
National Guidelines for

# Paediatric Provider-initiated HIV Testing & Counselling

in Zambia

# Foreword and Acknowledgements

## National Guidelines for Paediatric Provider-initiated HIV Testing and Counselling

Approximately 95,000 children aged 0 to 14 years in Zambia live with HIV. The majority of these children are unaware of their HIV status. As one of the most affected nations in sub-Saharan Africa, there is a dire need to implement services to identify, care and treat HIV infection in children and families. These guidelines were developed by the Ministry of Health (MoH) to support the implementation and scale up of paediatric provider-initiated HIV testing and counselling (PITC) services nationally. PITC is the routine testing of children as the first step in determining HIV status, which is the gateway to accessing treatment and preventing rapid progress of the disease.

The Government of the Republic of Zambia is committed to providing equitable access to quality health care which includes universal access to anti-retroviral therapy (ART) for adults and children. As part of the scale up of paediatric PITC, these guidelines also support the planning and implementation of services as well as quality assurance, monitoring and supervision in all healthcare settings where services are provided to children and their caregivers. A related training curriculum (National Training Package for Paediatric Provider-initiated HIV Testing and Counselling) and clinical support tools (wall charts, counselling cue cards and supervisory tools) are available to support facilities to build healthcare worker capacity to scale up and provide these services.

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# Abbreviations and Acronyms

| | |
|---|---|
| 3TC | Lamivudine |
| Ab | Antibody |
| AFB | Acid-fast bacilli |
| AIDS | Acquired immune deficiency syndrome |
| ALT | Alanine transaminase |
| AMC | Average monthly consumption |
| ART | Anti-retroviral therapy |
| ARV | Anti-retroviral |
| AZT | Zidovudine or Azidothymidine |
| BAL | Bronchoalveolar lavage |
| CAB | Community advisory board |
| CBO | Community-based organisation |
| CD4 | T-lymphocyte CD4 count |
| CDC | United States Centers for Disease Control and Prevention |
| CIDRZ | Center for Infectious Disease Research in Zambia |
| CMV | Cytomegalovirus |
| CNS | Central nervous system |
| CO | Clinical officer |
| CRAG | Cryptococcal antigen |
| CSA | Child sexual abuse |
| CSF | Cerebrospinal fluid |
| CT | Computerised axial tomography |
| CTX | Cotrimoxazole |
| CXR | Chest x-ray |
| DBS | Dried blood spot |
| DNA | Deoxyribonucleic acid |
| EPI | Expanded Programme on Immunisations |
| FBO | Faith-based organisation |
| HIA2 | Health Information Aggregation form |
| HIV | Human immunodeficiency virus |
| IMCI | Integrated Management of Childhood Illness |
| IYCF | Infant and Young Child Feeding |
| JCV | JC virus (type of polyomavirus) |
| kg | Kilogramme |
| LGE | Lineal gingival erythema |
| LIP | Lymphocytic interstitial pneumonia |
| LMIS | Logistics Management Information System |
| LPV | Lopinavir |
| mg | Milligram |
| MoH | Ministry of Health |
| mm | Millimetre |
| MRI | Magnetic resonance imaging |
| MTCT | Mother-to-child transmission (of HIV) |
| NPA | Nasopharyngeal aspirate |
| PCP | Pneumocystis pneumonia (also referred to as PJP) |
| PCR | Polymerase chain reaction |

| | |
|---|---|
| PEP | Post-exposure prophylaxis |
| PGL | Persistent generalised lymphadenopathy |
| PITC | Provider-initiated testing and counselling |
| PLHIV | People living with HIV |
| PML | Progressive multifocal leukoencephalopathy |
| PMTCT | Prevention of mother-to-child transmission (of HIV) |
| PTB | Pulmonary tuberculosis |
| QA | Quality assurance |
| SD | Standard deviation |
| SI | Stock in hand |
| SOP | Standard operating procedure(s) |
| STI | Sexually transmitted infection |
| TB | Tuberculosis |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| URTI | Upper respiratory tract infection |
| UTH | University Teaching Hospital (Lusaka, Zambia) |
| VCT | Voluntary Counselling and Testing |
| WBC | White blood count |
| WHO | World Health Organization |
| ZN | Ziehl-Neelsen |
| ZPCT | Zambia Prevention, Care and Treatment |

# Introduction

Identification and follow-up of HIV-exposed infants through prevention of mother-to-child transmission (PMTCT) services has been an effective approach to identify and treat HIV-infected infants. However, its success is largely limited to the children of women who enrol in the PMTCT programme during antenatal care, and remain in the PMTCT programme until the child's status is determined and mother and child are linked to ongoing care and treatment. Significant barriers delay or prohibit the identification of the children of women of unknown HIV status who do not (or did not) participate in PMTCT programmes, as well as the children of women living with HIV who participate in PMTCT programmes but are lost to follow-up before the child's HIV status is determined. Evidence from a variety of settings, including Zambia, suggests that many opportunities to diagnose infants and children at health facilities are being missed, thereby leaving HIV-infected children without access to life-saving care and treatment.

Recognising that low levels of HIV awareness are a critical barrier to universal treatment access, the World Health Organization (WHO) issued country-level operational guidance on provider-initiated HIV testing and counselling (PITC) of adults and children.[1] PITC is an approach in which HIV testing is a routine standard of care for all patients presenting at health facilities.

Implementation of paediatric PITC services should complement the ongoing national expansion of comprehensive PMTCT services and efforts to strengthen the linkages among antenatal, labour and delivery, postnatal and child health services. These services are critical to reducing paediatric HIV infection and to providing access to HIV prevention, care and treatment services for mothers and families.

The Republic of Zambia Ministry of Health (MoH) supports the national scale-up of PITC services in health facilities. These guidelines, and the accompanying paediatric PITC training package and job aides (including counselling cue cards, wall charts, and supervisory tools; see Appendix 1) are intended to guide and

support this nation-wide scale-up. To have the greatest impact on HIV-related paediatric morbidity and mortality, priority for the initial roll-out of paediatric PITC services is given to settings where children living with HIV are most likely to access the health care system — specifically hospitals, tuberculosis clinics and malnutrition clinics.

# Chapter I: Background and Rationale for Scale-up of PITC Services for Infants and Children

**Chapter overview**
- **Overview of the HIV epidemic in Zambia**
- **Rationale for paediatric testing**
- **Repositioning HIV testing from diagnostic HIV testing and voluntary counselling and testing (VCT) models to provider-initiated testing and counselling (PITC)**
- **Experience with PITC in Zambia: Successes and challenges**
- **Guiding principles for paediatric PITC**

According to a 2008 report from the Joint United Nations Programme on HIV/AIDS (UNAIDS), an estimated 2.1 million children under the age of 15 years worldwide are living with the human immunodeficiency virus (HIV).[2] The vast majority of children acquire HIV through mother-to-child transmission (MTCT) during pregnancy, labour and delivery or in the postpartum period through breastfeeding. Although effective PMTCT services can significantly reduce paediatric HIV infection, the full scale-up of effective perinatal HIV prevention services has been difficult to achieve in many resource-limited settings. As a result, each day more children become HIV-infected; in 2008, an estimated 430,000 children were newly infected with HIV.[3]

Zambia is one of the nations most affected by the HIV pandemic. The country has a population of 12 million people, and an estimated 1.1 million are living with HIV.[4] The HIV prevalence rate among pregnant women is 19.3%, meaning that almost 1 out of every 5 pregnant women in Zambia is living with HIV.[5] Despite significant progress in the scale-up of PMTCT services, approximately 95,000 children aged 0 to 14 years are living with HIV and an estimated 28,000 infants become infected with HIV annually.[6] Most of these children are not receiving HIV care and treatment because their HIV status is unrecognised. In 2007, only an estimated 34.5% of Zambian children in need of anti-retroviral therapy (ART) had initiated ART.[7]

HIV infection follows a more aggressive course in infants and young children than in adults; as a result, children frequently die of AIDS-related complications before a diagnosis of HIV infection is made. Without early access to ART and preventive interventions, such as cotrimoxazole (CTX) prophylaxis, 50% of children living with HIV will die before their second birthday and 75% will die by age five.[8] Currently, the majority of children in sub-Saharan Africa are identified as HIV-infected when they are older — generally after the age of five. These children often present with advanced levels of immunosuppression. [9,10] The high rates of death and illness in children with HIV can be prevented: provision of ART dramatically decreases morbidity and mortality, and helps restore and maintain normal levels of immune functioning in children living with HIV.[11] These facts highlight the critical need to identify HIV-infected children and to provide access to HIV care and treatment as early as possible so that HIV disease progression can be delayed and HIV-associated illness and death can be prevented.

