone who visits a health facility – this would use a lot of resources (human, logistic, financial) to identify just a single HIV infected individual.

Where on-site testing is not available, the focus should be on **non-test dependent primary prevention and counselling**, with **careful identification of potential risk factors** for acquiring HIV infection and clinical conditions associated with HIV infection. Where such risk factors are identified, **early referral to a centre where testing is available** will be necessary.

#### 3.1.4 Provider-Initiated Testing and Counselling

Health facilities are nevertheless an important point of contact with PLHIV or MARPs who may not know their status but who are in need of HIV prevention, education, diagnosis or CT&S. It is important not to miss opportunities to reach these individuals.

When a health care provider recommends HIV counselling and testing (rather than the individual asking for it), this is called provider-initiated testing and counselling (PITC) otherwise known as "opt-out" testing.

Decisions about PITC should be guided by the epidemiological and social context in the community.

Health care providers should recommend HIV testing and counselling – as part of routine care – to the following clinical groups:

- all adults, adolescents or children who present to health facilities with signs or symptoms that could indicate HIV infection (including TB and other OIs)
- all infants born to HIV-positive women <u>and all of her other children</u> (as a routine component of follow-up care for all those children)
- all children presenting with suboptimal growth or malnutrition in settings where risk assessment counselling identifies one or both parents as at-risk of HIV infection and/or the mother was not screened for HIV during the antenatal period.

In addition to these three clinical groups, PITC should be provided as an integral part of:

- STI services,
- health services for MARPs,
- antenatal, childbirth and postpartum services, and
- tuberculosis services.

Where an individual accepts a recommendation for PITC in a centre without co-located or nearby testing facilities, FCHVs, VHWs and NGOs can play an important role in facilitating transport and early follow-up.

### **3.2 Guiding Principles for VCT** in Antenatal Settings

#### 3.2.1 Antenatal VCT and Education as a Minimum Standard of Care

All MCH settings that provide a) family planning services for women of childbearing age and b) antenatal, labour and delivery, postnatal and other reproductive health care for pregnant women, must be able to provide a basic package of HIV counselling- and testing-related services.

This will include:

- as a minimum, non-test dependent counselling and individual risk assessment,
- pre-test information,
- testing (or referral for testing) where indicated, and
- post-test counselling (regardless of whether the test result is positive or negative).

As part of their counselling and pre-test information, all pregnant women presenting to ANC must receive information on the following:

- safer sex practices,
- prevention and treatment of STIs,
- prevention of HIV in unborn babies, infants and young children, including available PMTCT interventions, and
- HIV testing, post-test counselling and follow-up services (including access to ART).

There should also be a strong emphasis on counselling for partners or as a couple. This is particularly important for sero-discordant couples.



#### **3.2.2 Informed consent**

Informed consent is a fundamental principle of HIV counselling and testing.

Clear and accurate information about HIV testing must be part of the standard package of care. This is necessary to ensure that the patient understands his/her rights and that he/ she has the specific opportunity to consider and, if he/she wishes, to decline testing.

In the context of antenatal care, written informed consent is not necessary. However, the fact that the patient has provided informed and voluntary consent to an HIV test (and the test result) should be documented in the antenatal record.

It is the responsibility of staff providing antenatal counselling to ensure that it addresses the following aspects of care:

- understanding the purpose and benefits of testing
- understanding the counselling and testing process
- understanding the voluntary nature of HIV testing
- respecting the patient's testing decision

#### 3.2.3 When Testing is Declined

If a woman declines HIV testing, her HIV status will remain unknown.

In such circumstances, the provider should make a careful effort to identify any risk factors and attempt to resolve any issues – e.g. related to her partner or family – that may be preventing her from accepting testing.

Even though they are ineligible for ARV prophylaxis, women who decline testing should be considered at risk for MTCT and should be counselled accordingly during antenatal care. They should be made aware that testing will still be available at later ANC visits, and that PMTCT interventions may also be available. They should be reminded of the benefits of knowing their HIV status, and the benefits to the baby of commencing interventions as early in pregnancy as possible should HIV infection be diagnosed. Women who initially declined testing should be counselled again in labour and postpartum, if necessary as interventions will have benefit (albeit less so) even if initiated later.

#### 3.2.4 Confidentiality

Confidentiality is an essential aspect of VCT services, and is an important mechanism for establishing trust. Individuals may be more likely to seek counselling and testing where it is perceived as confidential.

Although information and pre-test counselling may be provided on a group basis (see Sections 3.3.1 and 3.3.2), it is essential that a private setting (e.g. a separate closed room) is used for all one-on-one discussions of HIV-related matters. In particular, individual risk assessment and posttest counselling for an individual who has tested positive to HIV should take place away from other patients or staff not involved with that person's care.

Staff must maintain the confidentiality of HIV test results at all times; information that is shared between health care workers and patients must be kept private. This applies to both verbal and written communications. Breaches of confidentiality may result in disciplinary action.

It is also important to recognise that clinical care can be undermined by not recording HIV results or not communicating results to other health care providers who will be responsible for patient care. Patients should be advised that, as a way of ensuring that they receive appropriate medical care, personal and medical information (including the results of HIV testing) may be shared with other health care providers, but only if they have a direct role in the ongoing management of the individual and her family.

Women should be offered advice on the safe-keeping of patient- and parent-held records at home, including antenatal cards and child health cards.

Medical records administrators may need specific systems and training in handling confidential



medical records in clinical settings where HIV testing and counselling are carried out. Only those health care workers who are directly involved in the individual's care will have access to the patient's records.

#### 3.2.5 Stigma and Discrimination

HIV is not only the greatest health challenge of our time – it is also one of our greatest human rights challenges. Those aware they are HIV-infected shoulder the twin burdens of stigma and discrimination, and risk rejection from family and community, and blame and physical violence from partners and community members.

#### Origins –

Fear of becoming infected with HIV underlies all this behaviour, which remains a major global impediment to preventing HIV transmission, slowing the spread of the disease, and providing care, treatment and support to PLHIV and their families.

#### Role of health workers -

Health staff can serve as role models – both positive and negative – and their behaviour is often imitated in the community. Their attitudes towards PLHIV should be as supportive and compassionate as for any patient, and staff should aim to "normalise" all contacts with PLHIV.

Health centres and health care workers providing PMTCT services can take the lead in challenging long-held community perceptions and practices. Health workers should get to know their local community, identify local HIV-related stereotypes, rumours and mis-conceptions, and ensure that these are addressed at appropriate times during both clinic hours and community meetings.

Health workers need to be encouraged to challenge their own attitudes, and to be supported with information and activities that address any risk – no mater how inadvertent – of care being compromised by stigmatising behaviour in health care settings.

#### Partner participation –

Partners should participate in all aspects of PMTCT services, including exploration and counselling regarding their own attitudes to HIV, risk behaviour and gender equality. They need access to education about PMTCT risks and interventions (including ARV treatment and prophylaxis and modified infant feeding practices), to be supported and counselled to undergo testing.

#### Advocacy for women's rights -

Health workers and CSO partners should ensure that women diagnosed with HIV are educated about their rights and know where to turn for help, including for legal advice, to challenge discrimination and stigmatisation.

#### Peer and community support -

Support groups linked to antenatal, PMTCT and HIV CT&S services provide an opportunity for HIV-infected pregnant women to share experiences, and be linked to other support services.

### **3.3 Pre-Test Information and Counselling**

#### 3.3.1 Group Approaches to HIV Education and Counselling in Antenatal Settings

Providing pre-test information helps prepare women and their partners to understand the counselling and testing process.

Group approaches to background information and education can free up more of the counsellor's time for providing individual counselling to selected individuals.

ANC registration and waiting areas can be used for mass education methods, under the supervision of a nurse or health educator. Approaches include:


- Displays of PMTCT related materials
- Distribution of IEC materials on MTCT and PMTCT interventions

Larger group sessions should cover basic information about HIV and AIDS, how it is transmitted and the risks of perinatal transmission, risk reduction strategies, HIV testing procedures, and the advantages and disadvantages of testing. Printed materials, videos, guided discussions and roleplaying exercises can all be used in a group setting. The woman should be exposed to this information again during subsequent ANC visits.

When audiovisual materials are used to provide health education messages, screenings can be followed by group discussion to clarify understanding and answer questions.

With basic training in HIV and counselling techniques, a health care worker, FCHV, lay counsellor or even an HIV-infected mother can provide pre-test information on HIV in group sessions. (With additional training, they can also conduct post-test counselling, pre-discharge counselling for mothers who were not tested prior to delivery and provide advice and counselling on infant feeding).

Health care workers and counsellors should jointly identify women who need individual pre-test counselling and testing or referral.

Where peer or lay counsellors provide HIV and PMTCT counselling, clear policies on their training, required skill level, supervision and possible remuneration are needed.

# 3.3.2 Pre-Test Counselling in Small Groups

Where feasible, more specific and detailed information about HIV testing can be provided to smaller groups in the form of health education talks.

Information and discussion in the pre-test group session should include:

- Basic facts about HIV infection and AIDS, including the "window" period
- Risk reduction approaches (including consistent use of condoms and demon-stration of their use)
- Discussion of comprehensive family planning options, including condom use for dual protection against unintended pregnancy and HIV and STI
- The advantages and potential disadvantages associated with HIV testing (see Table 3.2)
- HIV testing procedures, including the availability of free HIV testing (regardless of what other routine antenatal tests may be performed)
- The voluntary nature of HIV testing it should not be mandated by health care workers
- Procedures for providing results
- Discussion about the confidentiality offered to the clients, and the circum-stances under which HIV test results may be shared with other health care workers
- Clarifying the meaning of available PMTCT interventions, including prophylactic ART and its benefits for the pregnant mother and the unborn baby
- Communicating HIV status with partner and /or family and friends
- Infant feeding options
- Information on referral for related health care and social support

Each woman should receive all the information she needs to make an informed decision about being tested for HIV.



#### Table 3.2

### Advantages and Disadvantages of HIV Testing

# **ADVANTAGES**

- Knowledge of the result can reduce anxiety and stress
- Pregnant women infected with HIV can make decisions on how to reduce the chances of transmission to the baby and to her sexual and other contacts
  - o ARV prophylaxis during pregnancy, labour
  - o options for delivery
  - o ARV prophylaxis for baby during neonatal period
  - o explore infant feeding options
  - prevent infection to others through safer sex practices and/or harm reduction activities
- Positive living
  - o Symptoms can be identified and treated promptly
  - o Clients can also protect themselves from further infection
  - o Clients can improve their health by good sanitation, healthy diet, etc
- Access to ART if needed to prolong and improve quality of life.
- Planning for the future of one's family might be made more easily
- Making choices about her sexual behaviour and future childbearing

# DISADVANTAGES

- Stress and uncertainty: HIV positive clients may have difficulty accepting or adapting to a positive result, e.g.
- Fear and anxiety
  - o fear of how to approach partner
  - watching for the development of clinical symptoms of AIDS
  - fear of how to maintain secrecy around diagnosis
- May face stigma or rejection if information is shared with family and friends.
- May find maintaining relationships difficult.
- May find restrictions placed on job opportunities, access to financing and insurance

# 3.3.3 Timing of Counselling and Testing

Especially in rural and mountain districts, many women attend antenatal care late in pregnancy or may be seen only once or twice before delivery. Providers should therefore support and encourage women to be tested at the initial visit.

However, the decision to accept testing may require support from partners or other family members. This may entail a return visit with family decision makers, who should be given the same information and pre-test counselling that was provided to the woman.

Each woman must be reassured that declining an HIV test will not affect her access to antenatal care or related services.

If a woman is unable to afford other routine antenatal testing (e.g. haemoglobin, blood group, etc), she will still be eligible for free HIV screening.

She should also be advised that, if she changes her mind, an HIV test can be provided during any subsequent antenatal visit right up to the onset of labour. However, the later the test is performed, the more limited the protection that can be offered to the baby.

### 3.3.4 Repeat testing in pregnancy

Retesting during the 3<sup>rd</sup> trimester is recommended for women who tested earlier in pregnancy and who:

- Have specific incidents of known HIV exposure within the past 3 months.
- Have a continuous or ongoing risk of acquiring HIV
- Have a sexually transmitted infection



# 3.3.5 Individual Pre-Test Counselling

Individual pre-test counselling and the opportunity for women to ask further questions in a more confidential setting will ideally be incorporated into routine ANC visits.

Where this is not practical, health care workers may refer patients to nearby VCT centres for individual pre-test counselling or for clarification of information provided in the small group sessions.

# 3.3.6 Pre-Test Counselling for Couples

A woman's partner's HIV status is a very important aspect of the family's decision-making framework.

Women attending for HIV-related counselling should therefore be encouraged – but not forced – to bring their partners to ANC counselling and testing sessions as:

- during counselling, health care workers can emphasise the man's responsibility for protecting the health of his wife or partner and their family;
- counselling male partners of pregnant women provides an opportunity to encourage men to practice safer sex (including by using condoms and limiting the number of concurrent partners);
- involving the male partner in HIV- and test-related counselling can help ensure that he is supportive of his partner's choices in relation to HIV, infant feeding and family planning (including decisions on whether or not to become pregnant or to terminate the pregnancy);
- testing both partners together as a couple may reduce the likelihood that the woman will be "blamed" or stigmatised for bringing HIV infection into the family;
- identifying discordant couples (i.e. where one partner is infected with HIV but the other is HIV-negative) during counselling will provide the opportunity to discuss safer sex practices – see also Section 4.5.

Strategies for increasing partner involvement include providing women with a card from the ANC to take home to their partners, inviting them to "new fathers' evenings", fathers' health checks or couples' information sessions. In addition to testing partners of HIV positive women, it is important that women with partners at high risk for HIV (i.e. labour migrants to India, IDU) should be encouraged to test, even though the woman is negative. High risk partners of HIV negative women need HIV testing in order to prevent acquisition of HIV during pregnancy or breastfeeding which poses a very high risk of MTCT.

# **3.4 HIV Testing**

# 3.4.1 Availability

PMTCT programs should provide same day results of HIV testing to reduce loss-to-follow-up and ensure prompt action. Rapid HIV antibody testing in (or close to) PMTCT settings enables sameday turn-around for test results – usually within 20-40 minutes.

This means clients can receive their test results and post-test counselling on the same day as they receive pre-test, and a higher proportion of tested mothers, their partners and families will be offered and enrolled in PMTCT services.

Providing a same-day, one-stop HIV counselling and testing service depends on the test being available in the centre providing PMTCT services or at a co-located or nearby VCT centre. This reminds us that the expansion of *PMTCT services should not out-pace the expansion of VCT – if mothers have to travel too far for antenatal VCT, they are more likely to be lost to follow-up and remain unaware of their HIV status.* 

Same-day counselling and testing also limits the risk of specimen mix-up, loss or delay. Where testing is co-located with ANC or takes place in a VCT centre that is conveniently located nearby, less human, facility and financial resources are needed. In PMTCT sites located within hospitals, systems should be developed to ensure that HIV rapid testing and results are de-linked from other ANC tests, and that results are provided to patients on the same day as pre-test counselling occurs. It is preferable for facilities and dedicated staff to be available within the ANC clinic to perform rapid tests on site.



Other health care staff (e.g. nurses, health educators and other qualified professional staff) could potentially become involved in HIV rapid testing, provided they have completed and passed the National Public Health Laboratory's accredited training course on testing procedures.

To ensure the quality of testing, regular supervision, periodic assessment of skills and a quality assurance (QA) system should be in place and maintained (see Section 3.4.3).

# 3.4.2 Algorithms

HIV testing should follow the algorithms in the national *VCT* and *Laboratory Guidelines*, using a screening test of appropriate sensitivity. The diagnostic accuracy of the rapid testing available in Nepal is generally comparable with ELISA.

Where the screening test is reactive, the specimen should be re-tested using a second, highly specific test.

If the results of the two tests differ, a third rapid test known as a "tie-breaker" as per national testing algorithm or referral to a laboratory for confirmatory testing will be necessary.

# 3.4.3 Quality Assurance for Testing

A QA system is crucial for a laboratory to detect and reduce errors, improve consistency among testing sites and help contain costs.

A QA system includes the following components:

- Systems to hire, retain, train, supervise and manage staff.
- Procedures to select, purchase, install, calibrate, maintain, service and repair equipment.
- Procedures to manage inventory.
- Procedures (including standard operating procedures) to manage specimens.
- Procedures for developing, approving, distributing forms and for storing records.
- Systems and staff to manage information and data, and assure client privacy and confidentiality.
- Procedures for reporting, addressing and recording errors.
- Systems for external quality assessment and internal audit or self-evaluation.
- A method for monitoring and improving the testing process and customer satisfaction.
- A system for ensuring occupational safety for staff conducting testing.

All centres offering rapid or laboratory-based testing must ensure that they comply with internal quality control and external quality assurance system (EQAS) procedures according to the new *EQAS Guidelines for laboratories* and national *VCT Guidelines*.

# **3.5** Post-Test Information and Counselling

Initial post-test counselling and all HIV test results, whether positive or negative, must be provided to the individual in person, separately and privately for each patient.

# 3.5.1 Negative Test Result

A negative result on an HIV antibody test means that a woman is either not infected with HIV or, rarely, that she is in the "window period" of very early HIV infection and her level of antibodies is too low to be detected.

Post-test counselling provides an opportunity for a woman who tests HIV negative to learn how to protect herself and her infant from HIV infection. Post-test counselling – even for those who test negative for HIV – provides women with a powerful incentive to adopt safer sex practices, discuss family planning, understand the issue of discordance (see Section 4.5), and to encourage partner testing.



