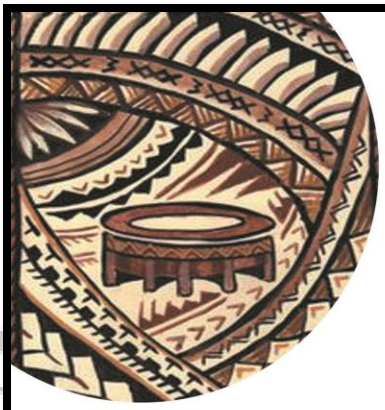

Ministry of Health
S A M O A

2018

NATIONAL GUIDELINES ON PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV, SYPHILIS, AND HEPATITIS B & C

This guideline is an adaptation of the WHO Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infections (Second Edition 2016)

UNDP

World Health Organization

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Director General/CEO Ministry of Health

FOREWORD

The Ministry of Health is proud to present Samoa's adapted WHO Guidelines for;

1. Use of Anti-retroviral Therapy
2. Preventing Mother to Child Transmission of HIV
3. HIV testing services
4. STI Diagnosis, Treatment and Management

This document is the adaptation of the 2016 WHO guidelines that have been contextualized for Samoa's healthcare system and clinicians. The health sector, stakeholders and partners were consulted in order to tailor these guidelines to better fit Samoa's resources, service delivery systems, multilateral partnerships, and ultimately the needs of patients.

Samoa, as well as the Pacific region as a whole, has long faced high rates of STI's, which are only projected to increase within the coming 5 years. Ensuring quality clinical case management of STI's is an absolutely essential part of the national response to these diseases. Linked to STI management is HIV Testing Services (HTS), which involves clinicians, laboratories, public health, and the communities themselves in detecting infections and connecting people to the services they need. Samoa has historically adopted a treat all approach to those that test positive for HIV, giving all people ART free of cost. It is therefore essential that providers in Samoa are fluent in the latest practices for treatment.

Additionally, Preventing Mother to Child Transmission (PMTCT) encompasses all services, interventions, care, protocols and standards to support patients in maintaining their health and preventing the spread of infection from parent to infant. Samoa has always demonstrated a firm commitment on improving maternal and child health through both the Millennium and the Sustainable Development Goals.

These guidelines serve to provide clinicians a reference for the latest in global best practices, as well as the local context for implementing them. Throughout the document are clinical notes labeled below.

"  "

These notes come from numerous consultations on the guidelines and how to implement the recommendations nationally. We hope that providers will find this useful in their practice.
We are grateful for all of the work from our national and international partners in health that has gone into the development of these guidelines.

Ma lo'u fa'aaloalo lava,

Leausa Toleafoa Dr. Take Naseri

ACKNOWLEDGEMENT

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Therefore the Ministry of Health would like to thank the following consultants, individuals and organizations for the development of the updated guidelines. Their valued advice and review was essential for contextualizing these guidelines to Samoa's health system;

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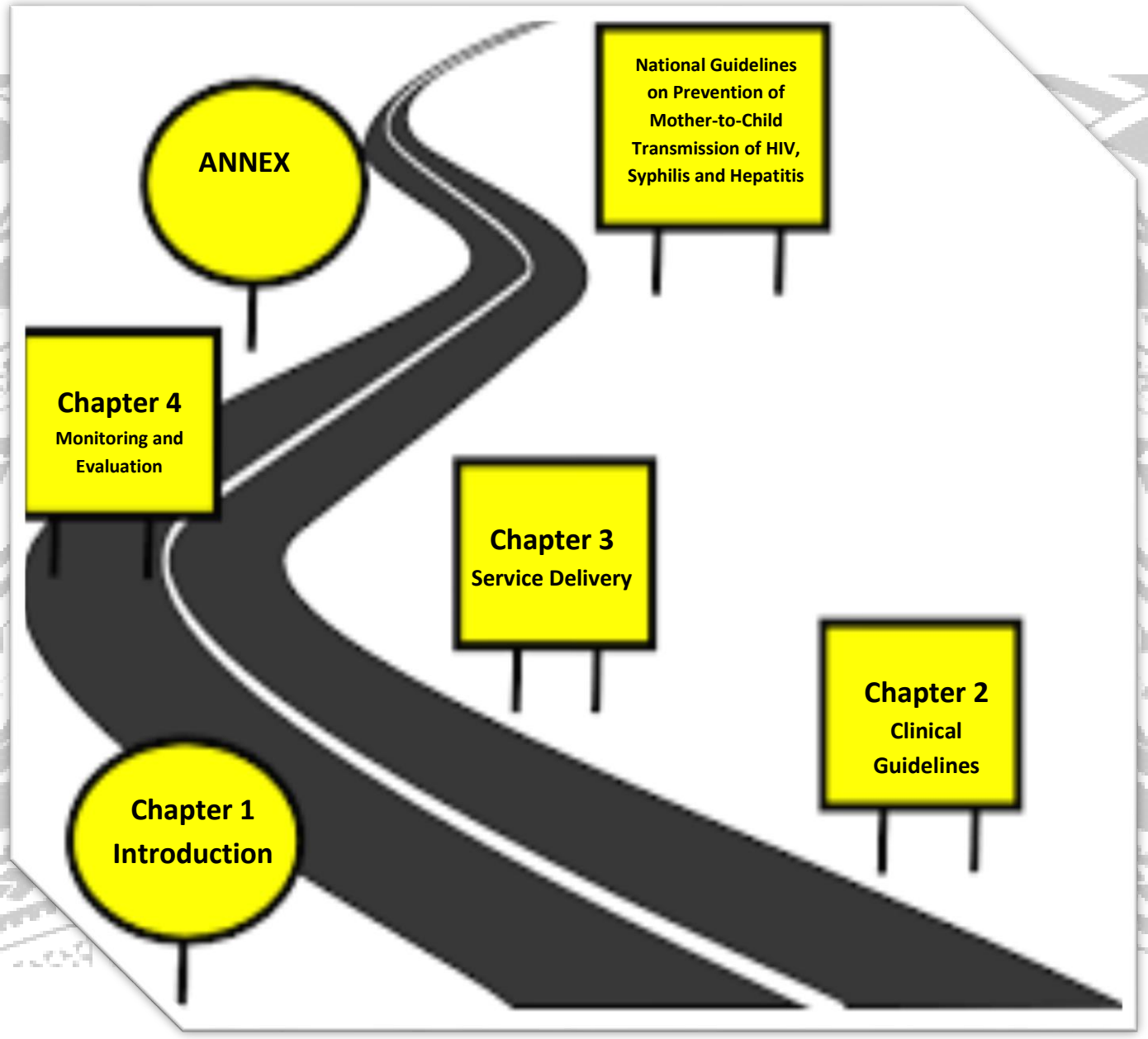
Dr. Yadav Subhash (WHO)

ACRONYMS

ANC	Antenatal Care
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Zidovudine
BCC	Behaviour Change Communication
DPs	Development Partners
EBF	Exclusive Breast Feeding
EID	Early Infant Diagnosis
e-MTCT	Elimination of Mother–to-Child Transmission
EFV	Efavirenz
EPI	Expanded Programme of Immunization
HBV	Hepatitis B Virus
HEI	HIV Exposed Infant
HIV	Human Immunodeficiency Virus
LPV/r	Lopinavir/ritonavir
3TC	Lamivudine
MTCT	Mother-to-Child Transmission of HIV
NVP	Nevirapine
OIs	Opportunistic Infections
PMTCT	Prevention-of-Parent-to-Child-Transmission of HIV
NVP	Single-Dose Nevirapine
SRH	Sexual and Reproductive Health
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
UNICEF	United Nation International Children Emergency Fund
WHO	World Health Organization

Table of Contents

This guideline is divided into four main chapters, with an annex section.



CHAPTER 1

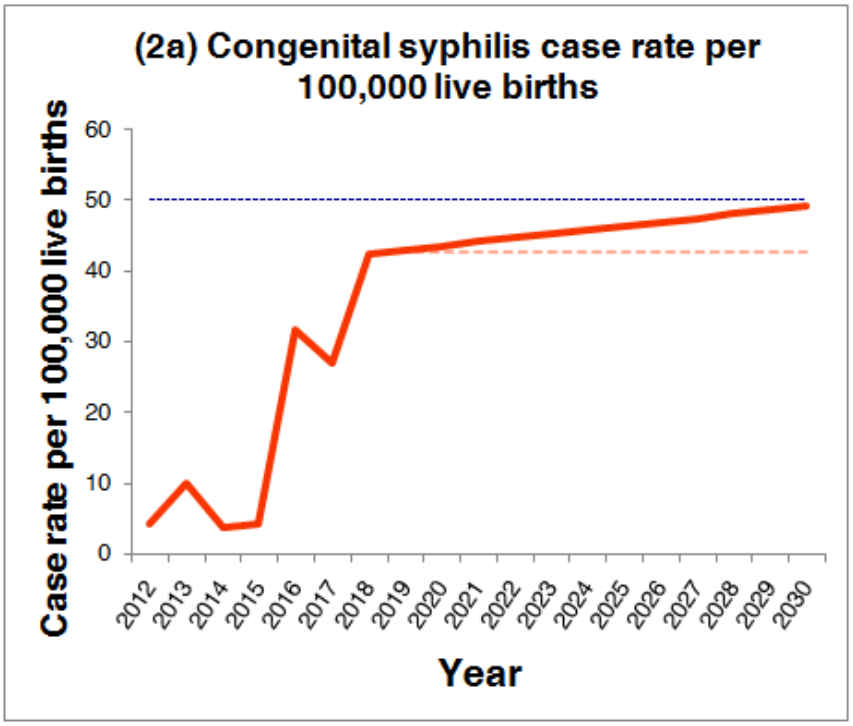
INTRODUCTION

1.1 Background:

Historically there have been 6 children born to 5 mothers living with HIV that were not on preventative ART regimens. Currently there are 2 children living with HIV from these mother-to-child (MTC) transmissions and 1 stillbirth to an HIV positive mother occurring in 2015. There have also been 2 successful cases of PLWHIV given proper ARV regimens to prevent HIV transmission that were successful. This low incidence of MTC transmission is largely due to the work of the Communicable Disease Clinic in ensuring treatment is brought to all cases to support adherence.

Preventing mother to child transmission (PMTCT) of HIV and STI's has always been a national priority in Samoa. Screening of all women who report to Antenatal Care (ANC) are mandatorily screened for HIV and STI's, in addition to HIV and STI testing be included as part of infant blood panels.For pregnant women, Samoa has used WHO Option B+ (i.e. treat all ANC women free of cost) which has been implemented country-wide.

Congenital Syphilis in particular is a rapidly growing threat. The current global target for mother to child transmission of Syphilis is 50 cases or less per 100,000 live births. Samoa is currently below that target, however congenital Syphilis cases are estimated to greatly increase, which threatens PMTCT.

