



Prevention of mother-to-child transmission (PMTCT) of HIV

Protocol

MSF International AIDS Working Group

Revised August 2017

Introduction

Collectively, countries have reduced new pediatric HIV infections from 270 000 [230 000-330 000] in 2009 to 110 000 [78 000-150 000] in 2015. More than 90% of these children are infected through Mother to Child Transmission (MTCT). Without intervention, the risk of transmission is 15-30% in non-breastfeeding populations. Breastfeeding by an infected mother adds an additional 5-20% risk for an overall transmission rate of 20-45%. In resource limited settings, without combined triple antiretroviral therapy (ART) treatment, 50% of HIV infected children die before the age of two.

In developed countries, effective prevention of mother to child transmission (PMTCT) has reduced HIV transmission to < 1 %. The systematic implementation of these protocols has made pediatric infection an increasingly rare problem in contexts where adequate health care is accessible. Over the last few years significant impact has also been made in resource limited settings. In the 21 African priority countries in the Global Plan, which account for over 90% of all pregnant women living with HIV and new infections among children globally, PMTCT coverage in 2015 increased to 80% with mother-to-child transmission rates declining overall from an estimated 26% [24-30%] in 2009 to 8.9% [15-20%] in 2015¹. Despite the significant scale up in services a lot remains to be done.

In resource-limited settings, the current WHO 2016 guidelines² recommend lifelong antiretroviral therapy (ART) for all HIV positive pregnant women regardless of their CD4 count (formerly called option B+). These recommendations make it possible to reduce mother to child HIV transmission to less than 5%.

This approach provides the basis for:

- Earlier ART for all HIV-positive pregnant women, benefiting both the health of the mother and preventing transmission to her child during pregnancy and in future pregnancies;
- Provision of antiretroviral (ARVs) to the mother to reduce the transmission during the breastfeeding period;
- Potential reduction of sexual transmission if the partner is HIV negative.

The implementation of such recommendations does however pose several challenges:

- Many women do not access antenatal care (ANC) services due to a number of socio and economic barriers; even less to postnatal care (PNC);
- The majority of the women attending antenatal services are unaware of their HIV status;
- When testing is available, many women find it difficult to disclose their status to their partner or relatives making it more difficult for them to adhere to ARVs;
- Many women attend antenatal services only once or twice during their pregnancies and/or do not deliver in health facilities making the implementation of the entire PMTCT protocol difficult;
- Despite the relative simplicity of the new PMTCT guidelines, it still may be difficult to implement these recommendations within existing weak health services. Mother and child health (MCH) services faced with a lack of human resources or adequate infrastructure, with poor working conditions for professional staff etc, may face the greatest difficulties in introducing them on a large scale.

The present document is an updated version of the April 2014 MSF Protocol for PMTCT. It reviews the currently recommended interventions to reduce transmission from the HIV infected mother to her child, as well as the clinical management of HIV exposed infants including early infant diagnosis. Prevention of HIV infection, family planning and management of unwanted pregnancies in HIV positive women are also part of the PMTCT strategy, but are not addressed in this document.

This document provides practical guidance to the teams in the field and will need to be used alongside existing national guidance where it exists. As such it does not propose all the possible alternatives. Rather, it proposes the preferred choices, in consideration of:

- the usual contexts where MSF works
- the need to avoid complex protocols

For more information, refer to the WHO consolidated guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV infection. Recommendations for a public health approach. 2016.

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Abbreviations and acronyms

3TC: Lamivudine
ABC: Abacavir
ANC: Ante Natal Care
ART: Antiretroviral Therapy
ARV: Antiretroviral
ATV/r: Atazanavir/ritonavir
AZT: Zidovudine
BD: Bis in Die or twice daily
BF: Breast feeding
CTX: Cotrimoxazole
DBS: Deoxyribonucleic acid
DNA: Desoxyribonucleic acid
DTG: Dolutegravir
EAC: Enhanced Adherence Counselling
EFV: Efavirenz
EID: Early HIV Diagnosis
EPI : Expanded Program on Immunization
FTC: Emtricitabine
FDC: Fixed Dose Combination
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
Lop/r: Lopinavir/ritonavir
MCH: Mother and Child Health
NAAT: Nucleid Acid Amplification Test
NAT: Nucleic Acid Testing
NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitors
NVP: Nevirapine
OD: Once/Day
PCR: Polymerase Chain Reaction
PI: Protease Inhibitor
PMTCT: Prevention of Mother to Child Transmission (*of HIV*)
POC: Point of Care
PNC: Post Natal Care
PSEC: Patient Support Education and Counselling
RDT: Rapid Diagnostic Test
SP: Sulfadoxine-pyrimethamine
TB: Tuberculosis
TDF: Tenofovir
VL: Viral load

Chapter 1: HIV testing, clinical staging and ART preparation

1.1. HIV testing in the pregnant women

See annex 1 for a description of the testing procedures.

All pregnant women of unknown HIV status should be offered HIV testing at their first antenatal visit. Women who initially test negative and seroconvert during pregnancy or breastfeeding are at especially high risk of transmitting the virus to their infant (see chap 3.1). Hence women who test negative early in pregnancy should be retested in the third trimester, at delivery and regularly (3-6 monthly) throughout the breastfeeding period. It is suggested that attendance at expanded program of immunization (EPI), under 5 clinics and inpatient/outpatient departments (IPD/OPD) is an opportunity to test women who have not attended ANC and re-test women previously tested negative.

Pregnant women usually enter PMTCT services either through an HIV program, or through antenatal consultations. In general, women who come for antenatal visits are informed that they can take an HIV test while they wait for their consultation. Often, this is the first time they hear of HIV. Information and counselling is essential to encourage women to test, to enroll into a PMTCT program and to adhere to treatment.

Pre-test information: the opt out^b strategy

This can be given individually or in a group (no more than 12-15 persons at a time), in the waiting room. It should not last longer than 20 min. If done in a group, ensure that everybody can hear.

- Give information on HIV/AIDS, modes of transmission and prevention
- Explain the risk of HIV transmission to the child if the pregnant woman is HIV positive (30 – 40% without PMTCT; less than 5% with PMTCT)
- Explain possible ways to prevent the mother to child transmission of HIV
- Explain the testing procedure
- Explain that the result of the test will remain confidential
- Explain that the woman may refuse to take the test now but will be free to take it at a subsequent consultation

Individual testing procedure

- Repeat that the woman has the choice to refuse the test (opt out)
- Address any fears related to testing. Insist on the benefits for the woman's own health and in terms of protecting her child from becoming infected.

^b Opt out means that the test will be done unless the mother specifically refuses. This information is given during the talk

Individual post-test session

The post-test session is crucial. It is meant to encourage and support a woman with HIV infection to accept her status and the PMTCT intervention that will benefit both her health and that of her future infant.

If the woman has tested negative:

- Explain the meaning of a negative HIV test and the importance of remaining HIV negative
- Re-discuss methods of prevention (already explained in the pre-test information)
- Discuss risky behaviors and the need for protection particularly during pregnancy and post-partum^a
- Encourage the woman to return to take a test in 3 months or before delivery
- Encourage her to bring her partner for testing
- Give condoms now and at each antenatal visit

If the woman has tested positive:

- Explain the positive result and provide emotional support
- Explain that she has a good chance to stay healthy and well for a long time, and that her child has a good chance to be HIV negative if she continues to come to the clinic and to follow the advice given
- Explain the risk of transmission of HIV to the child if there is no intervention
- Explain the PMTCT intervention, focusing on ARV for her own health, prophylaxis for her child and delivery in a medical environment (hospital or health center)
- Explain the importance of regular follow-up, before and after birth
- If she has other children, discuss issues around their health and the possibility to test them
- Encourage her to bring her partner for testing

1.2. Clinical staging and assessment of CD4 (if available)

- HIV positive pregnant women should have their clinical status assessed including screening for tuberculosis (TB) as soon as possible after the HIV diagnosis or at the first contact with antenatal services for women who know their status already.
- The main objective is to start ART treatment as soon as possible, usually at the first visit.
- Cotrimoxazole (CTX) prophylaxis should be started the same day, whatever the WHO stage or CD4 count. A pregnant woman receiving CTX does not need to receive malaria intermittent preventive treatment (Sulfadoxine/Pyrimethamine) as CTX also provides protection against malaria.
- If available, the baseline CD4 count remains useful in order to provide urgent and specific care to those presenting with advanced immunosuppression.