Components of post-test counselling for women testing HIV-negative include:

- Communicate with the client that the test result is ready now
- Provide test results clearly and simply and show her the test results
- Review the meaning of test result, and discuss the "window period" if she has a recent risk exposure. Explain to the client that, if there is no significant risk in the previous three months, no repeat testing is required; if recent risk exposure is revealed at the time of post-test counselling, a specific date must be set for re-testing of the woman (and, if possible, her partner)
- Discuss and negotiate a specific, concrete risk reduction plan skills in condom use, demonstration as necessary, and a supply of condoms for dual protection
- Inform seronegative women about the implications of acquiring HIV during pregnancy and breast feeding i.e. that the high viral load associated with acute HIV infection greatly increases the risk of transmission to an unborn baby or breast feeding infant.
- Discuss test result disclosure for partner and partner testing for HIV testing
- Retesting during the 3<sup>rd</sup> trimester is recommended for women who tested earlier in pregnancy and who:
  - Have specific incidents of known HIV exposure within the past 3 months.
  - Have a continuous or ongoing risk of acquiring HIV
  - Have a sexually transmitted infection

# **3.5.2 Positive Test Result**

A woman who tests HIV-positive is infected with HIV.

The health care worker must remain non-judgmental, supportive, and confident throughout the counselling process. Because women may present late in pregnancy or only attend ANC once, key PMTCT messages will need to be provided during the post-test counselling session – this includes encouraging the woman to attend for subsequent ANC visits.

During those follow-up visits, key PMTCT messages can be reinforced, counselling and support provided, ARV prophylaxis commenced (Chapter 5) and referral for initiation of HIV-related care and support, with ART if indicated (Chapter 7).

It is important that the client gets her test result as soon as possible, to clarify the implications for the pregnancy and to ensure that she takes appropriate HIV prevention measures.

Components of post-test counselling for women testing HIV-positive include:

- Inform client that the test results are ready
- Provide test result clearly and explore the client's understanding of test result
- Discuss the meaning of the test result and provide time to acknowledge it
- Determine whether she understands the meaning of the result and let her talk about her feelings
- Talk about her immediate concerns
- Inform her about essential PMTCT issues: discuss the benefits and limitations of ARV prophylaxis and various infant feeding options
- Discuss disclosure and partner testing specifically explore the risk of disclosurerelated violence from her partner and strategies to reduce it



- Encourage her to attend subsequent ANC visits and discuss the importance of giving birth in a facility where perinatal PMTCT support (i.e. appropriate infection control, availability of intra-partum and neonatal prophylaxis) is available
- Provide information about how she can stay healthy, and how to access HIV-related services (e.g. co-trimoxazole prophylaxis, CD4 testing, treatment of Opportunistic Infections (OI) and, where indicated, ART); this should be addressed early, as it provides hope to the mother and an understanding that health care providers are concerned about her and her partner's well-being as well as that of her baby.

Women found to be infected with HIV should be referred immediately for CD4 testing and clinical staging to see whether life-long ART or triple ARVs is needed. ARVs should be initiated even in the absence of CD4 results, if she is beyond 14 weeks of pregnancy. Drug choices can be modified at a later date based on CD4 results. If at all possible, have a health care worker or volunteer accompany her to the HIV care clinic to ensure that she gets the necessary care, support and treatment.

# 3.5.3 Disclosure of HIV Status

It is very difficult for HIV-infected pregnant women to keep their status confidential as they need specific and ongoing follow-up and treatment.

During the initial post-test counselling session, the counsellor and the HIV positive mother should begin to discuss disclosure, as this may help to:

- encourage the partner(s) to present for counselling and testing
- prevent the transmission of HIV to her partner(s).
- access PMTCT interventions
- receive support from her partner(s) and family when accessing PMTCT and HIV care, treatment and support services.

It is important to respect the woman's choices regarding the timing and process of disclosure. A woman may perceive disadvantages to herself and her family in disclosing her HIV diagnosis; in some communities, this may include stigmatisation, discrimination, rejection or physical violence.

If the woman has indicated that her partner(s) and family may react negatively to her being infected with HIV, the counsellor can help the woman to problem-solve and build skills to use when she discloses her HIV status.

# **3.6 Testing Women of Unknown HIV Status** in Labour

ARV prophylaxis for PMTCT should only be provided on the basis of HIV infection confirmed by rapid or laboratory-based testing. *ARVs should never be provided based on risk assessment or clinical suspicion alone*.

If women with unknown HIV status (i.e. who did not attend ANC or have not been tested during the antenatal period) present to a health service in labour, there may be time to perform HIV rapid testing and provide ARV prophylaxis to the mother and the infant. If labour is well advanced or delivery is imminent, it is still possible to give nevirapine prophylaxis to the infant, begin maternal ARV prophylaxis or life-long ART and provide infant feeding counselling to the mother.

Under these circumstances, rapid testing with informed consent but with an abbreviated approach to pre-test counselling is recommended. The health care worker should remain sensitive and supportive to the woman, and respect her right to refuse testing.



It is recommended that maternal ARV prophylaxis be provided on the basis of a single positive rapid test. The result can be confirmed after delivery.

If there are any delays in confirmatory testing, neonatal prophylaxis may also be provided on the basis of a single positive maternal rapid test in labour.

More detailed, individual post-test counselling will be provided after delivery.

(ARV protocols for this situation are discussed in Chapter 5).

# **3.7** Quality Assurance for Counselling Services

It is essential that the quality of both counselling and testing can be assured with appropriate monitoring and evaluation as a key and planned component of interventions.

Counsellors and other health care providers involved in PMTCT interventions sites must have adequate training, on-site coaching and technical support with supportive supervision.

Periodic audits of centres offering PMTCT and VCT services should be conducted to ensure that approaches meet the appropriate quality standard.

# **3.8 Priority Actions**

Priority actions include linking the NCASC's current mapping of VCT sites with proposed expansion of PMTCT sites. This will involve careful collaboration and communication with DHOs and DPHOs.

Once potential links are identified, DHOs can work with health staff to ensure that centres offering VCT and PMTCT services that are either co-located or near to each other develop ways of working closely and in collaboration – especially to ensure same-day turn-around of testing and post-test counselling.

Centres offering VCT and PMTCT services should identify and orientate interested NGOs and community level health staff and volunteers. NGOs – especially those working with MARPs – are valuable partners for community level follow up of tested individuals and their families, patient and specimen transportation, and promoting VCT and PMTCT services among the communities they support.

# **3.9 Further Reading**

CDC, WHO, UNICEF, USAID. Testing and Counselling for Prevention of Mother-to-Child Transmission of HIV (TC for PMTCT): Support Tools (2005).

Available from http://www.womenchildrenhiv.org/wchiv?page=vc-10-00#S2.4X

NCASC. National Guidelines for Voluntary HIV/AIDS Counselling and Testing (August 2007).

UNICEF. Scaling Up Voluntary Counselling and Testing Services: Lessons Learned from Cambodia (2007).

WHO. Guidance on provider-initiated HIV testing and counselling in health facilities (2007).

WHO SEARO. Voluntary HIV counselling and testing: manual for training of trainers (2004)

Available from http://www.searo.who.int/en/Section10/Section18/Section1562.htm

WHO, UNAIDS and International HIV/AIDS Alliance. *Scaling-Up HIV Testing and Counsel-ling Services: A Toolkit for Programme Managers* (2005)



# 4.1 Strategic Overview

# 4.1.1 HIV and Parenthood

In most societies, childbearing plays a central role in the social identity of both men and women. For many people – including PLHIV – the ability to express oneself sexually and the desire to experience parenthood give meaning to many people's lives.

Many PLHIV experience strong pressure from their family, community and health providers to give up the idea of having children – either because of the risk of HIV transmission to the baby or out of concern for the welfare of the children, if their parents struggle to care for and support them in later childhood.

Some PLHIV (especially those with established families) may prefer to prevent pregnancy, either to delay and space their childbearing until they are clear about quality-of-life issues and access to ART, or to avoid childbearing altogether as a way of minimising demands and complexity in their lives.

# 4.1.2 HIV and Pregnancy

Pregnancy and breast feeding do not appear to have an adverse effect on the progression of HIV infection or disease.

Conversely, for reasons that are not completely clear, HIV infection may have an adverse effect on both male and female fertility; it also appears to be associated with an increased risk of miscarriage, preterm delivery and low birth weight.

Men and women living with HIV who are considering becoming a parent, either biologically or through adoption, clearly need special counselling and support.

# 4.1.3 Unplanned Fertility in Nepal

Despite an increasing use of contraception in Nepal, data from the 2006 *Demographic and Health Survey* indicate that unplanned pregnancies remain common (Table 4.1). This will influence strategic choices in scaling up primary prevention of HIV and prevention of unintended pregnancies in PLHIV.

# Table 4.1Key Fertility Indicators and Contraception Useinforming PMTCT Strategies, Nepal, 2006

Indicator	Urban	Rural	Total
Fertility			
Total fertility rate (children per woman)	2.1	3.3	3.1
Family Planning (married women, age 15–49)			
Currently using any modern method	60%	46%	48%
Married women with an unmet need for family planning	20%	26%	25%

Source: Nepal Demographic and Health Survey – Key Findings (2006)



#### Fertility -

The current fertility rate is 3.1 children per woman, ranging from 2.1 for urban women to 3.3 children in rural areas.

Fertility also varies with maternal education (uneducated mothers have more than twice as many children as women who have completed secondary education) and economic status (women in the poorest households have more than twice as many children as women in the wealthiest households).

#### Contraception –

Use of modern contraceptive methods among married Nepalese women has increased steadily, from 26% in 1996 to 44% in 2006 (Figure 4.1).

More than 90% of all women and men know about female and male sterilisation, the oral contraceptive pill, injectable contraception and male condoms.





Source: Nepal Demographic and Health Survey – Key Findings (2006)

Nevertheless, unplanned pregnancies are common, with 16% of births in the 5 years preceding the 2006 survey not wanted and 14% wanted but mistimed (i.e. wanted later).

The median interval between births is relatively long - 33.6 months - but 22% of non-first births still occur within two years of a previous birth.

Because sexual intercourse is the single most common means of transmission of HIV infection in Nepal, prevention efforts must address the SRH needs of PLHIV and connect them with excellent family planning services.

# 4.1.4 Preventing Unintended Pregnancy in PLHIV

If an HIV-infected woman becomes pregnant, the risk of transmission of HIV to her child can be reduced to <5% (or even more) using a combination of triple ARV prophylaxis or life-long ART during pregnancy, delivery and the entire breastfeeding period along with safer delivery practices.

Optimally, these interventions work best when the mother's HIV status is known before conception so that the pregnancy can be carefully planned and counselling, support and medical interventions can be put in place as early as possible in the pregnancy.

The strategic approaches at different levels are summarised in Table 4.2. Well orientated, trained and motivated health care workers are the essential cornerstone of the strategy.



#### Table 4.2

#### Prevention of Unintended Pregnancies in HIV-Infected Women Integrated Summary of Strategic Components

COMMUNITY	HEALTH FACILITY
• Promote active family planning awareness-raising and case finding among MARPs by community health workers	<ul> <li>Ensure strong links and inter-referral with STI and TB programmes and groups supporting MARPs</li> </ul>
<ul> <li>Establish partnerships and linkages to NGOs / CBOs</li> <li>Community-based AIDS service organisations</li> <li>NGOs serving needs of MARPs (e.g. IDUs, FSWs, sexual minorities)</li> <li>Faith-based initiatives and organisations</li> <li>Facilitate access to and utilisation of counselling and support services, and provide post-test counselling and support</li> <li>Provide long term care and support through linkages with home based care programs, food support, income generating activities, NGOs, CBOs, FBOs, PLHIV support groups, etc</li> </ul>	<ul> <li>Train and orientate MCH staff on risk assessment and VCT to increase timely identification of HIV positive status in pregnant women</li> <li>Encourage prevention, and promote dual protection</li> <li>Help women plan or avoid pregnancies – Identify the "family planning element" in every clinical contact</li> <li>Provide STI screening and treatment</li> <li>Encourage involvement of partner and family</li> <li>Initiate ART if indicated, and adjust as necessary if pregnancy occurs</li> <li>Adjust partner's ART regimen if unable to negotiate protection</li> <li>Offer all elements of essential ANC package if pregnancy partner</li> </ul>
DISTRICT	NATIONAL
<ul> <li>Ensure strong coordination, links and inter-referral with STI and TB programmes and groups supporting MARPs</li> <li>Increase VCT acceptability through client initiated or provider initiated mechanisms</li> <li>Resource mobilisation and harmonisation, ensuring access through HIV services for HIV+ women</li> <li>Develop linkages between VCT services and HIV services for HIV+ women</li> <li>Monitoring and evaluation</li> </ul>	<ul> <li>Coherent strategies to increase early diagnosis and detection of HIV infection</li> <li>Training (family planning, counselling)</li> <li>Resource mobilisation and harmonisation, prioritising MARPs and their spouses and sexual partners</li> <li>Ensure strong integration across MCH, family planning and other programmes</li> <li>Ensure strong links and inter-referral with STI and TB programmes and groups supporting MARPs</li> <li>Monitoring and evaluation</li> </ul>

# 4.2 Reproductive Decision-Making for PLHIV

# 4.2.1 Counselling

To avoid unintended and unplanned pregnancies among HIV positive women, careful reproductive health and family planning counselling is essential for all PLHIV.

HIV-positive couples should be able to make informed choices, free of coercion and have access to quality services to implement these choices. Discussion should:

- balance the desire for pregnancy against the risks, consequences and choices related to an unplanned, unintended pregnancy,
- take into account the woman's and couple's previous and current contraceptive practices, and



• consider the concept of "dual protection" – i.e. the importance of protecting sexual health in parallel with contraception (see Section 4.3).

# 4.2.2 Considerations in Choice of Contraceptive Method

Counselling should help women or couples with HIV to examine a number of factors, which may influence their choice of contraceptive method:

- The safety of the method
- Its effectiveness in preventing pregnancy
- Whether it is appropriate for short-term or long-term use, or whether it is likely to be permanent
- Possible side effects of the method, including side effects related specifically to the woman being infected with HIV
- How easy it will be to use
- Whether it is affordable, with easy access to future supplies
- If a woman is postpartum, what effect the method may have on breast feeding
- How it may interact with medications, especially ARVs
- Whether it provides protection from HIV and STI transmission
- Whether partner involvement or negotiation are required.

# **4.3 Contraceptive Methods for PLHIV**

# **4.3.1 Effectiveness of Different Methods**

Contraceptive options for women infected with HIV are similar to those of women who are HIV negative, and include:

- barrier methods (male and female condoms, diaphragms, spermicides);
- hormonal methods (oral, injectable or implantable);
- the intra-uterine contraceptive device (IUD);
- female and male sterilisation (tubal ligation and vasectomy);
- the lactational amenorrhoea method; and
- fertility awareness-based methods.

Contraceptive effectiveness is the most important consideration for most PLHIV, but not all methods are equally effective.

Figure 4.2 compares the pregnancy ("failure") rate of different methods when they are used "perfectly" and under typical use. The red bars show how often a method fails when it is used correctly and consistently. The blue bars show pregnancy rates for "typical" use, reflecting real life situations (when it may not always be used correctly and consistently).

Failure during "typical" use depends on user characteristics and behaviour, the adequacy of counselling, and access to re-supply. The difference between "correct" and "typical" use is greater for "client-controlled" methods (e.g. combined oral contraceptives, barrier methods and spermicides) than for "provider-controlled" methods (e.g. sterilisation, IUD and injectable contraception).

Note that women who use no method at all may have a risk of pregnancy as high as 85% over a one year period.



Figure 4.2 Effectiveness of Different Methods of Contraception, comparing "Perfect" and "Typical" use



Source: FHI. Contraception for Women and Couples with HIV (2005)

# 4.3.2 Male or Female Condom

Male (or female) condoms are the only methods that have the ability to prevent trans-mission of STIs and HIV in addition to preventing pregnancy – called "*dual protection*". Condoms are less effective for pregnancy prevention than some other methods, but other methods provide no protection at all against HIV or STIs.

The female condom gives women more control over the initiation of barrier contraception and can be inserted hours before intercourse. Their widespread use is currently limited by their higher cost than male condoms.

The effectiveness of "dual protection" depends greatly on condoms being used correctly and consistently. If used correctly every time a couple has intercourse, the male condom is associated with a pregnancy rate as low as 2%, while the female condom has a pregnancy rate of about 5%. However, in common use, their pregnancy rates are much higher – around 15% for the male condom and 21% for the female condom.

Typical condom use results in an 80% reduction in HIV transmission, i.e. it is slightly less effective than the protection it provides against pregnancy.

With consistent condom use, HIV infection rates among uninfected partners can be less than 1% per year. They would also be expected to prevent transmission of one sub-type of HIV to a person who is already infected with another sub-type – called "HIV super-infection".

However, inconsistent condom use has been shown to be just as risky as not using condoms at all -13.3% transmission among inconsistent users compared with 14.4% among non-users.

Condoms are most effective in preventing those STIs that are transmitted through body fluids (e.g. HIV, gonorrhoea, *Chlamydia*). Because a condom may not cover the entire affected area, it is less effective against STIs that are transmitted through direct skin-to-skin contact (e.g. genital herpes and warts).



#### Recommendations –

- Condoms are <u>highly recommended</u> for family planning for PLHIV either alone or, preferably, in combination with another contraceptive method.
- Counselling of clients or couples should focus on strengthening their ability to consistently and correctly use condoms, and should include a demonstration and advice on lubrication, storage and handling.
- Emergency contraception (see Section 4.3.9) should always be available as a backup.