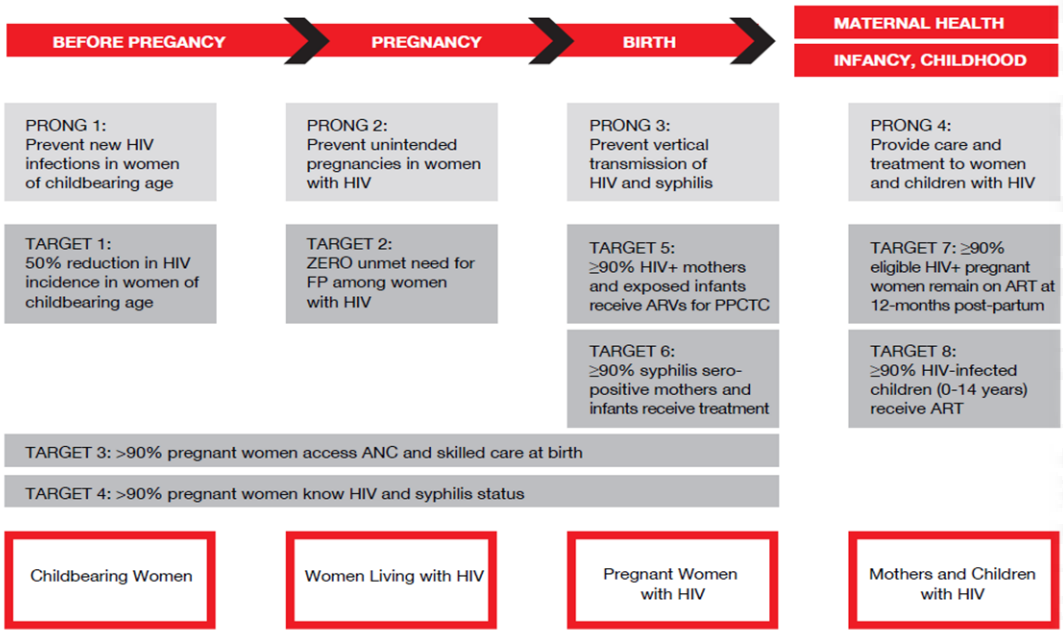


Samoa 2018 Congenital Syphilis projections for the 2030 Global Target from the Spectrum Model

The challenge remains with encouraging higher rates of ANC attendance by pregnant women. Out of all estimated pregnant women in the country, 26% reported for ANC care in 2016.[1] This increased significantly in 2017 to 50.2%. This is tremendous progress but more work remains to be done with access to antenatal care and birth services. The Apia Birth Health Study conducted in 2016 by the HIV, STI, and TB National Programme revealed that out of all the births that occurred at TTM between 2014-2015, 71.2% of women (4,280) had at least 1 recorded antenatal care visit at a healthcare facility (and therefore had HIV/STI screening). However, only 47.1% (2,829) had the minimum recommended number of ANC visits (4). Married women are more likely to have less than 4 recommended antenatal visits. Birth cases that reported to TTM between 2014-2015 were mostly from Upolu (specifically the Apia Urban Area and North West Upolu regions. This indicates the women that do receive mandatory HIV and STI testing are largely representative of the Apia Urban Area and Northwest Upolu and have access to TTM Hospital in Apia for their births. Though this may not be adequate access as the study also found that majority of birth complications between 2014-2015 were related to not accessing healthcare services at the right time for labour. This may also have implications for ANC HIV and STI testing.

1.2 Overarching principle in PMTCT

Figure 2: The Eight Programmatic Targets Correlate to the Four Prongs of the Comprehensive Approach to PPTCT



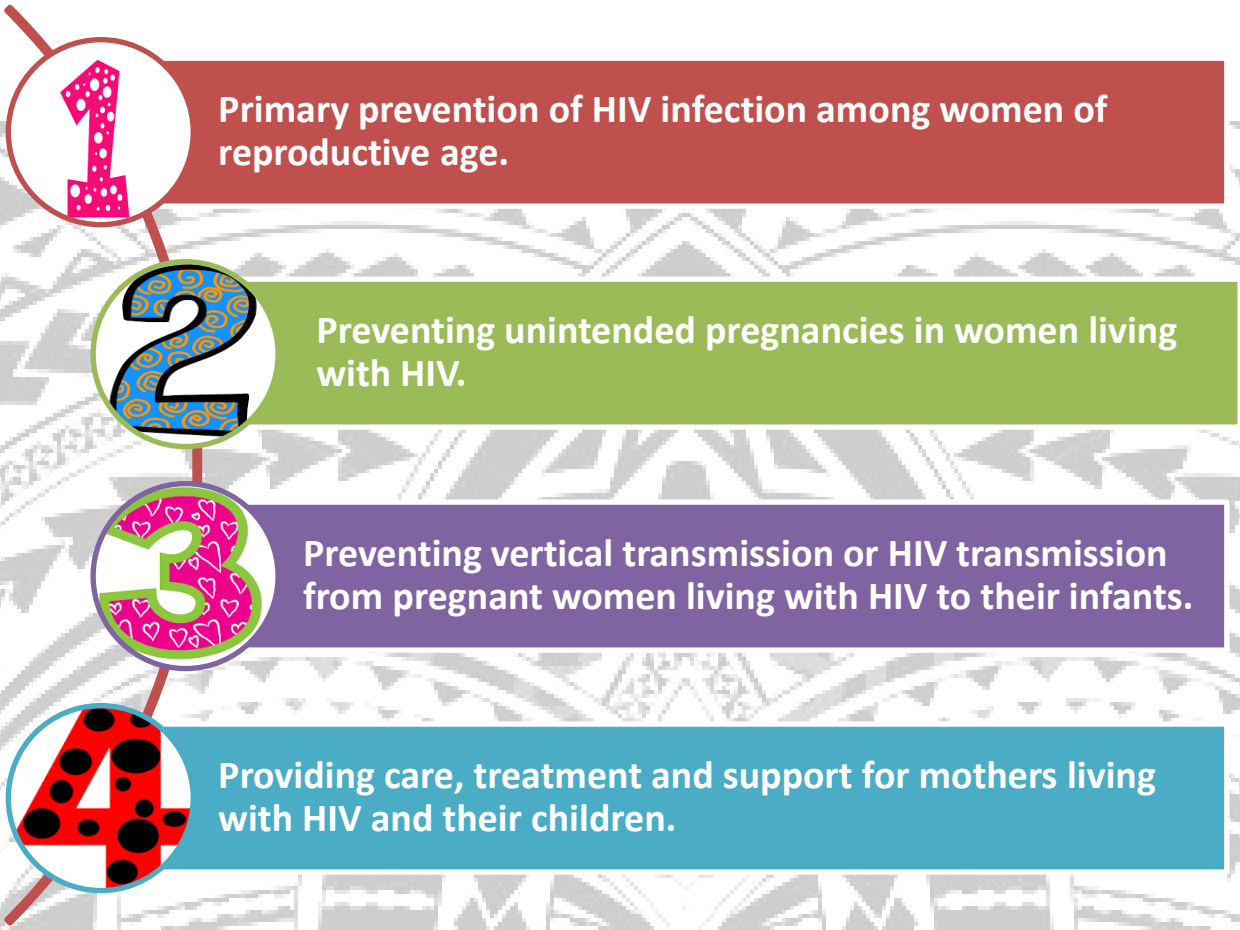
[1]This measure was calculated using the following formula: WRA/1,000 * {(B*Pb) + (A*Pa) + (D*Pd)}, whereareas WRA =women of reproductive age in Samoa 2015, B= Fertility Rate, A=Abortion Rate, D=Fetal Loss (death) rate per 1,000 women, and Pb, Pa, and Pd representing the proportion of the year a woman is pregnant; 9months=.75, 2 months=.167, 3 months=.25, respectively. According to the calculation, approximately **9,615.7** women were pregnant at any given point in time in 2015. Assuming that each pregnant woman has only 1 partner, the estimated target population that includes both antenatal mothers and their male partners would be **19,232** at any given time in 2015 (based on the point-in-time estimate of antenatal women).

CHAPTER 2

CLINICAL GUIDANCE

2.1 Goals of PMTCT

In line with WHO standards, the National HIV programme recognizes the four elements fundamental to preventing HIV transmission among women and children. These are:



The National HIV programme adopts a public health approach to provide these services to pregnant women and their children. This approach seeks to ensure equitable access to high-quality PMTCT services at the grass-root level while taking into account what is feasible on a large-scale within available health infrastructure, human and financial resources.

The PMTCT services provide access to all pregnant women for HIV diagnostic, prevention, care and treatment services. As such, the key goal is to ensure the integrated PMTCT services delivery within existing Reproductive Health programme.

The Essential Package of PMTCT Services includes:

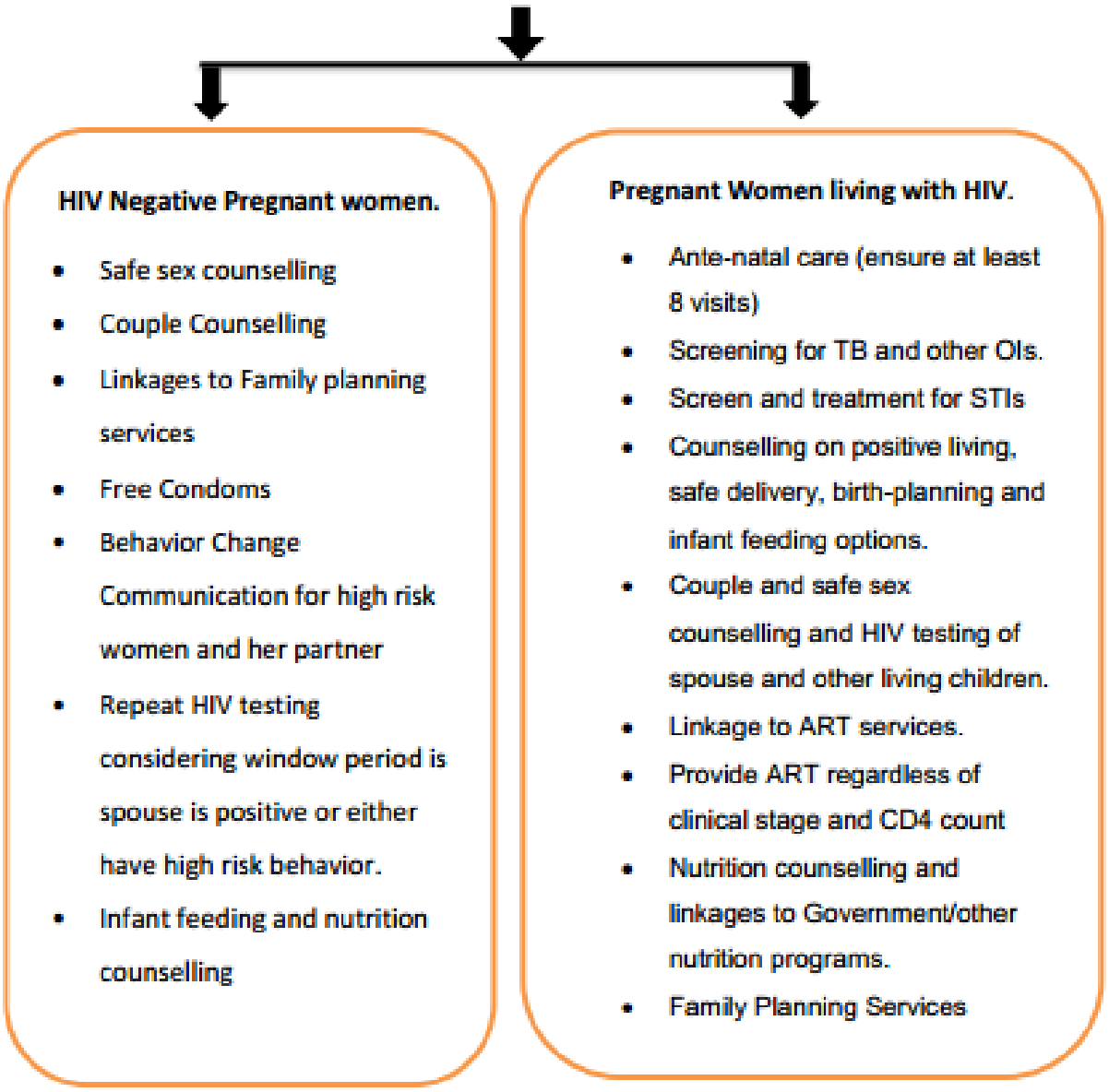
- Routine offer of HIV counselling (Group/Individual counselling) and testing to all pregnant women attending ante-natal care, with 'opt out' option.
- Ensure involvement of spouse & other family members and move to a family centric approach.
- Provide ART to all Pregnant Women living with HIV regardless of WHO staging and CD4 count results. Preferred regimen is TDF+3TC+ EFV.
- Promote hospital delivery for all Pregnant Women living with HIV.
- Provision of care for associated conditions (STI, TB & other Opportunistic Infections (OIs).
- Provide nutrition counselling and psychosocial support for Pregnant Women living with HIV. (Linkages with other support services. Dieticians provide advice to clients on the right foods to take and be available for nutritional support.
- Provide counselling and support for initiation of exclusive breastfeeds within an hour of delivery as the preferred Option and continue for at least 6 months, Up to 12 months with complementary feeding and can continue for up to 24 months or longer (as for the general population) while being fully supported for ART adherence.