The comprehensive approach to preventing HIV infection in children, including the provision of PMTCT services, provides the primary means of preventing, and thereby reducing, the number of paediatric HIV cases in Zambia. However, even with ongoing efforts to scale-up and improve these programmes, services are not available to all women and couples. Furthermore, routine infant follow-up, which should be a component of PMTCT, has been difficult to achieve even for those families enrolled in PMTCT programmes;[12] opportunities to identify HIV infection in infants and children are therefore missed. Since HIV-exposed and -infected children are at high risk for medical problems and illness, they are likely to attend health facilities and require hospitalisation more frequently than uninfected children. By offering paediatric HIV testing in a range of health facilities, including those offering maternal and child health services, more children living with HIV will be identified and lifesaving treatment offered promptly.

## Repositioning HIV Testing

The implementation of paediatric PITC services is a mechanism by which to expand HIV testing of children because it establishes HIV testing as a standard of care for all paediatric patients attending health facilities. PITC casts a wider net than standard models of HIV testing, which to-date have included diagnostic testing (provider-initiated testing of people with AIDS-related disease) and voluntary counselling and testing (VCT) (for individuals who request it). These models and the PITC model all include the provision of basic information about HIV and the risks and benefits of testing, but differ in approach. Under PITC, the HIV pre-test session and HIV testing become a routine part of healthcare for every individual; healthcare workers approach caregivers and an HIV test is conducted as part of routine services unless the caregiver declines. In the diagnostic testing model, testing occurs at a point when HIV disease is already advanced. Under the VCT model, caregivers are required to specifically request the HIV test and give verbal or written consent.

Paediatric PITC, therefore, has the potential to be more effective, compared to previous efforts, at identifying and providing follow-up and treatment to exposed and infected children, while normalising HIV testing and thereby reducing stigma.[13] Appendix 2 provides guidance for comprehensive paediatric HIV care. Table 1.1 provides the rationale for paediatric testing and counselling.

**Table 1.1: Rationale for implementing paediatric testing and counselling programmes**

**Early recognition of paediatric HIV allows for provision of:**

- Timely initiation of ART for infected children.
- Reduced child morbidity and mortality.
- CTX prophylaxis and the prevention and treatment of other opportunistic infections.
- Screening, prevention and management of tuberculosis (TB).
- Regular clinical and laboratory assessment, including close monitoring of growth and development.
- Counselling and support for optimal infant and young child feeding and child nutrition.
- Access to care, treatment and support for the mother and family.
- Psychosocial support for the family, including linkages to community support resources.

Paediatric PITC, also referred to as "opt-out" testing, means that healthcare workers routinely offer HIV testing for children because they recognise that knowing the HIV status of a child is the first step to providing appropriate care. While testing is routine, it proceeds with a clear understanding on the part of caregiver (or patient) and the healthcare worker that testing may be declined.

## Experience with PITC in Zambia

A nationwide assessment of PITC programmes conducted by the MoH and the United States Centers for Disease Control and Prevention (CDC) in 2008 found significant progress in the implementation of PITC services for adults in health facilities in Zambia.[14] The assessment found successful integration of testing and counselling in routine antenatal and TB care services, high levels of acceptance of HIV testing and clear linkages and referrals for care, treatment and support. However, the assessment also noted that little progress had been made in implementing paediatric PITC programmes.

A pilot test of a paediatric PITC programme was conducted at University Teaching Hospital (UTH) in Lusaka. In order to improve the identification of paediatric cases of HIV, UTH implemented routine HIV antibody testing and counselling for all hospitalised paediatric patients. Over the course of 18 months

in 2006-2007, among 15,670 children with unknown HIV status, 84% received counselling and 87% of those counselled received HIV-antibody testing. Overall, 29% of those tested were HIV-antibody positive, confirming that HIV makes a significant contribution toward the disease burden on paediatric hospital wards in the country.[15] Later, the programme established early infant diagnosis services through the initiation of virologic testing with DNA PCR for HIV-exposed infants less than 18 months of age. Of note, the DNA PCR positivity rate of the population who tested HIV-antibody positive who were between six weeks and 18 months of age was greater than 50%.

In this programme, HIV diagnostic and treatment services were made available to more than 3,000 infants and children. There were also considerable secondary benefits to the programme — parents and caregivers were offered HIV testing. All HIV-infected adults were referred for HIV care, mothers of HIV-exposed infants were provided counselling to support safe breastfeeding practices.

With the exception of this pilot programme at UTH, regular follow-up and early diagnosis of HIV-exposed children have been difficult to achieve and opportunities to identify HIV in children are frequently missed. These missed opportunities result in increased morbidity and mortality in children, which may have been prevented with earlier access to care and treatment. The implementation of PITC services is a critical paradigm shift that offers an unequalled opportunity to significantly reduce paediatric morbidity and mortality. Simply put, given the high rates of HIV in Zambia, the HIV status of all children must be determined so that lifesaving HIV care and treatment can be provided to those in need. Every opportunity should therefore be utilised to offer PITC — this includes every point where children come into contact with health services, in primary, secondary and tertiary care.

## Guiding Principles

Guiding principles provide a basis for developing and promoting good clinical practice, and help to ensure that PITC services are appropriate and effective, and

that prevention, care and treatment outcomes are optimised. The approach of PITC services is to recognise and respond to the needs of children living with HIV and their caregivers.[16] Guiding principles include:

- **Urgency:** HIV prevention, diagnosis, care and treatment must be scaled up as quickly as possible to avert deaths among children who are exposed to or infected with HIV.
- **Universal access:** All children in need should have access to HIV prevention, diagnosis, care and treatment services.
- **Life-long care:** HIV is a chronic disease that requires ongoing care and treatment; there is an obligation to provide uninterrupted, lifelong care and treatment to adults and children living with HIV.
- **Family-centred care:** Family members should receive care in a manner that recognises and responds to the family as a unit.
- **High-quality care:** Care should be of the highest quality possible and should be monitored and improved through systemic, regular review and evaluation.