Dual protection includes not only condom use (along with another effective family planning method, which is "dual use"), but also mutual monogamy and use of an effective family planning method, abstinence and/or delay of sexual activity.

### 4.3.3 Spermicides

When used on their own, spermicides have lower contraceptive efficacy than other barrier methods, and they do not protect against STIs. Pregnancy rates range from 18% when used consistently and correctly to 29% with "typical" use.

Spermicides containing nonoxynol-9 (N-9) do not protect against HIV infection or other STIs. When used frequently, N-9 can cause inflammation of the vaginal epithelium (the skin lining the vagina) and this may actually <u>increase</u> the risk of HIV infection.

#### **Recommendation** –

• Spermicides are <u>not</u> recommended for HIV-negative women at risk of infection.

### 4.3.4 Diaphragm

Like the female condom, the diaphragm has the advantage of being controlled by the woman, and can be inserted several hours before intercourse.

Diaphragms offer contraceptive protection similar to other barrier methods but, to achieve this, it is recommended that they are used with spermicides. With "typical" use, they are associated with relatively high failure rates of around 20%

It is possible that diaphragms may offer limited "barrier" protection against STIs, including HIV. However, because diaphragms are generally used concurrently with spermicides to improve their contraceptive effectiveness, the protection against HIV transmission may be reduced.

#### **Recommendations** –

- The use of diaphragms and N-9 containing spermicides by HIV negative women at risk of infection is <u>not</u> recommended.
- If a woman infected with HIV is seeking reliable pregnancy protection, she should consider other, more effective methods of contraception.

### 4.3.5 Oral (Combined Hormonal) Contraceptives

Oral contraceptive pills (OCPs), used correctly, provide highly effective pregnancy prevention – provided the woman remembers to take her pills on time, failure rates are around 1%.

Although subject to ongoing research, available evidence also indicates that hormonal contraceptives are safe for use by HIV-positive women, and for uninfected women with positive partners. However, there are some issues related to interactions between hormonal contraceptives and ARVs:

*Effect of ARVs on Hormonal Contraceptives* – The protease inhibitors (PIs), particularly ritonavir and atazanavir and the non-nucleoside reverse transcriptase inhibitors (NNRTIs); nevirapine [NVP], efavirenz [EFV]) can affect liver enzymes, either speeding up or slowing down the metabolism of contraceptive hormones. Lower blood oestrogen levels can – theoretically – reduce the effectiveness of OCPs, while higher concentrations could increase hormone-related side effects.



*Effect of Hormonal Contraceptives on ARVs* – Similarly, contraceptives may reduce the efficacy of some – but not all – PI ARVs. Hormonal contraceptive use may also increase shedding of HIV-infected cervical cells, thereby increasing the risk of HIV transmission to an uninfected male partner.

#### Recommendations -

- Women with HIV infection can use hormonal OCPs without any restriction.
- OCPs may not be the best choice for HIV infected women on ART. If a woman on ART decides to start or continue hormonal OCP use, a low dose pill with very careful attention to taking the pill at the correct time each day is the best choice.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission, and may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.
- Back-up contraception should be available if a woman:
  - is taking medication that increases the metabolism of OCPs, including rifampicin (for TB) and any anticonvulsant medication other than valproic acid;
  - o is taking medication that reduces the absorption of OCPs, including broad-spectrum antibiotics such as ampicillin, amoxycillin or tetracycline; or
  - o if she has severe diarrhoea, which can also reduce the absorption of OCPs.

# 4.3.6 Injectable (Progestogen-Only) Contraceptives

Pregnancy rates for injectables are less than 0.5% under both "perfect" and "typical" use.

They are easy to use as they require very little action on the part of the client other than to remember to return for repeat injection every three months. Although all hormonal methods are reversible, fertility return may take somewhat longer after ceasing injectable contraception than with other methods.

NVP has been found to reduce serum progesterone levels by about 20%, but without reduced contraceptive efficacy.

Injectable progestogen-only contraception has been associated with an increased risk of cervicitis – both non-specific and due to *Chlamydia*. Research into its effect on ARV levels has been inconclusive.

#### **Recommendations** –

- Injectable progestogen is a suitable form of contraception for women with HIV infection, including those on ART.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission.

### **4.3.7 Progestogen Implants**

Progestogen-only implants offer pregnancy protection for up to 5 years. They even easier for the client to use, but staff require some training and additional skills to become proficient at insertion.

Pregnancy rates and interactions with ARVs are similar to those seen with injectable progestogen.

#### Recommendations –

- Progestogen-only implants are a suitable form of contraception for women with HIV infection, including those on ART.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission.



# 4.3.8 Intra-Uterine Contraceptive Devices

The IUD is a highly effective, long-term method of contraception with a failure rate of less than 1%. It can remain in place for up to 12 years – possibly longer. Its effectiveness is similar to that of sterilisation but, unlike sterilisation, it is reversible.

Studies have confirmed that IUDs are safe for PLHIV, with no impact on disease pro-gression or clinical well-being.

A theoretical concern about IUD use by women with HIV is that the slightly higher menstrual flow and irritation of the cervix by the "string" it could increase shedding of HIV, thus increasing the risk of transmission to a sexual partner. However, studies in Africa did not demonstrate increased viral shedding.

Another theoretical risk is that advanced immunosuppression could increase the risk of IUD-related complications (e.g. pelvic inflammatory disease and other genital tract infections).

**Recommendations** –

- IUD <u>may</u> be either initiated or continued in HIV-positive women who are clinically well (either WHO Stage 1 or 2, or already on ART).
- A woman who develops symptomatic illness (WHO Stage 3 or 4) while using an IUD can continue to use the device provided she is stable on ART.
- HIV-positive women who are not clinically well should generally <u>not</u> have an IUD inserted unless other methods are not available or acceptable.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission.

### 4.3.9 Emergency Contraception

Emergency contraceptive pills (ECPs) are the most common method of emergency contraception after unprotected intercourse. (Insertion of an IUD may also be used for this purpose, provided the woman meets the medical eligibility criteria; see Section 4.3.8).

ECPs are available as progestin-only or combined oestrogen-progestin tablets; they are taken as a single dose. The sooner ECPs are started, the more effective they are. If taken within 120 hours (5 days) of unprotected intercourse, ECPs reduce the risk of pregnancy by at least 75 percent; the progestin-only tablets are slightly more effective than the combined regimen.

There are no data on interaction between ECP and ARVs. ECPs contain a higher dose of hormones than regular OCPs, so their effectiveness in pregnancy protection may not be significantly affected by ARV drugs.

Like other hormonal contraception, ECPs do not provide any protection from STI or HIV transmission.

#### Recommendations –

- For HIV-positive women who have unprotected sex and may be at risk of an unwanted pregnancy, access to emergency contraception is <u>essential</u>.
- Providers who offer emergency contraception should also help women to choose a regular contraceptive method and counsel them about how to use the method correctly and when to begin using it.

### 4.3.10 Male or Female Sterilisation

For women and couples with HIV who already have children and have decided to have no more, female or male sterilisation may be a popular option.

Both forms of sterilisation are considered permanent, and both are very effective. The pregnancy rate following female sterilisation is about 0.5% during the first year, increasing to 1.85% over 10 years. Male sterilisation is associated with pregnancy rates between 0.1 and 0.15% during the first year.



#### Recommendations –

- Sterilisation is <u>highly recommended</u> for family planning for PLHIV.
- Informed voluntary choice is essential.
- Careful infection control is essential during the procedure, especially if the man or woman is immunocompromised.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission.

### 4.3.11 Lactational Amenorrhoea Method

The lactational amenorrhoea method is a temporary option that can be used by women who are a) in the first 6 months following delivery, b) exclusively breast feeding, and c) continue to have no menstruation. Provided a woman meets all three of these criteria, she has only a 1% to 2% chance of becoming pregnant.

Women infected with HIV need to know that their child may also become infected during breast feeding. However with new ARV interventions this risk is greatly reduced.

HIV-infected mothers who do not breast feed will not be able to rely on lactation amenorrhea. If they do not use appropriate family planning methods, they may have a shorter interval between births and an increased risk of an early subsequent pregnancy. It is therefore important to ensure that HIV-infected women receive contraceptive advice and have access to appropriate services within 6 weeks of delivery.

For women who are HIV negative during pregnancy but who become infected with HIV while breast feeding, the risk of HIV transmission to the baby will be very high (up to 29%). *All HIV negative lactating mothers need careful counselling on HIV prevention*.

#### Recommendations –

- HIV positive women must receive careful counselling regarding the advantages and disadvantages of:
  - o different methods of infant feeding (see Section 6.2.3)
  - o relying on lactational amenorrhoea for family planning.
- HIV negative women who do not want to have children should be counselled to consider other, safer methods of contraception.
- The consistent use of condoms must be recommended to prevent HIV and other STI transmission.
- As HIV-positive women will begin to feed their babies complementary food at 6 months and discontinue breast feeding at 12 months postpartum (see Section 6.3), family planning *must* be re-assessed frequently during the first year postpartum.

### 4.3.12 Methods Based on Fertility Awareness

Fertility awareness-based methods involve the identification of the fertile days of the menstrual cycle, either by observing signs of fertility (e.g. cervical secretions, basal body temperature) or by counting the days of the cycle.

These methods require extremely high motivation, discipline and diligence.

Pregnancy rates with "perfect" use are 2-5%, but are typically between 12% and 22%.



#### Recommendations –

- PLHIV who do not want to have children should be counselled to consider other, more reliable methods of contraception.
- The consistent use of condoms must be recommended to prevent transmission of HIV and other STIs.

# **4.4 Termination of Pregnancy**

Termination of pregnancy during the first trimester is legal in Nepal (and up to 18 weeks in cases of rape or incest, and at any time if a woman's life or health is in danger or if there is significant fetal impairment).

Termination must be voluntary and accompanied by counselling, and should follow the procedures of the appropriate national guidelines and legislation.

#### HIV infection alone is not an indication for termination of pregnancy.

If a woman who is infected with HIV is concerned about transmission to her unborn baby, she should be counselled about the options and risks associated with available PMTCT interventions.

# **4.5 Special Considerations for Discordant Couples**

# 4.5.1 Definition

If one partner is infected with HIV and the other is not, the couple is said to be discordant (or serodiscordant).

### 4.5.2 HIV Prevention

In discordant couples, the correct and consistent use of male condoms is the only method to effectively prevent HIV transmission.

They should be used even when another method is chosen to prevent pregnancy.

#### **4.5.3 Contraception**

All the above limitations and recommendations for different methods of contraception in PLHIV (Section 4.3) apply to discordant couples.

### 4.5.4 Conception

If, after careful consideration and counselling, a discordant couple wishes to have a baby, very careful planning of the pregnancy is essential.

#### If the woman is infected with HIV and the male partner is not -

Artificial insemination using the male partner's sperm may be available in a specialist centre. It is essential that the woman is in good health and, if CD4 or viral load assays are available, that these indices are satisfactory and stable.

If the woman is already taking ART and her regimen contains EFV, that drug should be substituted as it is teratogenic during the first trimester; it may be replaced with NVP or a PI. From the second trimester, either EFV may be resumed or the replacement drug may be continued.



Recent evidence suggests that circumcision in HIV negative males may reduce the risk of transmission from an infected partner by up to 60% where unprotected contact occurs.

#### If the man is infected with HIV and the female partner is not -

In this situation, the couple's options are very limited.

If the couple have the resources to attend the Thapathali Maternity Hospital in Kathmandu, "sperm washing" may be used (to remove HIV from a specimen of semen). This then makes artificial insemination with the man's semen an option.

If the infected male partner is on ART, a low viral load will reduce the risk of transmission to the woman during unprotected sex.

#### Options relevant to both types of discordant couple -

Other options require unprotected intercourse for conception to occur. This should be guided by very careful counselling and advice, including by keeping number of occasions of unprotected sex to a minimum.

The couple should be provided with cycle-based advice about the woman's fertility and the likely timing of ovulation menstrual cycle and the (approximately mid-cycle). To limit the risk to the uninfected partner while maximising the likelihood of pregnancy, attempts to conceive should only take place around the time of ovulation and with a minimum number of unprotected contacts.

Treatment of any active STIs in either partner may reduce the risk of HIV transmission and should take place prior to any unprotected contact.

# 4.6 Priority Actions

### **4.6.1 National and District**

In consultation with the NCASC, the NHTC will have the responsibility for ensuring that training materials on SRH and family planning include appropriate guidance on the needs of PLHIV.

The NCASC and NHEICC will support the production of IEC materials addressing the SRH needs of PLHIV.

The District level is responsible for coordination and management of integrated training in family planning and SRH, and for monitoring and mobilising family planning resources.

### 4.6.2 Health Facility and Community

In collaboration with NGO partners, health facilities must identify strategies that will increase early diagnosis and detection of HIV infection, especially among:

- women engaged in high risk behaviours,
- spouses and sex partners of high risk groups or individuals,
- men in high risk groups or with high risk behaviours, and encouraging their female partners and spouses to get tested, and
- increasing VCT acceptability through client initiated or provider initiated mecha-nisms, and increased general awareness

They should develop referral linkages with centres offering VCT and providing clinical services for PLHIV and MARPs (including STI and TB programmes), and emphasise the importance of careful family planning for these populations.



They will be responsible for identifying FCHVs and other community level health workers, establishing their training needs and conducting training in SRH and family planning, including for PLHIV and MARPs. This will increase knowledge of family planning among health volunteers and within MCH programs, and in centres offering VCT and providing clinical services for HIV positive women, and stimulate awareness-raising and case finding among MARPs by FCHVs and other community health workers.



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FHI. Contraception for Women and Couples with HIV (2005).

WHO. Medical eligibility criteria for contraceptive use, 3rd edition (2004)

WHO SEARO. Voluntary HIV counselling and testing: manual for training of trainers (2004)

Available from http://www.searo.who.int/en/Section10/Section18/Section1562.htm



# **5.1 Strategic Overview**

# 5.1.1 Available Interventions and their Timing

The three elements of PMTCT during pregnancy, labour and post-partum are:

- providing ARV prophylaxis (or therapy) during pregnancy, labour and post-partum to the mother, and to the baby following delivery
- implementing safer delivery practices
- providing ongoing counselling and support on safer infant feeding

These interventions can be offered before conception, antenatally, during labour, following delivery and throughout the first year postpartum. (Table 5.1).

# Table 5.1

# **Timing of Principal PMTCT Interventions**

		Setting	
Intervention	Antenatal	Labour and Delivery	Postnatal
ART during pregnancy (if available)	√	✓	$\checkmark$
ARV prophylaxis for mother (if available)	$\checkmark$	$\checkmark$	$\checkmark$
Interventions during delivery that are known to "IMTCT	(discuss)	✓	
ARV prophylaxis for infant (within 72 hours after birth)	(discuss)		$\checkmark$
Counselling and support for safer infant feeding	(discuss)	✓	✓
Provision of (or referral to) prevention and CT&S services for	$\checkmark$		$\checkmark$
women infected with HIV, their infants and their families			
Provision of (or referral to) prevention and support services for women who test negative to help them stay uninfected	1	V	$\checkmark$

Adapted from: WHO SEARO. Voluntary HIV counselling and testing: manual for training of trainers (2004)

# 5.1.2 Practical considerations in choosing ARV regimens for PMTCT

Practical considerations in scaling up PMTCT, including selecting which ARV regimens to use, include:

- access to and the availability of HIV counselling and testing services;
- access to antenatal care, and the proportion of women using ANC services;



- the timing of the first antenatal visit, which affects the stage of pregnancy each woman is diagnosed;
- the proportion of HIV-infected women who are aware of their status;
- the frequency of antenatal visits, which affects follow-up care and counselling, and monitoring adherence to ARV prophylaxis;
- the quality of ANC available;
- the proportion of births occurring in health care facilities or attended by a skilled birth attendant;
- the proportion of health facilities with ARVs available and universal precau-tions in place
- acceptability and ease of ARV dosage schedules;
- efficacy and safety of different ARV drug regimens, including their potential to compromise future treatment options; and
- access to early HIV-related care postpartum, including in community settings.

Patterns of breast feeding and the prevalence of infectious and nutritional illnesses during childhood will all influence our strategic choices and approaches to infant feeding, and are discussed in detail in Chapter 6.

Ongoing prevention, care, treatment and support after delivery are discussed in Chapter 7.

# **5.1.3 Maternal and Neonatal Health Context**

The DHS provides the most recent data on access to and utilisation of antenatal care and mater-nal and neonatal health services in Nepal (Table 5.2).

# Table 5.2 Key Antenatal and Delivery Care Indicators informing PMTCT Strategies, Nepal, 2006

Indicator	Urban	Rural	Total
Maternity Care			
Antenatal care from a skilled birth attendant (% of women)	85%	38%	44%
Delivery care from a skilled birth attendant (% of live births)	51%	14%	19%
Institutional births in the last 5 years (% of live births)	48%	14%	18%
Postnatal care for most recent birth (% of women)	54%	30%	33%

Source: Nepal Demographic and Health Survey – Key Findings (2006)

#### Maternal Mortality Rates -

The estimated maternal mortality rate (MMR) in Nepal is high – between 281 (2006 DHS data) and 539 (2005 MOHP data) per 100,000 live births. In the UN *Human Development Report 2006*, only 14 countries had a higher MMR than Nepal.

Over 90% of maternal deaths occur in women from rural areas.



#### Antenatal Care -

Almost half (44%) of mothers received antenatal care from a skilled birth attendant (i.e. doctor, nurse, or midwife). Fifteen percent of urban mothers but 62% of rural mothers did not receive antenatal care from a skilled birth attendant (SBA).