Due to challenges with ARV adherence, clinicians dealing with PLWHIV have opted to counsel against breastfeeding due to risk of transmission. Counseling and support for accessing breast milk products will be covered instead, as well as adherence counseling and viral load testing. Clinician's assessment holds the most weight, and women who are adherent with stable viral loads may be encouraged to breastfeed upon clinical case assessment.

- Provide antiretroviral prophylaxis to infants from birth up to a minimum period of 6 weeks.
- Integrate follow-up of HIV-exposed infants into routine healthcare services including immunization.
- Ensure initiation Early Infant Diagnosis (EID) as early as 6 weeks
- Strengthen follow-up and outreach through District level networks and other outreach workers to support Pregnant Women living with HIV and their family.

Offer of HIV Counselling and Testing Services to all Pregnant Women

The new model increases maternal and fetal assessments to detect problems, improves communication between health providers and pregnant women, and increases the likelihood of positive pregnancy outcomes. ***It recommends pregnant women to have their first contact in the first 12 weeks' gestation, with subsequent contacts taking place at 20, 26, 30, 34, 36, 38 and 40 weeks' gestation***



HIV Exposed Infant

- Exclusive breastfeeds up to 6 months and continued breastfeeds in addition to complementary feeds after 6 months up to 1 year for EID negative babies and up to 2 years for EID positive babies who receive Pediatric ART.

 *Due to challenges with ARV adherence, clinicians dealing with PLWHIV have opted to counsel against breastfeeding due to risk of transmission. Counseling and support for accessing breast milk products will be covered instead, as well as adherence counseling and viral load testing. Clinician's assessment holds the most weight, and women who are adherent with stable viral loads may be encouraged to breastfeed upon clinical case assessment.*

- Postpartum ARV prophylaxis for infant for minimum 6 weeks.
- Early infant diagnosis (EID) at 6 weeks of age; repeat testing at 6 months, 12 months & 6 weeks after cessation of breastfeeds.
- HIV care and Pediatric ART for infants and children diagnosed as HIV positive through EID.
- Growth and nutrition monitoring.
- Immunizations and routine infant care.
- Gradual weaning after 6 months and introduction of complementary feeds from 6 months onwards along with continuation of BF for at least 1 year for adequate growth & development of the child.
- Confirmation of HIV status of all babies at 18 months.

Priority Actions:

1. **Prong 1: Primary prevention of HIV and syphilis among women of childbearing age**
   Expanding implementation of effective HIV/STI prevention activities is especially important in the low and concentrated HIV epidemic settings of Asia-Pacific. This is particularly relevant for women in key affected populations (KAPs), such as female injecting drug users and sex workers (SWs), as well as for the regular female partners of men with high-risk behaviour (male clients of SWs, men who inject drugs and men who have sex with men (MSM)). The prevention of intimate partner transmission (IPT) takes on special significance, as it accounts for a significant percentage of new HIV infections among women in the Asia-Pacific region. As such, it is critical to strengthen prevention, counselling and testing services for KAPs and their female partners, particularly in light of the findings of the HPTN 052 trial, which demonstrate that initiation of ART in HIV-infected individuals substantially protected their uninfected sexual partners from acquiring HIV infection[24].

   The wider implementation of all HIV prevention services that prioritise male involvement are essential, as this can promote men to take greater responsibility for SRH decisions and contribute to a better uptake of HIV/STI prevention services overall, and PPTCT services in particular. Recognising this, settings where HIV prevention services are provided should be utilised as an avenue to introduce PPTCT and SRH interventions. Similarly, SRH/MNCH services should be employed as an entry point for HIV prevention for all women and their male partners.

2. **Prong 2: Prevention of unintended pregnancies among women living with HIV**
   The inclusion of FP services as part of routine care for HIV-positive women of childbearing age is critical to reduce the number of unintended pregnancies among women living with HIV. Effective FP services for HIV-positive women can improve the uptake of PPTCT services among those who choose to become pregnant, and will contribute to broader, established MDG 5 targets to reduce unmet need for FP among all women. The implementation of routine FP services for women enrolled in HIV care and treatment should prioritise male involvement as a means of strengthening overall SRH decision-making capacity.

3. **Prong 3: Prevention of HIV or syphilis transmission from a pregnant woman to her infant**
   In order to effectively prevent the vertical transmission of HIV, pregnant women with HIV must first be identified. The expansion of routine, opt-out HIV testing and counselling in all ANC settings will contribute significantly to improved identification of pregnant women with HIV, who require care and treatment for their own health, as well as effective PPTCT prophylaxis. Additionally, expanded use of rapid syphilis tests will enhance detection and treatment of sero-positive women and prevention of CS. Building capacity for expanded utilisation of more efficacious ARV and ART regimens is essential to achieve significant reductions in PTCT. This includes not only the prescription of combination ARV/ART regimens and clinical management during pregnancy and childbirth, but it also encompasses the need to support adherence to infant or maternal ARV prophylaxis throughout the breastfeeding period.

4. **Prong 4: Appropriate treatment, care to mothers living with HIV and their children**
   Strengthening the continuum of services between PPTCT/ECS interventions and lifelong HIV care and treatment is essential to improve the health and survival of mothers with HIV and their exposed children. Priorities include expanding prompt CD4 and ART eligibility assessment for pregnant women with HIV, and the early initiation of treatment for those who require ART for their own health. Linkage to HIV support services is essential for all pregnant women with HIV, who will require lifelong care and treatment services after delivery, irrespective of immunologic status. Additional priorities include EID services for exposed infants and prompt linkage to paediatric care services, including the initiation of co-trimoxazole prophylaxis for all HIV-exposed infants.

Table below can serve as reference in identifying priority actions at the country level when setting up or strengthening PPTCT Programme. Some recommendations have been updated specifically on the new WHO recommendations on ART initiation (Treat All, treat early). *Refer to 2018 ART Guidelines.*

Comprehensive Approach to PMTCT and ECS	Priority Actions
Prong 1: **Primary prevention of HIV and Syphilis among women of childbearing age**	• Integrate HIV and STI prevention for women of reproductive age in any setting where women and their male partners access ANC services • Strengthen HIV primary prevention services for male and female KAPS and enhance HIV counseling and testing for female partners of male KAPS • Ensure that PPTCT and STI counseling is part of harm reduction interventions for women in key at-risk populations, including PWIDS and SWs • Prioritise male involvement in the primary prevention of HIV among women, particularly in the prevention of IPT • Integrate PPTCT and SRH counseling for men and women in any setting where HIV testing and counseling is provided
Prong 2: **Prevention of unintended pregnancies among women living with HIV**	• Standardised the delivery of routine FP services for women attending services in HIV care settings • Enhance male involvement in routine SRH and MNCH services
Prong 3: **Prevention of HIV or syphilis transmission from a pregnant woman to her infant**	• Prioritise expansion of routine HIV abd syphilis testing in all ANC services • Implement and expand usage of highly efficacious combination ARV regimens and ART for women who need treatment • Promote safe infant feeding practices and support adherence to ARV prophylaxis during breastfeeding • Expand use of same day testing (RPR or rapid) and treatment (STAT) for syphilis in ANC settings
Prong 4: **Provision of appropriate treatment and care to mothers living with HIV and their children**	• Early CD4 assessment for treatment eligibility and prompt linkage to ART for women who require it for their own health • Early HIV diagnosis and co-trimaxazole in exposed infants and linkage to early ART for HIV-positive infants

The first and foremost important step for all pregnant women attending health services is to know their HIV status as part of the routine ante natal screening blood tests.

Four typical scenarios where pregnant women may attend the counselling and testing services include:

- Women attending ante natal clinics.
- Pregnant spouse of HIV-positive men, or those with high risk behaviour.
- Pregnant women screened at the dispensaries by health assistants
- Women presenting directly-in-labour (un-booked cases, require a HIV screening test before delivery).

2.2 General Principles

- Informed consent to be taken for all ANCs.
- Counselling to inform all pregnant women about the ante natal routine screening tests,
- Complete blood count, routine urinalysis, albumin/sugar, VDRL, blood grouping & typing and the benefits of testing for HIV, Syphilis, Chlamydia, Gonorrhea and Hepatitis B and C.
- Nurse/Counsellors to provide information on the ante natal screening comprehensive package including HIV testing through both individual counselling and group counselling information sessions.
- Pregnant Women who opt-out of HIV testing should be offered repeat counselling to explore the reasons for opting out, address any misunderstandings and encourage her to reconsider her decision. These women should be offered routine HIV testing at each subsequent clinic visit.
- Post-test counselling for all pregnant women is very important so as to educate those with negative tests to remain un-infected; while for those with confirmed HIV positive tests-further counselling, support and referrals to care & treatment services.
- Pregnant women who have been referred by outer dispensaries after screening tests must undergo pre-test counselling and follow the usual HIV testing protocol similar to the regular ante natal cases.
- Disclosure of HIV status is to be done at the clinics after appropriate confirmatory testing, followed by post-test counseling.

- All pregnant women referred to other HIV services, should be tracked to ensure that they actually reach the services, and have been registered at the respective centres.
- Partner/Spouse and family (other children) testing for HIV to be done as per HTS guidelines.
- Partner (Husband) involvement during the pregnancy and thereafter. PMTCT interventions and FP methods to be encouraged e.g., couple counselling for mutual psycho-social support, mother to ART and baby to ARV, Family planning counselling etc.

2.3 Sexually Transmitted Infections

Sexually transmitted infections are important public health problems. Studies suggest that around 30% per cent of the adult population in Samoais infected with one or more STIs (Samoa Spectrum Model 2018, MoH). Individuals with STIs have a significantly higher chance of acquiring and transmitting HIV. Moreover STIs are also known to cause infertility and reproductive morbidity. Controlling STIs helps decrease HIV infection rates and provides a window of opportunity for counselling about HIV prevention and reproductive health.

Syndromic Case Management is the cornerstone of STI management, being a comprehensive approach for STI control endorsed by the World Health Organization (WHO). This approach classifies STIs into syndromes, which are easily identifiable group of symptoms and signs and provides treatment for the most common organisms causing the syndrome. Treatment has been standardized as given in the table.Syndromic case management achieves high cure rates because it provides immediate treatment on the first visit at little or no laboratory cost. However, it goes hand-in-hand with other important components like counselling, partner treatment, condom promotion and referral for HIV testing.

Refer to the National Guidelines on STI, 2018.

Pregnant Women and STI Services

All pregnant women should be screened for syphilis. Syphilis is one of the easily treatable sexually transmitted Infection caused by Treponema pallidum, which can be transmitted to sexual partners as well as from infected pregnant woman to her new born child. Untreated syphilis is responsible for multisystem complications and other sickness among infected patients and may cause miscarriages, low birth weight and

premature delivery in the pregnant woman. Many patients of syphilis are asymptomatic and do not manifest any symptoms of the disease. The National HIV programme mandates a screening test to detect asymptomatic syphilis among all pregnant women attending Antenatal Clinics.

Level of Care Service Provider Modalities Package of Services

Level of care	Entry points*	Package of services
Primary	• District Health Centres • Outreach programming • Referral from Midwives • Mobile clinics/visits • Community Nurses • Ministry of Health offices, call line	• Information • Condom provision and promotion • Counseling • Referral for screening for STI, treatment and other services
Secondary	• Communicable Disease Clinic • Laboratory Services, TTM, Apia • All outpatient services	In addition to the above • Diagnosis • Treatment • Referral to tertiary care if needed
Tertiary	• Communicable Disease Clinic • Specialist clinicians • Private or overseas specialists	In addition to the above • Palliative care

** Entry points often provide services for multiple levels of care/referral, level of care not exclusive to primary service point*

Process of Screening ANC Women

- ANC at all level will do screening test for HIV and Syphilis using SD DUO HIV and Syphilis
- The pregnant woman will undergo pre-test counselling in ANC by the nurse or counsellor.
- After HIV and RPR testing, the patient returns for post-test counselling. During post-test counselling the counsellor provides the HIV and syphilis test report and counsels the patient to go to the Medical officer for treatment if required.

SYNDROMIC MANAGEMENT OF STI IN PREGNANT WOMEN

1) Treatment of Syphilis in pregnant women

Recommendation 1:

In **pregnant women with early syphilis** the WHO STI guideline recommends benzathine penicillin G2.4 million units once intramuscularly over no treatment.