^a HIV MTC transmission rates are very high if HIV infection occurs during pregnancy or post-partum
PMTCT /August 2017

Starting ART treatment early:

- Allows enough time for the mother to reach an undetectable viral load before the high risk period of mother to child transmission (late pregnancy, labour, delivery and immediate post-partum) and therefore significantly reduces the risk of transmission.
- Decreases the mortality also in exposed but uninfected infants by its impact on the survival of the mother.

1.3. ART preparation and counselling

Before ART is started, the pregnant woman should be retested prior to initiation (see annex 1). This re-test should be on another specimen and ideally by another healthcare worker. However if no other healthcare worker is available this should not delay the initiation of ART^b. She has to be prepared and counselled (see annex 5). For additional information refer to “MSF HIV-TB Adult PEC guideline, 2017”.

This process has to start as soon as the HIV status of the mother is known, and must be “fast-tracked” aiming for initiation on the same day as diagnosis. Starting an intervention in HIV infected pregnant women can be considered an ‘emergency’ especially for those who present in the 3rd trimester.

Depending on the context, patient education/counselling sessions are done by ANC nurses/midwives or by counsellors. Even though women generally arrive late in their pregnancy, it is still advisable to try to have at least 2-3 sessions with HIV infected women before delivery. After delivery, sessions should take place at least at M1, M3, M6, M12, or more often according to the needs.

Chapter 2: PMTCT antiretroviral protocols: HIV–1

2.1. ART for newly diagnosed HIV-infected pregnant women

ART should be initiated as soon as possible in all pregnant and breastfeeding (BF) women living with HIV regardless of WHO clinical stage at any CD4 count and continued lifelong. The ART regimen should be chosen taking into account local protocols for the preferred first line regimen for adults and adolescents in the country.

Dolutegravir (DTG) might become soon the preferred option as observational data are reassuring.

- The current regimen of choice for all pregnant or BF women is the same as for any adult tenofovir/lamivudine (or emtricitabine/efavirenz) [TDF/3TC (or FTC)/EFV]] as a one pill/once a day, fixed dose combination (FDC). This is also the regimen of choice for pregnant/breastfeeding women with TB;

- If TDF is not available or contraindicated (when available, a baseline creatinine clearance < 50ml/min^c) then zidovudine/lamivudine (AZT/3TC) or abacavir/lamivudine (ABC/3TC) may be used as an alternative according to local availability;
- Ideally creatinine clearance should be checked prior to initiation of TDF. If less than 50ml/min then AZT/3TC should be used (if Hb > 8g/dl) or ABC/3TC (if Hb < 8g/dl). Access to creatinine monitoring is however not essential and should not delay ART initiation;
- If EFV is contraindicated at baseline (history of neuropsychiatric disorders) it should be substituted with a protease inhibitor (PI), preferably Atazanavir/ritonavir (ATV/r) (or Lopinavir/ritonavir (LPV/r);
- If DTG is prequalified for use in pregnant women, it will certainly become the preferred first-line regimen (DTG + TDF/3TC (or FTC) for all adults.

Table 1: Recommended first-line in adults

First line ART	Preferred first-line regimen	Alternative first-line regimen
Adults	TDF/3TC (or FTC) + EFV	AZT/3TC + EFV (or NVP ^d) TDF/3TC (or FTC) + DTG TDF/3TC (or FTC) + EFV ₄₀₀ TDF/3TC (or FTC) + NVP ^d
Pregnant or breastfeeding women	TDF/3TC (or FTC) + EFV	AZT/3TC + EFV TDF/3TC + ATV/r AZT/3TC + ATV/r
Special circumstances	Regimens containing ABC or boosted PIs	

2.2. Women already on ART more than 6 months when becoming pregnant

If viral load (VL) is available:

- For patients on ART > 6 months, obtain a VL as soon as pregnancy is confirmed if VL was not performed within the last 6 months and < 1000 copies/ml.
 - If this VL is > 1000 copies/ml, perform Enhanced Adherence Counselling (EAC), repeat VL in 3 months and switch to 2nd line if the repeat VL is > 1000 copies/ml. If the first VL result is > 1000 copies/ml, infants are at high risk of transmission and enhanced infant prophylaxis will be prescribed. It must be ensured that the woman is actively followed up and the repeat VL and appropriate switch performed within three months. Where possible use point of care (POC) VL for pregnant and BF women to expedite the delivery of results.
 - If this is the 2nd consecutive VL > 1000, whatever the time the 1st VL was reported, the woman is in virological failure: switch to a 2nd line regimen. Continue counselling after the switch has been made. Infants are at high risk of transmission and enhanced infant prophylaxis will be prescribed.
 - If VL < 1000, the same regimen should be continued.

^c TDF is generally well supported in young women. CrCl availability is not a prerequisite to use TDF.

^d Nevirapine (NVP) should be started at half dose for 15 days. Contra-indicated in women > 350 CD4 and men > 400 CD4. See adult treatment guideline. If no CD4 available, choose another option.

^d NVP should be started at half dose for 15 days. Contra-indicated in women > 350 CD4 and men > 400 CD4. See adult treatment guideline

- If access to VL is not a problem, 6-monthly VL monitoring should be done during pregnancy and BF. Women with VL > 1000 should be managed promptly according to the usual suspicion of failure algorithm. Infants should be managed as high risk infants.
- If VL is unavailable, confirm adherence, continue ART. Use CD4 criteria (50% fall from the peak or return to below baseline) and/or clinical criteria (new opportunistic infection, stage 3 or 4) to diagnose failure.

2.3. Monitoring toxicity

Lack of biological monitoring should not be a barrier to treatment.

Table 2: drug toxicities

Mother's regimen	Monitoring toxicity
Containing NVP	Liver function test if available ^c
Containing TDF	Creatinine clearance if available ^d
Containing AZT	Hemoglobin if available
Containing EFV or ATV/r or DTG	No biological monitoring

For more details on side effects refer to MSF HIV/TB clinical guide 2015³

2.4. Prophylaxis for infants

Low risk HIV exposed infants

Low risk HIV exposed infants are those born to a mother who has been on ART for more than 4 weeks. Treatment success is best defined by VL < 1000 just before delivery and/or during pregnancy and BF.

Start NVP syrup once/day (OD) as soon as possible after birth for 6 weeks.

Table 3: infant prophylaxis for low risk infant

Low risk infant prophylaxis dosing	
Infant age	Dosing of NVP (10 mg/ml)
Birth to 6 weeks	
<ul style="list-style-type: none"> • Birth weight 2000-2499g 	10 mg OD (1 ml of syrup OD)
<ul style="list-style-type: none"> • Birth weight \geq 2500g 	15 mg OD (1.5 ml of syrup OD)

For infants weighing < 2000 g and older than 35 weeks gestation: NVP 2 mg/kg/day, OD

^c Recent study suggests that pregnancy itself, rather than a specific ARV regimen, could be associated with hepatotoxicity: "Increase risk of hepatotoxicity in HIV pregnant women". Ouyang et al. AIDS 2009. Do not use NVP, if CD4 measure unavailable.

^d If CrCL < 50 mL/min, choose preferably another ARV
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Cotrimoxazole prophylaxis should be added for all exposed and infected infants > 4-6 weeks of age till exclusion of infection (See table 6).

High risk HIV exposed infants

High risk infants are defined as:

- Born to women who have received less than 4 weeks of ART at the time of delivery
- **OR** born to women on ART but with VL > 1000 copies/mL documented before delivery if VL available
- **OR** born to women with incident HIV infection during pregnancy or breastfeeding^e
- **OR** women identified as positive for the first time at delivery or during the breastfeeding period

Mother: Start ART for the mother as soon as possible if not yet under treatment. If during labour, give first dose and continue for life. Ensure proper counselling is done after delivery.