Only 28% of women initiated antenatal care before the fourth month of pregnancy, and only 29% received four or more antenatal visits.

#### **Delivery Care –**

The majority (81%) of births take place at home or outside a health facility.

Only 19% of births were delivered with the assistance of a SBA; 19% were delivered by a traditional birth attendant, 50% by a relative or other untrained person, and 7% without any type of assistance at all. Trends since 1994 are summarised in Figure 5.1.



#### Figure 5.1

Source: Nepal Demographic and Health Survey – Key Findings (2006)

#### Postnatal Care -

One-third of mothers (31%) who had a live birth in the 5 years preceding the DHS received postnatal care within two days of birth. Two-thirds of mothers (67%) received no postnatal care at all.

### **5.1.4 Antiretroviral Prophylaxis and its Effectiveness**

The reason for providing antenatal ARV prophylaxis (or treatment) to the mother is to reduce viral replication in order to reduce the risk of transmission to the foetus during pregnancy, labour and delivery.

#### Women with indications for life-long ART -

To eliminate HIV infection in infants and young children, all pregnant women eligible for ART must be started on treatment as early as possible in pregnancy. Some ARVs (e.g. EFV) are teratogenic and are best avoided in the first trimester of pregnancy; however, maternal health and well being generally take precedence over foetal considerations.



#### Women without indications for life-long ART -

Pregnant women who do not yet need ART for their own health must be given highly effective triple ARV prophylaxis to prevent MTCT. The most commonly used drugs are two nucleoside reverse transcriptase inhibitors (NRTIs), usually zidovudine (ZDV) and lamivudine (3TC), and a third drug either efavirenz (EFV) (an NNRTI), Lopinavir/ritonavir (LPV/r) (a boosted PI) or, Abacavir (ABC) (as part of a triple NRTI regimen).

Many different prophylactic regimens have been trialled and evaluated. In resource limited settings, they have been shown to reduce MTCT from around 30% to around 12-14% for the simplest, single-drug approaches, e.g. single-dose nevirapine (sdNVP) at the onset of labour; to around 6% for multi-drug protocols starting during the last 4-8 weeks of pregnancy; and to around 2% for multi-drug protocols commencing no later than the start of the third trimester.

In general, *the more drugs the mother takes and the longer she takes them, the more effective the regimen*. However, the length of the prophylactic regimen and the choice of drugs may vary according to the stage of pregnancy a woman is identified as infected with HIV and her clinical condition.

#### ARV prophylaxis for the newborn infant -

Providing additional ARV prophylaxis for the newborn infant is intended to "mop up" circulating virus that may have been transmitted in spite of maternal ARV prophylaxis or treatment.

All HIV-exposed babies should receive daily NVP for the first 6 months of life starting as soon as possible after birth.

#### Risk of ARV Drug Resistance –

Viral drug resistance is potentially a problem for HIV positive women following short-term exposure to ARVs for PMTCT – especially single- and two-drug regimens – and for infants who become infected. This is a particular risk for NVP and 3TC, where a single mutation can lead to high-level resistance; multiple mutations are needed to confer resistance to ZDV.

NVP has a long half-life, and can be detected in the woman's blood for up to 21 days after a single dose. It is this prolonged exposure to non-suppressive drug levels that can give rise to resistance, which is seen in up to 60–89% of women receiving sdNVP.

NVP resistance is more common in women whose plasma viral load and/or CD4 cell count indicate that she is eligible for life-long ART, and less common in women who do not have indications for life-long ART. NVP (and 3TC) resistance are also less common when the drug is given in combination with other ARVs.

In the WHO option chosen by Nepal, recommendations are that ARVs will be given as triple ARV prophylaxis and will be taken from 14 weeks of pregnancy, throughout labour and delivery and breastfeeding until approximately 12 months postpartum, 1 week after complete weaning. Since NNRTIs may persist for longer than 4-7 days after discontinuation, continuing ZDV + 3TC for one extra week after EFV discontinuation helps reduce the risk of resistance at the time of triple ARV discontinuation.

### **5.1.5 Safer Delivery Practices**

#### Normal vaginal delivery -

The greatest risk of MTCT occurs intrapartum (i.e. during delivery), when the foetus comes in contact with maternal blood or cervical secretions and foetal and maternal blood mix after the placenta separates from the uterus. The risk is increased when prolonged rupture of the membranes or STIs result in inflammation of the lower genital tract, and when operative or manipulative delivery increase the risk of mixing of foetal and maternal blood.

Most published studies of successful PMTCT strategies in resource-limited settings allow women to deliver normally. However, to reduce MTCT during normal delivery, it is important to minimise both the duration of labour and obstetric interventions (including artificial rupture of the membranes); strategies are summarised below.



Published studies do not provide precise guidelines on how long to allow an HIV-positive mother to labour. However, if labour is not established quickly, augmentation of labour as per national obstetric guidelines should be initiated. If labour or the time after rupture membranes becomes prolonged <u>and</u> operative facilities are available, caesarean section should be considered or advice obtained from an obstetrician or physician skilled in management of HIV-affected pregnancies.

#### Operative vaginal delivery -

Operative or manipulative vaginal delivery (including forceps or vacuum extraction, breech extraction and manipulations during vaginal delivery of multiple pregnancy) increase the risk of mixing of fetal and maternal blood. They should be avoided.

#### Caesarean Section –

In the absence of any ARV prophylaxis, caesarean section performed before the onset of labour or rupture of the membranes may reduce the risk of MTCT by up to 50%.

For women with a viral load (VL) <1,000 copies/mL, the theoretical benefit is marginal. This includes where adequate viral suppression has been achieved through triple ARV prophylaxis or through life-long ART prescribed for maternal indications. If viral load testing is available and elective C-section is being considered for the purpose of PMTCT of HIV, it should be performed prior to the onset of labour, being careful to avoid iatrogenic prematurity. If the VL is > 1,000 copies/mL, C-section may be of benefit. If the VL is less than 1,000 copies/mL, the mother can safely deliver vaginally from an HIV perspective.

The cost and limited access to surgical facilities and a safe blood supply also mean that delivery by caesarean section is seldom feasible for many women in Nepal. Caesarean section carries a higher risk of postoperative sepsis and other complications in HIV infected women, and these are likely to be more difficult to manage in a resource-limited setting.

# 5.1.6 Integration with Existing MCH Services

Good maternal health care helps women with HIV infection stay healthy longer and care for their children better.

Since most elements of PMTCT services parallel a safe motherhood programme – quality ANC, safe labour and delivery, prevention and management of obstetric complications, postpartum care, family planning, and infant feeding support – integration of PMTCT activities with broader MCH services can be done relatively easily and effectively.

Improving services for HIV-infected mothers (whose HIV status will most likely not yet be known when they present for care) will improve services for all pregnant women and their babies. By strengthening existing services and integrating PMTCT into the different stages of MCH care – pre-pregnancy care, antenatal care, labour and delivery, and infant feeding and support – all mothers and babies will benefit, including those vulnerable to or living with HIV

For the successful implementation of PMTCT programmes, the following elements should be included as part of ANC:

- Health information and education
- Education about safer sex practices and HIV
- Education about injection safety
- HIV counselling and testing
- Partner HIV counselling and testing
- Interventions to reduce the risk of MTCT
- Infant feeding counselling and support
- Counselling and support for safe motherhood and maternal wellbeing including malaria and TB prophylaxis and treatment
- Diagnosis and treatment of STIs
- Syphilis testing for pregnant women is recommended. If the RPR is positive, appropriate treatment and follow-up of mother and baby is needed.
- Discussion of family planning choices to be used following delivery



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With some additional resources and training, current MCH personnel can implement all PMTCT activities in existing facilities, including strengthening the availability and quality of VCT in antenatal and labour ward settings (see Chapter 3).

# 5.1.7 Tightly Coordinated and Supervised Antenatal Care

ANC for women living with HIV includes the basic services recommended for all pregnant women. However, obstetric and medical care will also need to be expanded to address the specific needs of women infected with HIV.

All HIV-infected mothers must be evaluated for ART eligibility and offered either life-long ART or triple ARV prophylaxis and prophylaxis against OIs including Cotrimoxazole and Isoniazid Preventive Therapy. Individualised, flexible care and support should be provided by midwife or MCHW, with medical officer support and obstetrician back-up as necessary.

Antenatal care is strengthened considerably by the additional involvement of a treatment "buddy" at home and a community-based volunteer (e.g. a FCHV, a CHBC worker) or support person (e.g. working for an involved NGO). The "buddy" would jointly supervise adherence to home-based ART or ARV prophylaxis, and support attendance for targeted follow-up antenatal care and health facility-based delivery.

Careful counselling regarding options for infant feeding should also commence during the antenatal period (Chapter 6).

# **5.2** Assessment of Women found to be infected with HIV during Pregnancy

5.2.1 Clinical and Immunological Assessment

Treatment for a pregnant woman with medical indications to commence ART not only addresses her own health and well-being but also reduces the risk of MTCT, especially if she is at an advanced clinical stage of disease.

Treatment decisions should be based primarily on their need and eligibility for ART and secondarily on the well-being of the fetus. Other considerations include the gestational age of pregnancy and potential side-effects, particularly those related to pregnancy.

All women found to be infected with HIV during pregnancy should be rapidly assessed according to the *National Guidelines on ARV Therapy*. This will include

- All routine pregnancy-related examinations and investigations
- Clinical staging according to WHO criteria
- Baseline haematological and biochemical investigations
- CD4 T lymphocyte count
- Screening for tuberculosis

It is essential that **all HIV-infected pregnant women are immediately referred for ART evaluation** and commencement of either immediate life-long ART or triple ARV prophylaxis at 14 weeks. Programs need to put methods in place to support these women for rapid evaluation as soon as possible. If woman is already beyond 14 weeks of pregnancy, ARVs can be initiated even in the absence of CD4 results using regimens described below for Triple ARV Prophylaxis.



# **5.3** Life-long ART for pregnant women meeting criteria

# 5.3.1 Indications for Commencing Life-long ART

Criteria for commencing life-long ART -

The criteria for commencing life-long ART in pregnant women are:

- WHO Stage 4 disease, irrespective of CD4 cell count
- WHO Stage 3 disease, irrespective of CD4 cell count
- WHO Stage 1 or 2 disease with CD4 < 350/mm<sup>3</sup>

All pregnant women who meet these criteria should commence life-long ART.

### First-line ART regimen for life-long ART –

The recommended first-line ARV regimens for treating pregnant women, who need life-long ART is:

ZDV 300mg bid + 3TC 150 mg bid + NVP 200mg bid (start NVP od first 14 days)

Or

### ZDV 300mg bid + 3TC 150 mg bid + EFV 600 mg od (do not start EFV in first trimester)

ART should be given from diagnosis. This should continue antenatally, through labour and postpartum for life.

Fixed dose combinations of ZDV + 3TC and of ZDV + 3TC + NVP are currently available and may improve adherence to ART.

NVP precautions: NVP is the NNRTI drug of choice for ART in pregnancy for women who need life-long ART; it should be introduced gradually, to enable careful monitoring for toxicity (including hepatitis, skin rash). This means start NVP 200mg od for the first 14 days and increase to bid if no reactions occur.

- CD4 250-350: NVP reactions may be more common in women starting NVP- containing ART with a CD4 cell count between 250 and 350 cells/mm<sup>3</sup>. In this case, close monitoring should continue for the first 12 weeks of treatment. If close clinical and liver function test monitoring is not possible, consider another option (i.e. EFV) for these women
- CD4 >350: If a woman requires ART, but has a CD4 over 350, do not use NVP due to increased risk of severe hepatic reactions. EFV is a better option.

EFV precautions: EFV is teratogenic. Do not start EFV in first trimester. Ensure postpartum family planning in all woman taking EFV after delivery.

Infants of women who require life-long ART should receive NVP suspension as soon as possible after birth and continue a daily dose until 6 weeks of life.



### Table 5.3

# Life-Long ART: Recommended First-Line ART Regimen for treating Pregnant Women, and Prophylactic Regimen for Infants

Recipient	Timing	ARV(s)
Mother	Start ASAP in pregnancy and continue throughout pregnancy, labour and delivery and postpartum, for life	<ul> <li>ZDV 300mg twice a day + 3TC 150mg twice a day</li> <li>+ NVP 200mg once a day for 14 days</li> <li>If no reaction, continue ZDV + 3TC and increase NVP to 200mg twice a day after 14 days</li> <li>OR</li> <li>ZDV 300mg twice a day + 3TC 150mg twice a day</li> <li>+ EFV 600mg once daily</li> <li>Do not start EFV in first trimester. Ensure postpartum contraception if woman is taking EFV.</li> </ul>
Baby	Neonatal	Infant NVP once daily for 6 weeks. NVP dose* is: 10 mg (1.0 mL) if birth weight is <2.5 kg 15 mg (1.5 mL) is birth weight is ≥2.5 kg First dose should be given as soon as possible after birth and continued until 6 weeks of life.

\* Low birth weight infants should receive mg/kg dosing, suggested starting dose is 2 mg/kg once daily.

For special circumstances including anaemia, delivering outside of PMTCT sites, previous PMTCT ARV exposure, tuberculosis co-infection, Hepatitis B co-infection, women who inject drugs, acute HIV infection and HIV 2, see below.

# 5.3.2 Women who become Pregnant while on ART

Ideally, couples living with HIV should receive ongoing counselling on reproductive choices including both contraception and if desired, safer conception advice. ART should be fully suppressive before conception and maintained throughout pregnancy, delivery and breastfeeding. Choice of ARV regimen is important.

#### Clinical and Immunological Assessment of women already on ART before pregnancy

Clinical assessment will be the same as that for women found to be infected with HIV during pregnancy. Additional considerations include the gestational age of the pregnancy, the clinical findings and the ART regimen being used.

#### If Pregnancy is recognised during the First Trimester

#### Continue ART-

Women already taking ART who become pregnant should continue ART. *Discontinuing ART during pregnancy has been associated with viral rebound and CD4 decline*, increasing the risk of MTCT and HIV disease progression.

#### Considerations regarding efavirenz –

The main concern is with EFV-induced fetal abnormalities. EFV should therefore only be used during the first trimester if the potential benefit to the mother exceeds the potential risk to the fetus (e.g. if previous adverse reactions to ARVs rule out other therapeutic options).

If pregnancy is <u>planned</u>, consider switching to a non-EFV containing regimen (e.g. ZDV + 3TC + NVP) several weeks prior to attempting to conceive.



If the woman <u>conceives while taking an EFV-containing regimen</u> and pregnancy is recognized in the first 6 weeks after the LMP. EFV should be stopped and substituted with either NVP or LPV/r. No lead-in dose of NVP is necessary in this case. If a woman is found to be pregnant, later than 6 weeks after LMP, continue EFV as the dangerous period has passed. Note: WHO recommends using 28 gestational days of pregnancy as the cut-off, this is the same as 6 weeks by LMP.

# Temporarily discontinuing EFV alone or EFV-based HAART until the second trimester is associated with virological and immunological deterioration and increased risk of MTCT, and is <u>not</u> recommended.

#### If Pregnancy is not recognised until the Second or Third Trimester

Women who are taking ART (including EFV-containing regimens) and are in the second or third trimester of pregnancy can continue their current ART regimen.

Exposure to EFV during the first trimester is not an indication for termination of pregnancy.

# 5.3.3 Opportunistic Infection prophylaxis

Cotrimoxazole is needed for all mothers who require life-long ART and all HIV-exposed babies. In addition, many mothers will benefit from Isoniazid Preventive Therapy (IPT) as well. See Chapter 7 for details.

# **5.4** Antiretroviral Prophylaxis to Prevent HIV Infection in Infants of Mothers who do Not yet Need Life-long ART

# 5.4.1 ARV Prophylaxis for HIV-Infected Women who do not yet need life-long ART.

Triple ARV prophylaxis should be provided for women who do not yet need life-long ART. It can be started antenatally from 14 weeks, during labour and delivery or during the first year postpartum.

All women diagnosed during the antenatal period, at labour and delivery or in the first postpartum year should be provided with one of the following prophylactic triple ARV regimens for PMTCT. All babies should receive daily nevirapine until 6 weeks as described below.

#### Triple ARVs as prophylaxis for PMTCT –

HIV-infected pregnant women who do not yet need life-long ART (i.e. CD4 is >350 and WHO stage is 1 or 2) should start three ARV drugs as soon as possible after 14 weeks of pregnancy. However, this same regimen can be started in 2<sup>nd</sup> or 3<sup>rd</sup> trimester of pregnancy, during labour and delivery or during the first year postpartum.

Unknown CD4: If CD4 results are not yet available, start one of the following regimens to maximize the time on therapy before delivery.

Since life-long ART is not required in these women, they should stop triple ARVs one week after the cessation of all breastfeeding. For those on EFV, this should be in a phased fashion. EFV should be stopped first (1 week after breastfeeding stops), the 2 NRTIs should be continued for an additional week and then stopped. This "covering the tail" is to avoid future NNRTI resistance.



### Table 5.4

# Triple ARV Regimens for pregnant or lactating HIV positive women who do not yet require life-long ART

Recipient	Timing	ARV(s)
Mother	Start from14 wks of pregnancy, in labour/ delivery or in the first year postpartum. Continue throughout pregnancy, labour and delivery and the first year postpartum.	ZDV 300mg bid + 3TC 150mg bid + EFV 600mg once a day OR ZDV 300mg + 3TC 150mg + ABC 300mg all twice daily OR ZDV 300mg + 3TC + LPV/r 400/100mg all twice daily
Baby	Neonatal	Infant NVP once daily for 6 weeks. NVP dose is*: 10 mg (1.0 mL) if birth weight is <2.5 kg 15 mg (1.5 mL) is birth weight is ≥2.5 kg First dose should be given as soon as possible after birth and continued for the first 6 weeks of life.