Recommendation 2:

In **pregnant women with early syphilis**, the WHO STI guidelines suggests using benzathine penicillin G2.4 million units intramuscularly over procaine penicillin 1.2 million units intramuscularly once daily for 10days.

When benzathine or procaine penicillin cannot be used (eg: due to penicillin allergy where penicillin desensitization in not possible) or are not available (eg: due to stock outs) the WHO STI guideline suggests using, with caution, erythromycin 500mg orally four times daily for 14days or ceftriaxone 1g intramuscularly once daily for 10-14days or azithromycin 1g once daily.

REMARKS: Although erythromycin and azithromycin treat the pregnant women, they do not cross the placental barrier completely and as a result the fetus is not treated. It is therefore necessary to treat the newborn infant soon after delivery (see recommendations 9 and 10 for congenital syphilis). Ceftriaxone is an expensive option and is injectable. Doxycyline should not be used in pregnant women. Because syphilis during pregnancy can lead to severe adverse complications to the fetus or newborn, stock outs of bezathine penicillin for use in ANC should be avoided.

Recommendation 1:

In **pregnant women with late syphilis** or unknown stage of syphilis, the WHO STI guidelines recommends benzathine penicillin G2.4 million units intramuscularly once weekly for three consecutive weeks over no treatment

REMARKS: The interval between consecutive doses of benzathine penicillin should not exceed 14days.

Recommendation 2:

In **pregnant women with late syphilis** or unknown stage of syphilis, the WHO STI guideline suggests benzathine penicillin G2.4 million units intramuscularly once weekly for three consecutive weeks over procaine penicillin 1.2 million units intramuscularly once a day for 20days.

When benzathine or proicaine penicillin cannot be used (eg: due to penicillin allergy where penicillin desensitization is not possible) or are not available (eg: due to stock-outs) the WHO STIs guideline suggests using with caution, erythromycin 500mg orally four times daily for 30days.

***REMARKS*:** Although erythromycin treats the pregnant women, it does not cross the placental barrier completely and as a result the fetus is not treated. It is therefore necessary to treat the newborn infant soon after delivery (see recommendation 9 and 10 for congenital syphilis). Doxycline should not be used in pregnant women. Because syphilis during pregnancy can lead to severe adverse complications to the fetus or newborn, Stock-outs of benzathine penicillin for use in ANC should be avoided.

Ensuring stock of WHO standard treatment, options must be an ongoing priority coordinated between the health sector and Development Partners (DPs). Procurement processes amongst WHO and DPs must be aligned to the guidelines. Samoa often lacks recommended and alternative options. The updated treatment guidelines and recommendations must be reflected in procurement processes for Samoa and the Pacific Region.

2) Chlamydial infection in pregnant women

Recommendation (a)

The WHO STI guideline recommends treatment with azithromycin over erythromycin

Recommendation (b)

The WHO STI guideline suggests treatment with azithromycin over amoxicillin.

Stock outs of azithromycin often leave amoxicillin as the only alternative. WHO and development partners must support countries in ensuring availability of recommended regimens.

Recommendation (c)

The WHO STI guideline suggests treatment with amoxicillin over erythromycin.

Dosage:

- Azithromycin 1g as a single dose
- Amoxicillin 500mg orally three times a day for 7 days
- Erythromycin 500mg orally twice a day for 7days

REMARKS: Azithromycin is the first choice of treatment but may not be available in some settings. Azithromycin is less expensive that erythromycin and since it is provided as a single dose, may result in better adherence and therefore better outcomes

Azithromycin is preferred regimen and part of essential medicines, but preventing stock-outs needs to be continually prioritized, as disbursement is determined by consumption reports.

3) Bacterial vaginosis in pregnant women

- metronidazole, 200 or 250 mg orally, 3 times daily for 7 days, after first trimester
- metronidazole 2 g orally, as a single dose, if treatment is imperative during the first trimester of pregnancy (see text above)

Alternative regimen

- metronidazole, 2 g orally, as a single dose

OR

- clindamycin, 300 mg orally, twice daily for 7 days

OR

- metronidazole 0.75% gel, 5 g intravaginally, twice daily for 7 days

2.4 HIV-TB Collaborative Activities

Tuberculosis (TB) is a major cause of deaths among HIV infected individuals, globally. The risk of active TB is approximately 10 times higher in HIV-infected pregnant women compared to HIV uninfected women. Active TB in HIV-infected pregnant women can contribute to increased risk of maternal mortality, and is also associated with prematurity, low birth weight, and perinatal tuberculosis among infants. The key TB prevention interventions recommended by World Health Organization at HIV care settings include airborne infection control at HIV care settings.

Along with TB prevention, early detection and treatment of HIV-TB are also important for reducing mortality. Various activities need to be implemented to ensure early detection and treatment. These include:

Activities for Early Detection of HIV Associated TB

- HIV testing of presumptive TB cases
- HIV testing of diagnosed TB patients
- Intensified TB case finding (ICF)

Activities to Ensure Early Treatment of HIV

- Linkage of HIV-TB cases to ART

- Initiation of HIV-TB cases on ART

HIV testing of presumptive TB cases: Detection of HIV by offering HIV tests to diagnosed TB patients is being implemented by HIV Program since 2015 as part of routine patient intake procedures.

Intensified TB case finding is now implemented in all TB care, treatment and detection activities by MoH and the Communicable Disease Clinic.

Gene-Xpert testing has been procured by the HIV Program for early screening and testing for TB in both Upolu and Savai'i.

Process of Screening ANC Women

Women registered for ANC care would be screened for TB along with HIV and STI

Service providers check for TB symptoms. It may be accompanied by one or more of the following symptoms such as weight loss, chest pain, tiredness, shortness of breath, fever, particularly rise of temperature in the evening, in some cases there can be blood in the sputum, loss of appetite and night sweats).

Refer all HIV positive pregnant women for TB diagnosis and treatment at the earliest

2.5. Use of ART in PMTCT

The guiding principles for the use of ART to prevent HIV transmission from mother-to-child are:

- Pregnant Women living with HIV, in need of ART for their own health should receive life-long ART.
- Postpartum ART initiation to mother and ARV Prophylaxis to child are aimed at improving HIV-free child survival by reducing HIV transmission.
- HIV exposed infants should be followed up and managed.

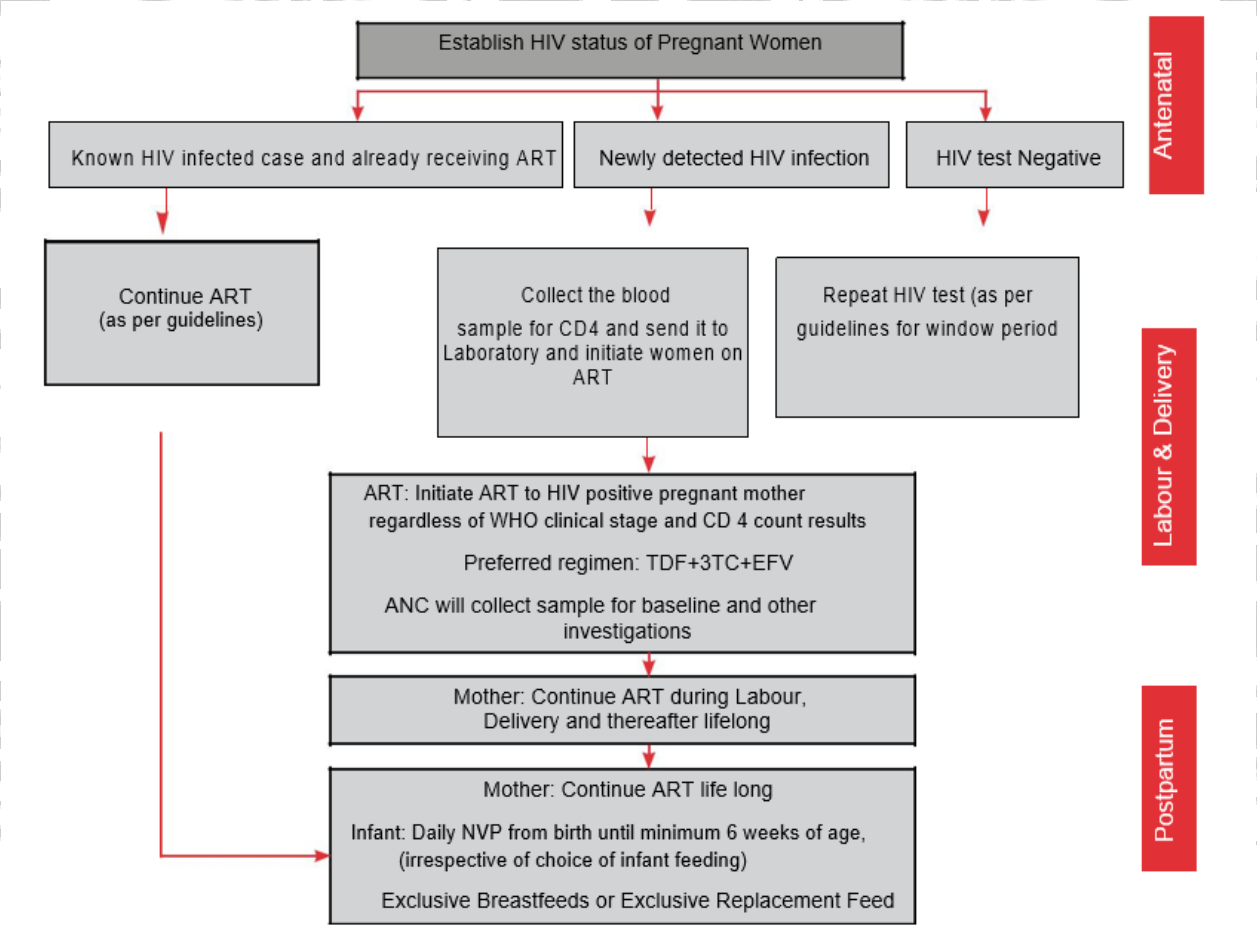
The National guideline recommends that:

1. All Pregnant Women living with HIV should be initiated on life-long ART regardless of WHO clinical stage or CD4 cell count.

2. Pregnant Women living with HIV should preferably be initiated on ART and should not be delayed for want of CD4 cell count report.

Care for the HIV-infected pregnant women begins on the first contact with health services during the ante natal period. Establishing a relationship or a rapport with the HIV infected pregnant woman is fundamental in providing a continuum of care involving prevention, care, support, and treatment for the mother and child. This requires the involvement of the clinical and para-medical team at the health facility – the Obstetricians, Pediatricians, Physicians, Medical Officers, Nurses, Lab Technicians, Counsellors and Outreach Workers should help support the HIV infected mother and her family.

The Summary of the Technical Guidelines and Options for theMore Efficacious PMTCT Regimen



CHAPTER 3

SERVICE DELIVERY

3.1PMTCT Services

3.1.1 Existing Facilities

In Samoa under the coordination of the National HIV/TB Programme at Ministry of Health, various HIV related services are provided through the Communicable Disease Clinic at the National Health Service. People living with HIV receive extensive support from Samoa Red Cross Society. HIV, STI, and TB testing and treatment services are available at all national health centres, and MoH and its partners routinely conduct outreach programs to bring these services to the community level. Mentorship, support and technical assistance for national clinicians working with patients experience HIV and STI's comes from multiple development partners.

The PMTCT services are provided through the Communicable Disease Clinic clinicians.

3.1.2. Continuum of care under PMTCT

National PMTCT programme should be seen as a continuum of interventions rather than a one-time activity. This requires close coordination between various implementing components for PMTCT-ART linkage, Early Infant Diagnosis (EID), Paediatric ART services etc.

PMTCT services are integrated with routine HIV care and support activities in Samoa. The NHS Communicable Disease Clinic coordinates clinical activities, while MoH handles resourcing, policy and public health interventions. There are strong protocols linked to routine HIV testing in antenatal care, and detected cases are linked to treatment as an urgent priority. ARV is currently procured through development partner support.

The continuum of care involves the following steps:

1. Increasing uptake of PMTCT services by pregnant women.
2. Counselling and Testing of pregnant women as an integral part of ANC Comprehensive Services package.
3. Detection of Pregnant Women living with HIV.
4. Linking Pregnant Women living with HIV to Care, Support and Treatment services.

