Operational guidelines on HIV testing and counselling of infants, children and adolescents for service providers in the African region

World Health Organization
REGIONAL OFFICE FOR Africa

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CONTENTS

Abbreviations

Ab	antibody
AFASS	acceptable, feasible. affordable, sustainable and safe
AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral treatment
ARV	antiretroviral
CBO	community-based organization
CHER	Children with HIV Early Antiretroviral Therapy
CITC	client-initiated testing and counselling
DBS	dried blood spot
DNA	deoxyribonucleic acid
ELISA	enzyme-linked immunosorbent assay
EPI	Expanded Programme on Immunization
FP	family planning
HIV	human immunodeficiency virus
HTC	HIV testing and counselling
IMAI	Integrated Management of Adult and Adolescent Illness
IMCI	Integrated Management of Childhood Illness
IPT	izoniazid preventive therapy
MCH	maternal and child health
M&E	monitoring and evaluation
MTCT	mother-to-child transmission
NGO	nongovernmental organization
OI	opportunistic infection
OVC	orphans and vulnerable children
PCP	*Pneumocystis jiroveci* pneumonia
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission
RNA	ribonucleic acid
sdNVP	single-dose nevirapine
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
UNICEF	United Nations Children's Fund
Up24Ag	ultra-sensitive p24 antigen
VCT	voluntary counselling and testing
WHO	World Health Organization

Definitions

Adolescent	young person between the ages of 10 and 19 years
Antenatal	occurring before birth (prenatal)
Child	person under the age of 18 years
Client-initiated HTC	HIV testing and counselling that is actively sought by a person
Disclosure	the process of sharing information about a person's HIV status with others
Infant	child below the age of 1 year
Neonate	infant below the age of 4 weeks
Orphan	child who has lost his/her mother (maternal orphan) or both parents (double orphan) through death
Perinatal	the period around birth; from 28 weeks' gestation to 1 week after birth
Postnatal	occurring after birth. Postnatal transmission of HIV refers to infection acquired after birth (i.e. through breastfeeding)
Provider-initiated HTC	HIV testing and counselling recommended by a health worker to a person attending health services as a standard component of medical care
Sensitivity of an HIV test	probability that an HIV test will correctly identify all individuals who are infected with HIV
Serodiscordant	when one partner in a couple is HIV positive and the other is HIV negative
Specificity of an HIV test	probability that an HIV test will correctly identify all individuals who are not infected with HIV
Vertical transmission	also known as mother-to-child transmission, it is the transmission of HIV from mother to child during pregnancy, delivery or breastfeeding
Vulnerable children	child who has little or no access to basic needs and rights. Specific indicators include abandoned children, refugees, children with physical or mental disabilities, or chronic illness (including HIV), children who have been subject to emotional, physical or sexual abuse, and children who are HIV negative but have parents who are living with HIV/AIDS.
Window period	the period of time from when a person is infected with HIV till the presence of HIV can be detected by an assay

A. INTRODUCTION

An estimated 33 million people are currently living with HIV. Of these, approximately 2.1 million are children below the age of 15 years, the majority of whom (90%) live in sub-Saharan Africa, often in under resourced settings. There has been pronounced progress in reducing the incidence and impact of HIV among children younger than 15 years in southern Africa. There were 32% fewer children newly infected and 26% fewer AIDS-related deaths among children; 90 000 versus 120 000 in 2009 compared to 2004 nevertheless the annual death toll from HIV-related illness remains high (260 000 children in 2009). South Africa is one of the few countries in the world where child and maternal mortality has risen since the 1990s. AIDS is the largest cause of maternal mortality in South Africa and also accounts for 35% of deaths in children younger than five years. (*1*)

It is estimated that globally, 370 000 infants were infected with HIV in 2009. The majority of childhood HIV infections are acquired through mother-to-child transmission (MTCT), i.e. during pregnancy, labour and delivery, and breastfeeding. The majority of these infections can be prevented by programmes providing antiretroviral therapy (ART) and antiretroviral (ARV) prophylaxis to pregnant and breastfeeding women and their infants. Less commonly, HIV can be acquired through sexual contact and contaminated blood products, however it is difficult to estimate the contribution of child sexual abuse to HIV incidence as abuse is often not disclosed and is underreported.

Over the past decade, there has been a significant expansion of HIV services internationally, with much emphasis on increasing the availability of ART. Many more adults are able to access treatment. However, the number of children receiving co-trimoxazole prophylaxis and ART remains low (*2*). This is especially true for infants and young children who are most vulnerable to HIV-related morbidity and mortality. Infection acquired before or at delivery progresses very rapidly during the first months of life, and infants often die within the first year of life; approximately 50% of vertically infected infants will die within the first two years of life. (*3*) In those children who do start ART, the response to treatment is very good. (*4*)

It is therefore important to increase access of infants, children and adolescents to HIV diagnostic services and ensure the availability of effective treatment.

Need for timely diagnosis

The Children with HIV Early Antiretroviral Therapy (CHER) study demonstrated that infants infected around the time of birth should receive ART as soon as HIV infection is diagnosed, regardless of their clinical and immunological status. This study demonstrated a significant reduction in morbidity and improvement in survival in young infants who received treatment early. In other words, early determination of HIV exposure and infection is critical to allow the early initiation of life-saving ART. (*5*,*6*) The World Health Organization (WHO) treatment guidelines for infants have been amended in light of this evidence. (*7*)

Current WHO policy recommends that, where possible, all infants born to HIV-infected mothers, be offered early infant diagnosis (i.e. at 4–6 weeks of age). (*7*) Unfortunately, at present, very few infants have access to early diagnosis and timely, effective treatment. It is estimated that only 15% of HIV-exposed infants are tested within the first two months of life. (*1*)

Specific obstacles that prevent the efficient scaling up of HIV diagnosis and treatment in children have been identified, and there are particular actions national health authorities can take to reduce these (see *Policy requirements for HIV testing and counselling of infants and young children in health facilities*, WHO/UNICEF 2010). These include limited HIV testing in the paediatric population, lack of an affordable and simple diagnostic test for HIV in children less than 18 months of age, insufficient understanding of the

efficacy of ART in children, limited experience with paediatric ART among health-care providers in resource-constrained settings, and few affordable and practical paediatric ARV formulations. (*8*)

Within the adolescent age group, some infections are acquired through MTCT, with the remainder being sexually acquired as a consequence of unprotected sexual intercourse (either consensual or as a result of sexual abuse or rape). A smaller proportion of adolescents are infected with HIV through intravenous drug use.

Provider-initiated HIV testing and counselling

In the paediatric setting, the entry points into HIV care are mainly through **provider-initiated testing and counselling (PITC)**. In Zambia and Uganda, the routine offer of HTC to paediatric inpatients showed high acceptance, and identified large numbers of positive children. (*9*,*10*) Health-care workers should see every patient encounter as an opportunity for providing PITC, and parents and caregivers should be encouraged to learn their status, as well as that of their children and family members. Where PITC is practised, more children are tested for and diagnosed with HIV, and can therefore access treatment services. (*11*) PITC should apply to all children in all circumstances with a generalized HIV epidemic, i.e. where HIV is firmly established in the general population such that HIV prevalence is consistently higher than 1% in pregnant women attending ANC.

In most instances, the parent/caregiver gives consent for an HIV test. Under some circumstances and depending on national legal requirements, a child considered to be sufficiently mature may give consent for an HIV test. (*12*)

Several different HIV tests are available, which can be categorized into virological or serological tests. A child's age and exposure to breast milk will determine which test is appropriate under which circumstances. These are discussed in detail in Section D, "HIV tests".

Diagnostics

Serological (antibody) testing can diagnose HIV in adults and children above the age of 18 months. Because of the passage of maternal antibodies across the placenta to the baby, serological tests in infants and children less than 18 months of age cannot confirm HIV infection. A positive result indicates **maternal infection** and the **infant's exposure to HIV**. A definitive diagnosis of HIV infection in this age group can only be confirmed with virological assays (HIV DNA polymerase chain reaction [PCR], HIV RNA PCR, ultrasensitive p24 antigen [Up24Ag]). When virological assays are not available, WHO recommends using a combination of serological testing and clinical symptoms to make a presumptive diagnosis of HIV infection in infants and children less than 18 months of age and decide whether or not to start treatment.

Proposed framework for expanded HTC services for infants, children and adolescents

An approach to decreasing the number of HIV-infected infants, children and adolescents, and reducing morbidity and mortality among those already infected must include the following:

1. Emphasis on the four WHO prongs of PMTCT (*8*) to reduce new, vertically acquired infections
2. Increase in early identification and testing of infants and children at risk for infection
3. Initiation of co-trimoxazole prophylaxis in all HIV-exposed infants and HIV-infected children
4. Fast-tracking of young infected infants and children into the HIV services, and placing them on ART
5. Public awareness of, and increased access to, HIV testing and counselling (HTC) services for infants, children and adolescents

6. Education programmes focused specifically on pre-adolescents and adolescents to encourage later sexual debut, safe sex practices, use of contraception and condoms, and diagnosis and treatment of sexually transmitted infections (STIs)
7. Interventions to prevent children and adolescents from becoming infected as a result of abuse and exploitation
8. Specific guidelines related to HIV testing, counselling, care and treatment for orphans and vulnerable children (OVC) (*13*) given the likely absence of adult supervision and guidance
9. Training and support of health workers to enable confident communication with children and adolescents and expansion of HTC services. HTC should be recommended to all children seen in paediatric health services in generalized epidemic settings. (*14*)

Integration of HTC services into other service delivery points

It is important that expanded HTC services be integrated into existing health-care services (primary, secondary and tertiary). This will maximize the use of resources, both human and physical, and provide multiple points of entry into the HIV service with opportunities for intervention and testing. Integration of services involves the delivery of services or multiple interventions at the same patient visit by the same health worker or clinical team. Details of HIV testing and treatment can be added to already existing standard forms, cards and registers.

This integration is particularly important in resource-limited settings. It may involve task-shifting between personnel and the use of simple, standardized protocols to facilitate care. It is not necessary for a specialized doctor to administer tests and treatment; trained and motivated primary health-care staff are just as effective. (*15*) Training and support are vital to the success of any expansion programme, as are efficient linkage and referral systems.

Objective for the guideline

This document is designed to provide practical, technical and operational guidance for the delivery of HTC services for infants, children and adolescents in Africa. It is to provide a framework to ensure that HTC services in children can be delivered in an integrated, efficient manner. It assumes a high prevalence of HIV (more than 1% HIV-infected pregnant women) in a resource-limited setting. This document is intended for use of programme managers and service providers at various entry points into the health-care system, which infants, children and adolescents are most likely to access.

Target audience:

This document is intended for use by providers working with pregnant women, newborn babies, children and adolescents on key aspects of service delivery in different facilities and at the community level. District health managers, personnel from nongovernmental organizations (NGOs) and community-based organizations (CBOs) involved in service provision and care of children in health facilities or at the community level, and managers of programs for orphans and vulnerable children (OVC) may also find this guide useful.

Health programmes into which HTC can be integrated:

I. HIV and STI programmes
II. Antenatal care (ANC) and prevention of mother-to-child transmission (PMTCT) services
III. Labour wards and delivery services
IV. Expanded Programme for Immunization (EPI) services

V. Any clinical care service for children and adolescents including Integrated Management of Childhood Illness (IMCI) facilities

VI. Malnutrition wards and outpatient services

VII. Tuberculosis (TB) clinics and inpatient facilities

VIII. Reproductive health and family planning programmes that also provide services to adolescents.

IX. Post-natal services

X. Community/home-based care services

Strategies to increase HTC for children should include:

- Increasing access to HIV testing through existing inpatient or outpatient health-care services/ programmes for children and their families
- Provision of clear indications for HTC of infants, children and adolescents
- Increasing access of HIV prevention, care and treatment services including infant feeding for children
- Training of health-care workers to recommend counselling and testing services for children and their parents or caregivers
- Developing and following procedures for disclosure to and counselling of children and adolescents according to their age and stage of cognitive development.
- Creation of child- and youth-friendly services to make HTC family-centred
- Provision of education and support for parents and caregivers

The health system requirements for the establishment of testing programmes and expansion of existing HTC services for infants, children and adolescents are beyond the scope of this guide. They are addressed in detail in other publications. Guidelines are also being developed for the monitoring and evaluation (M&E) of these services. (*17*)

This guide aims to provide a simple framework for the implementation of efficient, quality HIV testing services integrated into an already existing public health framework. Diagrams and algorithms summarize the text. The scale-up of HIV testing services does not require specialized clinics or doctors; every contact with the health-care system can be seen as an opportunity for HIV intervention. Some of the information has been published previously in WHO guidelines and recommendations. Two useful documents that should be cross-referenced when using this tool are Handbook for improving HIV testing and counselling services (WHO 2010) and the Operations manual for delivery of HIV prevention, care and treatment at primary health centres in high-prevalence, resource-constrained settings (WHO 2008) - both are available through the WHO website. This document consolidates those findings that are relevant to the scale-up of HTC of infants, children and adolescents in Africa.

B. Settings for HIV testing of infants, children and adolescents

Who should be offered an HIV test? (Table 1)

Eight **key entry points** to HIV health services for infants, children and adolescents must be targeted.

Table 1. Who should be offered an HIV test?

Service	Test
ANC and PMTCT	
• All pregnant women • All infants of HIV-infected mothers • All infants with mothers of unknown status	• HIV antibody (Ab) testing in the infant if the mother is of unknown HIV status • Virological assay for the infant if the mother is known to be positive or the infant tested HIV Ab positive: HIV DNA PCR
Labour wards and delivery services	
	• Rapid serological HIV assay on mothers to determine HIV status and infant exposure. If infants HIV-exposed, for preventive treatment and virological HIV test at 6 weeks of age
EPI	
• All infants of HIV-infected mothers (if not previously tested) • All infants with mothers of unknown status	• Virological assay: HIV DNA PCR* • HIV rapid antibody test; if positive confirmatory virological assay
IMCI/Well-baby clinics/Nutrition services	
• All infants of HIV-infected mothers (if not previously tested) whether symptomatic or not • All malnourished/underweight infants and children** • All children presenting with unusual/recurrent infections** • All children with signs and symptoms of HIV (see Table 3)** • All children with TB** • All children with siblings and/or family members who are HIV- or TB infected**	• Less than 18 months of age, status of mother or infant exposure unknown: establish exposure with serological test (HIV rapid test or HIV ELISA); if reactive confirm status with virological test (HIV DNA PCR)* • Less than 18 months of age, status of mother is known positive or known HIV-exposed infant: virological test (HIV DNA PCR)* • Older than 18 months: serological assay (HIV rapid test or HIV ELISA) • Previously negative but sick or breastfeeding: repeat test as appropriate for age
TB services	
• All infants, children and adolescents diagnosed with TB • All infants, children and adolescents with suspected TB	• Less than 18 months of age and of unknown exposure status: establish exposure with serological test (HIV rapid test or HIV ELISA); if reactive, confirm status with virological test (HIV DNA PCR)* • Less than 18 months of age and of known exposure status: virological testing. Consider initiating ART. • Older than 18 months: serological assay (HIV rapid test)
Sexual and reproductive health/family planning services	
• Adolescents presenting for contraception • Adolescents presenting with menstrual concerns • Adolescents presenting for treatment of STI • Adolescents presenting for male circumcision	• Serological assay (HIV rapid test or HIV ELISA)

Service	Test
Orphans and vulnerable children	
• Orphans in institutional care • Disabled children in institutional care • Children who are the victims of sexual abuse	• Less than 18 months of age: establish exposure with serological test (HIV rapid test or HIV ELISA); if reactive, confirm status with virological test (HIV DNA PCR)* • Older than 18 months: serological assay (HIV rapid test or HIV ELISA)
Adult HIV testing and treatment services	
• Children and partners of HIV-infected adults	

* When virological testing is unavailable, clinical algorithms along with serological testing allow for a presumptive diagnosis of HIV infection and for treatment with ART. If the mother is of unknown status, please either offer an HIV antibody test to the mother or the infant. If the test is positive then perform HIV virological testing.