\* Low birth weight infants should receive mg/kg dosing, suggested starting dose is 2 mg/kg once daily.

### Considerations in choice of "third drug" (i.e. EFV vs LPV/r vs ABC)

Efavirenz (EFV) precautions: EFV is teratogenic. Ensure postpartum family planning in all woman taking EFV after delivery.

Lopinavir/ritonavir (LPV/r) precautions: LPV/r is more expensive and is often preserved for secondline therapy as there are not many options currently in Nepal

Abacavir (ABC) precautions: ABC as part of a triple NRTI regimen is not as effective at viral suppression in adults with high viral loads. However, one study shows that it is very good at preventing PMTCT in women with CD4s over 200.

Some women on triple ARV prophylaxis need Cotrimoxazole even if they are not yet eligible for life-long ART (i.e. those in WHO Clinical Stage 2 with high CD4). Please see Chapter 7 for details.

# **5.5 Neonatal Prophylaxis**

All babies of HIV-infected mothers should receive Nevirapine suspension for the first 6 weeks of life. This regimen applies regardless of whether mother is on life-long ART or ARV prophylaxis, regardless of the duration of maternal ARVs, and regardless of infant feeding method.

The first dose should be given as soon as possible after birth. This should continue as once daily dosing until 6 weeks of life.

Nevirapine infant dose:

- 10 mg (1.0 mL) if birth weight is <2.5 kg
- 15 mg (1.5 mL) if birth weight is  $\geq$ 2.5 kg

Low birth weight infants should receive mg/kg dosing, suggested starting dose is 2 mg/kg once daily.

#### Mother found to be HIV-positive after delivery (within first year of breastfeeding):

When a mother is diagnosed HIV-positive after 6 weeks postpartum, start maternal ART/ARVs and consult paediatric HIV specialist for decisions regarding infant prophylaxis duration.



# **5.6** Laboratory monitoring of life-long ART or triple ARV prophylaxis

If available, full blood count (FBC) and liver function tests (LFTs) should be monitored at baseline and then two-weekly for the first month after initiating ART, then monthly for two months, then three-monthly if stable.

CD4 cell count should be monitored six-monthly.

If available, viral load testing should be used:

- To confirm treatment failure.
- If resource allow, obtain viral load every 6 months to detect viral replication.
- Pregnant women at 36 weeks on ART or triple ARVs and considering an elective caesarian section, should be offered viral load testing, if possible.
- Women starting NNRTI based ART after previous PMTCT exposure to SD-NVP or triple ARV with EFV and no ZDV/3TC tail, should have viral load testing 6 months after start, if possible.

# **5.7** Special Situations in Pregnant or Lactating <u>HIV-infected Women</u>

# 5.7.1 Women with Anaemia -

All women in areas with high prevalence of iron deficiency should take iron and folate during pregnancy regardless of haemoglobin.

ZDV may be associated with haematological toxicity (anaemia and neutropenia).

Pregnant women with severe anaemia (haemoglobin <7.5 g/dl) or neutropenia (neutrophil count < laboratory reference range) should be carefully investigated as usual for any other underlying causes (e.g. blood loss, nutritional deficiency, soil transmitted helminths) and haematinics prescribed.

Women with severe anaemia should take Tenofovir (TDF) in place of ZDV for either life-long ART or triple ARV prophylaxis . TDF is given 300mg once daily.

### 5.7.2 Women with previous PMTCT exposure -

Women with previous pregnancy may have taken Single-dose NVP or NVP in combination with other ARVs. They also may have been on triple ARVs, which were discontinued after breastfeeding. Some of these women are at risk for NVP resistance.

# ART Regimens recommended for women with prior sd NVP or sd NVP +ZDV exposure in PMTCT

Previous ARV exposure for PMTCT	Regimen to use at later initiation of ART
sdNVP (+/- antepartum ZDV) with NO AZT/3TC tail in last 12 months	Start PI based regimen (less preferred is triple NRTI)



If woman took any of the following PMTCT regimens, start NNRTI regimen:

- sdNVP (+/- antepartum ZDV) with ZDV/3TC tail in last 12 months
- sdNVP (+/- antepartum AZT) more than 12 months ago (with or without tail)
- Triple ARV- prophylaxis

In all of these cases, try to check viral load 6 months after ART start. If >5,000 switch to 2nd line ART with PI.

Consider consultation with PMTCT or ART expert clinician in these cases.

### 5.7.3 Women with active tuberculosis -

All HIV-infected women should be assessed for TB at every visit, and those presenting with cough, fever, night sweats and weight loss should be evaluated for TB.

In pregnant women with TB-HIV co-infection, the first priority is to treat the TB. All HIV infected women with TB should start ART, irrespective of CD4. ART should start as soon as clinically possible (within 8 weeks after the start of TB treatment).

Drug interactions between rifampicin and some of the ARVs (i.e. LPV/r) complicate treatment. An EFV-based regimen is recommended for first-line treatment for individuals with TB and HIV (starting after the first trimester).

If EFV is not tolerated an NVP-based regimen or a triple NRTI (e.g. ZDV+3TC+ABC or ZDV+3TC+TDF) can be used. In the presence of rifampicin, no lead-in dose of NVP is required.

# 5.7.4 Considerations regarding nausea and hyperemesis associated with zidovudine –

Nausea is commonly associated with ZDV which may aggravate pregnancy-related nausea or provoke *hyperemesis gravidarum*. If nausea and vomiting appear to be aggravated by ZDV and are not amenable to medication, consider switching ZDV to Tenofovir (TDF), while continuing the other ARV components.

### 5.7.5 HIV-infected women with Hepatitis B or Hepatitis C co-infection

Life-long ART is required for all women coinfected with Hepatits B and HIV when treatment is required for Hepatitis B, irrespective of WHO Stage or CD4. ARV regimen should contain Tenofovir (TDF) and Lamivudine (3TC). Immune-mediated hepatic flares may occur in response to immune reconstitution with therapy. Hepatic toxicity from ARVs may be increased due to hepatitis B infection. Flares may occur in women on triple ARV prophylaxis when ARVs are discontinued postpartum.

Hepatitis C: No specific changes in treatment are recommended in HCV co-infection. Careful clinical and laboratory monitoring is needed.

# 5.7.6 Injecting drug use

IDU with contaminated equipment is an important mode of HIV transmission in Nepal. Health workers and lay counsellors should always ask pregnant women living with HIV about their alcohol or drug use.

Injecting drug-using pregnant women may take methadone as opiate substitution therapy (OST) in combination with ARV prophylaxis or ART. Drug interactions can potentially result in decreased methadone levels or in increased ARV levels, increasing the risk of ARV-related side-effects.

NNRTIs reduce methadone levels and can precipitate withdrawal symptoms. In pregnant woman taking NNRTI- (NVP- or EFV-) based ART, the dose of methadone should be increased. Methadone increases the blood levels of ZDV. Close monitoring is needed for side effects (e.g. bone marrow suppression and anaemia). LPV/r slightly reduces methadone level. Increase of methadone dose may be needed.

There are limited data available on buprenorphine OST or naltrexone withdrawal therapy in pregnancy.



All newborn infants of women living with HIV who inject drugs should be provided with appropriate neonatal withdrawal syndrome management care.

All women living with HIV who inject drugs should be offered testing for hepatitis B and hepatitis C.

# 5.7.7 HIV-2 infection

The first case of HIV-2 was documented in Nepal in 2010. HIV 2 is much less transmissible from mother-to-child than HIV-1 (transmission risk 0-4%)

NNRTI ARVs are not effective against HIV-2 infection, but NRTIs like ZDV are very effective Lifelong ART should consist of a triple NRTI regimen (e.g. ZDV+3TC+ABC). Women not yet requiring life-long ART who have only HIV-2 infection, should start ZDV monotherapy at 14 weeks of gestation (or as soon as possible thereafter) and continue through labour and delivery. Infants should receive twice daily AZT (10 mg bid if birth weight is between 2.0 and 2.5 kg and 15 mg bid if birth weight >2.5 kg) from birth until 6 weeks of age. Women with both HIV-1 and HIV-2 coinfection should follow recommendations for HIV-1 infection.

# 5.7.8 Primary HIV infection during pregnancy

Primary HIV infection during pregnancy is associated with high viral loads and increased risk of MTCT. All HIV negative pregnant women should be counselled about HIV prevention (Chapter 2). They should be encouraged to bring all high risk partners in for VCT (i.e. labour migrant, IDU). All high risk women should be retested in the third trimester of pregnancy. Standard ARV prophylaxis regimens should be used as described above.

# 5.7.9 Women who have not yet started triple ARVs or life-long ART and deliver outside of a full PMTCT site

If an HIV-infected woman is not yet taking ARVs and delivers in a community health facility without full ARVs or at home, the mother should receive a single nevirapine tablet (200mg) and the baby should start infant daily NVP and continue for 6 weeks. The mother then needs immediate referral to the closest ART centre to start ARVs for the prevention of breast milk transmission and/or life long HIV treatment (depending on her clinical and immune status). Community health workers or Female Community Health Volunteers (FCHVs) can assist with NVP to mothers and babies or mothers can self-administer take-home dose, if alone at home. They should also assist to ensure that woman gets to ART site as soon as possible.

Single dose NVP has a reported "failure" rate (i.e. risk of HIV infection in the baby) of about 13% at 6 weeks of age. It also carries the risk of NVP resistance emerging in the mother and therefore is no longer considered an "option", but rather as emergency back-up only.

# 5.7.10 HIV-exposed Infant seen at health facility after birth (anytime in first one year of life)

All babies born to HIV-infected mothers who are not on ARVs, should be given daily NVP syrup at the above dosage for the first 6 weeks of life. Simultaneously, the mother needs immediate referral to the closest ART/Hospital site to begin either triple ARV prophylaxis or life-long ART to allow safer breastfeeding for the first year of the child's life. When a mother is diagnosed after 6 weeks postpartum, start maternal ART/ARVs and consult paediatric HIV specialist for decisions regarding infant prophylaxis.



# 5.7.11 HIV-exposed breastfeeding baby whose mother is not Adherent to triple ARV prophylaxis

In the rare instance where the mother has poor adherence or discontinues triple ARV prophylaxis before 12 months postpartum, but continues to breastfeed, the following should be prescribed: Infant Nevirapine daily until 1 week after cessation of breastfeeding.

INFANTAGE	NEVIRAPINE DOSE
Birth* to 6 weeks • Birth weight 2000"2499 g • Birth weight >2500 g	10 mg (1.0 mL) once daily 15 mg (1.5 mL) once daily
>6 weeks to 6 months	20 mg (2.0 mL) once daily
>6 months to 9 months	30 mg (3.0 mL) once daily
>9 months to end of BF	40 mg (4.0 mL) once daily

# Table 5.6 Extended infant NVP dosing recommendations

\* Low birth weight infants should receive mg/kg dosing, suggested starting dose is 2 mg/kg once daily.

# **5.8 Community Based PMTCT**

Community based PMTCT programs were initiated in several districts in Nepal beginning in 2009, based on recommendations from the 2007 PMTCT National Review and the knowledge that current facility-only based PMTCT models were not reaching the majority of pregnant HIV infected women in the county. These programs continue to evolve as lessons are learned during initial phases and operational research studies. Different modalities may be needed based on the settings and specific issues to optimize programme coverage and efficacy. Components of CB-PMTCT can include:

- Train and utilize female community health volunteers (FCHV) and other community level workers to raise awareness on HIV and PMTCT and educated pregnant mothers on the need to test for HIV in pregnancy.
- Decentralize HIV testing of ANC mothers to lower level health facilities.
- Make some ARVs available at lower level health facilities for decentralization of PMTCT services.
- Enable women to "take-home" ARVs for themselves and their babies to use at the time
  of labour and delivery, in the circumstances where they are unable to reach a PMTCT
  site for delivery.
- Support referral of HIV-infected pregnant or breastfeeding women to closest ART clinic for full evaluation and treatment options.
- Support referral of HIV-infected pregnant women for facility delivery.
- Link NGOs working in HIV including VCT sites and CHBC teams to government health facilities in a coordinated CB PMTCT effort.



# **5.9 Implementing Safer Delivery Practices**

# 5.9.1 Management of Labour and Delivery

Procedural recommendations that can reduce the risk of MTCT are summarised in Table 5.10.

Continuous support during the first stage can shorten labour and minimise the need for obstetric interventions.

Normal vaginal delivery with minimal intervention is recommended; alternative approaches will be guided by specific obstetric indications.

To minimise environmental contamination with HIV-infected material, it is important to take specific and active steps to *avoid postpartum haemorrhage*.

# 5.9.2 Caesarean Section

#### Elective Caesarean Section -

Elective caesarean section should be reserved for HIV-infected women who have failed to achieve adequate viral suppression through ARV prophylaxis or treatment by 38 weeks' gestation.

In women approaching term with a known high or rising viral load (or evidence of suboptimal immunological response where ART has been initiated), consideration should be given to the benefits and risks of vaginal delivery versus elective caesarean section. The decision should take into account the surgical and anaesthesia facilities, the availability of safe blood transfusion, standards of postoperative and neonatal care, and the attitude of the woman and her family towards birth by caesarean section.

Women on life-long ART or triple ARV prophylaxis, who are considering an elective caesarean section for PMTCT purposes, should have viral load checked (if available) at about 36 weeks gestation to ensure that results are back in time. If the viral load is <1,000 copies/mL, C-section is not needed. If viral load is over 1,000 copies/mL, Caesarean section can be considered together with other variables as described above.

#### Emergency Caesarean Section -

The need for emergency caesarean section (or transfer to a centre with suitable facilities) would be guided by the usual obstetric indications.

#### Table 5.7

### Management of Labour and Delivery to Reduce Risk of MTCT

- Ensure continuous support for the mother during labour
- Ensure good infection control
- Provide regular monitoring of vital signs
- Active management of labour using partograph
  - avoid early, artificial or prolonged rupture of membranes or prolonged labour
  - o consider using oxytocin to shorten labour when appropriate
  - Provide ARVs to mother according to agreed protocol
- Minimise vaginal examinations
  - Perform cervical examination only when absolutely necessary, and with appropriate clean technique
- Use non-invasive foetal monitoring to assess need for early intervention
- Treat signs of infection in the mother
- Minimise episiotomies, tears, and instrumental delivery
- Minimise risk of postpartum haemorrhage



- Actively manage the third stage of labour
- o Give oxytocin immediately after delivery
- Use controlled cord traction
- Perform uterine massage
- Repair genital tract lacerations carefully and promptly
- Carefully remove all products of conception
- Consider elective caesarean section, but only where adequate providers and facilities exist
- Provide postpartum care for mother, with careful monitoring for infection

# 5.9.3 Immediate Newborn Care of Infants who are HIV-Exposed and Infants with Unknown Exposure Status

The immediate care of the newborn exposed to HIV follows standard practice.

Regardless of the mother's HIV status, all infants should be kept warm after birth and handled with gloves until maternal blood and secretions have been washed off.

Immediate newborn care includes the following:

- Maintaining universal precautions throughout care and treatment:
  - o wear gloves when giving injections;
  - o clean all injection sites with surgical spirits;
  - o dispose of all needles according to facility policy.
- Wiping infant's mouth and nostrils with gauze when the head is delivered.
- Clamping the cord immediately after birth
  - o avoid "milking" the cord towards the baby;
  - o cover the cord with gloved hand or gauze before cutting.
- Using suction only when meconium-stained liquid is present; use either mechanical suction at less than 100 mm Hg pressure or bulb suction, rather than mouth-operated suction.
- Wiping the infant dry with a towel.
- Determining the mother's infant feeding choice
  - o if she is breast feeding, place the infant on the mother's breast.
  - if she is using breast milk substitute, place the infant on her body for skin-to-skin contact and provide help with the first feeding;
- Administering vitamin K, silver nitrate eye ointment, and Bacille Calmette Guérin (BCG; tuberculosis) vaccine according to national guidelines.
- Administering first dose of infant nevirapine as soon as possible after delivery.

# 5.9.4 Postpartum Care of Women who are HIV-Infected and Women with Unknown HIV Status

When providing postpartum care to women infected with HIV, health care workers may follow routine protocols, but several areas require additional attention:



#### Newborn feeding –

- Support mother with early and exclusive breastfeeding (see Chapter 6).
- Provide training, support and observe proper feeding technique prior to discharge.

#### Postpartum care of women with unknown HIV status -

Women whose HIV status is unknown should receive the same standard of postpartum care as women with HIV infection (as per the national *Safe Motherhood Guidelines*). They should be counselled regarding HIV and offered testing. They should be supported to follow national recommendations for infant feeding.

# 5.9.5 HIV Prevention in Health Care Settings

Infection control in labour ward, operating theatre and postnatal ward settings should follow national *Infection Control* and *Safe Blood Transfusion Guidelines*. Universal precautions should be used at all times, and should include: use of personal protective equipment; safe use and disposal of "sharps"; sterilisation of all equipment; and safe disposal of contaminated materials.

Occupational exposure to potentially HIV contaminated material should be managed according to current national *Post-Exposure Prophylaxis Guidelines*.

# **5.10** Summary of Strategic Steps and Priorities

# 5.10.1 Antenatal Care

Table 5.8 summarises the steps that will be necessary, at different levels, to introduce coordinated PMTCT services.