5. Initiating ART for all Pregnant Women living with HIV regardless of CD4 count, starting it as soon as diagnosed and continued for life. However, make sure to obtain samples for CD4 cell count and baseline tests at the time of initiating ART or soon after initiating ART.
6. Counselling on birth-planning and institutional deliveries of identified Pregnant Women living with HIV.
7. Screening emergency labour room deliveries (un-booked cases) for HIV. If HIV positive, providing ART and obtaining sample for CD4 cell count as soon as possible.
8. Linking of Pregnant Women living with HIV identified through emergency labour-room care services to Care, Support and Treatment services.
9. Provision of Nevirapine for the new born infant from birth till 6 weeks of age (minimum).
   At the end of 6 weeks, baby to be linked to the EID programme.
10. If the infant is detected positive in EID then ensure initiation of Pediatric ART for the baby as soon as possible.
11. Follow-up of HIV infected mother and baby until breastfeeding period is over.

Due to challenges with ARV adherence, clinicians dealing with PLWHIV have opted to counsel against breastfeeding due to risk of transmission. Counseling and support for accessing breast milk products will be covered instead, as well as adherence counseling and viral load testing. Clinician's assessment holds the most weight, and women who are adherent with stable viral loads may be encouraged to breastfeed upon clinical case assessment.

3.2 Care and Assessment of Pregnant Women living with HIV

3.2.1 Care during the Antenatal Period

Pregnant Women living with HIV may present at various stages of pregnancy

- Pregnant Women who are detected to be HIV infected during ante natal care should be initiated on ART (TDF+3TC+EFV) regardless of clinical stage or CD4 count. However, it is important to obtain sample of blood for CD4 count and for baseline tests before initiating ART. The initiation of ART should not be delayed for want of CD4 test results.

- Pregnant women who are detected to be HIV infected during active labour should be confirmed at the earliest and linked to ART if confirmed positive.

Pregnant Women living with HIV require joint management from both the HIV care team (for her HIV condition) and the Obstetric team (for successful outcomes of pregnancy). Pregnant Women living with HIV require all components of good antenatal care, including iron-folate supplementation, anaemia management, baseline CD4 count, screening of TB, prevention and management of OIs, STI treatment, special Obstetric practices especially during labour and delivery, ART initiation and its continuation, counselling for infant feeding options, post-natal care, follow-up, family planning and contraception. Postpartum care and follow-up for the well- being of mother and infant, as well as adherence to ART and other care, to prevent HIV transmission during breastfeeding is important.

Due to challenges with ARV adherence, clinicians dealing with PLWHIV have opted to counsel against breastfeeding due to risk of transmission. Counseling and support for accessing breast milk products will be covered instead, as well as adherence counseling and viral load testing. Clinician's assessment holds the most weight, and women who are adherent with stable viral loads may be encouraged to breastfeed upon clinical case assessment.

Good antenatal care ensures that pregnancy and delivery:

- Is a safe experience for the mother
- Builds the foundation for the delivery of a healthy baby

3.2.2 Initial assessment

All Pregnant Women living with HIV should have routine ante natal care for the well-being of her baby including:

- At least 8 ANC check-ups during pregnancy. It recommends pregnant women to have their first contact in the first 12 weeks' gestation, with subsequent contacts taking place at 20, 26, 30, 34, 36, 38 and 40 weeks' gestation
- History, physical and abdominal examination
- Antenatal routine blood screening:
  - CBC, blood group & Rh typing, at 1st visit; including tests for syphilis, chlamydia, gonorrhea, Hepatitis'B' and "C" and HIV.
  - Urine routine to be done at all visits, and Hb% to be re-checked at the 3rd visit at 28-32weeks gestation.

- 5 Doses of Tetanus Diphtheria (Td) to prevent maternal and newborn tetanus: First dose: at ANC registration.
- Second dose: at 4 weeks after the first dose
- Third dose: at 6 months
- Fourth dose: at 1 year post-natal
- Fifth dose: at 2 years postnatal

❖ Antenatal drug supplementation:
- IFA tablet daily for 90 days, after 1st trimester to prevent anaemia.
- Double the dose if anaemia persists.

Counselling on nutrition, rest, warning signs, ART linkages-CD4 testing if HIV positive and ART, birth planning, institutional delivery, exclusive breastfeeding within an hour of delivery, safe sex, HIV-specific advice and contraception.

From the HIV care aspect for pregnant women, the initial assessment follows standard adult ART guidelines including:

❖ Clinical screening for TB and STI symptoms Screen for TB at each visit.
- o Clinical screening–ask for cough (of any duration), cough with blood in sputum, unexplained fever or weight loss, fatigue, night sweats, loss of appetite, pleuritic chest pain; glands/nodes in neck, armpits/axilla or groin.
- The normal weight gain in a normal pregnancy is around 11 kg. Most of it occurs in the second and third trimester (approximately 5 kg in each trimester), while the first trimester is usually 1-2 kg. The weight gain patterns should be co-related clinically and other factors like twin pregnancy, hyperemesis gravidarum during the first trimester etc. A failure to gain weight should arouse the suspicion for further evaluation. Weight loss during pregnancy requires detailed assessment, because it can be a sign of underlying Opportunistic Infections (OIs) in HIV infected individuals.

❖ **Screen and treat any STIs:** any concurrent STIs may increase the risk of HIV transmission from mother-to-child, and may adversely affect the pregnancy. Treat STIs according to the national guidelines.

❖ CD4 cell count (baseline):

- Women who do not return for results should be actively traced back and brought to the continuum of care through the help of grass-root level health dispensaries and Community health workers

❖ Initiate adherence counseling (antiretroviral treatment for mother and ARV prophylaxis for infant) and it is re-emphasized that the initiation of ART for the pregnant women should not be withheld for want of the above laboratory investigations and clinical staging.

❖ Nutritional counseling for the mother: good food, rest and exercise.

❖ Adherence to iron-folate and vitamin/mineral supplements.

❖ Counsel for regular ante natal check-up and institutional delivery.

❖ Counsel for exclusive breastfeeding within an hour of delivery.

❖ No MIXED FEEDING in the first 6 months under any circumstances.

3.2.3 Criteria for ART Initiation

Initiation of ART in pregnant women needs to be done at the earliest and after adequate treatment preparedness for adherence to maintain her own health and also to prevent HIV virus transmission to the unborn baby.

In Pregnant Women living with HIV the dictum should be "do not delay ART initiation". The eligibility criteria for initiating ART in HIV positive pregnant women are as below:

ART eligibility in pregnant women:

- Initiate lifelong ART in all pregnant women with confirmed HIV infection regardless of WHO clinical stage or CD4 cell count. TDF + 3TC + EFV.
- It is recommended as first-line ART in pregnant and breastfeeding women,(including pregnant women in the first trimester of pregnancy and women of child bearing age)
- ART shall be initiated at the ANC

3.3 ART for Pregnant Women living with HIV

All Pregnant Women living with HIV (irrespective of CD4 count/Clinical stage) should receive lifelong ART.

This treatment serves two key purposes:

1. Improves health and prolongs survival of the mother.
2. Reduces the risk of HIV transmission from mother-to-child during pregnancy, labour, delivery, and throughout the breastfeeding period.

3.3.1 Pregnant Women living with HIV being Newly Initiated on ART

HIV-infected pregnant women who are initiated on ART should be referred for routine baseline clinical and laboratory evaluation. The absence or delay of laboratory investigations should not prevent the initiation of ART.

All Pregnant Women living with HIV should be seen as priority in the ANC

3.3.2 Principles of management

All HIV-infected Pregnant Women should Start ART

- Start ART as soon as possible and continue ART throughout pregnancy, delivery, breast feeding period and thereafter lifelong.
- Even if the pregnant women presents very late in pregnancy (including those who present after 36 weeks of gestation), ART should be initiated promptly.

Choice of ART Regimen for HIV-infected Pregnant Women

Pregnant Women living with HIV requiring ART, the recommended first-line regimen is

Tenofovir (TDF) (300 mgs) + Lamuvidine (3TC) (300 mg) + Efavirenz (EFV) (600 mg).

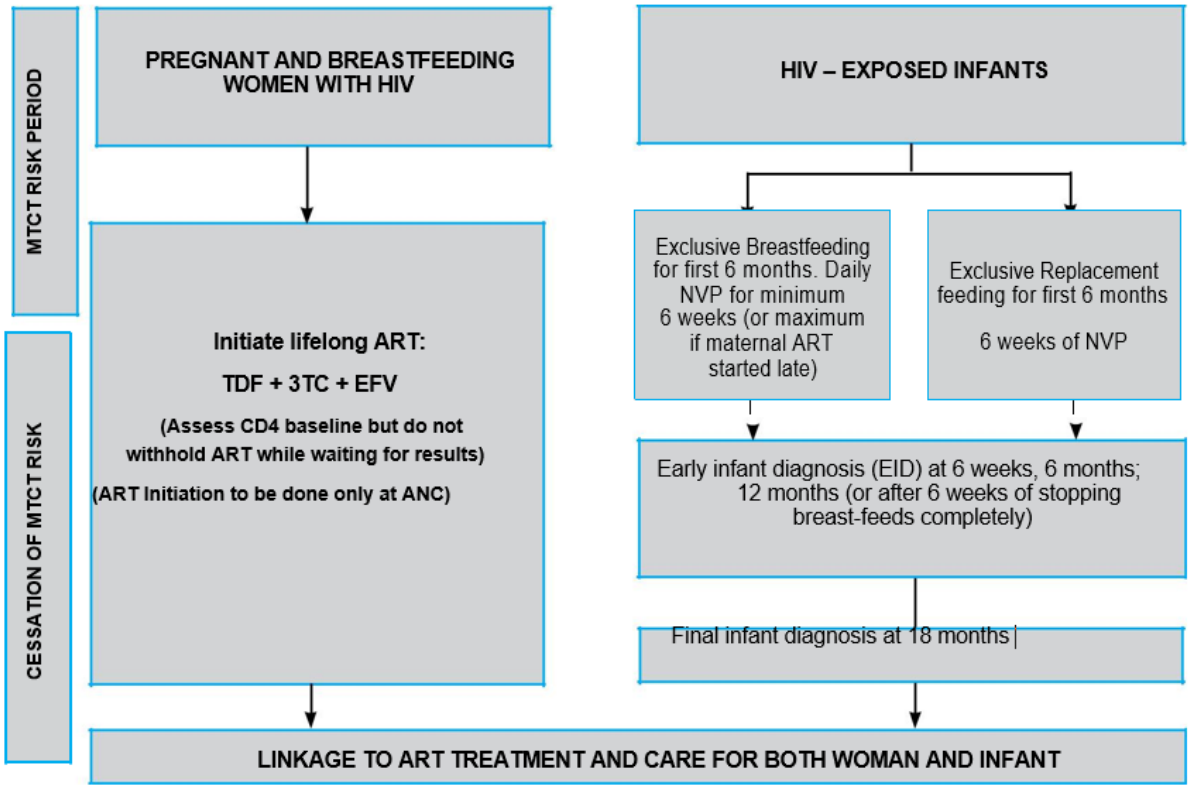
The recommended first-line regimen for Pregnant Women living with HIV isTenofovir (TDF) (300 mg) + Lamuvidine (3TC) (300 mg) + Efavirenz (EFV)(600 mg) at any gestational age

First line ART for pregnant and breastfeeding women and ARV drugs for their infants

- A once-daily fixed-dose combination of TDF + 3TC + EFV is recommended as first-line ART in pregnant and breastfeeding women, including pregnant women in the first trimester of pregnancy and women of childbearing age.

- Infants of mothers who are receiving ART and are exclusively breastfeeding or doing exclusive replacement feeding should receive at least six weeks of infant prophylaxis with daily Nevirapine. Infant prophylaxis should begin at birth or when HIV exposure is known

The recommended first-line regimen for pregnant and breastfeeding women, is available as a fixed dose combination (FDC), is safe for both pregnant and breastfeeding women and their infants, is well tolerated, has low monitoring requirements, is compatible with other drugs used in clinical care, and is harmonized with the new recommendations for non-pregnant women as well as for men. The algorithm for ART for pregnant women and their infants is described below:



The alternate regimen if the pregnant women are unable to tolerate preferred first-line regimen are as below:

First-Line ART for	Preferred First-line Regimen	Alternate First-line Regimens
HIV positive pregnant women	TDF + 3TC+ EFV	AZT+ 3TC+EFV AZT+3TC+NVP TDF+ 3TC+NVP

3.3.3 Pregnant Women Already Receiving ART

Pregnant women who are already receiving ART for their own health, should continue to receive the same regimen throughout pregnancy, labour, breast-feeding period and thereafter life-long.