# Chapter II: Phased Implementation of PITC Services

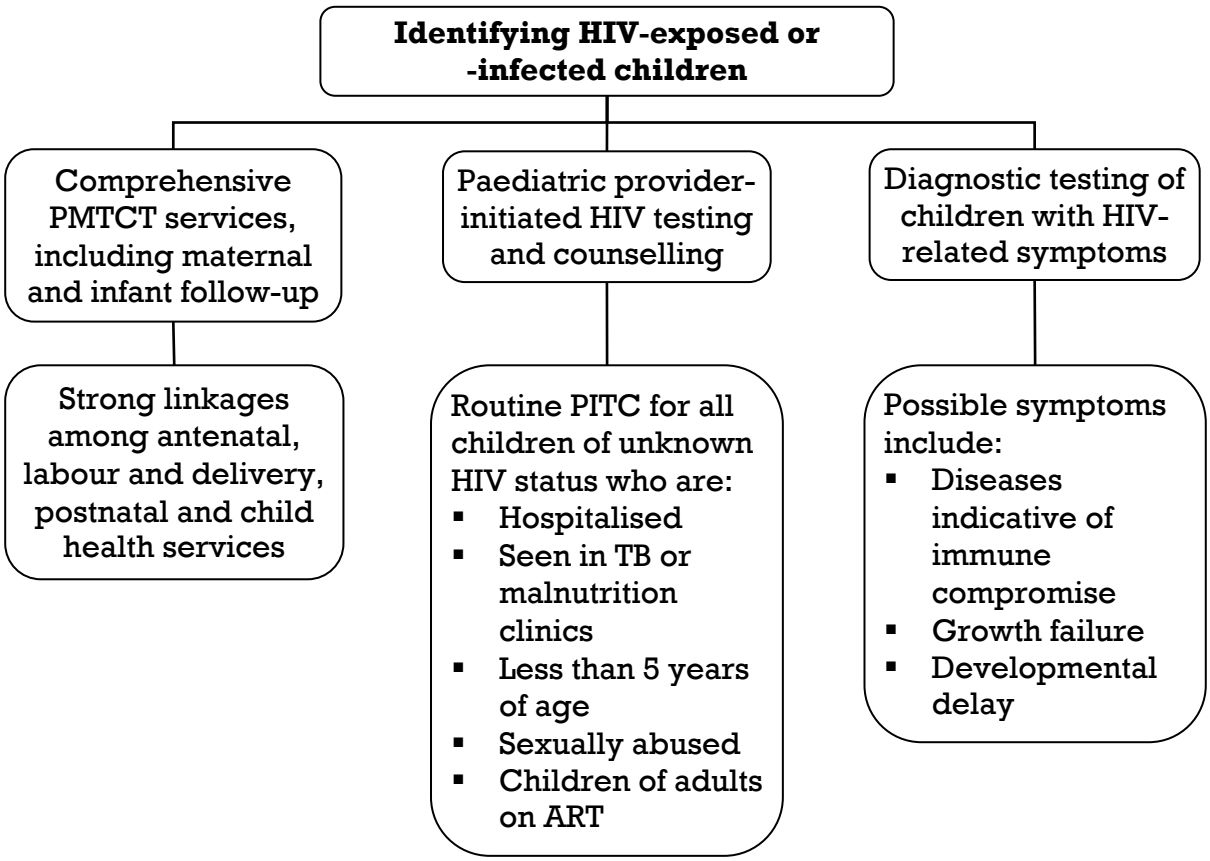
**Chapter overview**
- **Phased implementation of paediatric PITC services**
- **Pathways for identification of HIV-infected and -exposed children**
- **Importance of coordinating testing services with care and treatment**

The goal of paediatric PITC is to identify and document the HIV status of every child in Zambia. The best outcomes for infants and children are achieved when HIV status is determined as early as possible, and when families with children living with HIV gain access to and adhere to lifelong care and treatment following national guidelines. For the purposes of national implementation of paediatric PITC services, the MoH is employing a step-wise approach that prioritises programme implementation in facilities where PITC services will have the greatest impact. Hospitals and TB and malnutrition clinics will be the first to implement paediatric PITC services, after which paediatric PITC will be rolled out to immunisation, maternal and child health and other health facilities nationwide. Meanwhile, the MoH also recommends prioritising PITC services for the children of adults accessing HIV services and for children who have been sexually abused. In addition, diagnostic HIV testing for children with symptoms that may be consistent with HIV-related illness, including growth problems and developmental delay, should continue (regardless of the setting where the child is seen).

The MoH recommends phased implementation of paediatric HIV testing and counselling, with priority placed on children most likely to be HIV-exposed or -infected. These include:

1. Children that are hospitalised (for any reason)
2. Children presenting at TB clinics or malnutrition clinics
3. Children less than 5 years of age
4. Children of adults accessing HIV services
5. Children known or suspected to have been sexually abused

**Figure 2.1: Pathways to identify HIV-exposed or -infected children**




The identification of HIV-exposed and -infected children follows three possible pathways, as seen in Figure 2.1. These pathways include PMTCT, PITC and diagnostic testing of children presenting with symptoms of HIV. These symptoms include opportunistic and other infectious diseases indicative of immune compromise, as listed in Appendix 3. Symptoms of growth failure and developmental delay, detailed in Appendices 4 and 5 respectively, should always be investigated as these may be the first non-specific signs of HIV infection in children. HIV testing and counselling should be recommended if the causes of growth failure or delay are unexplained by other medical reasons.

As paediatric PITC services are rolled out, PMTCT services must continue to be strengthened and expanded — PMTCT services not only prevent a significant percentage of MTCT but can also provide for the HIV testing of those who are HIV-exposed so that they can be provided with or referred for life-saving care and treatment.

**The implementation of PITC services must not diminish efforts to routinely recommend HIV testing and counselling for any child with symptoms or signs suggestive of HIV seen in any health care setting.**

The following sections provide detail on the step-wise prioritisation for PITC implementation.

## Children that are Hospitalised

In generalised epidemics many patients hospitalised in medical wards are HIV-infected. As described in Chapter 1, almost 30% of hospitalised paediatric patients of unknown HIV status tested at UTH in Lusaka were HIV-exposed. Of those tested by DNA PCR who were between the age of six weeks and 18 months, more than 50% were HIV-infected. Thus, in Zambia and abroad, implementing paediatric PITC in hospitals presents an opportunity to identify large numbers of children living with HIV who would benefit from diagnosis, care and treatment. Given the high prevalence of HIV in Zambia and the high frequency of hospitalisation of HIV-exposed and HIV-infected children, **HIV testing and counselling is recommended for ALL children admitted to hospitals.**

Knowing a child's infection status is vital to the assessment and effective management of the child's symptoms or disease, which may need to be more aggressive or longer treatment in the child with HIV. Identification of HIV exposure or infection also allows for the initiation of preventive treatments — such as CTX prophylaxis and infant anti-retroviral (ARV) prophylaxis — and preparation of the family to provide care at home.

The experience of instituting routine HIV testing and counselling at UTH [17] has shown that such programmes identify large numbers of HIV antibody positive children. Therefore, prioritising implementation of PITC programmes in hospitals is an efficient way to identify large numbers of HIV-exposed and -infected children.

## Children Presenting at TB Clinics

PITC is recommended for all persons with TB in Zambia. Identifying children with TB who are HIV co-infected allows for the initiation of appropriate care, treatment and support for the child and his or her family. Young children are highly susceptible to TB disease; immunosuppressed infants and children are even more susceptible. In Zambia, the burden of TB has increased substantially — to 580 cases per 100,000 in 2005 from approximately 100 cases per 100,000 in 1984.[18] Much of this increase has been attributed to the high rate of co-infection with HIV — an estimated 50%–70% of TB patients are infected with HIV.[19] Adult patients with HIV who are treated for both HIV and TB have better health outcomes compared to those who are treated for TB first. Thus, there is strong evidence to aggressively treat children with both diseases. Early initiation of treatment is particularly important among co-infected children who have severe immune system compromise; it is critical in these cases that drug interactions be considered and closely monitored.[20]

Outpatient TB clinics initiating paediatric PITC services will need to plan the necessary changes in clinic policies and procedures required to accommodate HIV testing, including pre- and post-test counselling. This is discussed further in Chapter IV.