Infant: As soon as possible after birth, start prophylaxis in the infant **for 6 weeks** using a quarter of the triple dispersible AZT 60/3TC 30/NVP 50 tab twice daily (BD). Teach the mother on how to use a cutter for obtaining 4 equal parts. At or around 6 weeks, perform an early HIV diagnosis (EID) and switch to the dispersible NVP prophylaxis 50 mg tab ½ tab, OD (or 10 mg/mL syrup), **for another 6 weeks, unless the EID result is positive**. In such a case, switch to full triple therapy.

Table 4: simplified enhanced prophylaxis for high risk infants, birth to 12 weeks

Simplified high risk infant prophylaxis		
	Dose AZT 60/3TC 30/NVP 50 FDC tab dispersible	Dose NVP 50 tab dispersible (or 10 mg/mL syrup)
Birth to 6 weeks	1/4 BD	
6 weeks to 12 weeks		1/2 OD (or 2 ml syrup)

This simplified prophylactic regimen has not been formerly evaluated yet but has been discussed with WHO experts who recognize the importance of simplicity for success.

The classical WHO proposed regimen (2016) is described below and should be used if this is the national recommendation.

- From birth to 6 weeks, this is a 2 drugs regimen.
- From 6 to 12 weeks, there are two options: 1 drug only (NVP) or 2 drugs (AZT + NVP).

If this is too complicated for the mother, choose the simplified one above.

^e Defined as a new HIV diagnosis in a pregnant or BF woman with a previous negative test during pregnancy
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Table 5: enhanced prophylaxis for high risk infants, classical regimen from birth to 12 weeks:

High risk infant prophylaxis		
	Dose NVP (10 mg/mL syrup or 50 mg tab once daily-OD)	Dose AZT (10 mg/mL syrup or 60 mg tab twice daily-BD)
Birth to 6 weeks	15 mg OD (1.5 mL syrup OD)	15 mg OD (1.5 mL syrup OD) - or NVP alone-
6 weeks to 12 weeks	20 mg OD (2 mL syrup OD) or 1/2 50 mg tab OD	60 mg tab BD -or NVP alone-

Infant birth weight: 2000-2499 g: NVP 10 mg OD (1mL), AZT 10 mg BD (1 mL)

Infant birth weight < 2000 g and older than 35 weeks: NVP 2 mg/kg OD, AZT 4 mg/kg BD

Premature infants need reduced dosing.

*If AZT 60 mg tab, single drug, is unavailable, use AZT 60mg/3TC 30mg dispersible, in the same way as AZT single.

If none of these formulations are available, give NVP alone for 12 weeks

CTX prophylaxis is added for all exposed infants > 4-6 weeks of age till exclusion of infection (see table 6). Continue CTX prophylaxis for those infected.

2.5. HIV breast-feeding exposed infants whose mothers are identified post-partum.

HIV positive women may present for the first time with a breastfeeding infant, having not been through any PMTCT intervention. Such infants are at especially high risk of already having been infected and might therefore benefit from *presumptive treatment* until proven otherwise. The infant should be tested with an age appropriate HIV test (virological test^f if < 18 months; rapid testing algorithm if \geq 18 months) and considered as a “high risk infant”.

- The mother should start ART without delay and with counselling support.
- The infant:
 - o If the infant virological test is available same day (POC):
 - Result is positive, *start ART treatment* without delay according to weight with ABC (or AZT)/3TC + LPV/r^g. Confirm infection at next visit with a second sample^h.
 - Result is negative, start enhanced prophylaxis according to age (NVP) and weight (AZT) (table 6)
 - o If the infant virological test result is delayed (e.g. using DBS), *start presumptive treatment* with AZT (or ABC)/3TC + LPV/r while awaiting the result of DBS-PCR.
 - If the DBS-PCR result comes negative, presumptive treatment can be stopped and the infant continued on daily NVP for a total of 12 weeks since the mother started ART.

^f Nucleic Acid Testing (NAT) through POC or DNA-PCR through DBS

^g LPV/r in pellets is preferred from age 3 months.

^h To exclude errors during laboratory procedures

- Perform another DBS-PCR (or RDT first, according to age) at the end of the prophylaxis.

Table 6: High risk infant prophylaxis when exposure discovered during breastfeeding (AZT)

AZT prophylactic dosage		
Weight	AZT 60 mg or AZT 60/3TC 30 mg dispersible tabs	AZT syrup 10 mg/ml
3.0 – 5.9kg	1 BD	6 ml BD
6.0 – 9.9 kg	1.5 BD	9 ml BD
10 – 13.9 kg	2 BD	12 ml BD
14 – 19.9 kg	2.5 BD	15 ml BD

NVP prophylactic dosage	
Age	NVP 50 mg dispersible tabs (or 10 mg/ml syrup)
12 weeks to 6 months	20 mg OD (1/2 tab OD or 2 ml syrup OD)
6 to 9 months	30 mg OD (1/2 tab OD or 3 ml syrup OD)
9 months till end of breastfeeding	40 mg OD (1 tab OD or 4 ml syrup OD)

Note: for sake of simplicity, tablets dosage are rounded off

- At any age, if the infant has a HIV rapid diagnostic test (RDT) positive and clinical signs of HIV infection, start ART. Perform a nucleic acid testing (NAT) POC or collect a dried blood spot (DBS) prior to starting ART for later NAT testing to confirm HIV diagnosis. Infection should be confirmed with a NAT test before 18 months of age and a RDT after 18 months and/or 12 weeks post BF cessation whichever is later.
- Infants > 9 months and well but RDT positive need prompt NAT to confirm infection.
- Infant > 9 months and RDT negative, HIV is unlikely unless still BF. Continue clinical monitoring. Final status will be given with RDT after 18 months and/or 12 weeks post BF cessation whichever is later.

N.B: Management of infants who started ART early and for whom we wish to confirm HIV status at 18 months by RDT should be cautious:

- If serology negative, consider sero-reversion and perform DNA-PCR or NAT
- If DNA-PCR negative discuss with HIV Advisor (advice to perform ultrasensitive methods of HIV detection) since standard DNA-PCR (or NAT) might be falsely negative in some children starting ART early in life.

A presumptive clinical diagnosis of severe HIV disease can be made if:

The child <18 months is confirmed as HIV antibody positive (RDT)ⁱ
 - _____ And

<p>Other supportive factors to consider:</p> <ul style="list-style-type: none"> -Recent HIV-related maternal death or advanced HIV disease in the mother -Child CD4 < 20%

ⁱ HIV infection in a child < 18 months can only be confirmed by a virological PMTCT /August 2017

The child is symptomatic with 2 or more of:

- Oral thrush
- Severe pneumonia
- Severe sepsis

Or

The diagnosis of any AIDS condition(s) can be made

Do not delay ART initiation in children with clinical signs of HIV infection even if you don't have access to a fast virological test results.

2.6. CTX prophylaxis for exposed infants:

All HIV exposed infants should receive CTX prophylaxis from 4-6 weeks of age till exclusion of HIV infection:

Table 7: cotrimoxazole prophylaxis dosing and formulations

Simplified Cotrimoxazole prophylaxis			
Weight	Oral suspension 200/40 mg per 5 ml, OD	Dispersible tablets 100/20 mg OD	Scored tablets 400/80 mg OD
3-5.9 kg	2.5 ml	1	-
6-6.9 kg	5 ml	2	½ (crushed)
10-13.6 kg	5 ml	2	½ (crushed)
14-19.9 kg	10 ml	4	1

Chapter 3: specific cases

3.1. Special considerations during labour and delivery

Universal precautions (safe needle handling and storage, protective clothes etc.) should always be implemented in all maternity wards, for all patients regardless of their HIV status.

During labour

- Use the partograph to monitor progress in labour as recommended for all deliveries. Particularly in HIV positive women, prolonged labour must be avoided as the risk of transmission increases with the length of time.
- Limit the number of vaginal examinations, as lesions and infections in the birth canal will increase the risk of transmission.
- Limit time between rupture of membranes and delivery. For every additional hour of ruptured membranes, the risk of HIV transmission to the infant increases by 2%.
- Avoid artificial rupture of membranes.
- Stimulate labour according to protocol when spontaneous rupture occurs, to ensure rapid progress of labour. If the stimulation fails, proceed with c-section⁴.