#### Table 5.8 PMTCT during Antenatal Care

COMMUNITY	HEALTH FACILITY
<ul> <li>Engage family and community in birth and emergency transport planning</li> <li>Awareness raising, IEC materials and other information on PMTCT and availability of VCT and ART</li> <li>Ensure community-based adherence support (through health worker, health visitor or "buddy")</li> <li>Encourage all pregnant women to get antenatal care and HIV testing during pregnancy</li> <li>Facilitate follow-up antenatal visits and support</li> <li>Facilitate visit to ART clinic/hospital for all HIV- infected pregnant women and any HIV-positive family members as soon as possible.</li> </ul>	<ul> <li>Promote mother-friendly, continuous care</li> <li>Provide counselling, services and support on PMTCT</li> <li>Counsel on adherence to ARVs, and provide ARVs</li> <li>Initiate life-long ART if indicated</li> <li>If ART is not available at their facility, facilitate immediate referral of all HIV infected pregnant women to ART clinic/hospital</li> <li>Counsel on ARVs during delivery and provide ARVs</li> <li>Refer to community-based health workers and support systems, and to higher level facilities as needed</li> <li>Encourage involvement of partner and family</li> </ul>
DISTRICT	NATIONAL
<ul> <li>Establish a coordination team to support technically and programmatically on PMTCT interventions at district levels and below</li> <li>Ensure implementation of policies, with due regard for "on-the-ground" realities</li> <li>Monitoring and evaluation</li> </ul>	<ul> <li>Develop optimal recommendations on ARV prophylaxis, bearing in mind the variation in capacity of health care facilities, feasibility, safety and acceptability of the recommendations</li> <li>Training</li> <li>Resource mobilisation and harmonisation, M&amp;E</li> </ul>


#### 5.10.2 Labour and Delivery

Table 5.9 summarises the strategic approaches to PMTCT during labour and delivery.

Strategic Approach to PMTCT during Labour and Delivery		
COMMUNITY	HEALTH FACILITY	
<ul> <li>Identify and train community birth attendants on PMTCT and, if appropriate, administration of ARVs to mother and baby</li> <li>Supply home birth attendants with hygienic delivery kits, including disposable "sharps"</li> <li>Plan emergency transport system for all community members</li> <li>Link with health facilities</li> </ul> Following careful evaluation and training: <ul> <li>Supply ARVs through home birth attendants, CHBC workers or other community health staff/volunteers <u>once they have received</u> proper training</li> </ul>	<ul> <li>Ensure continuous support for the mother during labour</li> <li>Ensure good infection control</li> <li>Provide regular monitoring of vital signs</li> <li>Active management of labour using partograph – avoid early or prolonged rupture of membranes or prolonged labour</li> <li>Minimise vaginal examinations</li> <li>Treat signs of infection</li> <li>Minimise episiotomies, tears, and instrumental delivery</li> <li>Provide proper cord care – do not "milk" cord blood towards baby</li> <li>Consider elective cesarean section, but only where adequate providers and facilities exist</li> <li>Provide ARVs to mother according to agreed protocol</li> <li>Provide immediate newborn care, taking great care with suction to avoid trauma of upper airway</li> <li>Provide postpartum care for mother, with careful monitoring for infection</li> </ul>	
DISTRICT	NATIONAL	
<ul> <li>Develop optimal recommendations on obstetric practices, bearing in mind the variation in capacity of health care facilities, feasibility, safety and acceptability of the recommendations</li> <li>Training</li> <li>Resource mobilisation and harmonization</li> <li>Monitoring and evaluation</li> </ul>	<ul> <li>Develop optimal recommendations on ARV prophylaxis, bearing in mind the variation in capacity of health care facilities, feasibility, safety and acceptability of the recommendations</li> <li>Training</li> <li>Resource mobilisation and harmonisation</li> <li>Monitoring and evaluation</li> </ul>	

### Table 5.9Strategic Approach to PMTCT during Labour and Delivery

*With appropriate training*, CHBC workers are in an ideal position to help with ARV provision to mother and baby during and after home delivery. They can work in conjunction with birth attendants, who should call them when labour started. They could also assist at community level health facilities to provide ARVs in labour.

*With careful supervision from the health facility level*, it may be possible to undertake District and sub-District level pilot interventions to provide intrapartum and neonatal ARVs to HIV-infected women who are unable to deliver in a health facility.



### **5.11 Further Reading**

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## **Counselling and Support on Infant Feeding Methods**

## 6.1 Strategic Overview

#### 6.1.1 Recent changes in infant feeding recommendations by WHO

Significant programmatic experience and research evidence regarding HIV and infant feeding have accumulated since 2006. Evidence shows that ARV interventions either to the HIV-infected mother or the HIV-exposed infant can significantly reduce the risk of postnatal transmission of HIV through breastfeeding. National authorities should decide which infant feeding practice will be promoted given their local situation. Mothers known to be HIV-infected are now recommended to breastfeed until 12 months of age.

## 6.1.2 Risks associated with Different Methods of Infant Feeding in the absence of ARV interventions

MTCT of HIV through breast feeding has been well documented. The cumulative attributable risk of HIV transmission over a period of two years' breast feeding is about 16%, with about threequarters of all breast feeding transmission occurring during the first 6 months. The mode of infant feeding is therefore an important factor in MTCT.

Maternal factors associated with risk of transmission through breast feeding include her viral load in plasma and breast milk, her HIV-related immune status, her nutritional status and the presence of breast conditions like mastitis, abscess or cracked and bleeding nipples.

Infant factors include conditions that damage the oral mucous membrane, such as thrush or other sores in the mouth. One South African study found that girls were 40% less likely to become infected during breast feeding than boys.

Exclusive artificial feeding obviously eliminates the risk of MTCT through breast feeding. However, when done under unsafe conditions, artificial feeding exposes the infant to a much higher risk of diarrhoeal illness and acute respiratory infection than in breast fed infants, and overall mortality rates are increased compared to breast fed babies – of particular importance in Nepal where up to 25% of the population lacks access to a safe water supply.

*Mixed feeding (i.e. a combination of breast and giving any other food or liquids) is associated with much higher rates of MTCT* than either exclusive breast feeding or exclusive artificial feeding during the first 6 months of life.

A recent African study indicated that only one in eight HIV positive mothers who chose to breast feed were able to maintain exclusive breast feeding; the majority were mixed feeding, predominantly breast feeding, or predominantly formula feeding. Among mothers who chose exclusive formula feeding, almost one-third had breast fed their baby at some time between birth and nine months. The study highlights the need for close and careful support and supervision of actual feeding practices.

#### 6.1.3 Breastfeeding with ARV interventions

International experts state that 12 months represents the best cut-off for most HIV-infected mothers. Twelve months *of* breastfeeding provides the maximum benefit in terms of survival (excluding any consideration of HIV transmission). In the presence of ARV interventions to reduce the risk of HIV transmission, this combination would offer the best balance of protection from morbidity and mortality versus the risk of HIV transmission. In addition, a systematic review also examined the effect of prolonged breastfeeding on the health of mothers who are known to be HIV-infected. This review indicated that there was no clear evidence of harm to the mother if she continued breastfeeding.



#### 6.1.4 Environmental and Health Context

The DHS provides the most recent data on infant feeding and nutrition, child morbidity and survival, and utilisation of primary child care services in Nepal (Table 6.2). This information helped guide the national recommendation for breastfeeding HIV-exposed infant with mothers taking ARVs either as life-long ART or as triple ARV prophylaxis.

#### Water and Sanitation -

Ten percent of the urban population and one-fifth of the rural population lack access to an improved water supply. The most common sources of drinking water in the rural areas are a public tap or standpipe (29%) and a tube well or bore (39%). Very few households treat their water before drinking.

#### 6.1.5 New Evidence on Weaning Infants from Breastmilk

Research and programmatic experience consistently show that rapid and abrupt cessation of breastfeeding was very difficult for mothers to achieve and was associated with adverse consequences for the infant, such as growth failure and increased prevalence of diarrhoea. Breastmilk viral load is also known to spike with rapid cessation of breastfeeding. There is evidence that ARV prophylaxis should continue for one week after all exposure to breast milk has ended.

### Table 6.1 2010 WHO Principles on HIV and infant feeding

- · Balancing HIV prevention with protection from other causes of child mortality
- Integrating HIV interventions in to maternal and child health services
- Setting national or sub-national recommendations for infant feeding in the context of HIV
- When antiretroviral drugs are not (immediately) available, breastfeeding may still provide infants born to HIV-infected mothers with a greater chance of HIV-free survival
- Informing mothers known to be HIV-infected about infant feeding alternatives
- Providing services to specifically support mothers to appropriately feed their infants
- Avoiding harm to infant feeding practices in the general population
- Advising mothers who are HIV uninfected or whose HIV status is unknown
- Investing in improvements in infant feeding practices in the context of HIV



#### Table 6.2

#### Key Infant Feeding and Infant and Child Health Indicators informing PMTCT Strategies, Nepal, 2006

Indicator	Urban	Rural	Total	
Infant Feeding				
Median duration of exclusive breast feeding (months)	2.2	2.6	2.5	
Median duration of predominant breast feeding (months)	5.1	4.7	4.8	
Median duration of any breast feeding (months)	e"36	34	34.3	
Water Supply				
Availability of improved source of water (% of population)	90.2%	81.1%	82.5%	
Using appropriate water treatment method before drinking (% of population)	39.8%	8.6%	13.3%	
Sanitation				
No toilet facility, use bush or field (% of households)	15.3%	57.2%	50.1%	
Infant and Child Nutrition				
Prevalence of stunting (height-for-age 2 SD or more below reference population) in children aged <5 years	36.1%	51.1%	49.3%	
Prevalence of wasting (weight-for-height 2 SD or more below reference population) in children aged <5 years	7.5%	13.3%	12.6%	
Prevalence of underweight (weight-for-age 2 SD or more below reference population) in children aged <5 years	23.1%	40.7%	38.6%	
Prevalence of anaemia (children aged 6-59 months)	41%	49%	48%	
Infant and Child Health				
Children with fever during the last 2 weeks	22.3%	16.2%	16.9%	
Children with diarrhoea during the last 2 weeks	11.5%	11.9%	11.9%	
Proportion of children with diarrhoea given ORT	39.9%	40.9%	40.7%	
Children with symptoms of ARI during the last 2 weeks	5.0%	5.3%	5.3%	
Children fully immunised (age 12-23 months)	86.3%	82.4%	82.8%	

Source: Nepal Demographic and Health Survey – Key Findings (2006)

Half of the households in Nepal have no toilet facilities.

### The limited access to safe water and sanitation also limits the safety of replacement (artificial) feeding as a PMTCT strategy during infancy and early childhood.

#### Poverty -

An estimated 31% of the population (35% in rural areas, 10% in urban areas) lives in poverty.

The Government of Nepal does not currently provide free breast milk substitutes for children born to PLHIV. From the demographic profile of MARPs (Section 1.1.2), many PLHIV in Nepal may be expected to have incomes towards the lower end of the national range and may struggle to afford breast milk substitutes without financial assistance.



#### Breast Feeding -

Breast feeding is almost universal in Nepal, with a median duration of 34 months.

WHO, UNICEF and the *National Nutrition Policy* recommend exclusive breast feeding for the first 6 months of life, with the gradual introduction of complementary foods (in addition to continued breast feeding) thereafter. Contrary to these recommendations, only 53% of children aged less than 6 months are exclusively breast feed in Nepal; *the median duration of exclusive breast feeding is three months*.

#### Mortality Rates –

The infant mortality rate was 48 deaths per 1,000 live births in the 5 years preceding the DHS, and the under-five mortality rate was 61 per 1,000 live births; this means that one in every 16 children born in Nepal dies before reaching the age of 5 (Figure 6.1).



Source: Nepal Demographic and Health Survey – Key Findings (2006)

Infant mortality is consistently lower in urban areas and, in rural areas, lower in the Eastern region than in the Mid-western region.

Children born to women with no education experience an infant mortality rate of 69 deaths per 1,000, compared with 13 per 1,000 where the mother has completed her secondary education (Figure 6.2).



#### Figure 6.2

Infant and Under-Five Mortality Rates, by Mother's Educational Status, Nepal, 2005



Source: Nepal Demographic and Health Survey – Key Findings (2006)

#### Infant and Childhood Nutrition –

Malnutrition is still common in Nepal. Half the children aged under five years are stunted, almost 40% are underweight, and one-eighth show signs of wasting.

Malnutrition is the underlying cause of death in about 60% of children under 5 years of age worldwide. Although there are no data from Nepal, it is likely that the situation is similar or that malnutrition is an even larger cause of child death, considering the high prevalence of childhood malnutrition.

Poor infant feeding practices – such as those that provide insufficient calories and micro-nutrients or contribute to diarrhoea – are the major cause of the malnutrition. Malnutrition is largely associated with the initiation of complementary feeding, with food that is too often bulky, over-diluted and prepared under unhygienic conditions.

#### Childhood Illness –

During the two weeks leading up to the DHS, 17% of children aged less than 5 years had fever, 12% had diarrhoea, and 5% had symptoms of acute respiratory infection.

Only 41% of children with diarrhoea were treated with pre-packaged or home-made oral rehydration therapy (ORT).



# **6.2 Recommendations for Infant and Young Child Feeding**

Box 6.1 Summary of Infant feeding recommendations of HIV-Exposed Infants

#### HIV- Exposed infants who are:

- 0-6 months old: should exclusively breastfeed while mother is taking triple ARVS or life-long ART.
- 6-12 months old: should continue to breastfeed while complementary food is added at 6 months and mother continues to take triple ARVS or life-long ART
- From 12 months onwards: Babies should start weaning from breastmilk at about 11 months of age, if it is safe to do so with complete weaning by about 12 months. Complementary food should be continued.
- Mothers who do not yet require ART for their own health should stop triple ARVs 1 week after the cessation of all breast feeding.
- Weaning from breastmilk should take place gradually over about one month.
- If the child is found to be HIV-infected, he/she should continue to breastfeed until 2 years of age or beyond.

#### 6.2.1 Feeding Infants (0-6 months) Born to HIV-Infected Mothers

Maternal and Child Health (MCH) services should promote and support breastfeeding by HIVinfected mothers until the baby is about 12 months of age. The baby should receive exclusive breastfeeding during the first 6 months (i.e. nothing but human breast milk. No solids, other liquids, or even water). The mother should be taking three antiretroviral medicines during the entire breastfeeding period in the form of either life-long ART or triple ARV prophylaxis.

#### 6.2.2 Exclusive Breastfeeding

'Exclusive breastfeeding' means giving the infant no food or drink other than breast milk. WHO recommends exclusive breastfeeding:

- From birth to 6 months for all babies in Nepal, regardless of mother's HIV status. In other words, all mothers, whether HIV positive or negative should exclusively breastfeed their babies for the first 6 months.
- Breastfeeding should continue as an important source of nutrition from 6 to 12 months of age with the introduction of complementary foods for all babies from 6 months.
- Breastfeeding HIV-infected mother's should be given triple ARV prophylaxis or lifelong ART while breastfeeding.
- If an HIV-infected mother is unable to take ARV medications, but continues to breastfeed, the baby should be given daily extended nevirapine prophylaxis until one week after the cessation of breastfeeding (generally at 12 months of age).
- Even if ARV drugs are not immediately available, breastfeeding should be recommended while ARV interventions are being scaled-up.

#### 6.2.3 Extended NVP option for babies whose mothers stop taking ARVs

In the rare instance where the mother discontinues her triple ARVs before 12 months postpartum, but continues to breastfeeding, extended infant nevirapine should be prescribed.



### Extended Infant Nevirapine: Infant Nevirapine daily until 1 week after cessation of breastfeeding

PROPOSED EXTENDED SIMPLIFIED INFANT NVP DOSING RECOMMENDATIONS		
<ul> <li>Birth -6 weeks</li> <li>Birth Weight &lt; 2,500 gram</li> <li>Birth Weight ≥ 2,500 gram</li> </ul>	10 mg/daily 15 mg/daily	
$\geq$ 6 weeks to 6 months	20 mg/daily	
$\geq$ 6 to 9 months	30 mg/daily	
$\geq$ 9 months to end of BF	40 mg/daily	

## 6.2.4 Actions to Support Exclusive Breastfeeding of Infants (0 - 6) Born to HIV-Infected Mothers

- Promote early initiation of breastfeeding (within one hour after delivery) for all mothers. This is healthy for the infant, and it establishes healthy feeding patterns early on.
- Make sure that mothers know the risk of mixed feeding (giving both breast milk and other feeds, including water). The risk of HIV transmission significantly increases if mixed feeding is practiced.
- Make sure that mothers know good breastfeeding techniques to avoid cracked and sore nipples. Mastitis and breast abscesses increase the risk of transmitting HIV through breast milk. Mothers should be taught by demonstration correct positioning and latchon.
- Make sure that mothers know how to identify infant feeding or breast problems early on. They should promptly seeking medical care if the baby is not feeding well or has mouth sores, or if the mother has breast problems.

#### 6.2.5 International Code of Marketing of Breast milk Substitutes

In order to adequately promote universal adoption of exclusive breastfeeding by all mothers in Nepal, the International Code of Marketing of Breast milk Substitutes must be adopted and enforced by all health facilities and health care workers.

#### 6.2.6 Feeding Children 6 Months and Older

After six months, breast milk and other forms of milk <u>alone</u> are not adequate to meet a baby's nutritional requirements.

WHO recommends: "For children over six months of age.... Meals including milk-only feeds, other foods and combination of milk feeds and other foods, should be provided four or five times a day. All children need complementary foods from six months of age." (WHO, 2010)

Inform and support HIV-infected mothers to introduce nutrient-dense, complementary food when the infant is six months.