Samoa current implements WHO's Option B: Treat all approach for ART. Pregnant women are covered for ART as soon as they are detected positive.

3.3.4 Clinical and Laboratory Monitoring of Pregnant Women Receiving ART

Clinical and laboratory monitoring of Pregnant Women living with HIV on ART should be done as per national ART guidelines for adults and adolescents.

Key points to be noted in pregnant women in monitoring ART in pregnant women are:

- Look for clinically significant anaemia among HIV-infected pregnant women, since anaemia during pregnancy is common (usually developing around 28-34 weeks of gestation).
- WHO clinical staging will help in monitoring the patient clinically, potential disease progression or treatment failure.
- Weight loss is one of the indicators used to determine deteriorating clinical stage, but this can be difficult to assess during pregnancy. When defining the clinical stage of a pregnant woman, it is necessary to take into consideration her expected weight gain in relation to the gestational age of the pregnancy and her potential weight loss from HIV.
- ART-related side-effects may overlap with that of common pregnancy conditions eg. nausea and vomiting. Minor symptoms should be controlled symptomatically with medicines. Consult the Obstetrician for drugs that are safe for use in pregnancy.
- Due to pregnancy-related haemo-dilution, absolute CD4 cell count decreases during pregnancy. After delivery, body fluid changes normalise to the non-pregnant state, and CD4 levels may rise by

50-100 cells/ul. Therefore, a decrease in absolute CD4 count in a pregnant woman receiving ART in comparison to CD4 values prior to pregnancy may not necessarily indicate immunologic decline and should be interpreted with caution.

The recommended clinical and laboratory follow-up schedule for pregnant women is similar to that recommended for non-pregnant adults. Additional assessments of hemoglobin or Liver Function Tests (LFT), Renal Function Tests (RFT) should be performed when warranted by clinical signs & symptoms.

HIV care and follow-up of pregnant women should be scheduled to coincide with their antenatal visits, as far as possible. Document all investigation results in the Antenatal folder also, so that the Obstetric team is aware of test results. Inform patient to ensure that other health care providers in the team eg. Obstetricians & their support staff are updated on the progress of their HIV care.

After 6 months of pregnancy, in case a pregnant woman is unable to go to the health facility, the ART drugs can be given to an authorised member of her family. The drug dispensing to an authorised member can continue for 2 more months after delivery.

3.3.5. ARV Prophylaxis for Infants Born to Mothers Receiving Life-long ART

Infant ARV prophylaxis is required for all infants born to HIV infected women receiving ART to further reduce pre-partum and postpartum HIV transmission, in addition to the protection received from the mother's ART regimen. Infant ARV prophylaxis provides added protection from early postpartum transmission, particularly in situations where women started ART late in pregnancy, have less than optimal adherence to ART and have not achieved full HIV viral suppression.

The infant ARV prophylaxis where mothers are receiving ART is: Daily NVP for 6 weeks, regardless of whether the infant is exclusively breastfed or receives exclusive replacement feeding.

Dose and duration of infant daily NVP prophylaxis is given below

(based on WHO Guidelines)

Birth Weight	NVP daily dose (in mg)	NVP daily dose (in ml)*	Duration
Birth to 6 weeks:			
Infants with birth weight < 2000 gm	2 mg/kg once daily. In consultation with a paediatrician trained in HIV care.	0.2 ml./kg. once daily	Up to 6 weeks irrespective of whether exclusively breast fed or exclusively replacement fed. (maybe extended to 12 weeks, if mother has not received ART for adequate duration i.e at least 24 weeks
Birth weight 2000 – 2500 gm	10 mg. once daily	1 ml. once a day	
Birth weight more than 2500 gm	15 mg. once daily	1.5 ml. once a day	

**Considering the content of 10 mg Nevirapine in 1ml suspension*

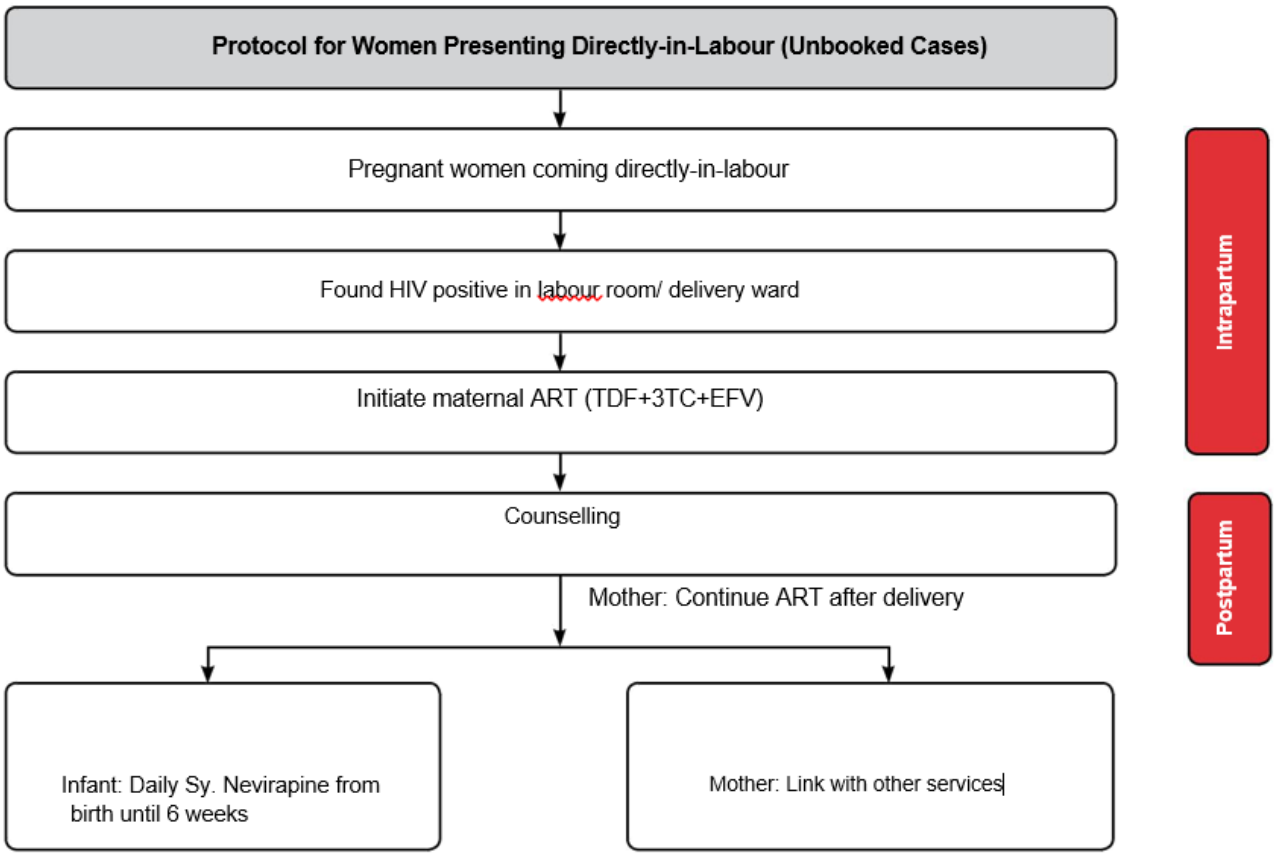
3.4 Interventions for Women Diagnosed with HIV Infection in Labour and Postpartum

Any pregnant woman who presents in active labour with unknown HIV status should be offered the routine screening of HIV, with opt-out option as per National Guidelines.

3.4.1 Pregnant Women in Labour Who are Found Positive in

1. Initiated on ART (TDF+3TC+EFV) immediately.
2. Counsel and advice for exclusive breastfeeding for 6 months.

Protocol for Women Presenting Directly-in-Labour (Unbooked Cases)



3.4.2 ARV Prophylaxis for Infants Born to Women Presenting in Active Labour

All infants born to women who present directly-in-labour and receiving intra partum ART and regularly thereafter, should be started on daily NVP prophylaxis at birth and continued for a minimum of 6 weeks.

These needs to be extended to 12 weeks as mother has not received adequate duration of ART to suppress viral replication. However, EID should be carried out at 6 weeks.

3.4.3 ARV Prophylaxis for Infants Born to Women who did not Receive Any ART (Home Delivery)

In case of infants who are born to HIV infected mothers who did not receive any antenatal or pre-partum ART, or in cases where maternal HIV infection is detected after the birth of the infant (home delivery):

- Infants should be started on NVP prophylaxis at their first contact with health services.
- Daily infant NVP prophylaxis can be started even if more than 72 hours have passed since birth.
- Daily infant NVP prophylaxis should continue for at least 12 weeks, by which time the mother should be linked to ART.

Do's for infants at 6 weeks

It is important to do the following for infants at 6 weeks

- Do emphasize for exclusive breastfeeding for the first 6 months
- Do EID testing
- Do immunization
- Do not stop NVP prophylaxis for baby at 6 weeks(maternal ART is not of adequate duration)

3.5 Special Consideration

3.5.1 Pregnant Women with Active TB

The risk of active TB is approximately 10 times higher in HIV-infected pregnant women compared to HIV uninfected women. Active TB in HIV-infected pregnant women can contribute to increased risk of maternal mortality, and is also associated with prematurity, low birth weight, and perinatal Tuberculosis.

- Intensified Case Finding must be instituted for all Pregnant Women living with HIV.
- All HIV-infected pregnant women presenting with a cough, fever, night sweats and weight loss should be evaluated for TB and started on TB treatment when indicated.

- HIV-infected pregnant women with active tuberculosis should start ART, *irrespective of CD4 cellcount.*

- The tuberculosis treatment should be started first, and followed by ART as soon as feasible (usually after 2 weeks)

3.5.2 Pregnant Women with Hepatitis B or Hepatitis C Virus Co-infection

Hepatitis B and Hepatitis C may be a concern in these areas.

For Women Co-infected with HIV and HBV

- If treatment is required for HBV infection, ART should be started irrespective of the CD4 cell count or the WHO clinical stage.

- The regimen preferred is TDF + 3TC + EFV.

- Pregnant women with HIV-HBV co-infection should be counselled about signs and symptoms of liver toxicity.

For Women Co-infected with HIV and HCV

- No specific changes in treatment are recommended in the adult ART treatment guidelines.
- Pregnant women co-infected with HIV and HCV should receive ART according to the general recommendations for HIV-infected pregnant women.
- Those women on ART require careful clinical and laboratory monitoring.

Provision of treatment for Hepatitis B & C for HIV co-infected pregnant women(with Hepatitis B or C) will be the responsibility of the general health systems

3.6 Labour and Delivery in the Pregnant Women living with HIV

3.6.1Intra-partum Management

The women's sero-status should be recorded in the (Antenatal card) and maternity register. Health care workers should check the woman's HIV status and details of the ART drugs during pregnancy. If her HIV status is unknown and she is in the first stage of labour, offer HIV counselling and testing. If found positive, she should be administered the first dose of ART. She should be counselled on Exclusive Breast Feeds to the baby for the first six months and the baby should be given Niverapine for a minimum of 6 weeks and another 6 weeks continuation if need be.

3.6.2 Intra-partum Anti Retroviral Therapy

Women on life-long ART should continue to receive ART as per the usual schedule including during labour and delivery.

3.6.3Special Circumstances: Caesarean Section

Caesarean section is not recommended for prevention of mother-to-child-transmission and only if there is an Obstetric indication for the same.

Use of ARV drugs during Caesarean Sections

- For planned (elective) Caesarean sections, ART should be given prior to the operation.
- Women on life-long ART should continue their standard ART regimen.
- In case of an emergency Caesarean section in pregnant women who are not on ART, ensure that the women receive ART prior to the procedure and continues thereafter.