During delivery

- Avoid invasive procedures during delivery (vacuum extraction, forceps and episiotomy) to limit the risk of HIV transmission. However, if these measures are necessary to save the life of the mother or the infant, they should be performed.

Newborn care

- As standard precautions are to be applied to any woman and newborn in the maternity ward, there are no special measures for HIV exposed infants.

3.2. PMTCT antiretroviral protocol: HIV-2 or HIV-1 & 2 co-infection

HIV-2 is not sensitive to the NNRTI class (NVP or EFV). Use a PI based regimen (ATV/r or LPV/r).

Integrase inhibitors work in HIV-2 but no data exist yet on safety during pregnancy. To use only if the potential benefit justifies the potential risk.

HIV-2 is much less transmissible from mother to child (1-3%) than HIV-1. WHO does not give any recommendation on when to start ART for PMTCT **in HIV-2 and HIV-1 & 2 co-infection. Follow national protocols.** However, don't use a NNRTI based regimens in pregnant women. Use TDF + 3TC (or FTC) with a PI (ATV/r or LPV/r) or a DTG containing regimen. Do not use NNRTI for the infant, even as prophylaxis, use AZT syrup (birth weight < 2500 g, 10 mg/dose twice daily; birth weight ≥ 2500 g, 15 mg/dose twice daily).

Chapter 4: Prevention of hepatitis

4.1. Prevention of hepatitis B (HBV) transmission in HIV co-infected pregnant women

High maternal HBV viremia and HBe Ag positive status^j are correlated with a higher risk of HBV transmission. However in HIV-HBV co-infected patients, the current recommended 1st line ART regimen TDF/3TC (or FTC)/EFV is treating and preventing transmission of both diseases^k.

Recommendations for screening

- All pregnant women presenting to PMTCT and ANC programs should receive HBs Ag testing at the first visit.

Prevention of MTCT in women with positive HBs Ag result:

1. Mother's treatment:

^j Without treatment, nor immunization, risk of HBV transmission is estimated at 70-90% in HBe Ag pos and 10-40% in HBe Ag neg mothers

^k HBV drugs in this regimen are TDF and 3TC (or FTC)
PMTCT /August 2017

- It has been shown that co-treatment of HBV and HIV with an ART regimen containing TDF/3TC is highly successful in preventing transmission of both virus to the infant. Choose an ART regimen containing TDF/3TC (or FTC)⁵.
- When changing to a 2nd or 3^d line, keep at least TDF (+/- 3TC (or FTC)) in addition to the new ART regimen regardless of previous exposure and HIV resistance to TDF¹.

2. HBV vaccination for newborns:

- Provide the first dose of hepatitis B vaccine (monovalent) at birth or within the first 24 hours. Use the adult monovalent vaccine at 1/2 dose (0.5 ml) or HepB pediatric vaccine.
- Ensure that the infant receives the other doses through the EPI (DPT-Hib-HepB pentavalent vaccine)

3. Prevention of HBV infection in HBs Ag negative women (if status known):

- Women with negative HBs Ag status and who have not been vaccinated in the past (see immunization card) should be vaccinated at Day 0, M1, M6.

4.2. Prevention of hepatitis C (HCV) transmission in HIV co-infected pregnant women

Pregnant women co-infected with HIV-HCV have a 5 to 20% risk to transmit the HCV virus to their infant. At the moment there are no data about the use of HCV drugs in pregnancy and BF. No recommendations are yet available. Where access to diagnosis (HCV RDT **and** HCV VL) is available, treatment using the new direct acting antiviral drugs may be offered after breastfeeding in order to prevent transmission in future pregnancies. (See Hepatitis C care for MSF projects. 2017. In validation process⁶).

Chapter 5: Follow-up of HIV exposed infants

5.1. Early Diagnosis of HIV Infection in Infants and Children <18 months

Infants and children can be infected with HIV during pregnancy, delivery or post-partum through breastfeeding. Infants infected *in utero* usually have already detectable HIV viral load when tested at birth. In contrast, infants infected during or around delivery usually have undetectable HIV viral load when tested at birth because it takes approximately 1-2 weeks following infection for the virus to be detectable by viral assays.

For infants and children under 18 months of age, serological antibody detection assays are not suitable because passive transfer of maternal antibodies may lead to a false positive result. Thus,

¹ Removing the HBV treatment can lead to severe hepatitis flare
PMTCT /August 2017

virological assays, such as NAT or HIV DNA (DNA-PCR) are recommended for EID in infants <18 months of age. For infants older than 18 months, an antibody detection test can be used because the maternal antibodies have been cleared from the infant's blood. Use the adult algorithm.

A NAT or a nucleic acid amplification test (NAAT) is a molecular technique used to detect a particular pathogen (virus or bacterium) in a specimen of blood or other tissue or body fluid. NAT is the recommended testing method to diagnose infants and children <18 months. **The DNA-PCR is a NAT test.** See annex 5.

Serological testing using rapid diagnostic tests (RDTs) can be considered in infants aged 9-18 months only to rule-out infection if NAT testing is not available. See annex 4.

Point of care (POC) devices for EID are now available and are a very practical option. Results are available within 2 hours.

If HIV NAT cannot be performed in the project, the specimens are to be sent to an external laboratory using dried blood spots (DBS). Refer to Annex 5.

According to WHO guidelines MSF recommends:

HIV Infant Diagnosis by NAT using Dried Blood Spot (DBS) or POC

Early testing is recommended to diagnosis HIV infected children as soon as possible in order to initiate them on ART and reduce early mortality.

Initial testing (NAT1) is usually recommended at the first post-natal visit (usually 4-6 weeks).

Some countries are starting to use DBS at birth (earlier case finding for perinatal infection and to possibly reduce early lost to F/up). Refer to national protocols and annex 2. Where birth testing with the subsequent repeats is not feasible for all exposed infants, priority may be given to those infants classified at high risk or where no PMTCT was provided to the mother.

Caution:

- If initial testing was done at/or around birth and was HIV negative, a second test must be performed at 4-6 weeks (to detect intra-partum and early post-partum transmission).
- **4-6 weeks is indicative. Week 6 is convenient because this is also the date of the first DPT-Hib-HepB1. But never turn away a mother because she comes earlier or later to test her infant.**

Result Interpretation

- If NAT1 is NEGATIVE: Report the result as "HIV-negative". There is no need to confirm a negative result with a second NAT, unless the first test was done at or around birth.
- **If the first result (NAT1) is POSITIVE: Start ART as soon as possible** and collect immediately a second specimen for confirmation (NAT2).

A positive HIV result obtained from virological testing of an infant or child younger