For all infants, complementary foods should be introduced after 6 months of age with continued breastfeeding until a nutritionally adequate diet can be sustained without breast-milk. Abrupt cessation of breastfeeding should be discouraged to avoid undue traumatic effects on both the mother and the infant.



Milk should continue as an important component of the diet. It should provide up to one-half or more of the nutritional requirements for children 6 to 11 months old and up to one-third of the requirements for children aged 12 to 24 months. Complementary foods should be made from nutrient-rich family foods. Those aged 24 months and above should be fed with three family meals and at least two snacks a day.

Preparation of the meals should take account of the following:

- Quality of food
- Amount of food
- Food safety and hygiene

#### 6.2.7 When HIV infected mothers decide to stop breastfeeding

This will generally occur at about 12 months of age. Babies should gradually stop breastfeeding starting at about 11 months of age. Rapid and abrupt cessation of breastfeeding is very difficult for mothers to achieve and is associated with adverse consequences for the infant, such as growth failure and increased prevalence of diarrheoa. Breast milk viral load is also known to spike with sudden weaning. One week after breastfeeding completely stops she should stop ARVs. If she is taking EFV, she should stop only the EFV 1 week after BF stops. She should continue ZDV+3TC for an additional week to prevent NNRTI resistance.

#### 6.2.8 When ARV drugs are not available

Even if ARV drugs are not (immediately) available, breastfeeding may still provide infants born to HIV-infected mothers with a greater chance of HIV-free survival. Mothers should still be counseled to exclusively breastfeed for 6 months and continue breastfeeding until one year of age.

## **6.3** Counselling on Feeding of HIV-exposed infants

Counselling and support for infant feeding can improve feeding practices and, in turn, prevent malnutrition and reduce the risk of death in children.

The balance between the health benefits of breast feeding and the risk of HIV transmission has recently changed enormously with the addition of ARV interventions that very significantly reduce the risk of HIV transmission through breastfeeding. This is a major breakthrough that should improve child survival and is considered transformational. Now babies can have the known benefits of breastfeeding including reducing mortality, with very little risk of HIV acquisition.

Infant feeding counselling for women who are infected with HIV is an integral part of PMTCT. Previously WHO recommended that mothers were asked to make a decision about appropriate infant feeding choices. This was very difficult to implement. WHO recommends a more directive approach to counselling- in which health care workers make clear recommendations for breastfeeding, rather than presenting different options.

New national recommendations are now to counsel and support women known to be HIV-infected to breastfeed and receive ARV interventions. Pregnant mothers and HIV-infected mothers should be informed of the recommendation to breastfeed to improve HIV-free survival of HIV-exposed infants. They should receive accurate information about alternatives, if requested.

Even if ARV drugs are not (immediately) available, breastfeeding may still provide infants born to HIV-infected mothers with a greater chance of HIV-free survival. Mothers should still be counselled to exclusively breastfeed for 6 months and continue breastfeeding until 12 months of age.

A woman who is HIV-positive should receive information and counselling that addresses the following topic areas:



- Information about recommendation to breastfeed
- Explanation of exclusive breastfeeding for 6 months
- Support to exclusively breastfeed for 6 months
- Appropriate complementary feeding starting at 6 months
- Management of mastitis, cracked nipples, and sores in baby's mouth
- Continuation of breastfeeding until 12 months of age
- Education on when and how to discontinue triple ARV prophylaxis (unless mother is taking life-long ART).
- Importance of adherence to ARVs and adherence to care
- Strategies for discontinuation of breast feeding and the introduction of replace-ment feeds by 12 months of age

#### 6.3.1 Postnatal Support and Follow-Up

During each postnatal visit, clinic staff should review progress with infant feeding, referring to information from the antenatal feeding counselling sessions and focusing on the issues most relevant to the mother. Adherence to maternal ARVs must be assured and counselling about adherence should take place at each visit. Mother-baby pairs should be seen frequently to enable timely refills of ARVs, ongoing adherence counselling and infant feeding support.

Reinforcing essential and relevant information supports optimal infant nutrition, growth and development while minimising risks.

Additional support may be required during special high-risk periods, such as:

- when the child is sick
- when the mother is sick
- when the mother returns to work
- at six months when complementary food is added
- when infant HIV screening or diagnostic testing is done
- around twelve months during the period of weaning
- when the mother decides to change feeding methods

To support continued care and referrals, networks and linkages should be strengthened with Safe Motherhood programs, and with NGOs and other sectors working in HIV.

#### Mother with poor adherence-

If a mother is showing poor adherence while on triple ARV prophylaxis, yet continues to breastfeed, consider extended daily nevirapine for the infant until 1 week after complete cessation of breastfeeding (see 6.2.3)

## **6.4 Transition from Breast to Replacement Feeding**

#### 6.4.1 Transition to Replacement Feeding at about 12 months of age

"Transition" describes the period and process used to accustom the infant and mother to new feeding patterns, after which all breast milk is replaced with breast milk substitutes.



It is currently recommended that transition to replacement feeding in infants of positive mothers should take place at about 12 months of age. This should take place slowly over about one month. Therefore, mothers should begin the process when the child is about 11 months old.

Mothers should avoid recommencing breast feeding after completing the transition to replacement feeding. This includes resisting the temptation to breast feed at night or when the child needs comforting.

An open cup, rather than a bottle with a nipple (which is difficult to clean), should be used for transitional and replacement feeding.

Many studies have identified what is called a "spill-over effect", where the promotion of replacement feeding for the children of HIV-infected mothers leads to a reduction in breast feeding in the wider community and associated increases in infant morbidity and mortality. It is essential to maintain IEC programmes for the promotion of breast feeding beyond 12 months in the general population.

## 6.5 Feeding the HIV-infected child

If virologic testing (polymerase chain reaction; PCR) is positive and a child is diagnosed as being HIV-infected (i.e. not just HIV-exposed with HIV antibodies), it is better for that child to continue breast feeding even after 12 months of life. They should continue breastfeeding until at least two years of life to gain the maximum immunological and nutritional benefits of breastfeeding. Parents and caregivers may need counselling and support for this as it deviates from the message given to parents of children HIV-exposed and not yet infected or of unknown infection status.

## **6.6 Feeding Infants of HIV-negative Mothers or Mothers with unknown HIV status**

These mothers should breast feed exclusively for the first 6 months of life, according to national *Maternal and Neonatal Health* and *Infant Feeding Guidelines*.

- Exclusive breast feeding means that the mother only feeds her infant breast milk;
  - the only exceptions are for drops or syrups containing vitamin or mineral supplements or medicines;
  - o the child receives no food or drink other than breast milk not even water.
- The mother should initiate breast feeding within one hour of birth, and help the newborn baby become well attached at the breast. She should continue to breast feed frequently, day and night. After the infant stops feeding from the first breast, she should offer the second breast.
- The mother should continue breast feeding when either she or the infant is sick.
- If she will be away from her infant for an extended period (e.g. to work during the day), she should express her breast milk and a caregiver can feed the expressed breast milk using a cup and spoon.
- After the infant reaches 6 months of age, complementary foods that provide sufficient calories and micronutrients and are safe should be introduced according to the national *Guidelines*.
- Breast feeding should continue for up to 2 years or longer.



## 6.7 Summary of Strategic Priorities

Table 6.3 summarises the strategic approaches and responsibilities at different levels that support PMTCT during infancy and early childhood through counselling on infant feeding.

### Table 6.4 Counselling and Support on Infant Feeding Methods for PMTCT

COMMUNITY	HEALTH FACILITY
<ul> <li>Promote exclusive breast feeding</li> <li>Promote condom use to avoid acute infection during lactation</li> <li>Provide support for infant feeding, cessation / weaning,</li> <li>Avoid reinitiating breast feeding after completing the transition to replacement feeding</li> <li>Provide training on treatment of breast infections to community health workers</li> <li>Provide home visits and ongoing support for exclusive breast or replacement feeding</li> <li>Organise local support systems and groups for mothers</li> <li>Provide support for ARV adherence to mothers</li> </ul>	<ul> <li>Provide counselling on infant feeding, adapting counselling to local and/or family situation</li> <li>Provide ongoing refills of ARVs and adherence counselling and support</li> <li>Provide training on infant feeding, cessation / weaning to health workers</li> <li>Refer mothers to local support systems</li> <li>Promote condom use to avoid acute infection during lactation</li> <li>Strengthen growth monitoring and promotion programs</li> <li>Promote Baby Friendly Hospital Initiative measures</li> <li>Maintain promotion of breast feeding for HIV-negative mothers and mothers with unknown HIV status – avoid "spill-over" effect</li> <li>Adapt IMCI and feeding guidelines to local situation</li> <li>Monitor infant feeding trends in areas of high HIV prevalence</li> </ul>
DISTRICT	NATIONAL
<ul> <li>Establish a coordination team to support technically and programmatically on PMTCT interventions at district levels</li> </ul>	<ul> <li>Develop optimal recommendations on infant feeding practices bearing in mind the variation in capacity of</li> </ul>

- Ensure implementation of policies, with due regard for "onthe-ground" realities
- Monitoring and evaluation

and below

- Develop optimal recommendations on infant feeding practices bearing in mind the variation in capacity of health care facilities, feasibility, safety and acceptability of the recommendations
- Training
- Resource mobilisation and harmonization
- Monitoring and evaluation



### 6.8 Further Reading

WHO Guidelines on HIV and infant feeding 2010: Principles and recommendations got infant feeding in the context of HIV and a summary of evidence (2010)

Coovadia HM, Rollins NC, Bland RM *et al.* Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. *Lancet* 2007; 369: 1107-1116.

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## 7.1 Strategic Overview

#### 7.1.1 Establishing and Managing Linkages

PMTCT needs multidisciplinary and multi-sectoral initiatives.

Linkages with various stakeholders are very important for ensuring adequate resources – human, financial and material – are available and allocated to PMTCT services. Related sectors like education, health, population and environment, law and justice, women and children, and social welfare should all be involved in HIV awareness and prevention, including PMTCT.

Linkages can be fostered in many ways:

- Integrating PMTCT services and community-based aspects of HIV CT&S into existing MCH, neonatal and community health services.
- Identifying community-based organisations that can support neces-sary referrals, and follow up to ensure families and individuals have ready access to linked services.
- Identifying community workers, including lay counsellors and volunteers, who can guide women through the testing and counselling process, monitor adherence to any ARV or OI prophylaxis provided, and assist them in accessing CT&S services.

To ensure that NGO and private sector partners supplement and complement the expansion of PMTCT services, these *Guidelines* should be the core reference document for all partners.

A monitoring mechanism will be established to ensure that the linkages are in place and active.

#### 7.1.2 Linkages between Community MCH and Clinical HIV services

MCH services are an important entry point for accessing PMTCT interventions and for the CT&S of women who are HIV-infected, their infants and other family members.

A certain amount of training (i.e. of FCHVs, VHWs and MCHWs, as well as clinical staff) and systems development is necessary to properly integrate PMTCT into MCH services. Likewise, training of HIV care providers (especially CHBC) workers on MCH related issues is important, with close communication between the two groups.

Children born to HIV-infected women need close follow up and appropriate care. Community MCHWs can be supported and encouraged to monitor attendance for clinical follow-up, supervise and support adherence to any prescribed treatment (e.g. prophylaxis against OIs), and provide information on health promotion, disease prevention, and CT&S services to these families.

Specialists in HIV who care for adults and children, provide clinical supervision and ART, and guide the ongoing management of HIV infection need to be aware of community level support that may be in place.

#### 7.1.3 Linkages with Other Health Programmes for Special Needs

Some programmes target specific health needs, such as family planning, treatment of STIs, or assistance with substance abuse.

Women who are HIV-infected and their families may need to access disease-specific programmes, such as those for people with tuberculosis. TB is a leading cause of mortality in persons infected with HIV.

Nutritional support programmes for mothers and children are especially important for PLHIV.



#### 7.1.4 Linkages to Community-Based AIDS Service Organisations

Linkages to community-based organisations can provide the resources to help women who are HIV-infected and their families cope with the isolation, social stigma, and the emotional pressures that often accompany a diagnosis of HIV. They may also provide women infected with HIV a way to become involved in voluntary or paid HIV-related work.

NGOs, faith-based organisations and similar agencies often provide HIV related and non-HIV care and support services for IDUs, FSWs and other members of MARPs, and are a valuable resource for mothers who are HIV-infected and their families. Linkages between health services and CBOs have the potential to greatly strengthen patient care, supervision and support.

Many NGOs are also active in education about HIV prevention and safer sex, peer education, support groups and networking for PLHIV, and referral for counselling and testing. They may have established linkages with (or be able to help women gain access to) programmes for preventing and treating malaria or TB, or to programmes that offer nutritional support needed services.

PLHIV organisations are one of the most important sources of support for mothers diagnosed with HIV infection in PMTCT programmes and for their families. They may also be able to help PLHIV with referral to specific services (e.g. housing, transportation, food assistance, legal assistance and advice) and income-generating activities.

CBOs that provide support services for PLHIV must ensure that confidentiality is respected at all times.

## **7.2** Treatment, Care, and Support of the Mother with HIV Infection

## 7.2.1 Maternal Prophylaxis and Treatment for Opportunistic Infections (antentally, during labour and delivery and postpartum)

Subject to the precautions listed in Table 7.1, the risk of life-threatening infections among women with a low CD4 count or clinical features of immunosuppression warrants prophylaxis against OIs.

#### Co-trimoxazole prophylaxis for PCP and toxoplasmosis -

Women who fulfil the following criteria for co-trimoxazole (TMP-SMX) prophylaxis for *Pneumocystis jiroveci* pneumonia (PCP) and toxoplasmosis should commence and remain on TMP-SMX throughout their pregnancy:

- WHO Stage 2, 3 or 4 disease, irrespective of CD4 cell count or
- WHO Stage 1 disease with CD4 < 350/mm<sup>3</sup>

The dose is one double strength tablet (800/160mg) daily.



#### Table 7.1

#### Considerations for Prophylaxis and Treatment of Opportunistic Infection in Pregnant Women

<i>Pneumocystis</i> pneumonia (PCP)	<ul> <li>TMP-SMX prophylaxis should be implemented according to standard criteria for non-pregnant PLHIV</li> </ul>
p,	- Dapsone and aerosolized pentamidine are also considered safe in pregnancy
Fungal infection	<ul> <li>Fluconazole has been associated with fetal deaths and fetal abnormalities in animal studies, but potential benefits outweigh the risks from treatment.</li> </ul>
	- Itraconazole shows embryotoxicity and teratogenecity in pregnant animals.
	- Amphoterecin B is preferred when fungal infection therapy is needed.
Hepatitis B	<ul> <li>Hepatitis B immunoglobulin should be given to a susceptible pregnant women after exposure</li> </ul>
Herpes simplex	- Use of acyclovir is controversial but experience has shown that it is safe
Infuenza vaccine	- Safe in pregnancy
<i>Mycobacterium avium</i> complex	<ul> <li>Clarithromycin is teratogenic in animals and must be used in pregnancy with caution.</li> </ul>
(MAC)	- Rifabutin has had limited experience in pregnancy.
	- For secondary MAC prophylaxis use azithromycin and ethambutol.
Toxoplasmosis	<ul> <li>Delay primary prophylaxis with pyrimethamine (risk cannot be excluded but potential benefits may outweigh risk) containing regimens owing to risk associated with this drug and low probability of toxoplasmosis.</li> </ul>
	- Secondary prophylaxis – Most could continue pyrimethamine because of high rate of relapse when drug is stopped.
	- Chest X-ray should be done with the appropriate lead aprons for pelvic protection
Tuberculosis	<ul> <li>Diagnosed cases should be treated according to National TB programme following directly observed treatment short-course (DOTS) protocols</li> </ul>
Varicella zoster	- Zoster immune globulin is not contraindicated in pregnancy and should be given to a susceptible pregnant woman after exposure.
	<ul> <li>Acyclovir is considered safe in pregnancy for severe or disseminated herpes zoster</li> </ul>

Although trimethoprim is hypothetically teratogenic to the baby during the first trimester of pregnancy, co-trimoxazole prophylaxis should nevertheless commence irrespective of the gestational age. This is because the benefits of the protective effect of TMP-SMX against OIs in the mother far outweigh the very small risk of adverse effects on the fetus.

Sulphonamides can displace bilirubin from plasma albumin, and are associated with an increased risk of jaundice and kernicterus in the newborn baby. Careful monitoring of the baby should be undertaken, but TMP-SMX should <u>not</u> be discontinued prior to delivery if required for maternal health.

If needed, dapsone and aerosolized pentamidine are considered to be safe in pregnancy.



#### Guidelines for other agents used for OI prophylaxis -

Table 7.1 provides guidance on the use of other anti-infective agents for OI prophylaxis in pregnancy.

Isoniazid preventive therapy (IPT) for TB should be prescribed in accordance with most recent National TB/HIV Guidelines. Isoniazid is given for 6 months for all PLHIV who do not have active TB. This includes women, men and children over 1 year of age. Children less than 1 year of age who are exposed to pulmonary TB should also receive IPT.

#### 7.2.2 Immediate Postpartum Care

Community-based health care workers should ensure that women who are infected with HIV and have given birth – whether in a health facility or at home – return for postpartum appointments or are visited at home.

<u>As a minimum</u>, women should be evaluated 1 week after the birth and again at 6 weeks. More frequent monitoring at home will assist in adherence to neonatal nevirapine prophylaxis and to maternal ARVs/ART and/or co-trimoxazole for the mother (if prescribed). Extra support for infant feeding choice is essential during the first weeks of life: questions or difficulties may arise.