All HIV-infected women who undergo Caesarean section should receive the standard prophylactic antibiotics. Complications of Caesarean section are higher in women with HIV, with the most frequently reported complication being post-partum fever.

Caesarean sections in HIV positive pregnant women should be performed for Obstetric indications only.

3.6.4 False Labour

In the case of false labour or mistaken ruptured membranes, for women taking ART should continue with normal dosing schedule of the combination regimen.

3.6.5 Safer Delivery Techniques

Mother-to-child -transmission risk is increased by the prolonged rupture of membranes, repeated examinations, assisted instrumental delivery (vacuum or forceps), episiotomy and prematurity. Thus, when delivering HIV-infected women, observe:

- Standard/Universal Work Precautions
- Do NOT rupture membranes artificially (keep membranes intact for as long as possible).The membranes should be left intact as long as possible and artificial rupture of membrane reserved for cases of foetal distress or delay in progress of labour.
- Minimize vaginal examination and use aseptic techniques.
- Avoid instrumental delivery as much as possible. Unless required in cases of foetal distress or significant maternal fatigue to shorten labour or the duration of ruptured membranes.
- Avoid routine episiotomy as far as possible.
- Suctioning the newborn with a nasogastric tube should be avoided unless there is meconium staining of the liquor.

3.7 Care during post-natal period

3.7.1The Post-partum Period

Within an Hour of Delivery;

- Infants born to HIV-infected mothers should receive NVP prophylaxis immediately after birth.

- Infants after delivery should be put on the mother's abdomen for skin contact to be established which helps in bonding and maintenance of baby's body temperature as well as helps initiation of breast milk within 1 hour of birth.

- Infants should be given exclusive breastfeeds for the first six months preferably. Exclusive replacement feeding may be done only if the mother has a terminal illness or decides not to breastfeed despite adequate counseling.

If the mother has not made a decision about feeding yet, she should be counseled to give exclusive breastfeeds for the first 6 months which is the preferred option, followed by complementary feeds after 6 months.

Counsel and support parent to give infant NVP prophylaxis using the syringe/dropper provided.

Emphasize on washing the equipment with clean boiled water after every use.

During the post-delivery period, it is important to continue follow-up and support the postpartum mother, considering the fact that this is a stressful period and she has to assume multiple roles and responisbilities as mother, wife and HIV infected person. Wherever possible, include family counselling (of husband, in-laws, direct family members) to support care of the HIV infected mother and HIV exposed infant. Postpartum depression & psychosis is common in HIV infected women.

- Involvement of men (husband/close male family members) is important so that the family support to the HIV-infected mother and infant is optimal. Husband's support to the mother-baby pair should be encouraged so as to:

1. To remind the HIV positive mother to take ART regularly
2. Support administration of daily infant NVP prophylaxis medications for 6 weeks to the baby.
3. Be involved in care and follow-up of the infant including clinic visits and immunization follow-up; EID

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4. Be involved in care of mother for ART visits
5. Support exclusive breastfeeding for a minimum period of 6 months and continuation of breastfeeds for 1 year in EID negative babies, and up to 2 years in EID positive babies with initiation of PaediatricART.Weaning foods should be introduced from 6 months onwards in all babies whether breast fed or replacement feeds fed.

6. Family planning counselling

Condom should be consistently used by all HIV infected males despite following any other Family Planning Method (Dual Protection)

3.7.2 Counsel and Follow-up Mother after Discharge

Counselling on Issues Related to the Mother:

- Counsel mothers taking ART for her own health for good adherence to life-long ART.
- The ART drugs will reduce the risk of HIV transmission through breastmilk during breastfeeding
- Counsel mother who came directly-in-labour about the importance of ART.
- Counsel mother to have adequate rest, nutrition and to take iron-folate during the lactation period, ensure enough proteins and fluids in the diet.
- Family support: involve husband and family members to help out with baby care so that she can rest and recuperate, and to remind her of her ART and infant ARV prophylaxis.
- Counsel mother for her post-natal checkup at 6 weeks to coincide with the infant's first immunization visit.
- Discuss and ensure contraceptives and condom use as dual protection at subsequent visits.
- Arrange for the mother on ART to be followed with the ART Centre.

Counselling for Issues of Infant to the Parents/ Caregivers:

- Counsel and reinforce decision on infant feeding practice whether exclusive breastfeeding for first 6 months (preferably) or exclusive replacement feeding (for first six months if not willing to breast-feed and resistant to doing so).

- All infants (irrespective of maternal ART in mother) must receive a minimum of 6 weeks of infant NVP prophylaxis daily until the first visit for immunization at 6 weeks of age.

- If exclusive replacement feeding is being done, then infant NVP prophylaxis may be stopped at 6 weeks of age.

- Stop NVP prophylaxis at 6 weeks for babies given exclusive replacement feeding.

3.8 Infant feeding practice

Malnutrition and anaemia are major causes of growth retardation in young children. The condition starts during pregnancy and is irreversible by age of two years if not corrected.

Exclusive breastfeeding is the preferred feeding option for HIV-exposed infants <6 months of age. However, it is recognized that for some women, breastfeeding may not be possible – for example in situations of maternal death and severe maternal illness in which case Exclusive Replacement Feeding should be done.

Due to challenges with ARV adherence, clinicians dealing with PLWHIV have opted to counsel against breastfeeding due to risk of transmission. Counseling and support for accessing breast milk products will be covered instead, as well as adherence counseling and viral load testing. Clinician's assessment holds the most weight, and women who are adherent with stable viral loads may be encouraged to breastfeed upon clinical case assessment.

3.8.1 Principles of Infant Feeding for Pregnant Women living with HIV

The 10 principles of infant feeding options for Pregnant Women living with HIV and their infants are:

1. All Pregnant Women living with HIV should have PMTCT interventions provided early in pregnancy as far as possible.

2. Exclusive breastfeeding is the recommended infant feeding choice in the first 6 months, irrespective of the fact that mother is on ART early or infant is provided with ARV prophylaxis for 6 weeks.

3. MIXED FEEDING SHOULD NOT BE DONE AT ANY COST WITHIN THE FIRST 6 MONTHS

4. Only in situations where breastfeeding cannot be done, then replacement feeding may be considered

5. Exclusive breastfeeding should be done for at least 6 months, after which complementary feeding should be introduced gradually, irrespective of whether the infant is diagnosed HIV negative or positive by EID.

6. Mother should be receiving ART during the whole duration of breastfeeding (remember it is lifelong ART for the mother).

7. For breastfeeding infants diagnosed HIV negative, breastfeeding should be continued until 12 months of age ensuring the mother is on ART as soon as possible.

8. For breastfeeding infants who have been diagnosed HIV positive, paediatric ART should be started and breastfeeding to be continued ideally until the baby is 2 years old.

9. Breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.

10. **Breast-feeding should NOT be stopped ABRUPTLY.**

3.9 Care and follow up of HIV exposed infants

A checklist for the care and follow up activities for all HIV exposed infants.

Any intervention or ARV prophylaxis given to the HIV exposed newborn should be documented in the child health card before discharge. The following should be noted in the card:

- Whether the infant had received ARV prophylaxis and the duration received/advice
- What feeding choice the mother has made? Whether EBF or ERF?
- Date of next follow-up.

3.9.1. During the First Post-delivery Visit at 2 Weeks/ First Immunization Visit

All HIV exposed infants must be checked for the following at the first immunization visit

- Adherence of infant NVP prophylaxis for the past 2 weeks.
- EID.
- For exclusively breastfed infants whose mothers are not taking ART:
  - The pattern of feeding, attachment and positioning & mother's breast condition must be enquired.
  - Any infant with problems must have a medical assessment.
  - Provide 6 weeks supply of infant syrup NVP prophylaxis
  - Arrange for monthly follow-up of the infants.

- Such mothers have to be on life-long ART

❖ For infants on exclusive replacement feeding, check with the parents and family if any problems faced so far:

- Emphasise good hygiene, use of clean boiled water, hand-washing.

❖ Any infant with problems must have a medical assessment. NVP infant prophylaxis is to be stopped at 6 weeks:

- How and what are being given as exclusive replacement feeds?

- All HIV-exposed infants should be followed-up monthly, in the first year of life and every3 months thereafter, regardless of the infant feeding practice being adopted.

- Any infant clinically suspected of having HIV should be tested for HIV, regardless of their age.

3.9.2 Confirmation of HIV Status in HIV Exposed Infants should be done at 18 Months, Regardless of Earlier Diagnosis

❖ **All HIV exposed infants and children regardless of HIV status** will be followed-up until 18 months of age for care, monitoring and the final confirmatory HIV test at 18 months

❖ If any **HIV exposed infant or child develops clinical signs and symptoms** suggestive of HIV infection, the Medical Officer at the health care facility should start immediate treatment for the acute illness, stabilize and perform HIV testing according to the national testing algorithm for infants and children <18 months also has to be done.

❖ **Follow-up of HIV infected infants and children started on ART** shall be done by health facilities in collaboration with the Paediatrician at the institution.

❖ No DBS & WBS (DNA/PCR) testing to be done at or after 18 months.

3.10 Essential Gynaecologic Care for Pregnant Women living with HIV

During the long term follow-up of Pregnant Women living with HIV, apart from ART and pre-ART care, key areas which must be discussed, are:

- Cervical screening
- Family planning and birth-spacing
- Contraception

3.10.1 Cervical Screening

Women infected with HIV are at higher risk of developing cervical dysplasia leading to cervical cancer. The Human Papilloma virus (HPV) infection is more common in Pregnant Women living with HIV,

Cervical screening, Pap smear be done annually for all Pregnant Women living with HIV.

3.10.2 Family Planning and Birth-spacing

With ART and PMTCT being increasingly available, Pregnant Women living with HIV and men are now living longer and healthier lives and desiring to have children. Accordingly, reproductive plans including pre- conception counselling, and counselling regarding reversible methods of contraception should be discussed with Pregnant Women living with HIV of child bearing age.

Pre-conception counseling –Pregnant Women living with HIV are similar to non-Pregnant Women living with HIV. The goals are to improve the health of the woman before conception and to identify risk factors for adverse maternal and foetal outcomes. These include:

- Safe sex practice
- Prevent test and treat STI.
- Reproductive history including numbers of pregnancies and outcomes of pregnancies.

- Length of relationship with current partner, HIV status of partner and couple's sexual history including condom use and sexual decision-making or control of reproductive choices.
- Patient's and partners reproductive desires and discussion of options.
- Reduce/avoid risky behavior eg. Smoking, substance abuse.
- Take folic acid before conception.

Family planning counselling information includes:

- Information about effective contraceptive methods to prevent pregnancy, dual protection; the effects of progression of HIV disease on the woman's health;
- The importance of family planning and birth planning;
- The risk of HIV transmission to an uninfected partner while having unprotected intercourse (for instance, when trying to become pregnant);
- The risk of transmission of HIV to the infant and the risks and benefits of Antiretroviral prophylaxis in reducing transmission; and
- Information on the interactions between HIV and pregnancy, including a possible increase in certain adverse pregnancy outcomes.

Contraceptive Methods

Most women with asymptomatic HIV and those who are on ART can safely use the available forms of contraception for preventing unintended pregnancies. However, prevention of cross-infection of HIV virus to the partner as well as STIs is important and hence **dual protection with consistent condom** use is important. Dual protection refers to simultaneous protection against both unplanned pregnancy and STIs and HIV by using:

- Condoms together with another effective method of contraception, including emergency contraception.

Available forms of contraception for Pregnant Women living with HIV include: Hormonal contraception: issafe in women living with HIV. These may be either:

- Oral contraceptives
- Depot medroxyprogesterone acetate

It is safe to use in women living with HIV as well as those on ART.

Lactational Amenorrhoea Method (LAM) does not protect against STIs, pregnancy and HIV. Correct and consistent condom use should be adopted at every sexual encounter.

Male sterilization (NSV): Males should be motivated at every mother-baby pair follow-up visit to undergo sterilization. No Scalpel Vasectomy (NSV) when the baby attains 18 months/2 years of age (at 18 months confirmatory test, irrespective of the baby's HIV status). However, after NSV operation, male should continue to use a condom at every sexual encounter.

CHAPTER 4

MONITORING & EVALUATION

4.1 Rationale

Monitoring that includes surveillance, supervision and evaluation should be considered as a continuous process for the purpose of maintaining and improving the delivery of efficient and high quality STI services.