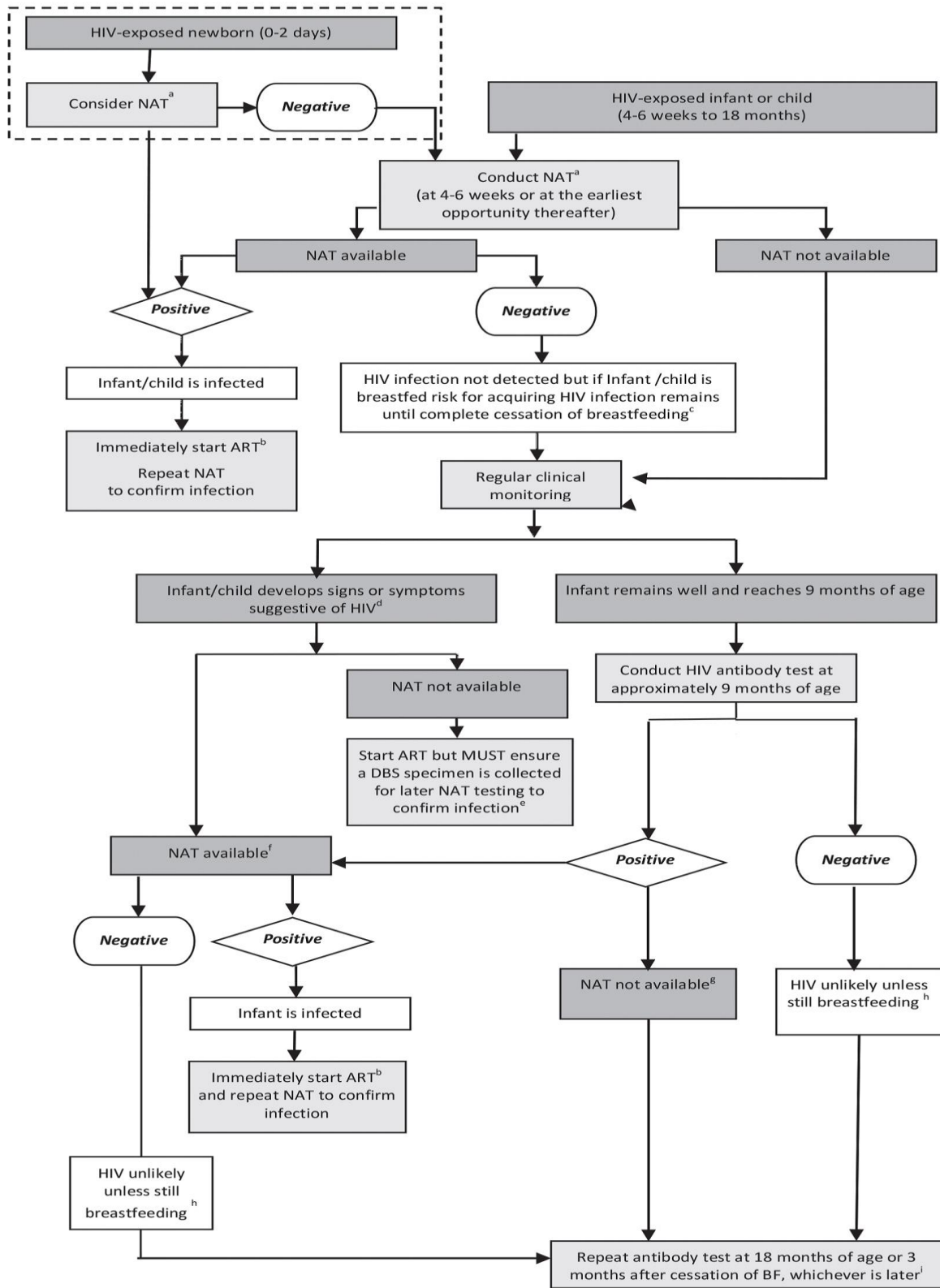
than 18 months should always be confirmed by a second virological test taken at the time when the first result is given.

- The confirmation of the initial positive result is recommended in order to reduce errors during sampling, transportation and/or testing.
 - The confirmation test should be performed in the same laboratory as the first test. This allows follow-up on the consistency of the results and investigation of discordant results.
 - Data should be collected including at a minimum: age of child, results of NAT1 and NAT2 and dates of blood collection.
- If the second result (NAT2) is also POSITIVE: Report final result as "HIV-positive".
 - If the second result (NAT2) is negative: This is a discordant result. Refer to your HIV referent or laboratory advisor.

Table 8: result interpretation

Result NAT1	Result NAT2	Final Result
Negative	Not applicable	NEGATIVE
Positive	Positive	POSITIVE
Positive	Negative	Perform a 3 ^d test before stopping ART. Refer to laboratory or HIV advisors

5.2. Algorithm for EID:



Source WHO guidelines 2016 'Consolidated guidelines on the use of Antiretroviral drugs for treating and preventing HIV infection'.

Important notes:

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- ^a Based on these revised guidelines, adding nucleic acid testing (NAT) at birth to the existing testing algorithm can be considered. Point-of-care NAT can be used to diagnose HIV infection at birth, but positive results should be confirmed using laboratory-based NAT assays because of limited experience with point-of-care assays close to birth.
- ^b Start ART, without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and the rates of mother-to-child transmission decline, false-positive results are expected to increase and retesting after a first positive NAT is important to avoid unnecessarily treatment, especially in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.
- ^c For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.
- ^d Signs and symptoms suggesting HIV (oral thrush, recurrent or severe bacterial infections such as pneumonia or sepsis, failure to thrive or wasting or AIDS indicator condition (<http://www.who.int/hiv/pub/paediatric/infants2010/en>))
- ^e If the infant presents with signs and symptoms of HIV disease (see footnote d above) but NAT is unavailable, consider starting ART, especially if an antibody test is conducted and the result is positive at 9 months or later. A DBS specimen must be collected before starting treatment for later NAT testing to confirm HIV diagnosis, because subsequent diagnostic testing while already on ART might be difficult to interpret.
- ^f If the infant presents with signs and symptoms of HIV disease (see footnote d above), consider starting ART while waiting for the NAT result. However, another DBS specimen should be collected before starting treatment for later NAT testing to confirm the HIV diagnosis.
- ^g Regular and periodic monitoring should be ensured while waiting for NAT to be available or for antibody testing to be conducted at 18 months. Infants presenting with signs and symptoms of HIV disease should be managed as described previously (see footnote e).
- ^h The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month antibody testing is conducted earlier than 3 months after breastfeeding ends, HIV infection acquired in the last days of breastfeeding may be missed, so retesting at 18 months should be ensured for final assessment of HIV status.
- ⁱ If breastfeeding extends beyond 18 months, final HIV diagnosis status can only be assessed when breastfeeding ends. If breastfeeding ends before 18 months, final HIV diagnosis status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after breastfeeding ends (to allow HIV antibodies to develop). For infants and children younger than 18 months of age, positive antibody testing requires NAT to confirm infection. If the child is older than 18 months, negative antibody testing confirms that the child is uninfected; positive antibody testing confirms the the child is infected.

Source: WHO: The use of antiretroviral drugs for treating and preventing HIV infection. 2016

Additional information:

- Children remain at risk of HIV infection as long as they are breastfed. All HIV NAT negative children must be re-tested using antibody-based tests (e.g. Rapid Diagnostic Tests) to confirm the final status after 18 months and/or 12 weeks after cessation of breastfeeding, unless child was never breastfed.
- In projects which do not have the capacity to do so, earlier discharge between 12-15 months may be considered if a negative antibody HIV test is obtained and the baby has not breastfed during the past 12 weeks.
 - Keep in mind that :
 - The likelihood of a false positive result decreases when clear clinical symptoms of HIV infection are present.
 - The likelihood of a false negative result increases when there are clear clinical indications of an HIV infection:
 - If a child tested negative once but has new symptoms compatible with HIV disease, testing must be repeated (and treatment started following the MSF Pediatric HIV Handbook).
 - The likelihood of a false positive increases with a well-functioning PMTCT program (as HIV prevalence in infants decreases, predictive positive value of the test decreases as well and false positive results increase).

It is recommended to **liaise with the HIV referent or lab advisor for discordant results and keep track of the results.**

5.3. Clinical follow up

HIV exposed infants should be followed until HIV infection can be ruled out or confirmed, usually till 18-24 months. During the first year, consultations should match the EPI calendar. From 6 weeks to 6 months, 1 consultation/month is needed. Thereafter, a 3-monthly schedule can be proposed. Ensure that the child health record with immunization (usually provided by MoH) is filled out at each visit. Always assess the mother and child's care together as a family. Encourage testing of the partner and other siblings.

At each consultation:

- Check age and weight. Plot on the WHO growth chart. If outside of normal percentiles, measure height and calculate BMI. If the growth curve is flattening or crossing lower centiles, action is required
- Check clinical status, growth and neuro-developmental status including cranial perimeter.
- Look for signs of TB and potential TB contacts. Ensure INH prophylaxis if mother is on TB treatment.
- Advise on nutrition (encourage exclusive breastfeeding till 6 months, complementary feeding to be introduced thereafter). Breastfeeding should be respected till around 24 months. In some projects, supplementation can be given^m.
- Prevent and treat mother's breast problems (mastitis, cracked nipples, abscess, herpes) and thrush in infants, conditions that are known to increase transmission.
- Check immunisation completion for age and verify the infant has a mosquito net.

Specificities for HIV exposed infants

- Prescribe antiretroviral prophylaxis according to risk assessment.
- Adapt the dose according to age of the infant for the ARVs and according to the weight for the cotrimoxazole (see tables 3 to 6)
- Start Cotrimoxazole at 4-6 weeks and continue until proven HIV negative.
- Perform HIV testing according to the early infant diagnostic algorithm.
- Take history and examine for signs suggestive of HIV infection. If found, test the child and discuss if presumptive treatment should be started.