## Children Presenting at Malnutrition Clinics

Children living with HIV are at high risk for malnutrition, as the infection places increased energy demands on the body. While growth faltering and growth failure may be the first clinical indication of HIV infection, malnutrition may represent advanced HIV disease. HIV testing of all children who present at malnutrition clinics should be routine. Access to treatment for HIV will address a primary underlying cause of malnutrition for these children.

Ideally, growth problems will be recognised through growth monitoring before the problem is severe enough to warrant referral to the malnutrition clinic. Growth monitoring consists of serial assessments and plotting of both weight and height over time so that growth velocity can be assessed. If the child's growth is evaluated at each visit and measurements recorded, a profile of the child's growth rate will emerge. As children will often exhibit failure to grow normally before more specific signs or symptoms of HIV are identified, routine growth monitoring can lead to earlier identification of HIV-infected children. For this reason, testing all children whose growth is faltering or who are experiencing growth failure — including those seen in immunisation clinics — will also assist in early identification of HIV-infected children, perhaps before the onset of opportunistic infections or other manifestations of HIV. See Appendix 4 for more information on growth monitoring.

**Growth monitoring enables early detection of disease or inadequate nutrition and is vital for all children.**

## Children Less than 5 Years of Age

HIV infection status should be determined and documented in all children less than 5 years of age. To realistically accomplish this goal, paediatric PITC services should first be implemented in hospitals, TB clinics and malnutrition clinics. Once PITC is established as the standard of care in these settings, while PMTCT services are simultaneously expanded and strengthened, implementing PITC services more widely to medical, maternal-child health and immunisation clinics will be achievable.

## Children of Adults Accessing HIV Services

Children of adults who accessing HIV services represent an accessible population for paediatric PITC outreach. Because adults accessing HIV services present to a health facility on a regular basis for care and medication, it is logical

to ask these patients to either bring their children and partners in for testing or to refer their children and partners for testing.

## Children Known or Suspected to have been Sexually Abused

Worldwide, sexual abuse affects a substantial number of children. Sexual abuse is described as forcing unwanted, improper or harmful sexual activity on another. Young children may be the object of sexual abuse because youth is associated with sexual purity. In some areas, the myth that having sex with a virgin can cure HIV persists. [21,22,23] Because of their small size, lack of empowerment, fear of being blamed and the fact that they often do not have the ability to express what has happened them, children are rarely able to protect themselves from sexual abuse, regardless of the motivation.

Studies have shown wide variation in the purported role of child rape or child sexual abuse in the transmission of HIV. One study estimated that 0.6–1.8% of children in high HIV-incidence countries in southern Africa will experience penetrative sex by a person living with HIV before they reach 18 years of age.[24] In South Africa, a seroconversion rate of 1% was found among a sample of child rape victims.[25] In Zimbabwe, half of the sexual abuse cases among children were reportedly detected when the children exhibited symptoms of sexually transmitted infections (STIs), including HIV.[26] While these statistics may not be representative of the situation in Zambia, these and other anecdotal reports suggest the strong need to initiate programmes to better recognise child sexual abuse and to link children who have been sexually abused to the appropriate clinical and psychosocial support services, including PITC and HIV post-exposure prophylaxis (PEP).

UTH initiated a programme to provide clinical, psychosocial and legal support for sexually abused children. The programme also conducts trainings on working with sexually abused children for healthcare workers, community organisations and other professionals, including members of the police department, who may have contact with child survivors of sexual abuse. Such programmes and training

are extremely important, as the sexual abuse of children frequently goes unrecognised, creating a risk for long-term physical and mental health challenges for these children. Guidelines for recognising sexual abuse are in Appendix 6.

In Zambia, PITC is recommended for any child who has been, or may have been, sexually abused. At the time the abuse is discovered, healthcare workers should address the child's safety, conduct a comprehensive history and physical examination, and provide HIV testing and counselling. If initial results are negative, testing should be repeated three months later. Follow national guidelines concerning the use and availability of PEP, which can be found in Appendix 6. The child should also be immediately referred for mental health services to ensure that assessment and treatment of psychosocial issues are addressed and monitored. Long-term counselling and follow-up may be required.

Evaluating, managing and supporting children who may have been sexually abused can be very difficult for healthcare workers. Interviewing and counselling children differs from working with adults and that specific skills are needed when speaking with children who have been traumatised. Appendix 7 provides general information on interacting with children and adolescents.

## Referral for care and treatment

Regardless of the clinical setting of HIV diagnosis, all children found to have HIV along with their families, must be linked to ongoing care and treatment services as well as community support services. Early diagnosis of HIV infection and immediate enrolment in lifesaving care and treatment, including ART reduces the risk of rapid progression of HIV disease in HIV-infected children.

# Chapter III: Human and Material Resources Required for Implementation of Paediatric PITC Services in Healthcare Facilities

**Chapter overview**

- **Requirements for paediatric PITC implementation**
  - **Stakeholder support and involvement**
  - **Human resources, training, supervision and mentoring**
  - **Capacity building**
  - **Laboratory logistics**

As with introduction of any new health programme or service, the best outcomes are achieved when the necessary resources and systems are in place to support implementation. Strategic planning for implementation of paediatric PITC includes a number of key steps:

- Assessing the current and required infrastructure
- Ensuring facility readiness
- Ensuring proper staff selection
- Training and supervision
- Establishing strong referral networks
- Clearly determining the time frame and responsibilities for implementation

The systems and resources needed to implement paediatric PITC in health facilities are listed in Table 3.1, below, and discussed further in this document. The new SOPs, guidelines and systems may be adapted from or informed by existing guidelines, for example for dried blood spot (DBS) collection and processing for DNA PCR testing, as outlined in the *Dried Blood Spot for DNA PCR Testing: Health Facility Handbook*.[27]

**Table 3.1: Resources required for implementation of paediatric PITC in health facilities**

- Stakeholder support and involvement
  - Community understanding and support
  - Staff (managers and workers) participation and support
- Human resources, training, supervision and mentoring
- Capacity building, including plans for orientation and training
- Sufficient space to ensure safe working conditions and confidentiality for patients (Chapter IV)

- Material supplies and resources for testing and a reliable supply chain (Chapter IV)
- Standard operating procedures (SOPs) for testing and counselling procedures (Chapter IV)
- SOPs for blood sample collection and testing (Chapter IV)
- Formal linkages to other services for post-test support, care and treatment (Chapter IV)
- Linkages to lab services, data management, quality assurance and other service components (Chapter V)
- Monitoring and evaluation systems, plan and tools (Chapter VI)

## Stakeholder Support and Involvement

### Community understanding and support

Lessons learnt from the scale up of PITC in this country and elsewhere have suggested that the active involvement and leadership by a variety of stakeholders is important for implementing a successful HIV testing and counselling service.

Community leaders and members, human rights advocates and others may be unaware of the benefits of HIV testing for children, have misconceptions about paediatric testing or have serious concerns about stigma and discrimination. It is important to realise that influential stakeholders can (officially or unofficially) support or block implementation of new services related to HIV, especially if the services are perceived as being imposed on the community rather than developed collaboratively. It is important to listen to stakeholders, address their concerns, revise plans based on their input and to take the time to explain to them the advantages and benefits of the new service. Stakeholders in the community have valuable information and ideas and can make important contributions to planning, implementation and evaluation. Establishing buy-in from stakeholders will promote and improve the implementation of PITC services.

Identifying or establishing a community advisory board (CAB) is one method of engaging stakeholders. A CAB is a group of community members who meet with high-level representatives of the facility (maybe weekly at first, graduating to monthly or bimonthly meetings later) to provide their input into service design.