** If HIV infection is clinically likely and HIV rapid test is positive, may consider initiating treatment while HIV virological testing is being processed; this is particularly important in very young infants and children who have higher mortality from HIV infection.

All infants or children who are found to be positive require immediate referral to treatment and initiation of co-trimoxazole prophylaxis, as well as access to malaria prevention and safe water interventions.

1. Antenatal care clinics and prevention of mother-to-child transmission services

The vast majority of paediatric HIV infection is acquired by vertical transmission. Without intervention, the risk of vertical transmission is 15–30% in non-breastfeeding populations. This increases to 20–45% when women breastfeed their children. (*18*) An obvious way to decrease the number of new infant and childhood infections is to improve access to, and quality of maternal, neonatal and child health services including PMTCT services. These programmes are currently being expanded in many countries; however, many women, especially the poor and vulnerable, remain outside the health system. The WHO PMTCT guidelines are summarized in Algorithm 1.

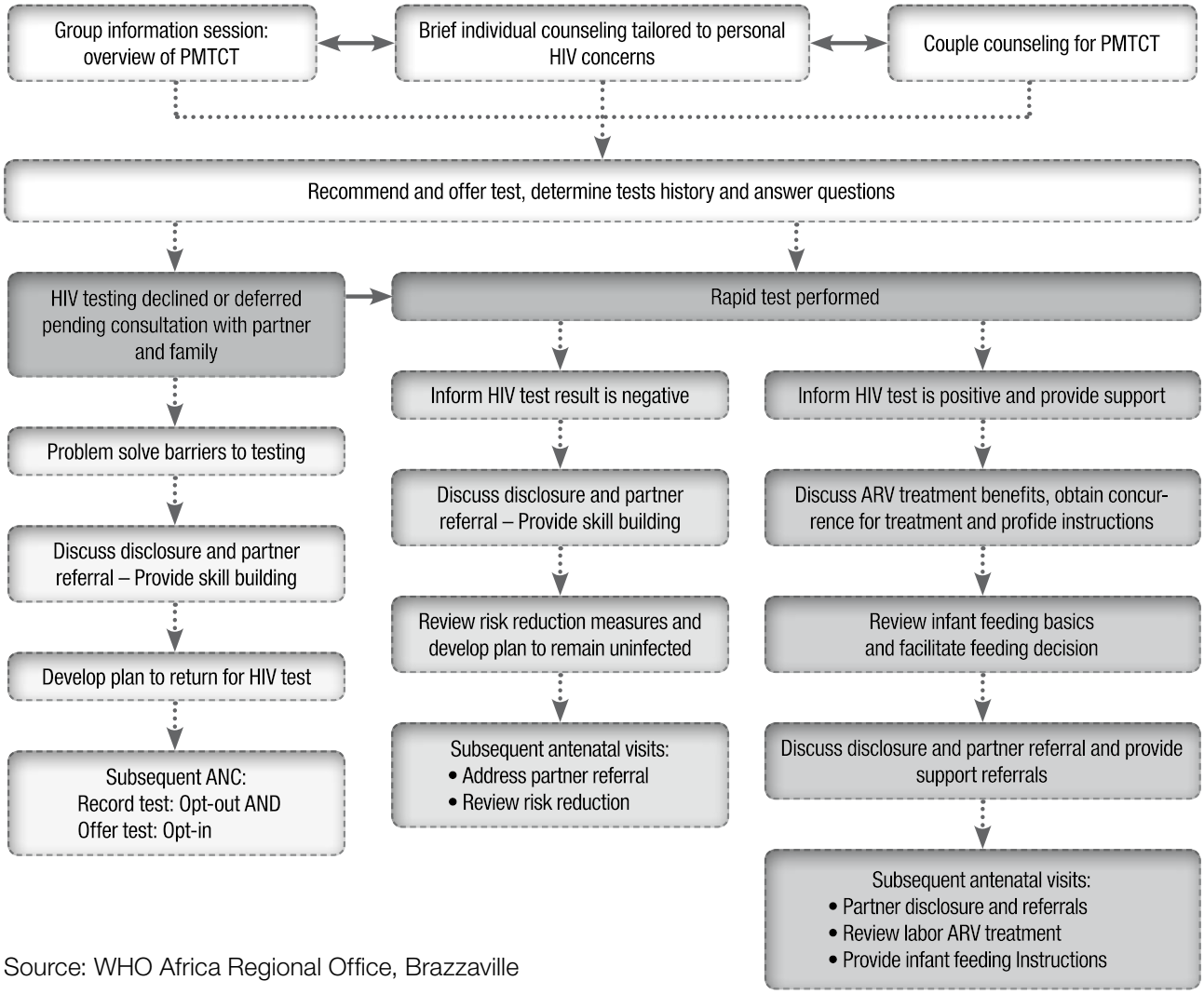
All pregnant women should be encouraged to attend ANC at least 3-4 times. All women attending ANC should be offered an HIV test. This is an opportunity for a woman to discover her own status and access care if necessary, as well as protect her unborn infant and encourage her partner to know his status. **If the HIV test is negative, re-testing during the third trimester of pregnancy (between 28 and 36 weeks) is recommended**. (*19*) If this test is positive, the woman should be provided PMTCT services as the risk of vertical transmission is high when HIV is acquired during pregnancy.

It is not only important for facilities to offer HTC to women during pregnancy, but also for systems to exist for the follow up and testing of HIV-exposed infants. HIV-infected mothers should be informed **before delivery** of the benefits of testing their infants between 4 and 6 weeks of age for early diagnosis of HIV, and where testing is offered. SEE SECTION D(b).

Where the mother's status is unknown, the infant's exposure to HIV must be established as soon as possible after birth by serological testing of the mother or infant.

It is recommended that all HIV-exposed infants be initiated on co-trimoxazole prophylaxis and tested for HIV using virological assays (PCR) at 4–6 weeks of age. In settings where virological assays are not

HIV counseling and testing for PMTCT in Antenatal clinic



Source: WHO Africa Regional Office, Brazzaville

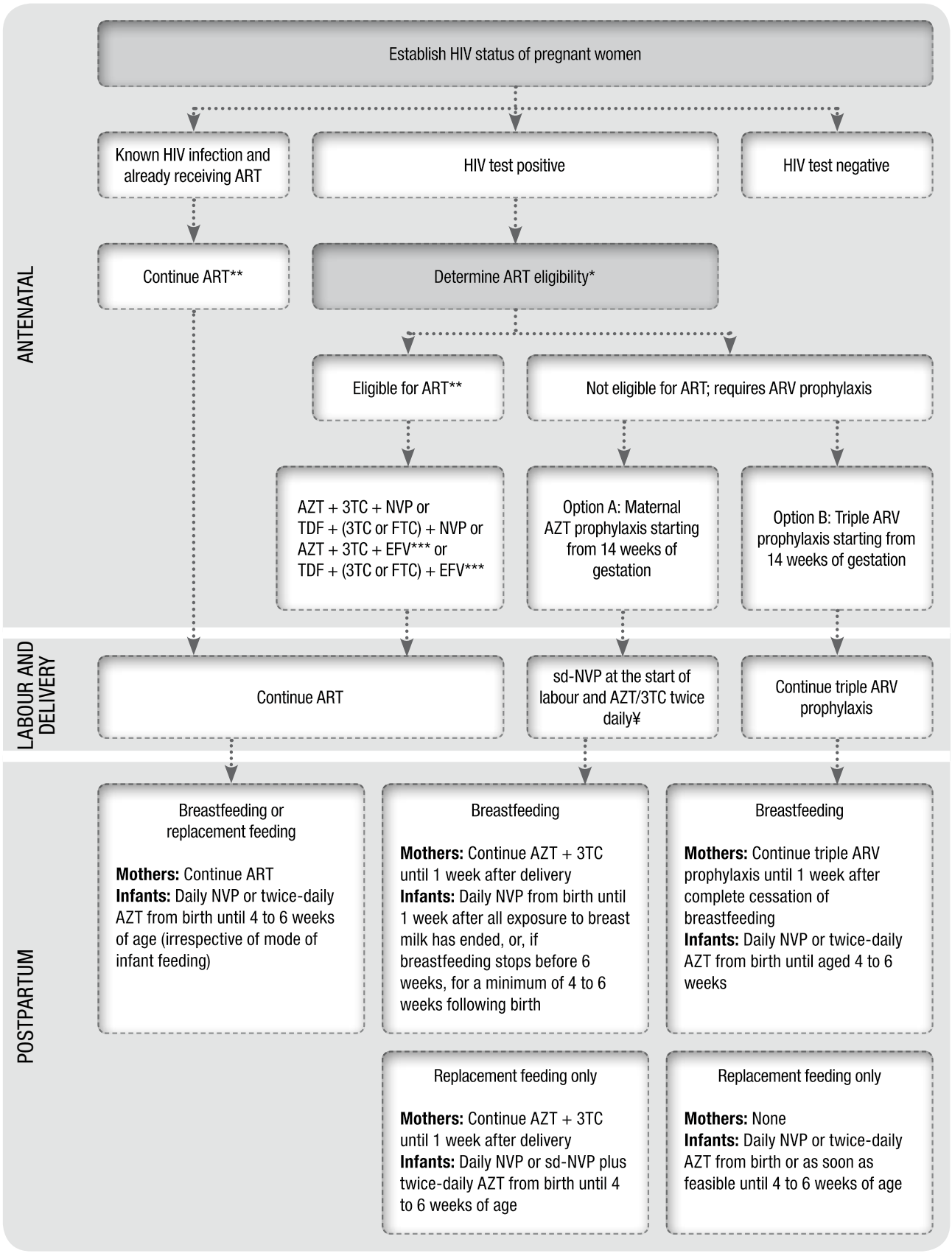
available, clinical algorithms along with serological testing allow for a presumptive diagnosis of HIV to be made and for initiation of ART (Algorithm 4).

Follow up of HIV-infected mothers and HIV-exposed infants is often difficult, especially in informal settlements and temporary communities. Documentation of a child's testing history and/or HIV status will make health-care provision at other points of entry more comprehensive – infants lost to follow up may be able to enter the HIV services at other points (e.g. EPI, IMCI, etc.).

Discussions about infant feeding with HIV-infected women should ideally be initiated before delivery to allow a well-considered and informed choice.

Infant feeding is discussed in detail in SECTION F(a.)

Algorithm 1: 2010 PMTCT recommendations



* Start ARV prophylaxis while waiting to determine ART eligibility.
** NVP or EFV, depending on national choice.
*** Avoid use of EFV in first trimester; use NVP instead.
¥ If AZT was taken for at least the last 4 weeks before delivery, omission of the maternal sd-NVP and accompanying tail (AZT/3TC) can be considered.

2. Birth and immediate postnatal services

All women in labour should know their HIV status. Those who are unaware of their HIV status at delivery should be offered a rapid HIV test as soon as possible. This allows those who are HIV infected to access PMTCT for their HIV-exposed infants as well as avail themselves of the health benefits of knowing their HIV status. Pregnant women who test negative in the 1st or 2nd trimester should be **recommended to return for another HIV test in their third trimester**.

Testing and counselling for women of unknown HIV status at the time of L&D: common scenarios

- **Woman presents to L&D in early labour:** This woman is provided pre-test information and rapid testing. HCWs should provide the HIV test results as soon as they are available (whether positive or negative). If the woman is HIV-positive, offer emotional support and ARV prophylaxis according to national guidelines. If the HCW is not able to discuss some of the post-test counselling information during labour, it is important to continue the discussion as soon as possible after childbirth, when the woman can better consider the information and ask questions, including those about infant feeding options.

  If the test results of a woman tested in L&D are not available within 1 hour of delivery, breastfeeding should be initiated. Breastfeeding should **not** be withheld pending results of the HIV test.

- **Woman presents to L&D in advanced labour with time for the pre-test session but insufficient time to give results:** Depending on the woman's comfort level, the HCW may conduct the pre-test session and draw the blood for testing as early as possible during labour. Every attempt should be made to obtain the results before delivery and provide the mother with ARV prophylaxis. If this is not possible, the HCW should obtain the results in time to inform decisions about infant feeding and infant ARV prophylaxis. Infant ARV prophylaxis will still reduce risk of transmission of MTCT if provided within 72 hours of birth.
- **Woman presents to L&D in labour with insufficient time for the pre-test session:** If the woman cannot be given pre-test information and tested during labour, the pre-test session, rapid testing and post-test counselling should be done after delivery. An infant can be given ARV prophylaxis up to 72 hours after birth.

Source: *Prevention of Mother-to-Child Transmission of HIV Generic Training Package*, July 2008 (http://www.womenchildrenhiv.org/doc/p03-pi/gtp-01-08/F_PM_Mod5GTP_final.doc accessed on 18 February 2011)

Women who are unaware of their HIV status or whose HIV status during pregnancy is not documented, and who are diagnosed as HIV-infected at or around the time of delivery may be at greater risk for defaulting PMTCT services and those for HIV-exposed infants. They require additional counselling and support. SEE SECTION D(a)

WHO recommendations state that all infants with unknown or uncertain HIV exposure being seen in health-care facilities at or around birth or at the first postnatal visit (usually 4–6 weeks), or other child health visit, have their HIV exposure status ascertained.

3. Expanded Programme on Immunization (EPI)/Maternal and Child Health (MCH) clinics

Data show that less than half (46.5%) of women in developing countries receive assistance from a skilled health worker when giving birth (*20*) ; immunization services often provide the first contact with the health system for most babies.