Managers need information for planning and implementing effective programmes for the prevention and care of STIs. Effective monitoring and evaluation will provide a process for describing successes, identifying problems and indicating potential solutions.

Additional breakdown by age and gender will provide valuable information for subsequent intervention strategies. This combination of information can be more useful to programme managers than individual items in focusing on key problems and pointing to solutions.

4.2 Components of PMTCT/PMTCTM&E

4.2.1 Monitoring

The purpose of monitoring is to ensure that work is progressing as planned and to anticipate or detect problems in implementation. Monitoring provides managers with information about the level of achievement measured according to standards of performance, and allows them to assess implementation by comparing actual progress to expenditure. Monitoring will help to validate results of outcome evaluation.

Monitoring focuses on implementation (adequacy of supplies, appropriateness of training, performance of service providers) rather than on intermediate outcomes (changes in knowledge or behaviour, changes in health systems) or impact (decreases in morbidity and mortality, improvement in health).

Monitoring of staff performance will be under the usual responsibility of the Division where the staff belongs to. Cross-programme collaboration will be enhanced (e.g. capacity building of clinical service providers on the specific knowledge and skills required by the programme).

4.2.2 Surveillance

Surveillance traditionally describes trends and patterns of disease in a given population over time. This information is necessary to managers in order to concentrate efforts and resources where there is the greatest need.

A surveillance system provides the information for estimating the size of the problem, its frequency and distribution and antimicrobial susceptibility of STI pathogens. Surveillance enables managers to reinforce and improve programme management. For example, surveillance of syphilis, chlamydial infection or gonorrhoea may reflect trends in condom use or the most appropriate selection of drugs for STI treatment.

Experience has shown that universal reporting for surveillance purposes is seldom sustainable and it is recommended that routine surveillance activities are confined to a number of sentinel sites and to periodic surveys for additional information on disease patterns and antimicrobial susceptibility. The sentinel sites can be promoted and strengthened to ensure compliance and efficiency.

4.2.3 Supervision

Supervision is one of the most important aspects of monitoring in that it assesses performance and outputs in the light of the situation and the resources available. Effective supervision narrows the margin between what exists and what potentially can be achieved through allocating resources and training on the basis of the needs of individual facilities or health care workers.

Supervision is a way of ensuring competence through observation, discussion, support and guidance.

4.2.4 Quality Assurance

Quality assurance needs to be conducted to check whether services being rendered are meeting specific requirements and that the systematic process to do this checking is functional.

4.2.5 Evaluation

The purpose of evaluation is to assess progress towards programme objectives and targets at a given point in time. Evaluation focuses on the periodic review and use of information to improve health programmes and guide allocation of resources. It assembles information from surveillance, monitoring and supervision to determine whether planned outcomes are being achieved.

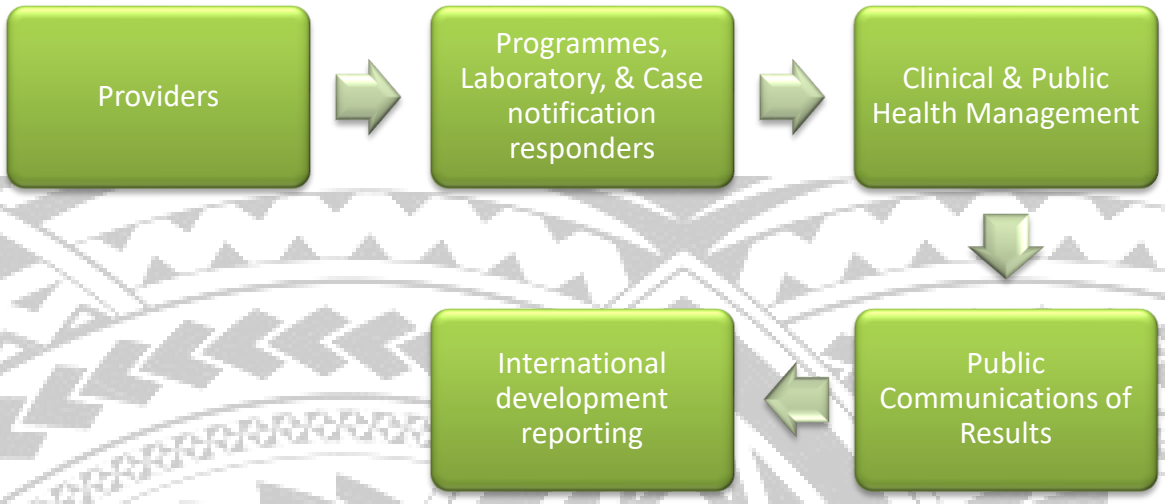
4.3 PMTCT/PMTCTData Collection Tools

All related forms such as the delivery birth register, ART register, Immunization register, daily tally sheet, patient encounter form must be collated.

Sources of relevant PMTCT data within the health sector that are regularly audited / collated by MoH include;

- ANC registries an logbooks
- ANC sero-prevalence surveys
- Private ANC clinics
- Labor and Delivery Records
- EPI Programme / Immunization Clinics
- Outpatient all healthcare facilities

4.4 Data Flow



4.5 Indicators to be collected

ANCs should collect the numbers of:

- Pregnant women
- Pregnant women tested for HIV
- Pregnant women tested positive for HIV
- HIV-infected pregnant women receiving ART
- Pregnant women tested for Syphilis
- Pregnant women confirmed positive for active Syphilis
- Pregnant women who completed treatment for Syphilis

Maternity inpatient services should collect the numbers of:

- Pregnant women living with HIV having vaginal delivery
- Pregnant women living with HIV having cesarean section

Indicators at outcome level

The following indicators will be monitored at outcome level:

- Number of HIV-positive pregnant women who delivered and received ARVs during the past 12 months to reduce the risk of mother-to-child transmission during pregnancy and delivery
- Newly initiated on antiretroviral therapy during the current pregnancy
- Already on antiretroviral therapy before the current pregnancy

- Percentage of infants born to HIV-positive women receiving a virological test for HIV within two months of birth
- Percentage of child HIV infections from HIV-positive women delivering in the past 12 months
- Registered percentage of child HIV infections from HIV-positive women delivering in the past 12 months
- Percentage of pregnant women with known HIV status
- Percentage of pregnant women attending ANC whose male partners were tested for HIV during pregnancy
- Percentage of HIV-exposed infants who initiated ARV prophylaxis
- Percentage of women accessing antenatal care services who were tested for syphilis at first visit
- Percentage of antenatal care attendees who were positive for syphilis
- Percentage of antenatal care attendees positive for syphilis who received treatment
- Percentage of reported congenital syphilis cases (live births and stillbirth)

The minimum data on individuals required for reporting by clinical syndrome are:

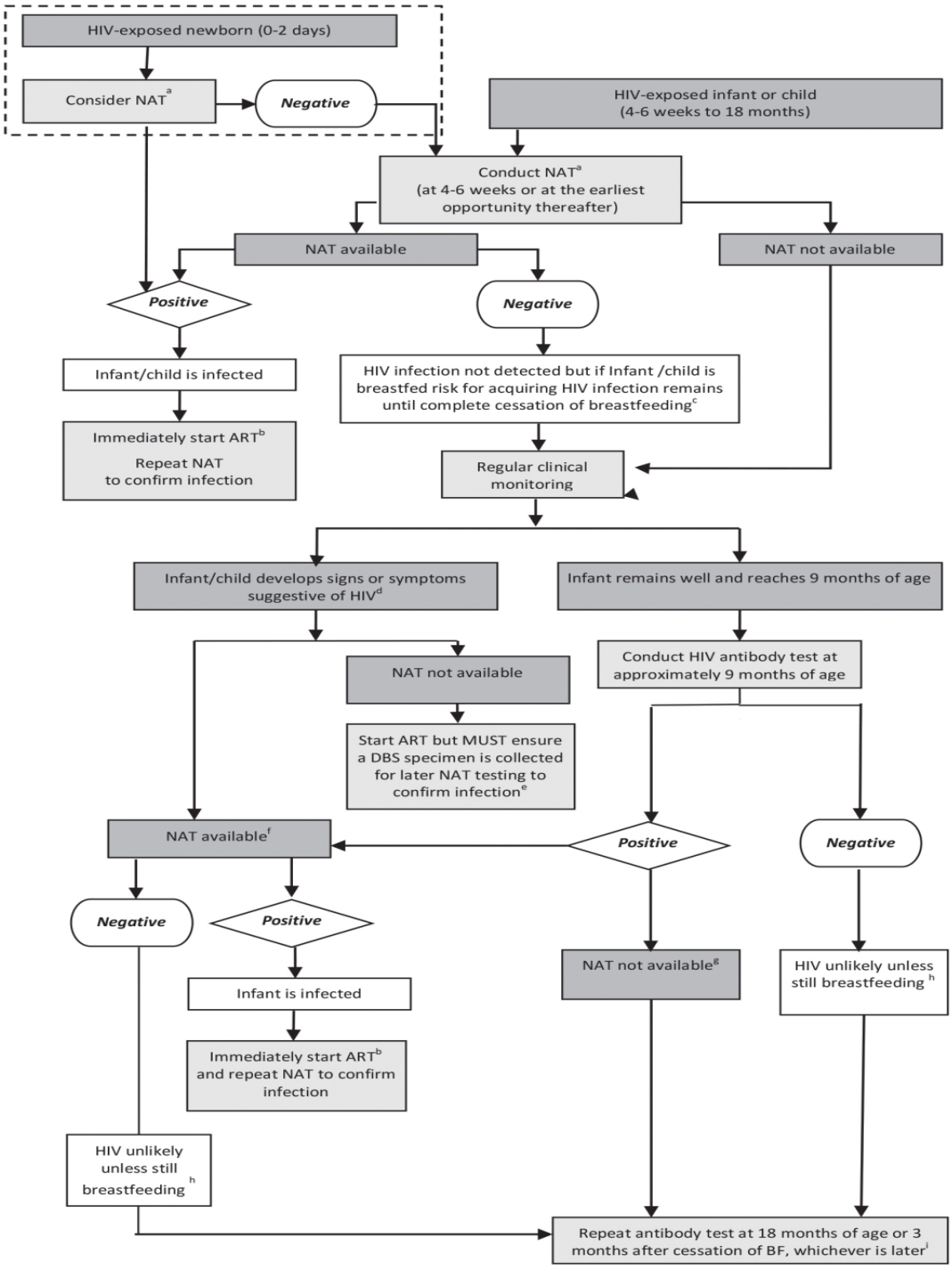
- Sex of patient
- Age or date of birth of patient
- Facility where diagnosed
- Type of syndrome
- Treatment given

The minimum data to be collected in diagnoses made etiologically are:

- Patient identifier /name or code
- Sex of patient
- Age or date of birth of patient
- Facility where test is taken from
- Type of tests done
- Type of specimen collected
- Test result

ANNEX

Annex 1: Testing strategy in infants and children



Annex 2: List of Core team members

- Reporting Clinician (case notification)
- Communicable Disease Clinic Nurse
- Communicable Disease Clinic Doctor
- Primary Care Manager
- Principal Officer HIV/AIDS
- Epidemiologist HIV, STI, TB
- Pharmacy Manager
- Port Health Clinician (where applicable)

Annex 3: List of testing sites

- Faleolo Health Centre
- Foailalo Health Centre
- Lalomanu District Health Centre
- Leulumoega District Health Centre
- Lufilufi District Health Centre
- MT2 Hospital Savai'i
- Poutasi District Health Centre
- Private Clinics
- Saanapu District Health Centre
- Safotu Health Centre
- Samoa Red Cross Society
- Sataua District Health Centre
- TTM Hospital Apia

Annex 4: List of data collection sites

- Faleolo Health Centre
- Foailalo Health Centre
- Lalomanu District Health Centre
- Leulumoega District Health Centre
- Lufilufi District Health Centre
- MT2 Hospital Savai'i
- Poutasi District Health Centre
- Private Clinics
- Saanapu District Health Centre

- Safotu Health Centre
- Samoa Family Health Association
- Samoa Red Cross Society
- Sataua District Health Centre
- TTM Hospital Apia
- TTM Laboratory Services