For both mother and child

- Assess adherence issues to treatment and prophylaxis at each consultation (check if on time to appointments). If any problem arises, refer to the counselling guide.

^m Such as plumpy Doz/BP 100
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Appendices

Appendix 1: HIV testing of the pregnant woman

MSF recommends following WHO recommendations on HIV testing based on the consolidated guidelines on HIV testing services 2015⁷. This strategy for diagnosis depends on the prevalence of the setting where the tests are used. Three positive RDT tests are needed to confirm a positive HIV status in low prevalence settings (< 5%) whereas 2 positive RDT tests are needed in high prevalence settings (> 5%). This means that there may be different testing strategies in use in one country or even within one testing facility (e.g. the ANC clinic may have a testing prevalence of 2%, thus should use the testing strategy for low prevalence settings but the HIV testing center at the TB clinic might have a prevalence of 10% and should therefore use the testing strategy for high prevalence settings). If the prevalence is unknown or if it is too complex to have 2 different algorithms within one testing facility, it is recommended to use the low prevalence testing strategy.

In both high and low prevalence settings, three different serological assays (A1, A2, A3) may be required to establish the diagnosis of HIV infection. A1 should be the most sensitive assay available and A2 (and A3) have the highest specificity.

MSF recommends using Determine as A1, STAT-PAK as A2 and SD Bioline or Uni-Gold as A3⁸.

Important: All individuals that are diagnosed HIV-positive should be retested prior to starting ART to verify their HIV-positive status. When same day initiation is being performed, the re-testing should be performed by a different person using a different sample.

Serological testing strategy for HIV diagnosis in high prevalence settings (≥5%)

According to WHO guidelines, MSF recommends, for high prevalence settings (> 5%) that a diagnosis of HIV positive be provided to people with two sequential reactive tests.

- For individuals with discrepant test results where A1 is reactive, A2 is non-reactive and A3 is reactive, the results should be considered inconclusive and the client should be asked to return in 14 days for retesting.
- For individuals with discrepant test results where A1 is reactive, A2 is non-reactive and A3 is non-reactive, the final result should be considered HIV negative.

The testing strategy for high prevalence settings is described in Figure 1.

Important: For individuals with A1+, then A2-, then A3+, using the reactive test result from the third assay as a tiebreaker to rule in HIV infection and issue an HIV-positive diagnosis is not recommended; it over-selects for false-positive results and, therefore, leads to greater potential for misdiagnosis of HIV infection.

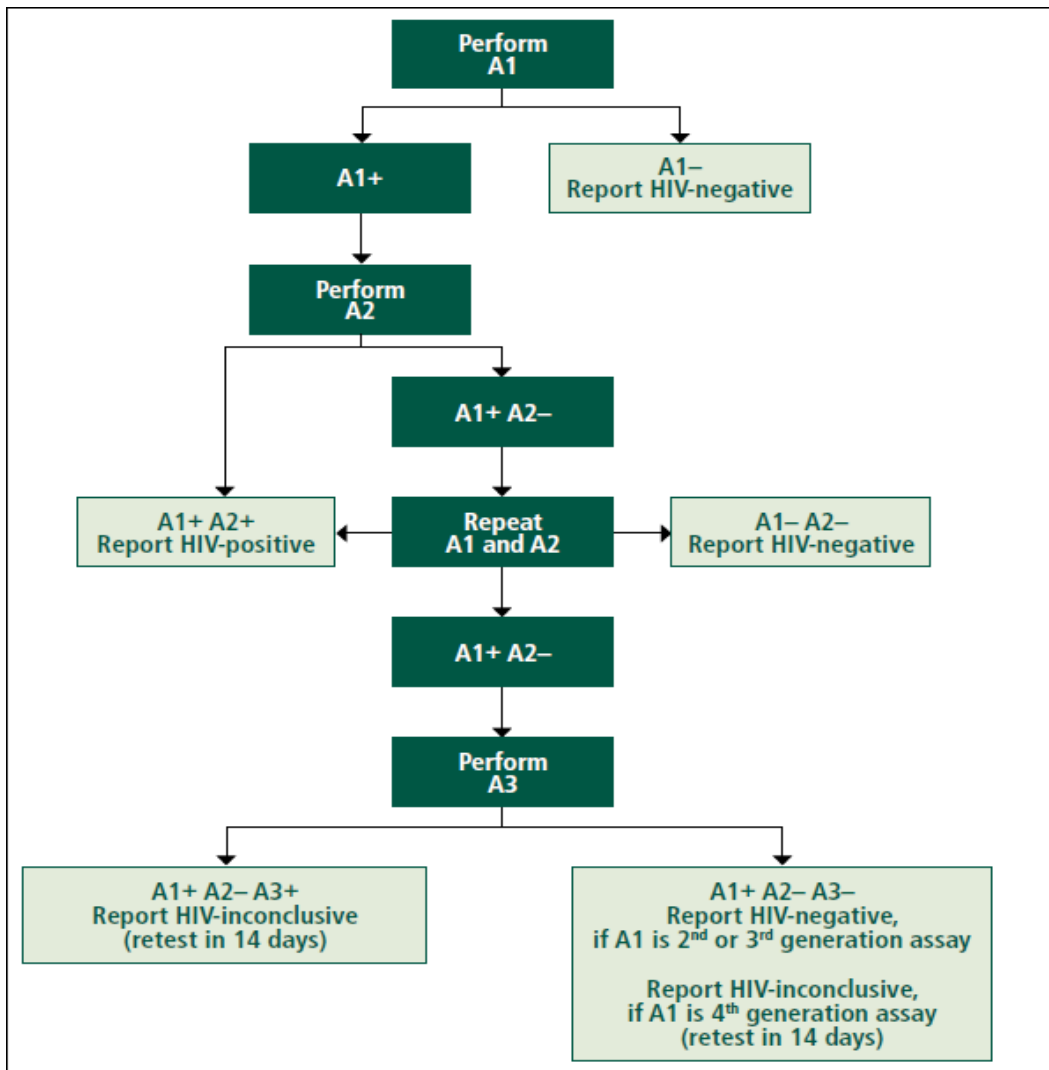


Figure 1: Serological testing strategy for HIV diagnosis in *high* prevalence settings ($\geq 5\%$). Source: *The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection*. WHO 2016.

Serological testing strategy for HIV diagnosis in *low* prevalence settings ($< 5\%$)

According to WHO guidelines, MSF recommends, for low prevalence settings ($< 5\%$) that a diagnosis of HIV positive be provided to people with three sequential reactive tests.

- For individuals where the Assay 1 result is reactive and Assay 2 result is non-reactive, the final result should be considered HIV negative.
- For individuals with results in which Assay 1 is reactive, Assay 2 is reactive and Assay 3 is non-reactive, the result should be considered inconclusive and the client should be asked to return in 14 days for retesting.

The testing strategy for low prevalence settings is described in Figure 2.

Important: In a low prevalence population, the positive predictive value based on two test results is too low to provide an HIV diagnosis. Therefore, for specimens that are reactive on the first and the second assays (A1+; A2+), a third separate and distinct assay (A3) should be used to confirm the results and issue an HIV-positive diagnosis.