The majority of children attend scheduled clinic visits for immunization (see EPI schedule usually at 4–6 weeks of age. These visits provide an opportunity for identifying HIV-exposed children as well as those

with clinical signs of possible HIV infection (*see below* and Annex 1). (*21*) Early identification of those with HIV infection allows provision of early care and prevention of disease progression.

Technical assistance, tools & advocacy required to scale up early infant diagnosis

- Circulate recommendations on the use of appropriate HIV testing technologies and diagnostic approaches, and clear and simple testing strategies to facilitate early infant diagnosis
- Provide guidance and resources for implementation and operations, including setting up of laboratory services and transport networks for rapid handling of specimens and delivery of results back to mother/carer/child
- Put in place systems for early identification of HIV-infected infants, their follow up and retention in care.
- Build health system capacity to perform testing, transfer specimens to the laboratory and return results to the site and to patients in a timely fashion. This would secure referral for care and treatment for all infants and children who test positive.
- Scale up of counselling and testing services for children including training of health care workers on assisting parents/caregivers with counselling and disclosure of HIV status to children
- Ensure that QA programmes are functional and well-supported (including external quality assessment and quality control), and providing training to laboratory personnel
- Package and ensure a supply of related consumables in 'bundles' or 'kits' for use at sites
- Ensure a sufficient supply of ART

Developed from *WHO Recommendations on the diagnosis of HIV infection in infants and children*. WHO 2010

The current recommendation is that HIV-exposed infants be initiated on co-trimoxazole prophylaxis and tested by virological assay at 4–6 weeks to coincide with the first immunization visit. Results are then collected at the next date (i.e. four weeks later at the 10-week visit). If testing is not possible at 4–6 weeks of age, it should occur at the earliest opportunity thereafter. In infants with a positive result, ART should be started without delay and a second confirmatory specimen sent for virological testing. **It is not necessary to delay ART while waiting for the result of a confirmatory test.**

- Children of unknown status should undergo HIV serological testing at birth or at the first postnatal visit to ascertain exposure. Those with a reactive serological assay should undergo virological testing to determine HIV infection status.*

HIV-exposed infants who have not been previously tested or who tested negative at 6 weeks of age should also undergo HIV serological testing at the nine-month immunization visit. Those with a reactive serological assay should undergo virological testing to determine HIV infection status.*

- *Where virological testing is unavailable, clinical algorithms along with serological testing allow for a presumptive clinical diagnosis of HIV in infants and children less than 18 months of age and for initiation of ART (Algorithm 4).

See section D(b).

4. Infants and children presenting to any health service for acute or chronic care (including nutrition programmes)

In areas of high HIV prevalence, any encounter with the health system is an opportunity for the health service provider to recommend an HIV test.

HTC must be offered to parents or caregivers of infants and children under the following circumstances:

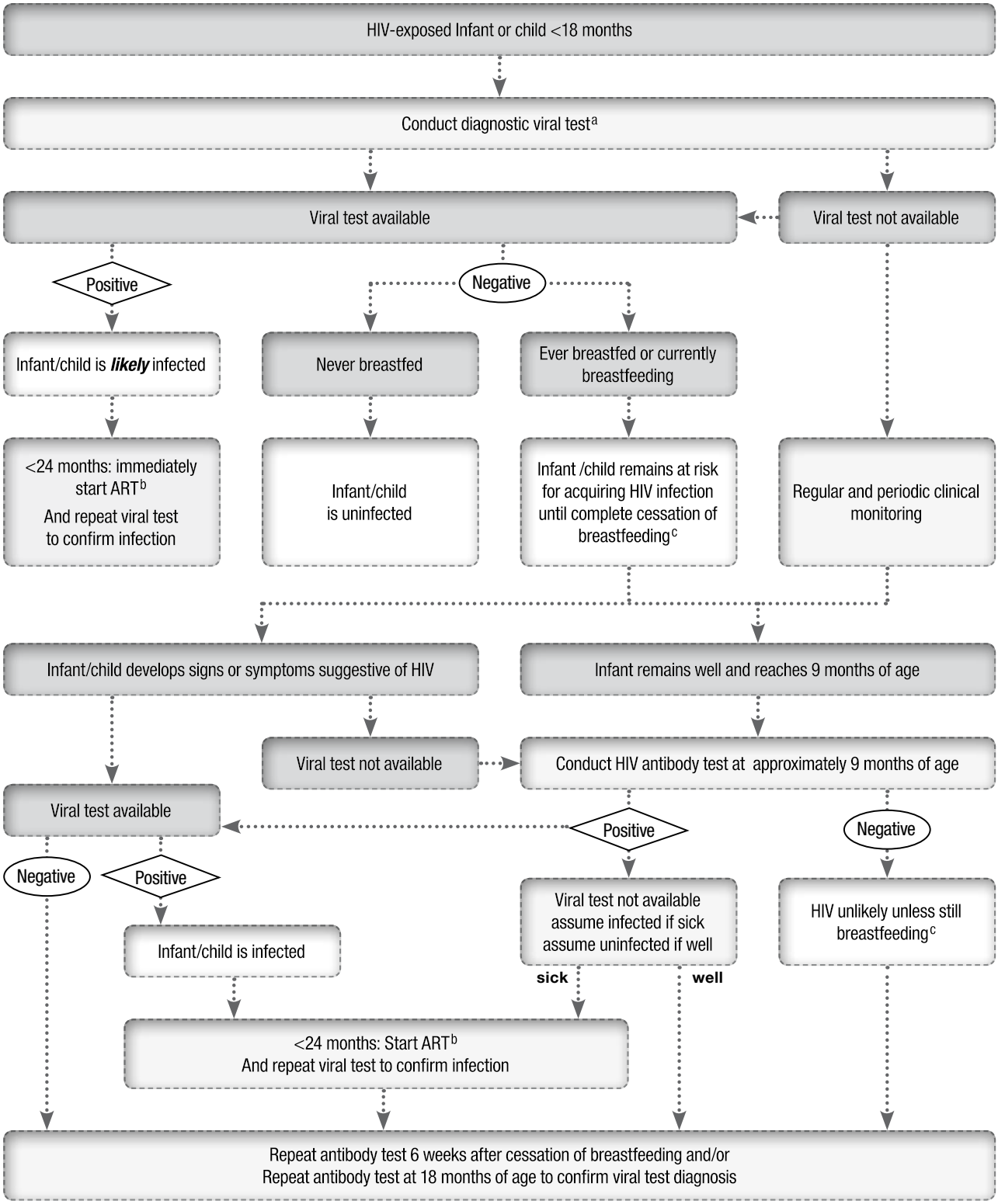
- infants and children of HIV-infected mothers (*see above*)
- malnourished/underweight infants and children
- infants and children presenting with severe, recurrent or unusual infections (severe or repeated episodes of pneumonia, severe or chronic diarrhoea, shingles, recurrent or chronic ear infection)
- infants and children with symptoms and signs of HIV (*21*)
- infants and children diagnosed with TB (*see below*)
- infants and children with siblings and/or family members who are HIV-infected
- all infants and children admitted to hospital with serious infections.

These infants and children should undergo serological testing to determine HIV exposure. Children less than 18 months of age with a reactive serological test should have a virological test to determine their HIV status. In children above 18 months of age, a reactive serological test indicates HIV infection.

- Where virological testing is unavailable, clinical algorithms along with serological testing allow for a presumptive clinical diagnosis of HIV and for initiation of ART (Algorithm 4).
- All HIV-infected infants less than 24 months of age should be started on ART regardless of their clinical and/or immunological status. This is of particular importance in children less than 12 months of age.
- All children less than 18 months of age with a presumptive clinical diagnosis of HIV (i.e. no virological confirmation) should be started on ART.
- HIV-exposed infants/children less than 18 months of age and HIV-infected children and adolescents must be initiated on co-trimoxazole prophylaxis to prevent *Pneumocystis jiroveci* (PCP) pneumonia and other infections (Algorithm 5).

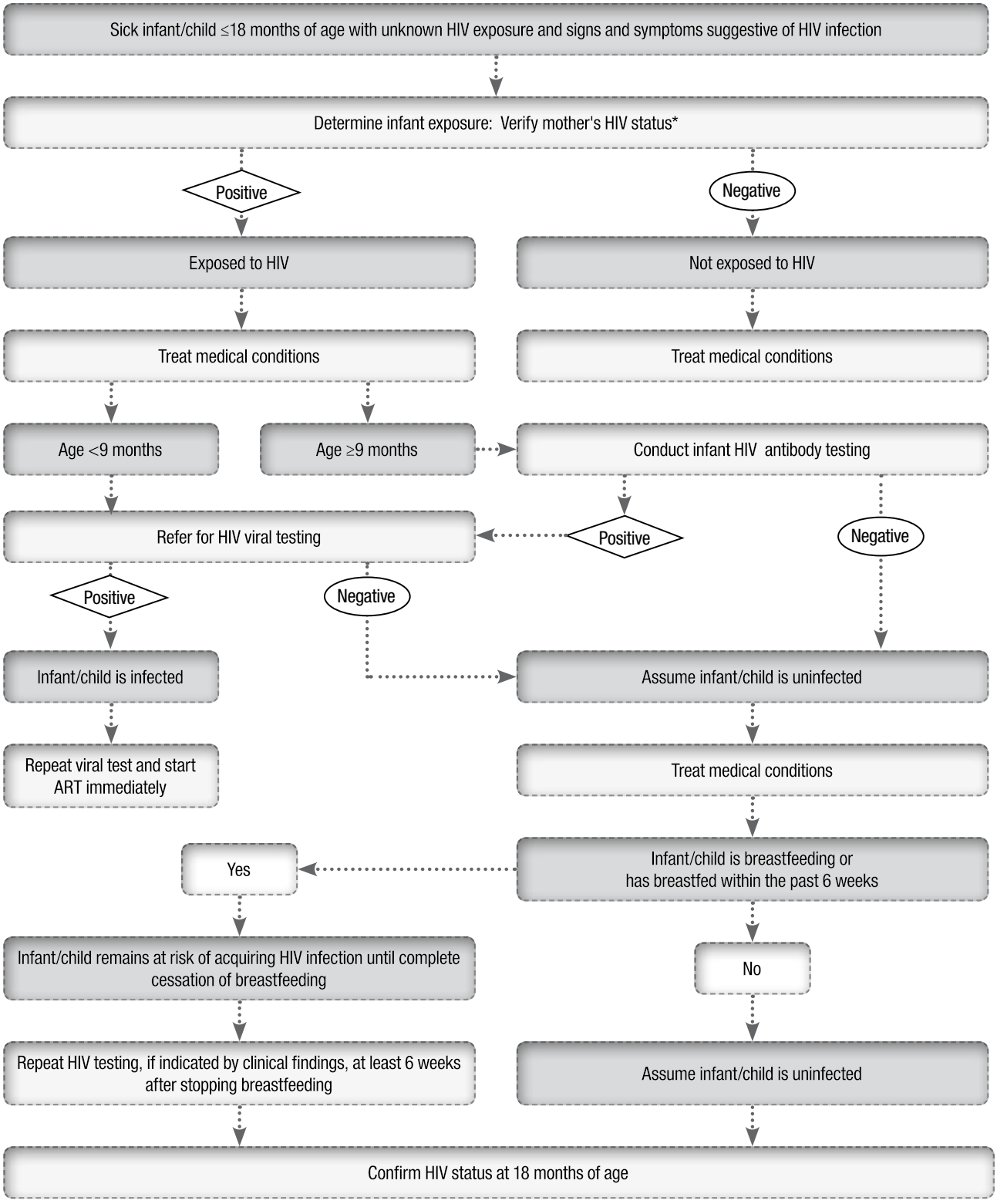
HIV-infected older children and adolescents should be staged according to the WHO clinical staging of HIV in children (Annex 2), and adults and adolescents (Annex 3). The WHO clinical stage, in conjunction with the CD4 count (immunological staging), is used to determine the timing for initiation of ART in children more than 24 months of age (Annex 4).

Algorithm 2. Establishing the presence of HIV infection in HIV-exposed infants and children less than 18 months of age in resource-limited settings



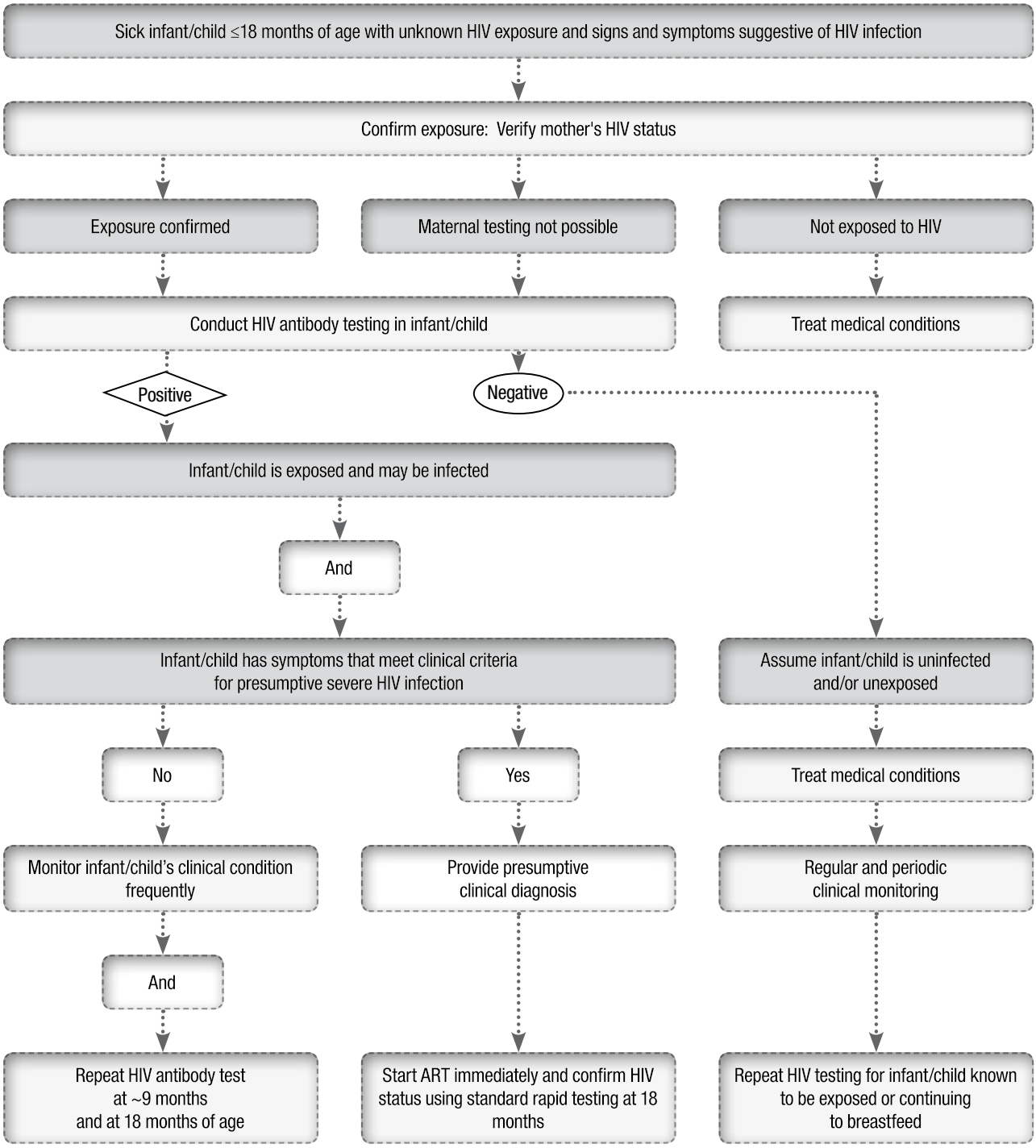
a For newborn, test first at or around birth or at the first postnatal visit (usually 4–6 weeks).
b Start ART, if indicated, without delay. At the same time, retest to confirm infection.
c The risk of HIV transmission remains as long as breastfeeding continues.