Include the following during visits:

#### Assessment of healing -

- Check perineal or caesarean section wound healing
- Monitor uterine involution
- Monitor for signs of puerperal infection
- Monitor lochia and any signs of secondary postpartum haemorrhage

#### Infant feeding support-

- Assess progress with and adherence to exclusive breastfeeding
- Assist the mother to safely breastfeed.
- Assess family support for breastfeeding; identify any risk factors for mixed feeding, and counsel and manage as appropriate
- Ensure women use a good breast feeding technique to prevent abscesses, nipple fissures and mastitis – if fever or other signs of breast infection or inflammation are present, advise or refer them promptly for treatment

Address sexual and reproductive health aspects of the postpartum period –

- Discuss resumption of sexual activity and contraception (refer to Chapter 4)
- Discuss the importance of safer sex to prevent the spread of HIV and other STIs.
- Discuss condom use as "dual protection"
- Provide ongoing support for the mother's choice of contraceptive method
- Provide advice regarding early STI symptom recognition and where to go for STI assessment and treatment
- Answer any questions the woman may have about safer sex behaviours

#### 7.2.3 Related services for HIV Care, Treatment and Support

The postpartum period is essential to link the woman who is HIV-infected to comprehensive care that will support her health, prevent complications and improve her ability to live with HIV, if she has not already done so. The majority, will have initiated comprehensive HIV care before delivery. Continuation and follow-up should be supported.

The range of services that should be provided, either directly or by referral, include:

#### Prevention and treatment of opportunistic infections -

Ols are a major concern in people with advanced HIV infection. Prophylaxis, treatment and health education for opportunistic and other infections must be provided to help a woman stay healthier and preserve her immune system, according to national *Guidelines*.



#### Antiretroviral treatment or triple ARV prophylaxis -

Women diagnosed in PMTCT settings should be linked to treatment services for themselves and their families as soon as possible. This should happen during antenatal care, ideally or as soon as possible after delivery. Life-long ART should be administered according to national ART *Guidelines*. Triple ARV prophylaxis should continue for about as 12 months postpartum, see details in Chapter 5.

#### Management of symptoms and palliative care -

PLHIV may experience symptoms related to their HIV infection or treatment that can limit participation in family and community activities. Health care interventions that focus on managing symptoms and relieving discomfort can improve a woman's quality of life.

Simple management of common HIV- or ART-related symptoms (including nausea, vomiting, fatigue and skin problems) can ease discomfort.

Assessment by an HIV clinician and management of more complex issues such as pain, weight loss and wasting resulting from disease progression can identify ways to improve comfort, function and emotional well-being.

#### Nutritional counselling, care and support-

PLHIV often have digestive symptoms that make eating and even food preparation difficult. Women receiving HIV-related medications require counselling on specific dietary practices and nutritional needs, in order to successfully manage side effects and avoid nutrition-related complications. Some PLHIV find that their appetite increases greatly following commencement of ART, and need strategies and support for managing their increased nutritional demands.

#### Personal and environmental hygiene -

PLHIV are especially vulnerable to bacterial infections as their immune systems become weakened. Emphasise the importance of good hygiene during food preparation and storage.

Adequate nutrition, exercise, rest, good hygiene practices, and abstinence from harmful habits such as smoking, alcohol and drug use support overall health and improve immune function.

#### Social and psychosocial support –

In many communities, PLHIV face stigma and discrimination and women who are HIV-infected may be reluctant to disclose their status to partners, family or friends.

The following support services should be offered, either directly or by referral:

- Counselling and support to help the woman come to terms with her diagnosis and consider her options for disclosure
- Specific psychosocial support and education for the mother whose infant has been exposed to HIV but whose HIV status is uncertain, or when a positive diagnosis is made
- Community support, including referrals to CBO and FBO programmes
- Peer group counselling and support from health agencies or NGOs
- Support and counselling to assist women who are HIV-infected and their partners with disclosure issues

#### Faith-based support -

Faith-based involvement can provide mothers who are HIV-infected with spiritual and psychosocial support. It may also provide them with an important sense of belonging to a larger community that offers them compassionate care.

Religious leaders are important members of their community, and should be engaged in discussion about care and support for PLHIV as a priority.

#### Community Home-based care-

Community home-based care provides services to PLHIV are expanding throughout Nepal. They are available to care for PLHIV throughout the continuum of HIV infection and can assist at diagnosis, during times of illness, around the start or continuation of ART, in follow-up from hospitalisation or



during the terminal stages of the disease. The advantages of home-based care for patients and families, and for communities and the healthcare system include:

- Care is provided in a familiar, supportive environment that allows for continued participation in family life
- Medical and transportation expenses are reduced
- Closer and more frequent follow-up by a health care worker may be possible, especially for those living far from health facilities
- The local community may be involved in care for PLHA, and this may help counter myths, misconceptions, stigma, discrimination and rejection
- The demands on the health care system are reduced

## **7.3** Assessment, Care, Antiretroviral Treatment and Support of Infants and Young Children Exposed to HIV

#### 7.3.1 Standard Care, Treatment and Support for Infants and Young Children

PMTCT interventions reduce, but do not eliminate, the risk of HIV transmission from mother to infant. Regular follow-up care is essential for infants born to mothers with HIV, and for infants whose mothers' HIV status is unknown.

PMTCT sites should consider the best, most efficient option for follow-up CT&S. All HIV positive pregnant women should be enrolled for care at the ART clinic by carers with training in HIV medicine and ART. Their exposed babies would also be followed up at the ART clinic until HIV infection is definitively excluded according to follow-up schedule and protocol in the Nepal *Paediatric Guidelines*.

Clinical and laboratory assessment, immunisation, care, ART and support should follow the *National Guideline on Paediatric HIV and AIDS*. Co-trimoxazole prophylaxis against OIs like PCP and bacterial infection is essential; it should commence at 6 weeks of age according to the national *Paediatric Guidelines*, and continue until HIV infection has been definitively excluded. If an ART clinic is being used as the single point of care, treatment and support for a family affected by HIV, it may be preferable for to provide co-trimoxazole prophylaxis, HIV testing and long-term follow-up for exposed children through that clinic.

All HIV-exposed infants need early infant diagnosis with DNA PCR testing at 6 weeks of life. Currently, DNA PCR availability is limited to a few facilities in Nepal. Sample collection can be performed using Dried Blood Spot (DBS) technique with mailing specimen centrally for testing. Screening of all exposed children at 9 months by antibody testing (i.e. Rapid tests or ELISAs), should be done with referral of all those testing antibody positive for DNA PCR. Any child found to be DNA PCR positive for HIV before 24 months of age needs immediate initiation of ART as this is found to save lives in this age group, irrespective of clinical status or CD4 count.

## 7.4 Further Reading

NCASC. National Guideline on Paediatric HIV and AIDS (2006).



## Site requirements

The minimum standard of requirements is as follows:

# 8.1 Sites offering Full PMTCT Services and Support

#### 8.1.1 Human Resources and Capacity

#### A core team, trained on all aspects of PMTCT, consisting of

- 1 midwife, with ready access to an obstetrician / gynaecologist and HIV clinician
- 1 2 staff nurses, with ready access to a doctor with skills in clinical HIV medicine
- 2 3 trained counsellors, according to the case load
- 1 laboratory technician (or other health worker accredited to conduct rapid testing)

The team should also explore, encourage and promote the involvement of NGOs, CBOs and community based health volunteers, who will also receive training. Community based health workers are an essential part of the PMTCT team

#### 8.1.2 Infrastructure

#### Space –

- An appropriate room for counselling, offering audible and visual privacy and containing basic furniture to sit and talk comfortably.
- Two additional rooms to accommodate one-on-one and couples counselling, as well as small group pre-test counselling.

#### Equipment and supplies -

- Appropriate equipment, test kits and supplies for HIV testing
- Essential drugs for PMTCT services
- Health education materials, condom supplies and a penis model
- Supplies for infection prevention (universal precautions)
- Updated list of referral institutions including contact name, eligibility requirements, location, hours of operation, telephone number and any fees.
- Appropriate record keeping, monitoring and evaluation forms (see Chapter 9)

Refrigerator for storing test kits requiring a "cool" chain, with appropriate back-up energy source and temperature monitoring



# 8.2 Community Based PMTCT Services and Support

#### 8.2.1 Human Resources and Capacity

A community based health worker (FCHV or CHBC worker) who is:

- trained on all community aspects of PMTCT, and
- actively supported by and involved in the PMTCT activities of the supervising PHC or sub-health post team.

#### 8.2.2 Infrastructure

#### Equipment and supplies -

- Essential drugs
- IEC materials to educate pregnant women and the community on HIV and PMTCT
- Health education materials, condom supplies and a penis model
- Supplies for infection prevention (universal precautions)
- After hours contact details for supervising health centre including contact name, telephone number and location of residence.



## **PMTCT Programme Monitoring**

## 9.1 Overview of Monitoring and Evaluation

Since PMTCT is a relatively new programme in Nepal, operational research and careful monitoring and evaluation will be necessary to understand the effectiveness, efficiency, costs, acceptability, sustainability and other characteristics of various packages of intervention, and to develop a strong evidence base for future revisions of PMTCT policies and programmes.

#### 9.1.1 What is monitoring?

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

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

#### 9.1.2 What is evaluation?

Evaluation is measuring the changes in a situation resulting from an intervention.

A *periodic formal evaluation* of the PMTCT programme will demonstrate to what extent the programme contributed to changes in the indicators. Formal evaluations should try to determine the ways in which the PMTCT programme is causing these changes.

## **9.2** Monitoring and Evaluation of the PMTCT Programme

Monitoring information is used for decision-making about PMTCT programmes at local, national and global levels.

UNICEF and WHO are currently revising the international guidelines for M&E of PMTCT programmes. The following sections describe the current approaches to M&E.

#### 9.2.1 The annual PMTCT Report Card

The implementation of the national PMTCT programme is monitored against the national PMTCT strategies and targets (Section 1.4.1), which reflect the UNGASS targets (Section 1.2.3).

Each year, a national survey is undertaken to monitor progress towards achieving PMTCT *targets* – both national and through the 2001 *Declaration of Commitment* on HIV/AIDS – and to provide information on the status of implementation of the national programme. This is compiled into a *PMTCT and Paediatric HIV Care Report Card*.

The objectives of the survey are:

- To measure population coverage and trends in coverage of PMTCT services
- To measure the uptake of PMTCT interventions, i.e. HIV-related counselling and testing, ARV prophylaxis, and infant feeding counselling
- To identify major challenges and gaps in PMTCT programme implementation, including advocacy, resource mobilisation, planning and implementation.



#### 9.2.2 Monitoring progress towards Universal Access to PMTCT services

To reach the national and UNGASS goals and targets for PMTCT, adequate *coverage* levels must be met for PMTCT-related interventions.

The UN Universal Access initiative recommends that country level M&E focuses on the coverage levels of the following programme interventions:

- Provision of information on PMTCT to pregnant women attending antenatal care
- HIV testing for pregnant women attending antenatal care, including those previously confirmed to be infected with HIV
- Provision of ARV prophylaxis for pregnant women living with HIV, to reduce the risk of MTCT
- Provision of ART for eligible pregnant women living with HIV, for their own health and to reduce the risk of MTCT
- Provision of co-trimoxazole prophylaxis for infants born to women living with HIV
- Infant feeding counselling and support at the first infant follow-up visit for mothers living with HIV
- Referral and enrolment of women living with HIV into comprehensive CT&S
- Virological HIV testing (where available) within two months of birth for infants born to women living with HIV

To monitor progress in the implementation of all four "prongs" of the UN comprehensive approach to preventing HIV infection among infants and young children, additional coverage indicators and targets are needed for primary prevention and family planning.

Examples of interventions for which additional data may be collected through service delivery points include:

- Provision of HIV testing and counselling for male partners of HIV-infected and noninfected women accessing PMTCT services
- Provision of family planning services (either on site or through referrals) for women living with HIV enrolled in PMTCT and care and treatment services

#### 9.2.3 Using monitoring information for national decision-making

National data collected under the *PMTCT Report Card* and Universal Access M&E frame-works are reviewed periodically by the national PMTCT Working Group to assess programme performance and improve procedures for programme implementation and expansion.

## **9.3 PMTCT Programme Performance** Indicators

#### 9.3.1 Annual PMTCT Report Card indicators

#### Facility coverage -

- Total number of health facilities in the country
- Total number of facilities nationally providing antenatal care services
- Total number of facilities nationally providing antenatal care services, which also provide HIV testing and counselling for pregnant women
- Total number of facilities nationally providing antenatal care services, which also provide HIV testing and counselling for pregnant women <u>and</u> ARVs for PMTCT



- Total number of antenatal facilities providing CD4 testing on-site, or with a system for collecting and transporting blood samples for CD4 testing for pregnant women
- Total number of facilities nationally providing ART
- Total number of facilities nationally providing ARVs for <u>both</u> PMTCT and ART
- Total number of facilities nationally providing paediatric ART
- Total number of health facilities that provide virological testing services (e.g. by PCR) for infant diagnosis of HIV infection, either on-site or using dried blood spot (DBS) methods
- Total number of facilities that have the laboratory capacity to perform CD4 testing onsite
- Total number of Districts that have CD4 testing services available

#### Pregnant women –

- Total number of pregnant women tested for HIV
- Total number of pregnant women tested for HIV and who receive their test results
- Total number of male partners of pregnant women tested for HIV
- Total number of pregnant women who tested HIV positive
- Total number of HIV-infected pregnant women who received ARVs to reduce the risk of MTCT of HIV
  - o sdNVP (the "minimum standard")
  - o a combination of three ARVs (the "recommended standard")
  - o HAART for eligible pregnant women
- Total number of HIV-infected pregnant women assessed for ART eligibility (CD4 cell count and/or clinical staging)
- Total number of HIV-infected pregnant women who received ART for their own health
- Total number of HIV-infected women attending HIV care and treatment services with unmet need for family planning

#### Infants born to HIV-infected pregnant women -

- Total number of infants born to HIV-infected women receiving any ARVs for PMTCT
- Total number of infants born to HIV-infected women started on co-trimoxazole prophylaxis within two months of birth
- Total number of infants born to HIV-infected women receiving a virological test for HIV diagnosis within two months of birth
- Total number of infants born to HIV-infected women tested for HIV (antibody or virological test) by 12 months of age
- Total number of infants born to HIV-infected women assessed for and whose infant feeding practices were recorded at three months of age
  - Total number reporting exclusive breast feeding at 6 months of age
  - o Total number reporting exclusive replacement feeding at 6 months of age
  - o Total number reporting mixed breast and replacement feeding at 6 months of age



#### HIV-infected children -

• Total number of HIV-infected children receiving ART

#### PMTCT Programme components -

- Is there a national PMTCT scale-up plan?
- Is there a national paediatric HIV care and treatment scale-up plan?
- Are there national PMTCT indicators?
- Are there national paediatric HIV care and treatment indicators?
- What is the most commonly used ARV regimen for PMTCT?
- Is PITC routinely offered at antenatal care facilities that provide HIV testing?
- What is the most common HIV testing method used in antenatal settings?
- Is DBS technology available for use in the PMTCT and paediatric HIV care pro-grammes?
- Is there a national policy on offering routine HIV testing for children? In which set-tings?
- What are the three major gaps and challenges in PMTCT implementation?
- What are the three major gaps and challenges in paediatric HIV care and treat-ment?

#### 9.3.2 Universal Access indicators

- Percentage of antenatal facilities that provide both HIV testing and ARVs for PMTCT
  - Numerator = number of antenatal facilities that provide both HIV testing and ARVs for PMTCT on-site
  - o Denominator = total number of antenatal facilities
- Percentage of HIV-infected pregnant women who received ARVs to reduce the risk of MTCT
  - Numerator = number of HIV-infected pregnant women who received ARVs during the last 12 months to reduce the risk of MTCT
  - Denominator = estimated number of HIV-infected pregnant women during the last 12 months
- Percentage of infants born to HIV-infected women who receive an HIV test within 12 months
  - Numerator = number of infants born to HIV-infected women during the last 12 months who received an HIV test within 12 months
  - Denominator = estimated number of HIV-infected pregnant women who gave birth during the last 12 months
- Distribution of feeding practices (exclusive breast feeding, replacement feeding, or mixed breast and replacement feeding) for infants born to HIV-infected women
  - Numerators = number of infants born to HIV-infected women during the last 12 months who are a) exclusively breast fed, b) exclusively replacement fed, and c) mixed breast and replacement fed
  - Denominator = number of HIV-exposed infants whose feeding practice was assessed (through the mother) at or before 6 months of age
- Percentage of HIV-infected infants born to HIV-infected mothers in the preceding 12 months
  - Numerator = number of infants born to HIV-infected women during the last 12 months in whom HIV infection was subsequently confirmed by virologi-cal or immunologi-cal testing
  - Denominator = estimated number of HIV-infected pregnant women who gave birth during the last 12 months



### 9.4 Further Reading

UNAIDS. National guide to monitoring and evaluating programmes for the prevention of *HIV* in infants and young children (2004).

Interagency Task Team on Prevention of HIV Infection in Pregnant Women, Mothers and their Children. Guidance on Global Scale-up of the Prevention of Mother-to-Child Transmission of HIV – Towards universal access for women, infants and young children and eliminating HIV and AIDS among children (2007)

UNICEF. PMTCT Report card (2005)

MOHP, UNICEF and WHO. PMTCT and Paediatric HIV Care Report Card – Nepal (2007)





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