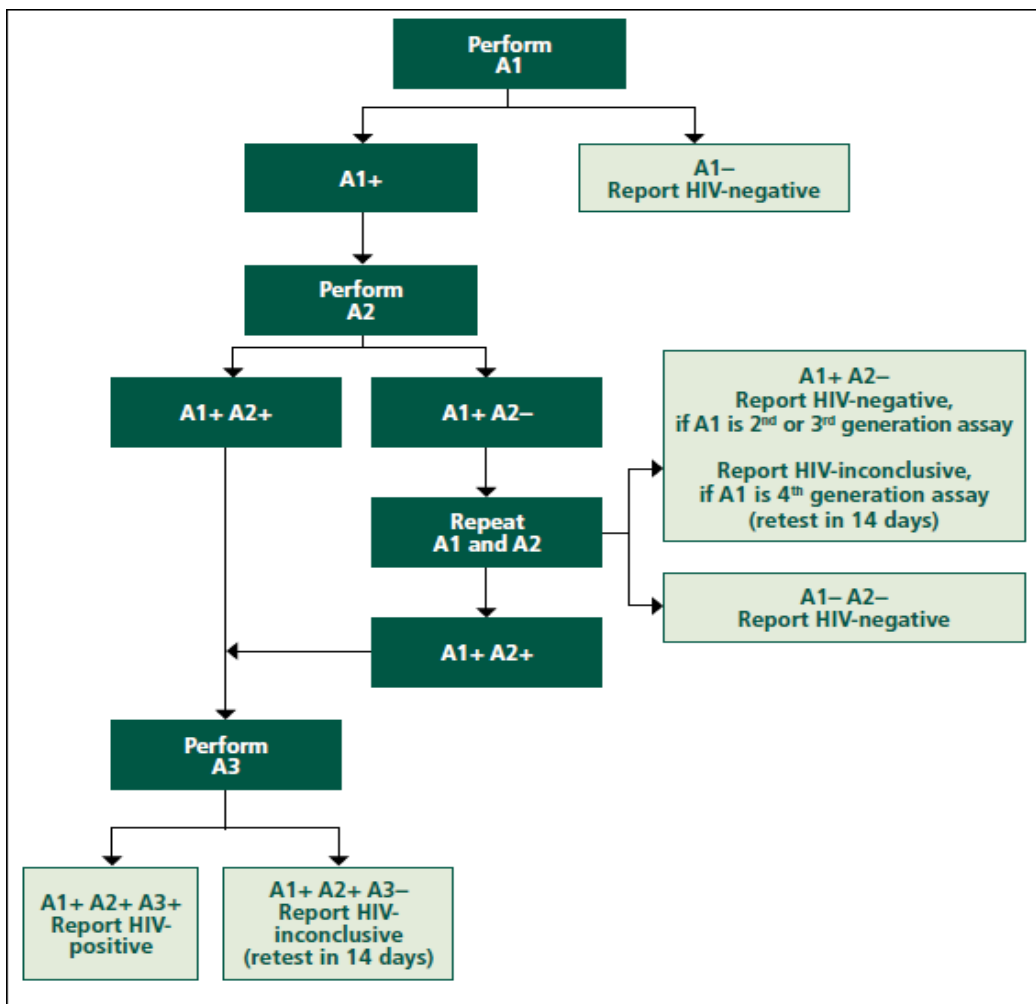


Figure 2: Serological testing strategy for HIV diagnosis in low prevalence settings (<5%). Source: The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. WHO 2016.

Appendix 2: Testing at birth

In settings where transmission risk is low (< 5% at 6 weeks) as result of good PMTCT coverage, adding birth testing may be considered as up to 70% of the residual perinatal transmissions (intrauterine and intrapartum) are expected to occur in utero. *Where resources are limited, priority should be given to high risk infants.* However as the positive predictive value of any test is lower in settings where the prevalence of HIV in the population being tested is low, the proportion of false positive results will be relatively high. It will therefore be critical to ensure retesting of any positive result, as recommended for all positive, by a NAT test. ART should be initiated without the result of the 2nd test because of the high risk of mortality with in utero infection; if the 2nd test is negative, a 3^d NAT should be performed before stopping ART.

In settings where transmission risk is high (> 5% at 6 weeks) as a result of poor coverage of PMTCT program, the proportion of children with in utero infection is lower. The negative predictive value of the test is low. It is therefore critical to ensure retention in the testing cascade and actively track infants who test NAT negative at birth.

Appendix 3: Summary table: use of RDT for HIV serology and NAT virology based on age

Age group	HIV exposed infant
0-9months	RDT cannot truly determine HIV infection. Use NAT. if NAT unavailable, treat upon HIV symptoms infants with a positive HIV RDT till true diagnosis according to age can be obtained
9-18 months	RDT useful to rule out HIV infection Infants with positive RDT needs NAT to confirm infection Infants with negative RDT who are still BF are still at risk of getting HIV so need NAT at the end of BF if NAT unavailable, treat upon HIV symptoms infants with a positive RDT HIV till true diagnosis according to age can be obtained
>18 months	RDT at 18 months or 12 weeks after end of BF whatever comes first to confirm status

Appendix 4: SOPs for Collection, storage and transportation of DBS samples

Dried blood spots [DBS] are clinical samples collected by applying a few drops of blood onto an absorbent sample collection [filter] paper. The blood is allowed to saturate the paper thoroughly and then air-dried. DBS cards [e.g. 903 protein saver card from Whatman, ref. code: 10531018 [MSF code: ELABPAPF903]] can be sent to laboratories where the samples are analyzed. Once in the laboratory, a small disc of saturated paper from the DBS card is punched out to elute the blood/plasma from filter paper, which is used for testing.

Caution: there is a high risk of cross contamination from capillary blood sampling to laboratory testing if proper procedures are not followed.

1. Required material

- Blood collection material incl. powder-free gloves
- Sample collection card: e.g. Protein Saver™ 903® Card Whatman or Munktell
- Drying rack
- Low gas permeable zip-lock bag
- Desiccant bags
- Humidity card: Tropack Indicator B/1
- Rip-resistant envelope

Important: For DBS collection in infant the HEEL LANCET for infants [MSF code: ELABLANC2H-] should be used as this lancet creates a higher blood flow than regular lancets.

2. Method: collection and storage of DBS

- a. Wear non-sterile powder-free gloves.
- b. Label card with appropriate identification and date of collection. Take care of not touching the circles.
- c. Clean and disinfect the puncture site [e.g. heel] thoroughly.
- d. Apply 1 drop or 50-75 µL of whole blood to each circle (e.g. heel prick sample), and fill the 5 circles (at least 4 circles).
- e. Then prick the site with a lancet and let blood drop [ideally freely dropping], onto the circles of the DBS card. The blood is allowed to thoroughly saturate the paper and completely fill at least three circles on the blood collection card. Alternatively, transfer 50 µL of whole blood onto each circle, using a pipette.
- f. Filter paper with blood spots needs to be air-dried horizontally for several hours [minimum 3 hours], ideally on a drying rack. Do not allow different filter paper cards to come into contact with each other, especially while wet. Keep the DBS cards away from direct sunlight and protect from dust and flying insects.
- g. Complete patient information in the appropriate laboratory register (identification number, age, date of blood collection).
- h. Once dried, samples are stored in low gas-permeability zip-lock plastic bags with desiccant to absorb humidity, along with a humidity card indicator. The cards can be kept at ambient temperature, even in tropical climates.
- i. The DBS cards should be checked for humidity regularly (e.g. weekly) and if the humidity indicator reaches 30%, the indicator and the desiccant should be replaced.

3. Transportation

DBS are not considered infectious material regarding international regulations (exemption from UN 3373 and UN 2814 shipment regulations). It is possible to transport them by regular mail services at room temperature.

Place zip-lock bags containing DBS in a rip-resistant envelope with the necessary documents: laboratory test request forms and list of enclosed DBS.

Appendix 5: Patient Support, Education and Counselling (PSEC) in PMTCT Services

For full guidance and access to counseling flipcharts please refer to MSF documents⁹.

ART initiation counselling in Pregnant and Breast feeding women

Pregnant and breast feeding mothers will all be offered ART initiation (TDF/3TC/EFV) on the same day they test positive. Therefore the content of the counselling session has to be prioritized. Assess:

- Motivation for taking medication – to keep the infant negative and in the longer term to keep herself healthy and to care for the child.
- How to take the medication. Once a day; same time; what tools will be used to remind.

At subsequent sessions ongoing counselling and assessment of HIV knowledge must be further developed. In addition the woman must be counselled, on planning a safe delivery, the NVP (+/-AZT) and CTX that her infant will need, testing her infant and feeding advice.

If the woman has concerns about life long treatment these should be further discussed during follow up sessions but for now encourage her that the immediate motivation is to keep her infant negative. In addition a baseline CD4 will be taken (needed to assess for late presenter treatment and to monitor treatment response if viral load not available). This will also guide further discussions. In future sessions it can also be explained that continuing on ART not only will keep her healthy but will also **protect any future pregnancy** much earlier.