Algorithm 3. Establishing the presence of HIV infection in sick infants and children less than 18 months of age, in resource-limited settings where viral testing is available

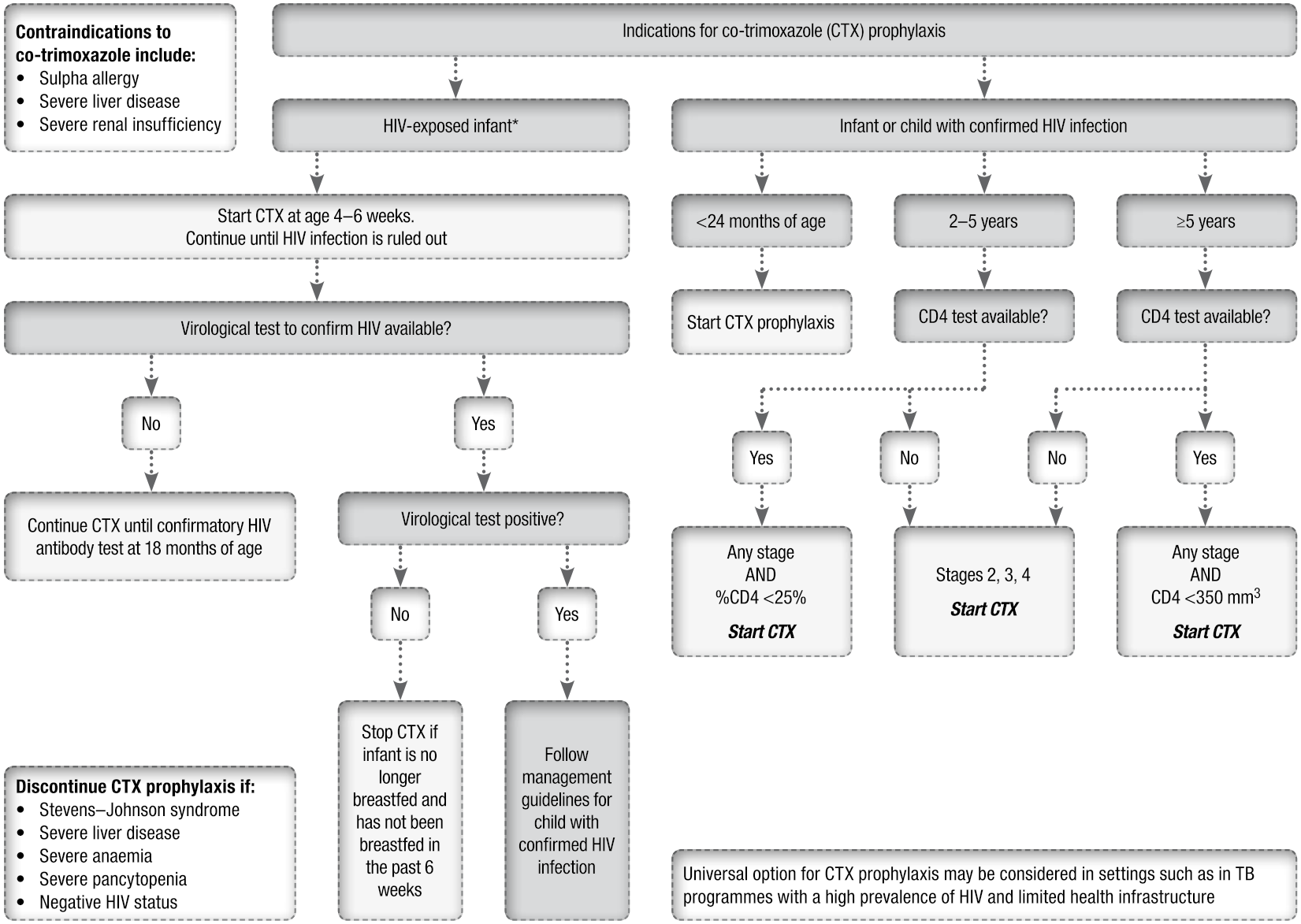


* If mother cannot be tested, then test child to determine exposure, but remember that an older infant may test negative, but if the mother is infected and breast feeding, the infant may remain at risk of acquiring HIV

Algorithm 4. Establishing the presence of HIV infection in sick infants and children less than 18 months of age, in resource-limited settings where viral testing is NOT available



Algorithm 5. Initiating co-trimoxazole prophylaxis



* An infant born to a mother infected with HIV and exposed to HIV during pregnancy, childbirth or breastfeeding

5. Infants, children and adolescents diagnosed with TB

HIV and TB coinfection is common and many areas carry a high burden of both diseases. TB can accelerate the course of HIV, and the morbidity and mortality associated with TB is often worse in cases with HIV coinfection (in adults). (*22*)

WHO recommends PITC for all patients with known or suspected TB. (*14*) In patients with TB/HIV coinfection, co-trimoxazole prophylaxis should be started immediately. ART should be started as soon as possible after the initiation of TB treatment, definitely within the first 8 weeks. ART should be started regardless of CD4 count. (*22*,*23*)

If possible, HTC should be offered at the same facility as the one the patient attends for TB treatment. Having the same health worker in the same venue administer treatment for both TB and HIV is often helpful in complying with frequent clinic visits and large numbers of drugs. (*24*,*25*)

HIV-infected infants, children and adolescents who are exposed to TB but with no evidence of active TB should be initiated on izoniazid preventive therapy (IPT).

6. Sexual and reproductive health (family planning) services

Adolescent girls may present to health services with menstrual concerns and questions, general health problems and questions or anxieties about sex, STIs, contraception and pregnancy. Boys may present for male circumcision, general health problems and concerns about sex, STIs and contraception. Even if such girls and boys are not sexually active, health-care workers should initiate discussions on pregnancy, contraception, STIs and HIV. This opportunity can be taken to advise against drug and alcohol use. The importance and benefits of knowing one's HIV status should be stressed. Adolescents presenting for contraception should be offered an HIV test as part of the consultation and counselled on safer sexual practices, consistent condom use and the need for prompt recognition and treatment of STIs. Condoms should be freely available at the clinic premises, in discrete locations.

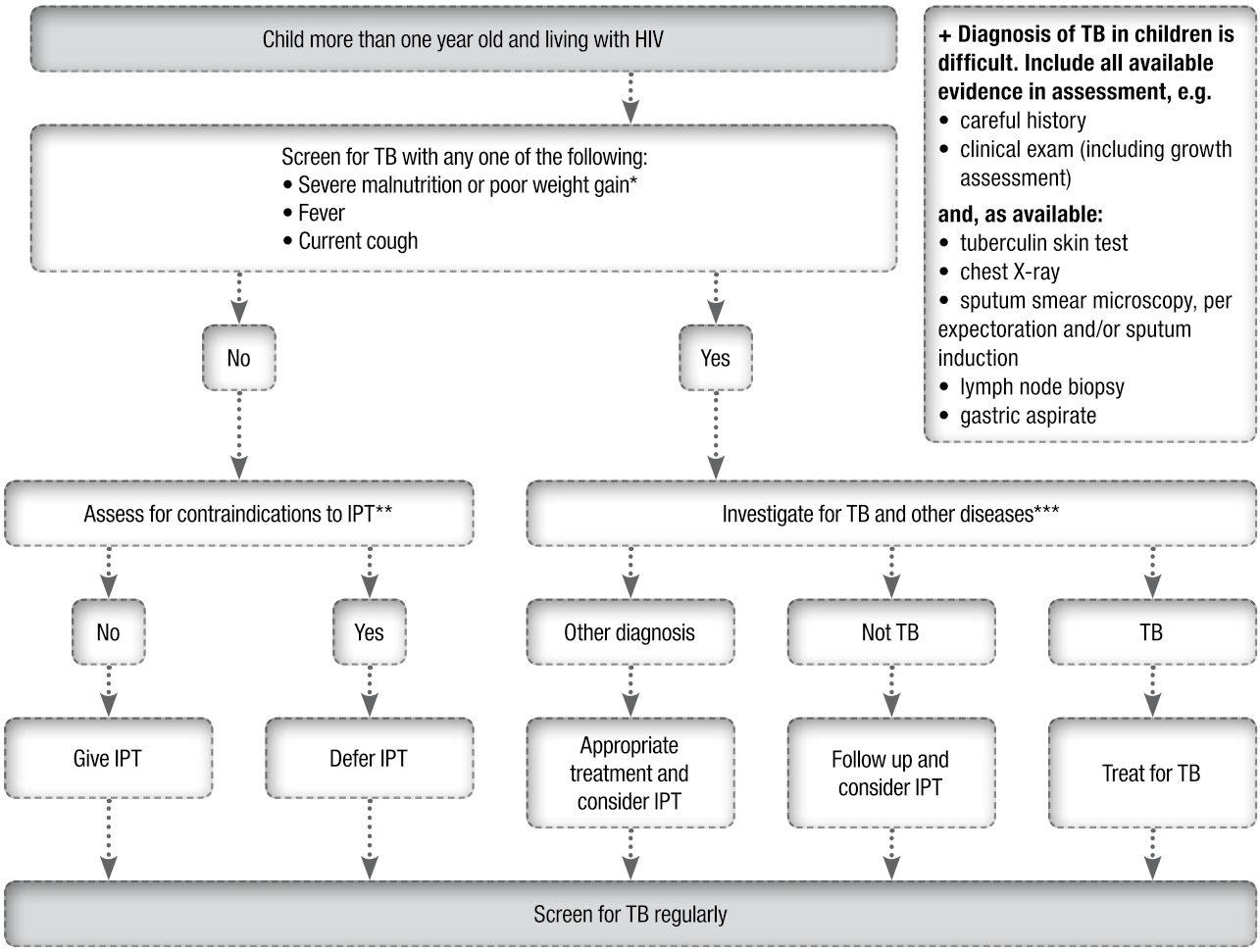
Young women who present to confirm pregnancy or who are already pregnant should be screened for STIs and offered an HIV test. The benefits of knowing one's HIV status for the individual and unborn child should be emphasized. If not pregnant, she should be counselled on how to prevent unwanted pregnancies or plan for wanted pregnancies and avoid HIV/STIs. If pregnant, she should be referred to the ANC services. This is an opportunity for health workers to recommend that she bring her partner for testing. It is possible for only one member of a couple to be HIV positive (serodiscordance); knowledge of one's status allows couples to use safer sexual practices and reduce the risk of HIV transmission to the negative partner.

Adolescent patients require specialized interventions due to a number of social and behavioural factors. Their treatment is often the same as that of adults but the manner in which it is delivered will have an impact on the success or failure of the intervention (SEE SECTION F(c.) "Special considerations: adolescent-friendly facilities").

- WHO recommends that all adolescents attending HIV, sexual and reproductive health services or family planning services receive PITC.

Children and adolescents who have been the victims of sexual assault should have a rapid test to determine HIV status. If this is negative, post-exposure prophylaxis (PEP) can be initiated and HIV testing repeated in 4–6 weeks and again at 3–6 months to determine whether HIV was acquired during the assault. (*19*) They should be referred to the appropriate facilities for medical and psychological treatment.

Algorithm 6. TB screening and IPT initiation among children living with HIV in resource-constrained settings



* Severe malnutrition as noted by signs of severe wasting, or oedema present in both feet, or weight-for-height less than -3 Z-score, or mid-upper arm circumference (MUAC) less than 115 mm in infants and children 6–60 months; 129 mm in children 5–9 years; 160 mm in children 10–14 years. Poor weight gain.

** Contraindications include active hepatitis (acute or chronic) and symptoms of peripheral neuropathy. Past history of TB is not a contraindication for starting IPT. Although not a requirement to initiate IPT, TST may be done as part of eligibility screening in some settings.

*** Per existing national guidelines.

Ensuring that all potentially exposed individuals have prompt and confidential access to PEP requires providing appropriate training for staff at all referral points: that is, frontline service providers as well as teachers, counsellors and police officers. Training programmes for these groups need to raise awareness of the availability of and rationale for HIV PEP, such that exposed individuals get to a clinic (or other place where it is available) without delay (within 72 hours of the assault. (*26*)

7. Orphans and vulnerable children

a. Orphans

An orphan is defined by the Joint United Nations Programme on HIV/AIDS (UNAIDS) as a child under 18 years of age who has lost his/her mother (maternal orphan) or both parents to death. (*27*) More details of the social circumstances of the child are required to estimate the extent of vulnerability. These include the nature of their homes; e.g. living with extended family, in foster care, child-headed households or institutional care.

It is important that children and adolescents in care facilities have access to HTC to ensure early treatment if necessary and to allow informed lifestyle decisions in the future. The guardian/caregiver may differ, depending on the laws of a country, and informed consent for HIV testing may need to be obtained from the appropriate person (social worker, foster parent), depending on the circumstances. In some countries, allowance is made for HIV testing of a minor without consent if the clinical condition is suggestive of infection with HIV and knowledge of the HIV status is in the child's best interests. (*12*)

b. Vulnerable children

The definition of the term vulnerable children is broad. It can be defined as a child who has little or no access to basic needs or rights. These rights include a right to a safe home and community environment; education; love, family care and support; sufficient food and nutrition; protection from maltreatment and neglect; protection from abuse and violence; adequate clothing and the right to make lifestyle choices. (*27*)

Vulnerable children may be at higher risk for HIV infection due to their circumstances. PITC is a priority in this group.

Health-care workers should be aware that the client may have suffered multiple losses and hardships, and may require additional care and support. If possible, the child should be accompanied by an adult with whom they have a trusting relationship. The requirements for consent and the basic principles of counselling listed above apply.