With support and training around paediatric testing, care and treatment, CAB members are an important resource. CAB members are a link to the community and can provide community input into all aspects of the service from SOPs and staff training to funding priorities.

While it may not be possible to constitute a CAB everywhere PITC services are implemented, depending on the community, engagement can take many forms. Some communities have similar existing groups that may facilitate linkages among communities and health facilities (for example, women's groups, people living with HIV (PLHIV) associations, support groups, community councils, etc.). Elsewhere, community-based organisations (CBOs), non-governmental organisations (NGOs) and faith-based organisations (FBOs) and/or community healthcare workers may serve as effective links between the community and the health facility. Any of these groups can be engaged to:

- Discuss rationale and planning for implementing paediatric PITC services.
- Share specific knowledge to help design services.
- Act as spokespersons in campaigns to raise community awareness.
- Identify other influential leaders to champion PITC services.
- Assist with training, including sharing the community perspective.
- Create linkages with community services for families living with HIV.
- Recruit lay volunteers to assist with support services.
- Gather and share community responses, feedback and suggestions on an ongoing basis.

Working with the community may simply involve meeting with community leaders and with PLHIVs to explain the services available at the health facility, the rationale for paediatric testing and soliciting input and providing answers to questions. It is important to recognise that interest, energy or commitment of community representatives may wane over time or the community's needs may change over time. Periodic re-evaluation of programme needs and community roles is important to sustain high quality services and address changing areas of need.

### Staff participation and support

In the context of healthcare service implementation, the concept of community stakeholders includes not only the groups that will be directly impacted by PITC

services, but also the healthcare workers who will implement the services. Overburdened healthcare workers who are given new responsibilities and tasks but no hand in planning, problem solving and work load are unlikely to be enthusiastic supporters.

As a first step in the process of paediatric PITC implementation, it is important that health facility managers and staff are supportive of and involved in the planning for the new systems to be instituted. If those leading the implementation of the new service are not from the health facility, ensure that local staff are available to advise and support all phases of planning, implementation and evaluation. There should be regular meetings with staff, during which they are not only updated on progress but asked for their input. Initial orientation sessions for paediatric PITC as well as training for the new processes and systems are another ideal forum for managers to engage in joint action and participatory planning with staff. These sessions can serve not only to educate staff and support skill development, but to get their buy-in and support, as well as to motivate them.

Healthcare workers are at the forefront of the HIV epidemic — they are well aware of the impact of HIV on families and children. With the right approach and with continuing support and motivation, staff may become strong proponents of the need for paediatric PITC. On-the-ground staff may also be in the best position to understand which processes will work; after implementation, they may follow-up by offering evaluative feedback on the need for modification of some of the newly implemented systems for paediatric PITC.

## Human Resources, Training, Supervision and Mentoring

Human resources are the most important component of any healthcare service, including paediatric PITC services. An assessment should be conducted to:

- Determine staffing needs — staffing requirements will vary depending on the expected volume of clients and the workload of existing staff.
- Review staff turnover rates.

- Evaluate staff capacity, assess training needs and willingness to initiate PITC services — a commitment is required at all levels to develop and support staff by providing training and supervision and a safe working environment.
- Describe the roles and responsibilities of staff and managers required by the new service. In some cases, roles associated with paediatric PITC can be integrated with other services or existing staff may be able to assume new roles.

In facilities where multidisciplinary teams will implement paediatric PITC, the roles of each team member must be defined and refined over time. While nurses may act as frontline staff when patients first present for testing, counselling and treatment, other members of the multidisciplinary team conduct important roles: medical doctors will often manage complex cases, social workers and lay counsellors will conduct outreach and assist with counselling needs, and facility managers and other staff may be involved with garnering community support. Each team member serves a vital role in the implementation of paediatric PITC. For the most effective impact, ongoing coordination, communication and consultation within the team is crucial.

The critical role of HIV testing as a standard of practice for children should be understood by all staff, not solely among those who provide these services. Participation and motivated leadership from the health facility staff and within communities is vital for raising community awareness of the benefits of testing and counselling and to engage in strategies for addressing stigma. This heightened level of awareness, coupled with improved capacity to deliver PITC services and strengthened systems to support services, will help to establish PITC as an accepted and effective standard of care and extend the reach of lifesaving HIV care and treatment to many more children in need.

### Paediatric PITC programme coordinator or director

Suggested minimum staffing to support paediatric PITC and specific roles and responsibilities are included below. A single individual at the facility should be identified to take primary responsibility for planning, implementing and supervising PITC services. She or he will also act as the contact person for the programme. The coordinator or director(s) will:

- Determine staffing needs and define the roles and responsibilities of all individuals involved in planning, implementation and monitoring.
- Evaluate staff capacity and training needs.
- Ensure that SOPs are in place and implemented for service delivery, quality assurance (QA), monitoring and evaluation, supervision and staff support.
- Support training and mentorship.
- Supervise staff.
- Conduct QA activities.
- Monitor and evaluate services; prepare reports and give feedback to staff and managers.

### Counsellors

A variety of service delivery models have been employed throughout the country for HIV testing and counselling, as shown in Table 3.2. To date, pre- and post-test counselling is conducted primarily by lay counsellors, but nurse counsellors or other healthcare workers are sometimes involved. Regardless of the model employed, it is critical that all healthcare workers, including physicians, nurses and lay providers, understand and advocate for PITC and be prepared to offer PITC services when a counsellor is not available. At a minimum, staff should be able to:

- Describe the rationale for testing.
- Conduct the pre-test session and post-test counselling.
- Conduct rapid antibody testing and interpret the results.
- Collect a DBS specimen sample.
- Provide referrals for repeat testing and ongoing care, support and treatment.

According to the MoH assessment of PITC services at selected health facilities conducted in 2008, human resource shortages posed the greatest obstacle to implementation of PITC services.[28] At the time of evaluation the nurse-patient ratio was often 1 nurse for every 40 patients. Although many nurses have received training as counsellors, few are counselling; counselling consistently becomes a secondary responsibility because of the need to conduct more basic nursing functions.

To help fill the need for counsellors and support task-shifting, implementing partners including Zambia Prevention, Care and Treatment (ZPCT) and the Centre for Infectious Disease Research in Zambia (CIDRZ) trained lay counsellors

(largely volunteers) to increase the number of personnel available and able to provide testing and counselling services. (Note that Zambia guidelines allow lay counsellors to provide counselling and rapid antibody or DBS collection for DNA PCR by finger or heel stick. Lay counsellors cannot obtain venous samples, but venous samples are not required for either rapid HIV antibody testing or DBS specimen collection.) In health centres and rural health clinics, the use of lay counsellors has proven critical to the ability of the facility to offer HIV testing and counselling services. However, the lay counsellor model requires more direct supervision and oversight; in many cases cited by the MoH, consistent supervision, QA and data management have been lacking.

Other facilities have paid nurse counsellors to provide testing and counselling services in their off-hours (during the time when they are not scheduled to be on regular duty). As with the use of lay counsellors, this model allows the services to be offered by dedicated staff members that do not have competing work priorities. In hospitals and other facilities with high patient volume, full-time nurse counsellors train and supervise part-time counsellors and provide leadership in data recording and reporting.

According to the MoH PITC assessment, services operated best when counsellors were devoted exclusively to PITC services. This model adds accountability to the system and aids coordination and organisation of services that may be lost or diluted when responsibilities are spread among several people without adequate coordination, supervision and oversight.[29] While not all facilities will be able to afford or identify dedicated PITC staff, this should not be seen as an impediment to initiating services. A combination of models, utilising part-time or volunteer staff, or using already existing full-time staff, can be employed that best fit the needs and resources of a facility.