Lack of disclosure is a very common reason for pregnant or BF women not to take their medication. Start to discuss options for how she might disclose to her partner but do not insist on it during the first session. This difficult theme will be discussed more deeply during further sessions.

Rapid initiation counselling session :

1. Give emotional support after post-test counselling

- Ask how they feel about their positive test result

2. Explain ways of transmission of HIV

- Explain 3 modes of transmission:

- Explain different ways mother can infect her child: during pregnancy 17%, at delivery 50%, during breastfeeding 33%.
- Explain chances of transmission from mother to child. With the correct follow-up on ART, there are high chances that your infant will be HIV negative!

3. Give ART/PMTCT education in a nutshell

Finding out you are HIV+ is a lot to deal with today but it is important that we already speak for a moment about the health of your infant. You could have a HIV- infant if you take the right precautions:

- *Start ART as soon as possible:*
HIV has no cure but there is a treatment to control HIV in your body. All pregnant women are to start this treatment as soon as possible as this gives a high chance of preventing the transmission of the virus from you to your infant. We invite you to start taking the treatment today, but it is up to you to decide if you feel ready for this.
- *Delivery in a health facility:*
It is safest to go to a health facility for delivery and inform the staff you are HIV positive; then the staff will be able to take all precautions to protect the infant during delivery.
- *Correct feeding of the infant:*
After delivery, it is important to only give breast milk for the first 6 months. After 6 months other foods can be introduced, while continuing breastfeeding until at least 12 months of age.
- *Correct treatment of the infant:*
The infant will be given different protective syrups right after birth until you stop breastfeeding.

Through these 4 actions you will protect your infant and the chances of him or her becoming infected are very small. Today we will focus on how to take the treatment for you and your infant correctly and we will cover other topics at later sessions. We will make a plan together to enable you to take the medication for you and your infant correctly.

4. Make a plan with the patient on how to take ARVs? Cover the following aspects

- Check and explore the motivation to start ART.
- What would be the best timing for you to take your drugs taking into account your daily habits.
- What tools will you use to remind to take your drugs (alarm, school,...).
- Where will you store your drugs.
- Where will you keep extra doses in case you are out of the house.

- How will you manage missed doses.
- What will you do in case of side effects (EFV related-dizziness, confusion, and Tenofovir related).
- What are your travelling plans in coming months (mobility issues).

5. Make a plan for Disclosure and testing of partner:

Discuss strategies to get their partner to come for testing (invitation letter clinic, communication with partner, retest both partners together) and how she may be able to disclose her status.

6. Ask if they have any questions and explain they are going to be booked for a second session at week 2 on ART

7. Aim where possible to link the woman with a community health worker or PMTCT “Champion” who can support them in the community

8. Ask their consent that if they miss an appointment they will be called or be traced.

Counselling follow up for pregnant and breastfeeding women

Counselling follow up should be at month 1, 3, 6 and 12 as for normal ART follow up. In addition to assessment of adherence, topics related to their stage of PMTCT should be incorporated into the counselling content: **planning a facility based delivery; NVP use; DBS testing; CTX use; Infant feeding advice.** There are also some key **“Transition points” in the journey of PMTCT** where key messages should be emphasized.

- Planning where the woman will deliver or if she will travel away from the facility who has initiated her ART. Consideration of cultural practices must be discussed and if needed extended drug supplies given or referral to another ART site.
- Exclusive breast feeding for 6 months is the recommended infant feeding option. When the woman is seen post-delivery it is very important to explain that the medication she is taking is making her **breast milk safe**. The chances of transmitting HIV to her infant if she takes the medication daily are very, very low. So her motivation for taking the medicine is still to keep her infant negative and to keep herself healthy
- **Family planning options** should be discussed¹⁰
- She should be reassured that the **medication she is taking is not harmful** to the infant
- During the subsequent sessions further discussion about lifelong treatment can be developed. **When she is about to stop breastfeeding** is an important stage as prior to this she has the additional motivation for treatment of keeping the infant negative. Now the treatment is for

her own health. She should also understand that continuing on the ART **will protect any future pregnancy.**

Follow Up Counselling Content Example

- **Assess adherence**
 - How are you doing after starting treatment?
 - What has changed in your daily life since you started ARVs?
 - What problems have you encountered (doses missed, side effects, disclosure issues).
Develop an individual plan together with the client on how he/she can overcome these problems
 - Are you experiencing any side effects? *(Mention that most of them will go away with time. Stress the importance of **not** stopping the treatment in case of side effects, but always seek medical care and advice.)*
 - What time do you take the ARVs? Why should ARVs be taken every 24 hrs?
 - What reminder tools do you use?

- **Give basic HIV and ART education and see what the woman remembers. Recap as needed**
- **Give PMTCT specific education**
- **Making a delivery plan:**

One of the key moments where transmission of the virus can occur is during delivery. This is why it is best to deliver at a health facility. If you inform the health staff about your status, they will know how to handle the delivery so that the risk of transmission to the infant is as low as possible. Preparing well for delivery means:

 - knowing to which hospital or health centre you will go
 - knowing how you will tell the medical staff you are HIV+
 - having identified someone who will take you there
 - knowing how you will reach the hospital (transport)
 - having prepared enough of your own medication to take with you
 - making arrangements for your absence from home (e.g., who will care for your other children while you are in the maternity).

If you cannot deliver at your regular health facility:

 - If you will travel and stay at a different house, you need to prepare enough medication for yourself and the infant: discuss this with the clinician so they can give you a transfer letter and enough drugs
 - Identify a treatment site near where you will be, for the delivery, ART drug refill and for check-up and drugs for your infant.

- **Explain about exclusive breastfeeding in first six months and inclusion of other foods later**
- **Explain about treatment for the infant:**
 - Right after birth, the infant will need to take a protective syrup for 6 (or 12) weeks, called Nevirapine – NVP (+/- zidovudine - AZT), this as well as the medication you are taking will protect the infant from becoming HIV positive.

- Four to six weeks later we need to change the syrup to another one, which the infant will take for the full period of breastfeeding. This syrup is called Cotrimoxazole and will protect him or her from other infections.
- We will show you how to administer this syrup to the infant. As with your own treatment, it is important to give this syrup every day without skipping a day.
- Demonstrate how to administer the syrup with a syringe.

- **Testing of the infant**

- The chance for your infant to become infected will be very small if you take the right precautions, but it's still possible. It is important to know as soon as possible if the infant is HIV+, so that he can start to take the treatment. This treatment will keep him strong.
- We will propose an HIV test for your infant a few times during the period of breastfeeding. The first test is usually done 6 weeks after birth but may be offered earlier (according to local protocols) . We will send some blood for analysis, after a few weeks you will receive the results. As during breastfeeding, the infant can still get infected, it is only after you stopped breastfeeding that we will take a final and conclusive test.

- **Assess Disclosure and testing of partner**

Discuss whether she has been able to disclose and also to get her partner to come for testing (invitation letter clinic, communication with partner, retest both partners together)

Ask the women if they have any questions and explain they are going to be booked for a next session at month 2

¹ http://www.unaids.org/sites/default/files/media_asset/GlobalPlan2016_en.pdf

² Consolidated guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV infection. Recommendations for a public health approach. WHO: June 2016.

http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf

³ https://mymsf.org/jcms/195995_DBFileDocument/fr/msf-hivtb-clinical-guide-2015-english

⁴ “Obstetric in remote settings –Practical guide for non-specialized health care professionals”. MSF 2014 version.

⁵ HBV in pregnancy. CID 2016:62 (suppl 4)

⁶ Hepatitis C care for MSF projects. MSF-OCP, 2017.

⁷ http://apps.who.int/iris/bitstream/10665/179870/1/9789241508926_eng.pdf?ua=1&ua=1

⁸ MSF policy on HIV testing and monitoring; LWG, July 2017

⁹ HIV-TB Adult PEC guideline 2017. More specifically to annexe-21 (PEC guide PMTCT B+_eng-final-May 2013³.doc) and the flipcharts in Annex-22 (PMTCT_B+_Flipchart_2013_EN.pdf)

¹⁰ *The Family Planning Handbook* (<https://www.fphandbook.org/>)