Children living in care facilities and institutions should be tested for HIV infection and provided with the appropriate treatment where necessary.

Counselling and assessing disabled children and children who have suffered trauma (e.g. sexual and/or physical abuse) require additional expertise. These children need specialized help and emotional support. Linkages to appropriate medical and psychological assessment and care are important. Disclosure to the child or adolescent who has been the victim of sexual abuse necessitates special skills and is best addressed by a trained and experienced counsellor.

8. Adult HIV testing and treatment services

Adults testing positive at HTC sites or presenting for treatment of HIV should be encouraged to bring their partners, children and other family members for testing. This is particularly true for HIV-positive mothers whose infants or young children may have been vertically infected. For convenience, this should occur ideally at the same facility attended by the adult family member, who can bring the child/children for a clinic visit.

C. Counselling for HIV testing of infants, children and adolescents

Counselling offered within HIV services should include a brief explanation on why HIV testing is appropriate, the testing methods that will be used and when to return for the result. Types of counselling offered by an HIV service would include:

1. pre-test and post-test counselling
2. adherence counselling
3. information on safer sex practices and risk reduction, advice on reproductive health (including STI) and family planning, partner and couples counselling for adolescents and emancipated minors
4. disclosure support – the content of this will vary with the age and aptitude of the child
5. information on male circumcision (adolescent males)
6. information on PMTCT (pregnant adolescent girls)
7. advice on infant-feeding and nutrition, which will depend on the age of the infant and whether or not the child is breastfed.

As mentioned before, in the case of children and young people, HIV testing is often **provider initiated** (PITC) and the parent or main caregiver of the child gives consent for the HIV test on their behalf. Depending on the national law, adolescents and some older children deemed to be sufficiently mature may give consent for an HIV test themselves. **The service provider should be aware of the legal age of consent for an HIV test in the country**. Likewise, depending on the law of the land, the presence of a parent or caregiver may not always be required to give consent for an HIV test.

Client-initiated HIV testing and counselling (CITC), where the client seeks an HIV test, is more relevant to adolescents. It is often beneficial for an adolescent to attend HTC services with a trusted adult to provide the support required.

Principles of PITC

Facilities providing HIV testing should comply with the minimum acceptable standards, which reflect the following principles: (*14*)

- All HTC is voluntary, i.e. performed with the client's informed consent. However, in the case of children, health workers can obtain authorization to conduct an HIV test without the consent of the parent or guardian this is in the best interest of the child.
- HIV test results are treated with confidentiality by all involved.
- Pre-test information describes the purpose and procedure of HIV testing, and the care, treatment and support available after testing.
- The person consenting for the test should have sufficient information and understanding to provide consent.
- Post-test information, counselling and support should be provided.
- Clients testing positive should be counselled and linked to care and follow up to ensure that they attend for assessment and treatment.
- Clients testing negative should be supported and educated to remain negative.
- Declining an HIV test will not prejudice the client's access to services.

a. Counselling parents/caregivers

Informed consent is required before all HIV testing. This can be either written or verbal, depending on national policy. Informed consent refers to an individual's ability to arrive at the decision to undergo an HIV test after having received appropriate information on the benefits of HIV testing, the testing procedure and the implications of knowing their HIV status.

As part of pre-test counselling, the counsellor should:

1. Assess the parent/caregiver's and child's knowledge of HIV and the diagnostic procedure.
2. Explain the indication and purpose of the test, and the benefits of knowing one's HIV status.
3. Explain the test/sampling procedure to the parent/caregiver and the child to allay anxiety. The parent/caregiver's help may be enlisted in the sampling procedure.
4. Provide reassurance to the parent/caregiver that confidentiality will be respected.
5. Discuss the test result (positive or negative), and provide appropriate referrals for medical follow up.
6. Give an appointment for collection of results, if necessary.
7. Encourage the parent/caregiver to learn their own status and emphasize the importance of testing for partners or other family members.

With infants and young children, it is the parent/caregiver who participates in pre- (and post-test) counselling. With older children and adolescents, the child's participation is recommended at some level.

The legal age at which a person can give informed consent varies from country to country. With respect to a minor child below 10 years of age, the parent or legal guardian may give consent because of concerns regarding the child's developmental stage and emotional maturity. In some countries this has been broadened to allow the "primary caregiver" – even if not the parent, to provide consent for an HIV test. Yet other legislation makes allowances for children above the age of 12 years, who are deemed to be mature enough to understand the implications of an HIV test, to request and give consent for testing unaccompanied. National policies and laws need to offer clear protocols that strike a balance between protecting the child's rights and ensuring their access to medical care. (*12*)

In the absence of a parent/caregiver, consent for an HIV test can be given by the representative of a designated child protection agency, the superintendent of a hospital or the children's court.

Under some circumstances, exceptions are made to the requirement for parental/caregiver consent. Situations in which it is deemed to be in the best interests of the child, a surrogate such as a health-care provider or clinic/hospital administrator can authorize an HIV test. These include:

- providing medical care in an emergency, including post-exposure prophylaxis after sexual violence
- to ensure the child's health and right to appropriate medical care.

Diagnosis and treatment should not be delayed because of the absence of a biological parent.

The skills and training required by a counsellor are applicable in all situations and include the following:

1. Empathy: the counsellor should attempt to view the situation from the parent/caregiver's and child's perspective.
2. Active listening: the counsellor should be attentive and sensitive to the client's communication (verbal and non-verbal).
3. Open and effective questioning: the counsellor should avoid "yes" and "no" answers. The counsellor's questions should prompt detailed answers.
4. Non-judgemental attitude and unconditional care: this is particularly important when dealing with adolescents.

5. Ensuring confidentiality: all discussions with the counsellor are private.

The same principles apply to post-test counselling. In all cases, it is important that clear follow-up arrangements are made (for receipt of results, continued post-test counselling, etc.). Young children will not understand the implications of a positive or negative result. With the younger age group, the focus is on the parent/caregiver and responding to their fears and anxieties. Some children with a limited knowledge of HIV may be afraid of death or illness. These anxieties must be acknowledged and the child reassured.

b. Counselling children

Counselling of children varies according to the age, understanding and level of education of the child. An informal, playful environment may help to put the family at ease. In young children, the information is given to the parent/caregiver. In older children, the purpose of the test and any procedures that need to be conducted should be explained in simple language and any questions answered. The child's cooperation is helpful during the examination and phlebotomy. Often, anxiety and fear are allayed by gentle, non-threatening aspects of the physical examination; the same level and type of explanations that are given for blood drawing for other reasons (malaria, anaemia, etc.) may be appropriate for the child. Allowing small children to examine equipment beforehand may be helpful. This is the beginning of an ongoing discussion with the child about HIV, with more detailed information and sophisticated concepts being added as the child matures.

c. Counselling adolescents

Counselling of adolescents requires a non-judgemental attitude and assurance of confidentiality. It is preferable if the client is accompanied by a trusted adult able to provide support and assimilate information. Information should be appropriate for the adolescent patient's level of understanding and education. Books and pamphlets can be provided, (*28*) which can be taken home and studied in private. Staff must be available to answer any questions at a future date.

Adolescents may have concerns about sex, current and future relationships, fear of rejection and having a family in the future. All these fears can be addressed during post-test counselling and at subsequent visits. Often, people need some time alone to assimilate a positive HIV test result, and formulate questions and concerns. The role of post-test counselling is to contain any anxieties, provide support and reassurance, and to initiate plans with respect to disclosure, and follow-up visits for treatment and counselling. (*29*)

Children and adolescents who test HIV negative must be counselled and advised on how to protect themselves to stay negative, as well as the importance of re-testing and testing with any current or future sexual partners.

Additional tools for counselling and treating adolescents are available. (*30*)

d. Disclosure

Disclosure refers to the process of informing a child about their HIV status. It also refers to a person telling others of their HIV status.

In HTC with infants and children, disclosure is an ongoing process, continuing as the child matures. The parents/caregivers must be involved, although the support of the health-care worker is often required. It is important for the child to be able to participate in their own health care.

Many parents/caregivers are reluctant to disclose the HIV test results and status to young children and often seek to postpone the discussion well into the teens. (*31*)

Reasons why parents/caregivers may be reluctant to disclose the HIV status to their children include:

1. children are too young to know about HIV and AIDS
2. children should not have to worry about illness and death
3. children need protection from stigma
4. disclosing the child's status will give away information about the parents' status
5. children may disclose the information indiscriminately
6. the parents may suffer a burden of guilt for having infected the child.

Many of these are *perceived* fears about the child's reaction exacerbated by parental guilt. However, these fears and anxieties need to be acknowledged and the benefits of disclosure for the child and family should be emphasized. While disclosure will ease the burden of secrecy, it does not resolve all the problems of living with HIV. These will need to be discussed openly with the child as concerns arise.

Table 2. Long-term benefits of disclosure to children and adolescents

Empowers the child to make choices
Communicates respect for the child and strengthens child/caregiver relationship
Allows the child to be an active participant in his/her treatment and may improve adherence
Recognizes the child's rights
Enables the child/adolescent to acquire knowledge and information about HIV and so have the confidence to cope with discrimination – this is highly age dependent
Allows the child/adolescent to seek support as the need occurs
Allows the child/adolescent to make positive life choices

Source: *Safe disclosure to children with HIV and AIDS*. The Talking Book was originally published by the Regional Psychosocial Support Initiative(REPSSI) and the European Commission Humanitarian Aid and Civil Protection (ECHO), 2007.

Table 3. Long-term benefits of disclosure to the caregiver and family

Be clear	Use words the child will understand
Be honest	Do not be afraid of saying difficult things
Use good timing	Choose the right moment; go slowly and allow for questions
Be calm	
Be child-centred	Don't give unnecessary details or blame others
Be focused	Be able to summarize important points
Be patient	Be prepared to repeat things as necessary
Be realistic	Do not raise hopes/make promises that cannot be kept
Listen	Hear and respond to the child

Source: *Safe Disclosure to Children with HIV and AIDS*. The Talking Book was originally published by REPSSI and ECHO (2007).

As with counselling, the process of disclosure must take into account the child's development and level of understanding. Disclosure is a process and the child should not be overloaded with information at one sitting.

When should the HIV status be disclosed?

It is recommended that the process of disclosure start as early as possible and that the child have an understanding of their HIV status before entering adolescence. As children approach adolescence, they begin to question parental motivation and treatment routines. Without a thorough understanding of why it is important to adhere to treatment plans, young people may stop taking their treatment. It is important that adolescents have control of their health and are empowered to make future decisions about safer sexual practices.

The family needs to be involved in disclosure with/without the health worker or counsellor. Separate support groups for parents/caregivers and children are often helpful. Within a parent/caregiver group, people are given the opportunity to discuss their own feelings, experiences and attitudes about HIV in a safe environment.

Children are often more aware of their status and treatment than their families suspect. As children enter adolescence they may resent the fact that information is being withheld and begin to resist or refuse treatment. It is not uncommon to find a child who was previously well controlled show virological failure as they enter adolescence. Disclosure, reassurance and an explanation of how HIV affects the body and how the treatment works may empower the adolescent and ensure that they take responsibility for their health as they mature.

Information and explanation of examination, the disease process and treatment can all empower young people, thereby enabling them to become active partners in protecting their own health.

There are several age-appropriate tools and texts developed by local organizations and service providers that help with the process of disclosure. The parent/caregiver should always be involved.

Table 4. General principles of disclosure of HIV status to children

Relieves the stress and anxiety that accompany secrecy and deception
Promotes normalization of the situation
Strengthens the child/caregiver relationship
Enables the family to plan together for the future
Allows easier access to services and treatment

Source: *Safe disclosure to children with HIV and AIDS*. The Talking Book was originally published by REPSSI and ECHO (2007).

D. HIV tests

Which assay should be used?

A basic knowledge of the HIV tests available and the specific indications for their use is required in order to inform clients of the testing procedures, reliability of the test and time frame for results.

Test results should be returned to the parent/caregiver as soon as possible, ideally on the same day, and no later than four weeks from the time of specimen collection in the case of virological testing.

When the client gives consent for an HIV test, the specimen should be taken immediately and the soonest possible return date for results given. Careful handling and documentation of samples is essential to prevent contamination and sample mix-ups. The sampling, labelling and packaging of each client specimen should be completed before the next one is begun. This will mitigate confusion and mistakes, and ensure that clients receive an accurate result.

HIV is diagnosed in adults and children older than 18 months by testing the blood for antibodies to HIV (i.e. testing the body's response to HIV). Antibody tests can indicate HIV exposure but **do not confirm HIV infection** in infants and children less than 18 months of age. *In utero*, the mother's antibodies pass across the placenta to the baby, and persist in the infant for several months, providing protection as the infant's own immune system develops. Consequently, HIV antibody tests in infants may detect *maternal antibodies* which can persist for up to 18 months, giving an erroneous positive result. Confirmation of HIV infection in children up to the age of 18 months requires testing for the viral products of HIV (virological assays). However, when virological testing is unavailable, a presumptive clinical diagnosis of HIV infection in infants and children less than 18 months of age can made based on clinical algorithms and serological testing (Algorithm 4).

a. Antibody tests/serological assays

These tests are based on the detection of antibodies to HIV, i.e. they detect the body's immune response to HIV. With serological assays there is a "window period" between the time of infection and a positive test. This delay is due to the time taken for antibodies against HIV to develop.

WHO recommends that serological tests used for HIV diagnosis have a sensitivity of 99% and a specificity of 98% under quality-assured, standardized and validated laboratory conditions. (*32*)

In children less than 18 months of age, antibody tests can be used as a screening assay to determine **HIV exposure**. They cannot be used to make a definitive diagnosis of HIV infection at this age as a positive result may represent maternal antibodies still present in the baby's blood. However, in settings where virological testing is not available, clinical algorithms along with serological testing allow for a presumptive clinical diagnosis of HIV and initiation of ART (Algorithm 4).

In children above the age of 18 months, HIV antibody tests can be used as a diagnostic assay (i.e. in children, adolescents and adults).

A number of HIV antibody tests exist in the market, and the most suitable products should be identified according to national and programme circumstances. (*32*) Testing approaches (*see* Annex 5) show the HIV tests required for different testing purpose, and the subsequent action to be taken.

Two types of antibody tests are commonly used:

1. HIV enzyme-linked immunosorbent assay (ELISA)

ELISA is the current gold standard for the diagnosis of HIV in children above 18 months of age. It detects antibodies to HIV. The newer, fourth-generation ELISAs detect both antibodies and HIV p24 antigen, thereby shortening the window period. The assays are performed in the laboratory and require specialized staff and equipment. Transport of whole blood to the laboratory is required, which often leads to a delay in receiving the result (*see* annex for Tool 1: collection of blood sample from children by venipuncture). This method of testing may be of use in sites with high patient numbers or those for testing of inpatients. The results are not usually available on the same day in most resource-limited settings where this testing modality is available.