Table 3.2 summarises three staffing models and the perceived advantages and disadvantages of each.

| Table 3.2: Models for provision of PITC services | | |
|---|---|---|
| **Model** | **Advantages** | **Disadvantages** |
| Dedicated full-time professional testing and counselling staff | ▪ Roles and responsibilities clear<br>▪ Clear accountability for services<br>▪ Staff develop expertise valuable for training and mentoring others<br>▪ Services always available | ▪ Increased cost<br>▪ Increased drain on human resource availability<br>▪ Reduces accountability of other members of the team |
| Part-time testing and counselling by staff (usually nurses) working outside their normal work hours | ▪ Counsellor is free from other responsibilities<br>▪ Counsellor is motivated by opportunity for additional income<br>▪ Payment can be matched to actual performance | ▪ Increased cost<br>▪ Reduced accountability for programme coordination, reporting and data accuracy<br>▪ Other staff may lose interest in the services and become less motivated to contribute<br>▪ Service availability limited by part-time assignments |
| Lay counsellors (paid or volunteer) | ▪ Clear role and responsibilities; no competing priorities<br>▪ Readily available<br>▪ Lower cost (compared with professional counsellors)<br>▪ May be PLHIV and able to share first hand experiences<br>▪ Knowledge of community resources and support | ▪ Lack formal clinical and psychosocial background and training<br>▪ May have limited knowledge and skills and reduced areas of responsibility<br>▪ Requires more supervision/direct oversight<br>▪ Not as effective in large and busy settings where experienced staff are too busy to supervise them |

### Support for testing and counselling staff

Providing HIV testing and counselling services can be stressful and emotionally demanding and, without proper attention to staff support, may cause low morale, burnout and attrition. In addition to the professional workload and emotional demands, healthcare workers may also be living with or providing support for

family members or friends living with HIV; these healthcare workers may be in need of support and access to services. A detailed plan to provide ongoing support and supervision for all professional and lay counselling staff should be in place prior to initiating paediatric PITC services. This may include:

- Regularly scheduled meetings for mentoring, performance appraisal and supportive feedback.
- Provision of a supportive working environment, for example, giving regular breaks, starting a healthcare worker support group, organising non-work, social activities.
- Acknowledgement of positive staff performance; recognition of roles.
- Ongoing staff development and in-service training.
- Regular (weekly or monthly) one-to-one peer support meetings. Staff can pair with a peer within their own organisation or a neighbouring facility. Where possible, these meetings should take place during work time.

Appendix 8 includes additional information on supportive supervision in the healthcare setting.

### Staff to manage data, QA and monitoring

It is important to have staff (for example, the PITC coordinator or a member of staff not directly involved in programme implementation) with explicit responsibility for monitoring, data management, reporting, evaluation and assurance (QA) activities. In many facilities there are no dedicated staff responsible for these functions; so, for example, the counsellors may be responsible for monitoring and the manager responsible for reporting. Where this occurs, it is important that data management and QA activities are coordinated with feedback leading to the improvement of procedures and services.

## Capacity Building

Because human resources are the most critical component of PITC services, capacity-building is required to ensure that healthcare workers have the knowledge, skills and support to effectively deliver PITC services. Scaling up paediatric PITC services requires orientation, initial trainings and ongoing capacity building to ensure that services are of consistently high quality and that they meet the needs of the children and families they serve.

**Capacity building goes beyond training and the individual attainment of knowledge and skills; it also includes strengthening systems, establishing and supporting linkages and networks, effective use of multidisciplinary teams, mentorship and building knowledge within the larger community.**

### Staff orientation

A critical first step in establishing paediatric PITC services is to conduct a general orientation to PITC for all health facility staff, including those not directly involved in PITC service delivery. Orientation of the entire staff will help to ensure participation and buy-in and a facility-wide coordinated effort to make PITC a standard of care. Topics for staff orientation are found in Table 3.3. PITC is more likely to be supported if the service is not perceived as a non-essential, new task added to a workload already overburdened with competing priorities.

A greater understanding of the benefits to children, their families and the community may help to motivate staff to provide better access to quality, focused, appropriate care for children. The orientation should also discuss PITC as a national (and international) standard of care. It may be useful to share paediatric PITC success stories from Zambia and elsewhere, and a discussion of how routine offer of testing and counselling may help to reduce testing-related stigma. Finally, a general orientation should serve to familiarise all staff with changes and updates in the facility's SOPs, particularly those that relate to the management of paediatric patients.

| Table 3.3: Paediatric PITC orientation topics for all staff |
|---|
| ▪ Rationale for implementing paediatric PITC services<br>▪ National guidelines for routine "opt-out" testing<br>▪ Overview of facility-specific paediatric PITC protocol and services<br>▪ Overview of HIV testing and counselling procedures in children<br>▪ Communicating with caregivers and children about HIV testing<br>▪ Importance of confidentiality<br>▪ Roles and responsibilities of staff<br>▪ Linkages to care and treatment and community support<br>▪ Legal framework for consent when no parent/guardian is available |

## Staff training

In addition to the general orientation, specific and detailed training is required for personnel who will be involved in paediatric testing, counselling, data management or monitoring. Many nurses and other professional workers may have received some related training but do not have comprehensive knowledge in all required areas or skills or comfort working with children. Testing and counselling in paediatrics requires specific skills (for example, blood tests requiring heel sticks, pre- and post-test counselling for caregivers and older children) and background knowledge (rationale for PITC, understanding of PMTCT, infant feeding, disclosure to older children with HIV and the complexities of determining HIV infection status in children less than 18 months of age). See Appendix 9 for more information on disclosure.

A comprehensive training package for PITC has been developed; the training package includes a manual for trainers and another for participants, a poster to guide DBS sampling, pre- and post-test cue cards and a supervision and QA tool. These will serve to support the rollout and decentralisation of training for multidisciplinary staff of health facilities, including managers. Table 3.4 describes specific topics and skills featured in the training package. See Appendix 1 for more information and a sample agenda.

The use of lay counsellors and volunteers may help facilities cope with the demands of scaled-up HIV testing and counselling. With training and

supervision, lay counsellors are able to conduct rapid HIV-antibody testing and DBS collection for DNA PCR testing (using heel stick or finger prick) as well as pre- and post-test counselling. Lay counsellors cannot draw venous samples (for example, for CD4 testing for individuals with HIV-infection). Before starting in their new roles, lay counsellors will need comprehensive training, once they are functioning in their role, they will need regular supervision and mentoring.

Similar to the professional staff, training for lay counsellors must include the basics of HIV disease, HIV care and treatment, universal precautions, PMTCT, infant feeding and ethical issues (such as confidentiality and informed consent) as well as for development of complex skills such as pre- and post-test counselling, testing procedures and recording data. Training sessions for lay counsellors may be given along with those for nurses, since some of these topics (for example, recording data specifically for paediatric PITC) may also be new for the nurses. These sessions may be used to introduce paediatric PITC and to review/teach the skills specific to the implementation of PITC. Nurses should be available to mentor and supervise lay counsellors on newly acquired skills and provide support and supervision on an ongoing basis.