2. HIV rapid tests

HIV rapid tests work on the same principle as the ELISA but do not require specialized staff or equipment. Results are available within 10–30 minutes depending on the assay used, and can be given on the same day. Venous or capillary blood (or plasma or serum) can be used, and a finger- or heel-prick is all that is required. Most kits contain the necessary reagents and can be stored at room temperature. The expiry date must be checked and *the reagent and test must be from the same kit*. These tests have been extensively used in resource-limited settings allowing for same-day provision of results to patients. Training of health-care providers and quality control are critical as HIV testing extends to multiple entry points in a health-care facility. Clear and available standard operating procedures (SOPs) are needed at all points where this type of testing is offered in a facility.

HIV rapid tests must be validated by the relevant national reference laboratory as part of a national testing programme.

The entire process of HIV testing, from pre-test information and education to the collection and processing of specimens and record-keeping, should follow the steps stipulated in the SOPs of the facility.

b. Virological assays

HIV viral products are detected by HIV DNA and RNA assays and the ultrasensitive assay to detect p24 antigen (Up24Ag). These are indicated for the diagnosis of HIV infection in infants and children less than 18 months of age. (*32*)

The sensitivity of virological assays depends on the timing of the test and the particular assay/technology used. In infants infected *in utero* (i.e. infection transmitted during pregnancy and before birth), virological assays may be positive at birth. In infections acquired perinatally (i.e. during labour and delivery), the assays may become positive only some weeks after birth. The sensitivity and specificity of current virological assays at 6 weeks of age is discussed below. As newer technologies become available, these will need to be evaluated for their efficacy at various time points in the African setting. (A more detailed explanation of the methodology of virological assays and quality control can be found in the *WHO Recommendations on the diagnosis of HIV in infants and children*. (*32*))

Virological assays (i.e. HIV DNA PCR, HIV RNA PCR and Up24Ag) can be performed on dried blood spots (DBS) or whole blood and require a specialized laboratory and equipment. Their sensitivity and specificity depend on the timing of the test. At 6 weeks of age, the sensitivity of HIV DNA PCR is 95¬–98% and specificity 98% under quality-assured, standardized and validated laboratory conditions. This is the recommended test for infant diagnosis at, or after, 6 weeks of age and will diagnose 95% of infants infected *in utero* and intrapartum. (*33*,*34*,*35*)

HIV RNA PCR assay can also be used to diagnose HIV infection. It is primarily used to measure viral load (quantitative assay). Viral load can be useful in determining when to start ART and for monitoring the client's response to treatment.

Up24Ag assays can be used as an alternative to HIV DNA and RNA PCR for the diagnosis of HIV in areas with limited laboratory facilities. (*36*,*37*)

All the above virological assays can be performed on DBS. DBS sampling does not require a specialist paediatric phlebotomist and the technique is easily learnt. A drop of blood from a finger/toe- or heel-prick is transferred directly onto a filter paper card (*see annex* for Tool 2). Only a small volume of blood is required and the dried samples are easy to store and transport to the laboratory.

Individual packs for each client specimen can be prepared (Tool 4). Each pack should comprise:

- DBS filter paper with space for labelling
- alcohol wipe for cleaning the heel/toe/finger
- lancet

DBS must be kept dry and caution must be taken to avoid cross-contamination and labelling errors. They are transported by mail or courier to specialized testing facilities. The assays are performed in the laboratory and required specialized staff and equipment. Consistent quality assurance is required.

The nature of virological assays and the need for transport to a specialized laboratory means that there is often a delay in receiving the results. WHO recommends a maximum of four weeks between HIV testing and giving the result.

- It is strongly recommended that all HIV-exposed infants have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter. In settings where virological testing is not available, clinical algorithms along with serological testing allow for a presumptive clinical diagnosis of HIV and for initiation of ART (Algorithm 4).

If the virological assay is POSITIVE, the child should be referred for treatment as soon as possible (see section E. Importance of referral for HIV treatment and care for infants, children and adolescents) and a second sample sent for virological testing as confirmation. **Treatment should not be delayed while waiting for the result of the confirmatory test.**

E. Importance of referral for HIV treatment and care for infants, children and adolescents

Once HIV has been diagnosed in a child or adolescent, appropriate referral is essential. Ideally, testing and treatment should be offered at the same site. The health-care provider should ensure that HIV-infected children are followed up by:

- preferably giving a specific date for a follow-up appointment
- providing a map to the referral site
- calling the referral site to inform them of the patient's appointment
- giving a referral slip.

Table 5. Criteria for ART Initiation in specific populations

Target population	Clinical condition	Recommendation
Asymptomatic individuals (including pregnant women)	WHO clinical stage 1	Start ART if CD4 ≤ 350
Symptomatic individuals (including pregnant women)	WHO clinical stage 2	Start ART if CD4 ≤350
	WHO clinical stage 3 or 4	Start ART irrespective of CD4 cell count
TB and hepatitis B coinfections	Active TB disease	Start ART irrespective of CD4 cell count
	HBV infection requiring treatment*	Start ART irrespective of CD4 cell count

* The current standard definition of chronic active hepatitis in industrialized countries is mainly based on histological parameters obtained by liver biopsy, a procedure not usually available in the large majority of resource-limited settings. A global definition of chronic active hepatitis for resource-limited settings based on clinical and more simple laboratory parameters is under discussion.

Source: *Antiretroviral Therapy for HIV Infection in Adults ad Adolescents. Recommendations for a public health approach. 2010 revision*. WHO 2010.

Table 6. Preferred first-line ART in treatment-naive adults and adolescents

Target population	Preferred options	Comments
Adults and adolescents	AZT or TDF + 3TC or FTC + EFV or NVP	Select the preferred regimens applicable to the majority of PLHIV Use fixed-dose combinations
Pregnant women	AZT + 3TC + EFV or NVP	Do not initiate EFV during first trimester TDF acceptable option In HIV+ women with prior exposure to PMTCT regimens, see WHO ART recommendations 2010
HIV/TB coinfection	AZT or TDF + 3TC or FTC + EFV	Initiate ART as soon as possible (within the first 8 weeks) after starting TB treatment NVP or triple NRTIs are acceptable options if EFV cannot be used
HIV/HBV coinfection	TDF + 3TC or FTC + EFV or NVP	Consider HBsAg screening before starting ART, especially when TDF is not the preferred first-line NRTI Use of two ARVs with anti-HBV activity required

F. SPECIAL CONSIDERATIONS

a. Infant feeding

Feeding choices should ideally be discussed with women before delivery, i.e. as part of the ANC service.

Feeding choices presented to HIV-infected mothers should support the greatest likelihood of HIV-free survival for their children. It is now recommended that the national authorities in each country decide on which infant-feeding practice to promote, supported by the health services (i.e. exclusive breastfeeding with ARV cover or replacement feeding). Depending on the circumstances, prevention of HIV transmission must be balanced with the need to meet the nutritional requirements of the child, and prevent non-HIV related morbidity and mortality.

- Where national PMTCT policy provides ARVs to breastfeeding women, it is recommended that women breastfeed exclusively for six months and then continue to breastfeed along with solids to the child for 12 months. Weaning away from breast milk should be done gradually over one month. Infant ARV prophylaxis should be continued for one week after cessation of breastfeeding.
- Breastfeeding should NOT be discontinued for the purposes of testing or treatment. Breastfed infants who test negative at 4–6 weeks of age must have a second HIV test six weeks after discontinuation of breast-feeding to exclude/confirm postnatal HIV transmission.

In infants known to be HIV positive, breastfeeding can be continued for up to two years or more.

Avoidance of all breastfeeding and use of replacement feeds (milk formula) can be recommended if the social and economic environment supports safe and sufficient feeding. Acceptable, feasible. affordable, sustainable and safe (AFASS) criteria have been previously used. Practically, the HIV prevalence and local causes of infant morbidity and mortality need to be considered, as the benefits of replacement feeding (low likelihood of postnatal HIV transmission) must outweigh its risks (possible increased incidence of diarrhoeal diseases, malnutrition, risk of mixed feeding in the first six months, which increases the risk of transmission). The family needs to have access to clean water and sanitation, and a reliable supply of formula. There must be facilities for frequent cleaning of bottles and preparation of feeds, and access to comprehensive health-care services. It is important that the family and community are supportive of replacement feeding, which is often questioned when the mother has not disclosed her HIV status.

Table 7. Conditions need to safely formula feed

a. safe water and sanitation are assured at the household level and in the community
b. the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant, and;
c. the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition, and;
d. the mother or caregiver can, in the first 6 months, exclusively give infant formula milk, and;
e. the family is supportive of this practice, and;
f. the mother or caregiver can access health care that offers comprehensive child health services

Taken from *Guidelines on HIV and Infant feeding*. WHO 2010.

Recommendations 1– 7. *Guidelines on HIV and infant feeding*. WHO, 2010 (*38*)

Recommendation 1. Ensuring mothers receive the care they need
Mothers known to be HIV-infected should be provided with lifelong ART or ARV prophylaxis interventions to reduce HIV transmission through breastfeeding according to WHO recommendations.
Recommendation 2. Which breastfeeding practices and for how long
In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions. Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.
Recommendation 3. When mothers decide to stop breastfeeding
In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.
Recommendation 4. What to feed infants when mothers stop breastfeeding
In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development.
Recommendation 5. Conditions needed to safely formula feed
Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV-uninfected infants or infants who are of unknown HIV status, when specific conditions[1] are met. a. safe water and sanitation are assured at the household level and in the community; and b. the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; and c. the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition; and d. the mother or caregiver can, in the first six months, exclusively give infant formula milk; and e. the family is supportive of this practice; and f. the mother or caregiver can access health care that offers comprehensive child health services.
Recommendation 6. Heat-treated, expressed breast milk
Mothers known to be HIV-infected may consider expressing and heat-treating breast milk as an *interim feeding strategy*: in special circumstances such as when the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; **or** when the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; **or** to assist mothers to stop breastfeeding; **or** if antiretroviral drugs are temporarily not available.
Recommendation 7. When the infant is HIV-infected
If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding as per the recommendations for the general population, that is, up to two years or beyond.

1. These conditions were referred to as AFASS in the 2006 WHO recommendations on HIV and infant feeding

b. Child- and family-friendly facilities

Paediatric services usually form part of the regular health services at a given facility. If possible, a separate waiting area should be provided for children where they are contained and safe, and able to play and explore. As with all medical and HIV services, privacy and confidentiality must be ensured, with separate counselling and examination rooms. Health-care workers who are identified as being good with children or have been specifically trained in paediatrics should staff the clinic. Counsellors may require special training to provide age-appropriate counselling and be sensitive to non-verbal communication. Children and their parents/caregivers should feel able to ask questions. Medical procedures (phlebotomy, injections) should be explained to the child to allay anxiety. Toys can be used to demonstrate any procedures that need to be performed.

Ideally, the additional services required (e.g. immunizations, nutritional advice, medical care, social support) should be located nearby (within the same facility) and accessible on the day of the consultation.

c. Adolescent-friendly facilities

Adolescent-friendly health services should be able to respond effectively to the specific needs of adolescents by being accessible, acceptable and appropriate.

Adolescence is a phase in life during which major physical, psychological and social changes occur. It is during this period that much negative behaviour is established, which may have health implications for the client. By providing a safe, non-judgemental environment, health workers can identify and attempt to modify risky behaviour and provide information, counselling and clinical services.

Treatment of adolescents is often the same as that for adults but the manner in which it is delivered will have an impact on the success or failure of the intervention.

Adolescents are often acutely aware of being identified by friends and community members as being HIV positive. If possible, adolescents should be able to attend the clinic on certain days or at specific times or have a separate waiting area. It would be ideal if all services were available at one venue (e.g. STI treatment, contraception, male circumcision services). Confidentiality must be ensured. Staff who are skilled at dealing with young people should be identified and supported. It is essential to have a non-judgemental approach, with emphasis on educating and empowering young people to prevent pregnancy and STIs, and to avoid drug and alcohol use. Promotion of consistent condom use at every opportunity is vital. **Adolescent volunteers and peer support groups may be helpful.**

Many adolescents are reluctant to disclose information or ask questions in the presence of their parents and caregivers. They should be seen alone, if they wish, and must be reassured that all discussions are confidential. In the context of HIV or other serious health problems, an adolescent should be encouraged to disclose to or bring a trusted adult to the consultation to provide support.

A successful adolescent-friendly facility will ensure that clients return when they need to and will recommend the service to their friends.

Table 8. What to do and what to avoid when communicating with adolescents

DO	AVOID
• Be **truthful** about what you know and what you do not know.	• Giving inaccurate information (to scare them or to make them "behave").
• Be **professional** and be technically competent	• Threatening to break confidentiality "for their own good"
• Use words and concepts to which they can understand and relate to. Assess if they **understand** • Use pictures and flipcharts to explain	• Giving them only the information that *you* think they will understand • Using medical terms they will not understand.
• Treat them with **respect** in terms of how you speak and how you act	• Talking down to them, shouting, getting angry, or blaming them
• Give all the information/choices and then help **them decide** what to do.	• Telling them what to do because you know best and they "are young".
• Treat all adolescents **equally** • Be understanding and supportive even if you do not approve of their behaviour.	• Being judgemental about their behaviour, showing disapproval, imposing your own values
• **Accept** that they may choose to show their individuality in dress or language.	• Being critical of their appearance or behaviour unless it relates to their health or well-being.Older than 18 months: serological assay (HIV rapid test or HIV ELISA)
Life skills An important part of normal adolescent development is learning life skills. Life skills include problem solving, critical thinking, communication, interpersonal skills, resolving conflict and coping with emotions. Health workers cannot teach adolescents the full range of life skills as they neither have the time nor the capacity to do this. But, they should know where life skills are taught in the community, so that they can refer adolescents living with HIV to them and support the programmes. However teaching adolescents life skills that relate to specific health issues (e.g. how to delay sexual debut, how to negotiate safe sex, and how to use a male and female condom correctly) is part of the health worker's responsibility. Such skills help adolescents deal with the difficult challenges of being an adolescent and living with HIV.	

Source: *IMAI one-day Orientation on Adolescents living with HIV*. WHO 2010. http://www.who.int/child_adolescent_health/documents/fch_cah_9789241598972/en/ accessed 2 February 2011).

Annex 1. Symptoms and signs suggestive of HIV infection (age-appropriate HIV testing is required)

HISTORY
• Parent/sibling/family member HIV infected • Death of parent/sibling • Recurrent upper respiratory tract infection (e.g. ear infections, tonsillitis, sinusitis) • Recurrent diarrhoea • Previous hospitalization for pneumonia • Two or more hospitalizations in one year (not for pneumonia) • Poor growth • History of TB in the family or child • HIV testing history
EXAMINATION
• Failure to thrive (poor weight for age) • Any malnutrition • Delayed developmental milestones • Persistent generalized lymphadenopathy (not inguinal) • Painless bilateral parotid swelling • Recurrent or persistent oral thrush • Any persistent or recurrent mouth ulcers or infections • Herpes simplex virus oral ulcers >4 weeks • Chronic suppurative otitis media (discharging ears) • Persistent skin conditions (seborrhoeic dermatitis, extensive molluscum contagiosum or warts, fungal nail infections) • Enlarged liver and spleen • Herpes zoster infection (shingles) or scarring from previous infection • Persistent or recurrent diarrhoea (>2 weeks) not responding to appropriate treatment • Persistent unexplained fever (>4 weeks) • Anaemia, low platelet and low white cell counts • Severe pneumonia • Recurrent bacterial pneumonia • Any tuberculosis infection • Chronic lung disease • *Pneumocystis jiroveci* pneumonia (PCP) • Cryptococcal disease • Invasive Salmonella infection • Kaposi sarcoma • Lymphoma • Genital fistula • Toxoplasmosis

Annex 2. WHO clinical staging of HIV for infants and children with established HIV infection

All clinical events or conditions referred to are described in Table 4a

Clinical stage 1
Asymptomatic Persistent generalized lymphadenopathy
Clinical stage 2
Unexplained persistent hepatosplenomegaly Papular pruritic eruptions Extensive wart virus infection Extensive molluscum contagiosum Recurrent oral ulcerations Unexplained persistent parotid enlargement Lineal gingival erythema Herpes zoster Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) Fungal nail infections
Clinical stage 3
Unexplained moderate malnutrition not adequately responding to standard therapy Unexplained persistent diarrhoea (14 days or more) Unexplained persistent fever (above 37.5 ºC, intermittent or constant, for longer than one month) Persistent oral *Candidiasis* (after first 6 weeks of life) Oral hairy leukoplakia Acute necrotizing ulcerative gingivitis/periodontitis Lymph node TB Pulmonary TB Severe recurrent bacterial pneumonia Symptomatic lymphoid interstitial pneumonitis Chronic HIV-associated lung disease including bronchiectasis Unexplained anaemia (<8.0 g/dl), neutropenia (<$0.5x10^9/L^3$) or chronic thrombocytopenia (<$50 \times 10^9/L^3$)
Clinical stage 4[1]
Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy Pneumocystis pneumonia Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration, or visceral at any site) Extrapulmonary TB Kaposi sarcoma Oesophageal candidiasis (or candiadisis of trachea, bronchi or lungs) Central nervous system toxoplasmosis (after the neonatal period) HIV encephalopathy Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age more than 1 month Extrapulmonary cryptococcosis including meningitis Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis) Chronic cryptosporidiosis (with diarrhoea) Chronic isosporiasis Disseminated non-tuberculous mycobacterial infection Cerebral or B cell non-Hodgkin lymphoma Progressive multifocal leukoencephalopathy HIV-associated cardiomyopathy or nephropathy

1. Some additional specific conditions can be included in regional classifications (e.g. penicilliosis in Asia, HIV-associated rectovaginal fistula in Southern Africa, reactivation of typanosomiasis in Latin America). Ref: http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf

Presumptive and definitive criteria for recognizing HIV-related clinical events in infants and children with established HIV infection

Clinical event	Clinical diagnosis	Definitive diagnosis
Stage 1		
Asymptomatic	No HIV-related symptoms reported and no clinical signs on examination	Not applicable
Persistent generalized lymphadenopathy (PGL)	Persistent swollen or enlarged lymph nodes >1 cm at two or more non-contiguous sites, excluding inguinal, without known cause	Clinical diagnosis
Stage 2		
Unexplained persistent hepatosplenomegaly	Enlarged liver and spleen without obvious cause	Clinical diagnosis
Papular pruritic eruptions	Papular pruritic vesicular lesions	Clinical diagnosis
Fungal nail infections	Fungal paronychia (painful, red and swollen nail bed) or onycholysis (painless separation of the nail from the nail bed). Proximal white subungual onychomycosis is uncommon without immunodeficiency.	Clinical diagnosis
Angular cheilitis	Splits or cracks on the lips at the angle of the mouth with depigmentation, usually responding to antifungal treatment but may recur	Clinical diagnosis
Lineal gingival erythema (LGE)	Erythematous band that follows the contour of the free gingival line; may be associated with spontaneous bleeding	Clinical diagnosis
Extensive wart virus infection	Characteristic warty skin lesions; small fleshy grainy bumps, often rough, flat on sole of feet (plantar warts); facial, more than 5% of body area or disfiguring	Clinical diagnosis
Extensive molluscum contagiosum infection	Characteristic skin lesions: small flesh-coloured, pearly or pink, dome-shaped or umbilicated growths, may be inflamed or red; facial, more than 5% of body area or disfiguring. Giant molluscum may indicate advanced immunodeficiency.	Clinical diagnosis
Recurrent oral ulcerations (two or more in six months)	Aphthous ulceration, typically with a halo of inflammation and yellow-grey pseudomembrane	Clinical diagnosis
Unexplained parotid enlargement	Asymptomatic bilateral swelling that may spontaneously resolve and recur, in absence of other known cause; usually painless	Clinical diagnosis
Herpes zoster	Painful rash with fluid-filled blisters, dermatomal distribution, may be haemorrhagic on erythematous background, and may become large and confluent. Does not cross the midline.	Clinical diagnosis
Recurrent upper respiratory tract infection (URTI)	Current event with at least one episode in past six months. Symptom complex: fever with unilateral face pain and nasal discharge (sinusitis) or painful swollen eardrum (otitis media), sore throat with productive cough (bronchitis), sore throat (pharyngitis) and barking croup-like cough (laryngotracheal bronchitis [LTB]), persistent or recurrent ear discharge	Clinical diagnosis

Clinical event	Clinical diagnosis	Definitive diagnosis
Stage 3		
Unexplained moderate malnutrition	Weight loss: low weight-for-age, up to -2 standard deviations (SDs), not explained by poor or inadequate feeding and/or other infections, and not adequately responding to standard management	Documented loss of body weight of -2 SD, failure to gain weight on standard management and no other cause identified during investigation
Unexplained persistent diarrhoea	Unexplained persistent (14 days or more) diarrhoea (loose or watery stool, three or more times daily) not responding to standard treatment	Stools observed and documented as unformed. Culture and microscopy reveal no pathogens.
Unexplained persistent fever (intermittent or constant for longer than one month)	Reports of fever or night sweats for longer than one month, either intermittent or constant, with reported lack of response to antibiotics or antimalarials. No other obvious foci of disease reported or found on examination. Malaria must be excluded in malarious areas.	Documented fever of >37.5 ºC with negative blood culture, negative malaria slide and normal or unchanged CXR, and no other obvious foci of disease
Oral candidiasis (after first 6 weeks of life)	Persistent or recurring creamy white, soft, small plaques which can be scraped off (pseudomembranous), or red patches on tongue, palate or lining of mouth, usually painful or tender (erythematous form)	Microscopy or culture
Oral hairy leukoplakia	Fine small, linear patches on lateral borders of tongue, generally bilateral, which do not scrape off	Clinical diagnosis
Lymph node TB	Non-acute, painless “cold” enlargement of lymph nodes, usually matted, localized in one region. May have draining sinuses. Response to standard anti-TB treatment in one month.	Histology or isolation of M. tuberculosis from fine needle aspirate
Pulmonary TB	Non-specific symptoms, e.g. chronic cough, fever, night sweats, anorexia and weight loss. In older children, productive cough and haemoptysis as well. Abnormal CXR.	Isolation of M. tuberculosis on sputum culture
Severe recurrent bacterial pneumonia	Cough with fast breathing, chest indrawing, nasal flaring, wheezing and grunting. Crackles or consolidation on auscultation. Responds to course of antibiotics. Current episode plus one or more in previous six months.	Isolation of bacteria from appropriate clinical specimens (induced sputum, bronchoalveolar lavage [BAL], lung aspirate)
Acute necrotizing ulcerative gingivitis or stomatitis, or acute necrotizing ulcerative periodontitis	Severe pain, ulcerated gingival papillae, loosening of teeth, spontaneous bleeding, bad odour, and rapid loss of bone and/or soft tissue	Clinical diagnosis
Symptomatic lymphoid interstitial pneumonitis (LIP)	No presumptive clinical diagnosis	CXR: bilateral reticulonodular interstitial pulmonary infiltrates present for more than two months with no response to antibiotic treatment and no other pathogen found. Oxygen saturation persistently <90%. May present with cor pulmonale and may have increased exercise-induced fatigue. Characteristic histology.

Clinical event	Clinical diagnosis	Definitive diagnosis
Chronic HIV-associated lung disease (including bronchiectasis)	History of cough productive with copious amounts of purulent sputum (bronchiectasis only), with or without clubbing, halitosis, and crepitations and/or wheeze on auscultation	CXR: may show honeycomb appearance (small cysts) and/or persistent areas of opacification and/or widespread lung destruction, with fibrosis and loss of volume.
Unexplained anaemia (<8 g/dl), or neutropenia (<0.5 x 10^9/L) or chronic thrombocytopenia (<50 X 10^9/L)	No presumptive clinical diagnosis	Laboratory testing, not explained by other non-HIV conditions, or not responding to standard therapy with haematinics, antimalarials or anthelminthics as outlined in the IMCI.
Stage 4		
Unexplained severe wasting, stunting or severe malnutrition not adequately responding to standard therapy	Persistent weight loss not explained by poor or inadequate feeding or other infections and not adequately responding in two weeks to standard therapy. Characterized by: visible severe wasting of muscles, with or without oedema of both feet, and/ or weight-for-height of -3 SDs, as defined by the WHO IMCI guidelines	Confirmed by documented weight loss of >-3 SD +/- oedema
Pneumocystis pneumonia (PCP)	Dry cough, progressive difficulty in breathing, cyanosis, tachypnoea and fever; chest indrawing or stridor. (Severe or very severe pneumonia as in IMCI.) Usually of rapid onset especially in infants <6 months of age. Response to high-dose co-trimoxazole +/- prednisolone	Confirmed by: CXR, typical bilateral perihilar diffuse infiltrates; microscopy of induced sputum or BAL or nasopharyngeal aspirate (NPA)
Recurrent severe bacterial infection, e.g. empyema, pyomyositis, bone or joint infection, meningitis but excluding pneumonia	Fever accompanied by specific symptoms or signs that localize infection. Responds to antibiotics. Current episode plus one or more in previous six months.	Confirmed by culture of appropriate clinical specimen
Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration or visceral at any site)	Severe and progressive painful orolabial, genital, or anorectal lesions caused by HSV infection present for more than one month	Confirmed by culture and/or histology
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)	Chest pain and dysphagia (difficulty in swallowing), odynophagia (pain on swallowing food and fluids) or retrosternal pain worse on swallowing (food and fluids); responds to specific treatment. In young children, suspect particularly if oral *Candida* observed and food refusal occurs and/or difficulties/crying when feeding.	Confirmed by macroscopic appearance at endoscopy, microscopy of specimen from tissue or macroscopic appearance at bronchoscopy or histology
Extrapulmonary/disseminated TB	Systemic illness usually with prolonged fever, night sweats, weight loss. Clinical features of organs involved, e.g. sterile pyuria, pericarditis, ascites, pleural effusion, meningitis, arthritis, orchitis	Positive microscopy showing AFB or culture of *Mycobacterium tuberculosis* from blood or other relevant specimen except sputum or BAL. Biopsy and histology

Clinical event	Clinical diagnosis	Definitive diagnosis
Kaposi sarcoma	Typical appearance in skin or oropharynx of persistent, initially flat, patches with a pink or blood-bruise colour, skin lesions that usually develop into nodules	Macroscopic appearance or by histology: • typical red-purple lesions seen on bronchoscopy or endoscopy; • dense masses in lymph nodes, viscera or lungs by palpation or radiology; • histology
CMV retinitis or CMV infection affecting another organ, with onset at age >1 month	Retinitis only CMV retinitis may be diagnosed by experienced clinicians: progressive floaters in field of vision, light flashes and scotoma; typical eye lesions on serial fundoscopic examination; discrete patches of retinal whitening with distinct borders, spreading centrifugally, often following blood vessels, associated with retinal vasculitis, haemorrhage and necrosis	Definitive diagnosis required for other sites. Histology or CMV demonstrated in CSF by culture or DNA-PCR
CNS toxoplasmosis with onset at age >1 month	Fever, headache, focal neurological signs, convulsions. Usually responds within 10 days to specific therapy.	Postive serum *Toxoplasma* antibody and if available, neuroimaging showing single/ multiple intracranial mass lesions
Extrapulmonary cryptococcosis including meningitis	Meningitis: usually subacute, fever with increasing severe headache, meningism, confusion, behavioural changes that respond to cryptococcal therapy	Isolation of *Crytococcus neoformans* from extrapulmonary site or positive cryptococall antigen test (CRAG) in CSF or blood.

Ref: http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf

Annex 3. WHO clinical staging of HIV disease in adults and adolescents

Clinical stage 1
Asymptomatic Persistent generalized lymphadenopathy
Clinical stage 2
Moderate unexplained weight loss (under 10% of presumed or measured body weight) Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papular pruritic eruptions Seborrhoeic dermatitis Fungal nail infections
Clinical stage 3
Unexplained severe weight loss (over 10% of presumed or measured body weight) Unexplained chronic diarrhoea for longer than 1 month Unexplained persistent fever (intermittent or constant for longer than 1 month) Persistent oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 10^9/l) and/or chronic thrombocytopenia (below 50 x 10^9/l)
Clinical stage 4[1]
• HIV wasting syndrome • *Pneumocystis jiroveci* pneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site) • Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) • Extrapulmonary tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous system toxoplasmosis • HIV encephalopathy • Extrapulmonary cryptococcosis including meningitis • Disseminated nontuberculous mycobacteria infection • Progressive multifocal leukoencephalopathy • Chronic cryptosporidiosis • Chronic isosporiasis • Disseminated mycosis (extrapulmonary histoplasmosis, coccidiomycosis) • Recurrent septicaemia (including nontyphoidal *Salmonella*) • Lymphoma (cerebral or B cell non-Hodgkin) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

Source: *Revised WHO clinical staging and immunological classification of HIV and case definition of HIV for surveillance*. 2006.

Annex 4. Recommendations for initiating ART in infants, children and adolescents

Age	Infants and children <24 months	>24 months to 59 months (5 years)	Older than 5 years
% CD4+	All*	≤25%	N/A
Absolute CD4	All*	≤750 cells/mm^3	≤350 cells/mm^3 as for adults and adolescents

* CD4 testing or results are not needed to make the decision to start ART in this age group. Clinicians may begin treatment either without a baseline CD4 test or while awaiting the result of a CD4 test that is being processed.