**Table 3.4: Key training topics and skills for the PITC team**

- Overview of MTCT and PMTCT
- Counselling and support for infant and young child feeding in the context of HIV
- Overview of paediatric HIV care and treatment (including care and treatment of HIV-exposed infants)
- Family-centred care, including counselling caregivers and family members on HIV testing
- Universal precautions and safety
- Communication and counselling skills (including individual counselling and effective communication to groups)
- Pre-test counselling
- HIV antibody testing, interpretation of results and confirmatory testing
- Post-test counselling
- Linkages and referrals to care and treatment, as well as psychosocial support
- Post-test follow-up and tracking
- Counselling for DNA PCR testing
- Dried blood spot (DBS) technique for DNA PCR samples
- Data recording and management
- Quality assurance/control
- Logistical systems and supply management
- Monthly reporting for monitoring and evaluation

## Laboratory Logistics

With the implementation of paediatric PITC, each health facility is expected to manage the increased load in HIV antibody testing. However, DNA PCR testing is conducted only at specific central laboratories. Therefore, DBS specimens collected for DNA PCR testing will need to be packaged and transported to the designated laboratory. The expected increases in DNA PCR testing resulting from implementation of paediatric PITC, will necessitate improved linkages with laboratory facilities and lab transportation services if the facility is not co-located with one of the three central laboratories.

Other laboratory tests relevant to diagnosis and management of HIV may be conducted outside the primary care or district level facility. Table 3.5 lists the recommended facility for eight tests often used to support the management of individuals living with HIV. More information on logistics systems is in Appendix 10.

There are three central laboratories that process DBS specimen samples for DNA PCR testing.

- The laboratory based at Arthur Davison Hospital receives DBS tests from the northern provinces, including Copperbelt, Northern, North Western, Central and Luapula provinces. This includes of ZPCT supported facilities
- The Kalingalinga laboratory processes samples from CIDRZ-supported facilities in the Western, Eastern and Lusaka provinces.
- The UTH research laboratory receives specimens from UTH, all Mission Hospitals and the Southern province.

## Table 3.5: Recommended tiered laboratory capabilities for ART

| Diagnosis and monitoring laboratory tests | | Primary care level | District level | Regional/ Referral level |
|---|---|---|---|---|
| **HIV Antibody testing**[a] | | ✓ | ✓ | ✓ |
| **HIV virological diagnostic testing**[b] | | - | + | ✓ |
| **Haemoglobin**[c] | | + | ✓ | ✓ |
| **WBC and differential** | | - | ✓ | ✓ |
| **CD4 (absolute count and %)** | | - | ✓ | ✓ |
| **Pregnancy testing**[d] | | + | ✓ | ✓ |
| **ALT** | | - | ✓ | ✓ |
| **Full chemistry (including but not restricted to: liver enzymes, renal function, glucose, lipids, amylase and serum electrolytes)** | | - | - | ✓ |
| **Diagnostic tests for treatable co-infections and major HIV AND AIDS-related opportunistic diseases** | Basic microscopy for TB and malaria (sputum smear for TB and blood film for malaria diagnosis)[e] | + | ✓ | ✓ |
| | Full cerebrum spinal fluid (CSF) aspirate examination (microscopy, India ink, Gram stain, Siehl-Neelsen). Syphilis and other STI diagnostic tests. | - | ✓ | ✓ |
| | Diagnostic tests for hepatitis B, hepatitis C serology, bacterial microbiology and cultures and diagnostic tests and procedures for PCP, Cryptococcus, toxoplasmosis and other major OIs | - | + | ✓ |
| **HIV viral load measurement**[f] | | - | - | + |

Key:
- ✓ Essential test
- \+ Desirable, but not essential test
- \- Not essential test
- ALT Alanine transaminase
- CSF Cerebrospinal fluid
- WBC White blood count
- PCP Pneumocystis pneumonia

Notes:
- [a] Rapid tests are recommended at primary level and conventional methodologies can be used at district and regional/central levels.
- [b] Virological testing for establishing HIV diagnosis in infants and children less than 18 months of age can be ocnducted using dried blood spots (DBS).
- [c] Should be available if AZT is being considered for use.
- [d] Should be available if EFV is being considered for use.
- [e] Referral if microscopy is not available.
- [f] Viral load measurement is currently not recommended for decision-making on initiation or regular monitoring of ART in resource-limited settings. Technology for assessment of viral load can also be used to diagnose HIV infection, although it is not yet standardised for this purpose.

Source: Republic of Zambia Ministry of Health. (2008). Paediatric HIV Care Training Course: Participant's Manual.

There are 72 districts in Zambia and each District Medical Office serves as the district hub for the distribution of all DBS-related supplies, which are all received from the central Medical Stores Limited. These district offices receive DBS specimens from the primary health facilities in their district. Couriers then transport specimens from district offices to one of the three central laboratories. Laboratory results are brought back from the central labs to the district hub by the same couriers for further distribution to the primary health facilities. Target turnaround time is approximately four weeks, however there have been challenges. There are currently efforts underway to investigate efficiencies and ways of streamlining the process to reduce turnaround times.

# Chapter IV: Policies and Standard Operating Procedures to Support Paediatric PITC Services

**Chapter overview**

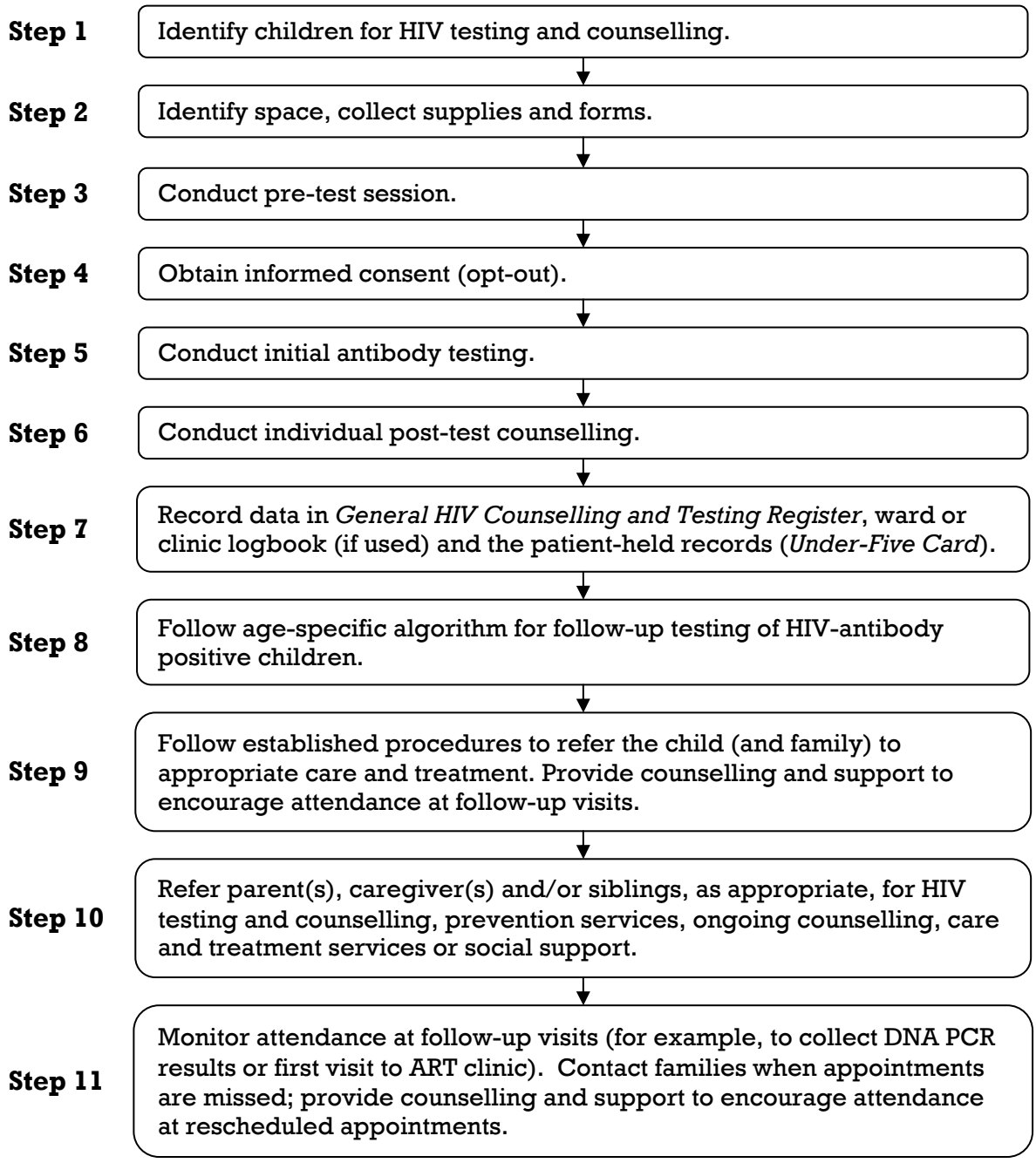
- **Steps in the PITC process**
- **Identify children for HIV testing and counselling**
- **Identify space, collect supplies and forms**
- **Conduct pre-test session**
- **Conduct testing**
- **Conduct individual post-test counselling**
- **Record data**
- **Specimen tracking**
- **Linkages to HIV care, treatment and support**