Source: *Antiretroviral therapy for HIV infection infants and children: towards universal access*. WHO 2010.

Annex 5. Summary of recommended testing approaches (*32*)

Category	Test required	Purpose	Action
Well, HIV-exposed infant	Virological testing at 4–6 weeks of age	To diagnose HIV	Start ART if infected
Infant – unknown HIV exposure	Maternal HIV serological test **or** infant HIV serological test	To identify or confirm HIV exposure	Need virological test if HIV exposed
Well, HIV-exposed infant at 9 months	HIV antibody test (at last immunization, usually 9 months)	To identify infants who have persisting HIV antibody or have seroreverted	Those HIV seropositive need virological test and continued follow up; those HIV negative, assume uninfected, re-testing required if still breastfeeding
Infant or child with signs and symptoms suggestive of HIV	HIV serological test	To confirm exposure	Perform virological test if <18 months of age
Well or sick child seropositive >9 months and <18 months	Virological testing	To diagnose HIV	Reactive - start HIV care and ART[1] if under 24 months, or based on national start criteria if 24 months or over[2]
Infant or child who has completely discontinued breastfeeding	Re-testing 6 weeks or more after breastfeeding cessation - usually initial HIV serological testing followed by virological testing for HIV-positive and <18 months of age	To exclude HIV infection after exposure ceases	Infected infants and children <24 months of age need to start HIV care, including ART[2]

1. In some countries specific thresholds/criteria for initiating ART may be applied.

2. *See Antiretroviral therapy for HIV infection in infants and children*. WHO. 2010.

Well child health visits and schedule of HIV testing.

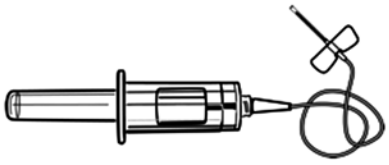
Time	Child health schedule[1]	Rationale
Birth	Vitamin K BCG Polio	HIV serological test of the mother or infant if maternal status unknown
4–6 weeks	Diphtheria, pertussis and tetanus (DPT 1) Polio Hepatitis B Hib	1. HIV serological testing if exposure status not known 2. Virological testing for all HIV-exposed (or HIV serology-positive) infants
10–12 weeks	Polio DPT 2 Hepatitis B Hib	Testing if unwell and HIV suspected If HIV antibody positive/HIV exposed and not previously had virological test –> HIV virological test
14 weeks	Polio DPT 3 Hepatitis B Hib	Testing if unwell and HIV suspected If HIV serology positive/HIV exposed and not previously had virological test –> HIV virological test
9 months	Measles	HIV serological testing for all HIV-exposed infants followed by HIV virological testing in case of positive serological testing
18 months or older		HIV exposed and HIV infection status not previously determined –> HIV serological testing

1. http://www.who.int/immunization/policy/immunization_tables/en/index.html

Tool 1: Collection of blood sample from children by venipuncture.

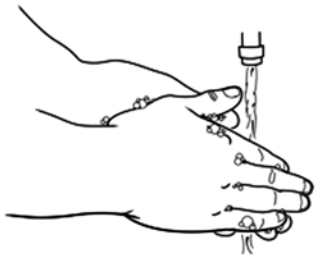
(Source: *Operations manual for delivery of HIV prevention, care and treatment at primary health centres in high-prevalence, resource-constrained settings*. Geneva, WHO, 2008).

For use with butterfly and vacuum tubes



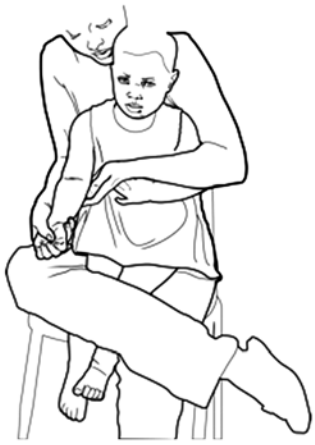
1. Vaccum tube and butterfly needle.

2. Collect supplies.



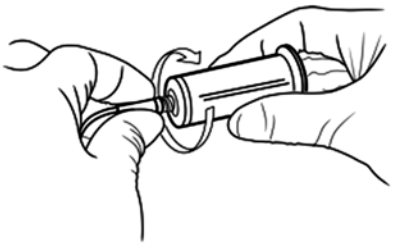
3. Wash hands.

4. Glove hands.

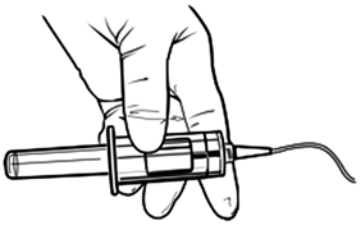


5. Restrain the child either a: lying down or b) having them sit upright on a parent's lap. The parent should wrap their arm around the child and over the arm that is not being used.

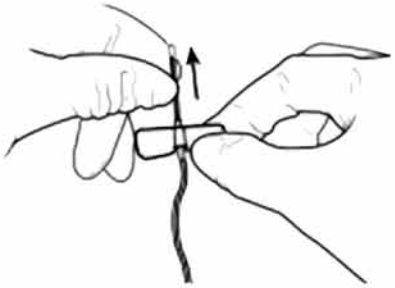
7. Put tourniquet on client about 2 finger whidths above venipuncture site.



9. Attach the end of the winged infusion set to the end of the vaccum tube.



10. Insert the collection tube into the holder until the tube reaches the needle.



12. Remove plastic sleeve from end of butterfly.

13. Clean collection site with 70% isopropyl alcohol. Allow to dry.

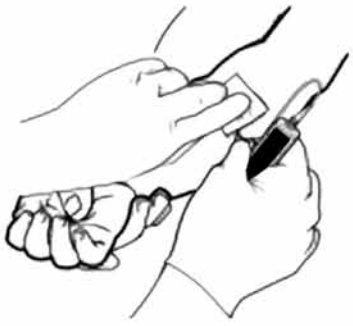
14. Use your thumb to draw skin tight about 2 finger widths below the venipuncture site.

15. Bend the wings and instert the needle, bevel side up, into the vein. Establishment of lood flow is indicated by spurt of blood into the tubing.

16. Push the vacuum tube completely onto the needle. Blood should begin to flow into the tube

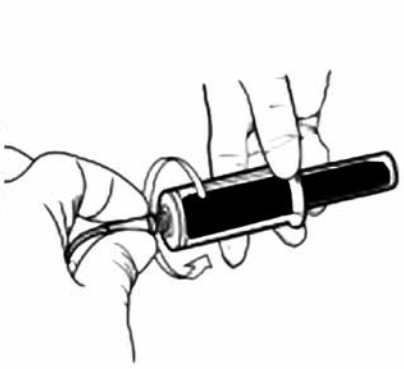
17. Fill the tuve until it is full or until vacuum is exhausted. If you are filling multiple tubes, carefully remove the full tube and replace with another tube. Try not to move the needle in the vein. Shake by inverting removed tube back and forth 5-10 times.

18. After the desired amount of blood has been collected, release the tourniquet. (place tube)

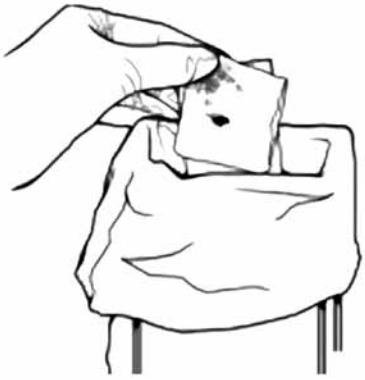


19. Release patient's hand, place dry gauze over the venipuncture site ans slowly withdraw needle.

20. Have mother continue applyig mild pressure.



21. Remove butterfly from vacuum tube holder and dispose in sharps container.



22. Property dispose of all contaminated supplies.

23. Label tube with the client identification number, date and

24. Put on an adhesive bandage if necessary.

Tool 2. Collecting DBS from infants for virological testing

(Source: *Operations manual for delivery of HIV prevention, care and treatment at primary health centres in high-prevalence, resource-constrained settings*. Geneva, WHO, 2008).

Virological testing for infant HIV diagnosis is usually done in a national or regional reference lab. It is extremely important to follow infants from PMTCT programmes and to test them as early as possible.

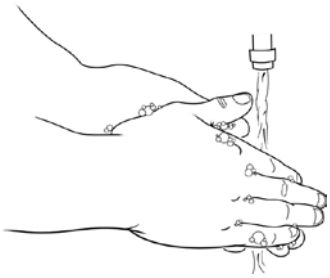
The specimen collected from the infant is capillary blood from a heel, big toe, or finger prick that is put onto a filter paper (dried blood spot (DBS)).

Instructions for collecting dried blood spots (DBS) from infants for virological testing:

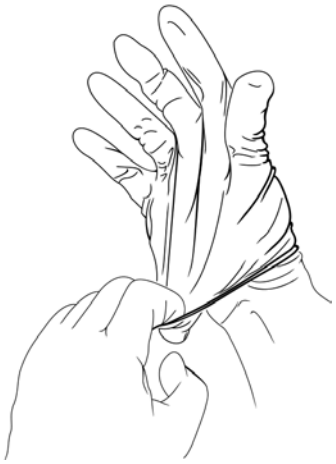
1. Gather necessary supplies gloves
- aLancet (2 mm)
- 70% isopropyl alcohol
- Gauze or cotton wool
- Pen

2. Complete all necessary paperwork.
- Infant diagnosis registration form clinic register
- Laboratory request/report form

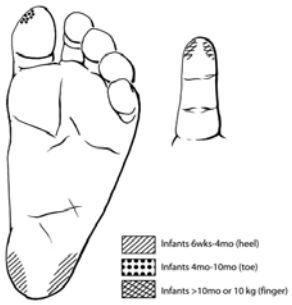
3. Wash hands.



4. Glove hands.

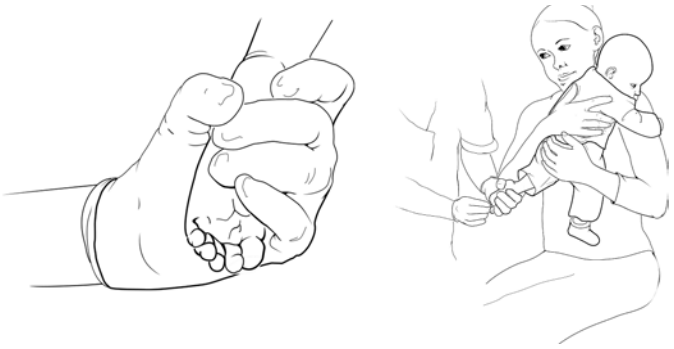


5. Examples of areas to be pricked – heel, toe, finger.

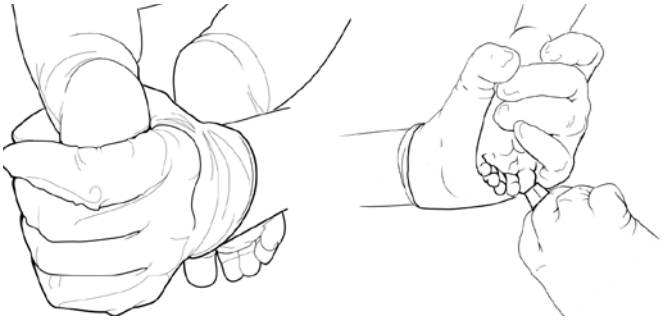


6. Ask the mother to warm this area.

7. Position the baby with the foot or hand down, then clean the spot to be pricked with 70% isopropyl alcohol, and allow to dry for 30 seconds.

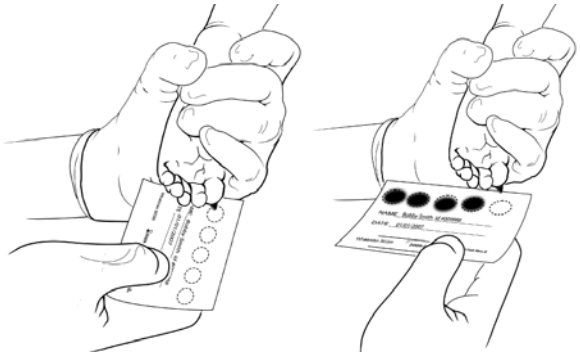


8. Gently squeeze and release the area to be pricked until it is ready to bleed, and then prick the infant in the selected spot with the 2mm lancet.



9. Wipe away the first spot of blood, and then allow a large drop of blood to collect.

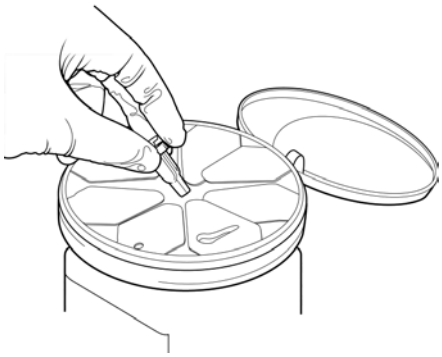
10. Touch the filter paper gently against the large drop and allow it to completely fill the circle. Collect at least three good drops.



11. Clean area; no bandage is needed.

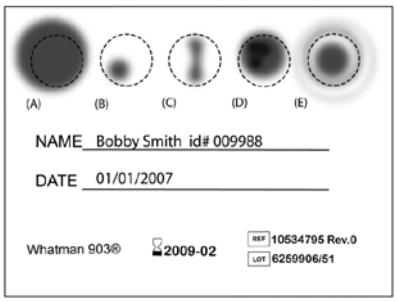
12. Fill our DBS card.

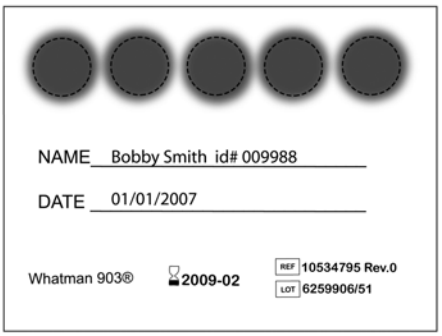
13. Dispose of lancet.

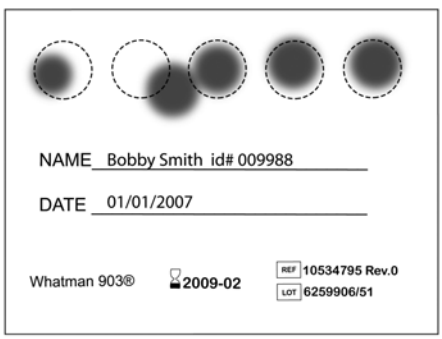


Two examples of valid DBS specimens
Three good specimens

12. Invalid DBS specimen
A. May have been soaked with syringe
B. Drops too small
C. “spots” that are streaky
D. Clotted/layered
E. Yellow serum rings around blood drops.







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