Figure 4.1 illustrates the steps in the PITC process, all of which require the establishment or revision of specific procedures. The relevant policies and procedures for each step are described in this Chapter and Chapter V. It is important to understand the national policies related to paediatric PITC when establishing facility-specific procedures.

Infants born to women enrolled in a PMTCT programme should be tested according to existing policies outlined in the *Zambia Guidelines for Prevention of Mother-to-Child Transmission* and the *Zambia Guidelines for Antiretroviral Treatment of HIV-infected Infants and Children.* The *Zambia Guidelines for Voluntary Testing and Counselling* remains in effect for parents, caregivers or adolescents able to provide informed consent.

Similarly, diagnostic HIV testing for infants and children with signs or symptoms consistent with HIV infection (including diseases associated with immune compromise, growth failure and developmental delay) should continue in accordance with the policies outlined in the *Zambia Guidelines for Antiretroviral Treatment of HIV-infected Infants and Children.*

**Figure 4.1: Steps in the PITC process**



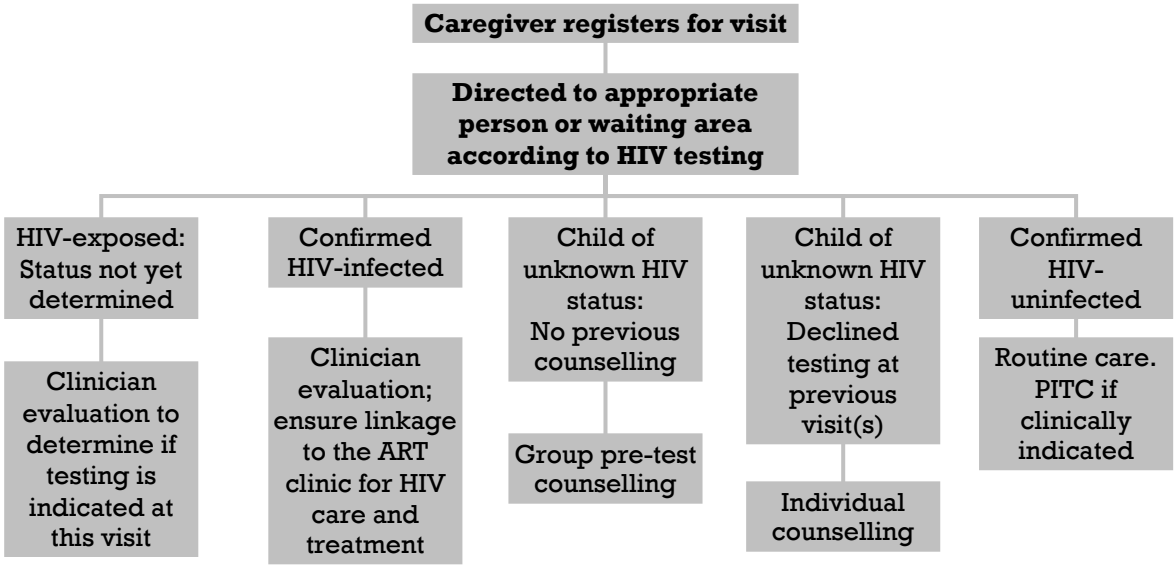

## Identify children for HIV testing and counselling

Each facility will need to establish a system for routine identification of children whose HIV status is unknown. In outpatient clinics, one member of staff should list in the *General HIV Counselling and Testing Register* (Appendix 11) all patients scheduled for a clinic visit with an unknown HIV status. Some clinics prepare the registers a week in advance and others prepare the register the day before the

scheduled visit. As patients arrive at the clinic and register, testing and counselling services can be organised according to the diagram shown in Figure 4.2. If no information is available in advance, HIV testing status should be checked when the caregiver registers.

At UHT, where paediatric PITC for all children admitted to the hospital was pilot tested, each ward has an HIV testing and counselling logbook. Upon admission, the child's name is added to the logbook; counsellors use the logbook to track admissions and record testing and counselling information.

**Figure 4.2: Patient flow for HIV testing and counselling in the outpatient setting**




## Identify Space, Collect Supplies and Forms

Ideally, a separate room is used for testing and counselling purposes. Where a private room is unavailable, arrange the available space to maximise privacy by using screens and/or rearranging furnishings.

- **One-to-one (or couple) counselling**: Consideration should be given to ensuring that counselling space maximises visual and auditory privacy and confidentiality between the client(s) and the counsellor. Table space is needed for testing supplies and recording data.
- **Group pre-test session**: For group pre-test education sessions, arrange seating so that all participants are able to see and hear the counsellor.

Implementation of paediatric PITC services will require a significant increase in the volume of test kits, DBS collection supplies and other materials to support testing procedures. Each health facility should have a list of needed supplies, along with a tracking system to reduce the possibility of stock-outs. A listing of the supplies needed to conduct PITC services follows:

HIV antibody test kits

- Determine® HIV 1 /HIV 2 and Chase buffer
- Uni-Gold
- Bioline

Supplies for DNA PCR testing (for sites conducting early infant diagnosis)

- DBS filter paper blood collection card
- Drying rack
- Glassine paper
- Sealable plastic bags
- Desiccant packs
- Humidity indicator cards
- Permanent marker to label bag
- Large envelope
- *DNA PCR Test — Laboratory Requisition Form*
- *Specimen Delivery Checklist*

Supplies to support rapid antibody testing and DNA PCR testing

- Timer or stop watch
- Sterile lancets (2 mm long)
- A Pasteur or precision pipette
- Sharps container
- Sterile gauze pads or cotton wool
- Alcohol wipes or disinfectant for skin (70% spirit)
- Non-sterile disposable gloves (latex, powder-free preferred))
- Goggles or eyeglass shield (if available)
- Plasters (adhesive bandages)
- Rubbish bin
- Pen
- *General HIV Counselling and Testing Register*

The Drugs and Medical Supplies Logistics Management System (Figure 4.3) is the nation-wide system through which medical commodities are selected, quantified, procured, transported, stored, distributed and issued or dispensed. A related

system, called the Logistics Management Information System (LMIS) is responsible for gathering information about the quantities issued or dispensed to users. All health facilities have a standardised procurement system linked with the national Drugs and Medical Supplies Logistics Management System. Districts and hospitals determine their needs and use the standard drug requisition form to order drugs and medical supplies from Medical Stores Limited, which is responsible for storing, handling and distributing all medical commodities, except vaccines and blood supplies.

**Figure 4.3: Logistics management cycle**


Adequate supplies must be on hand at all times. In order to prevent stock-outs or stocks of outdated kits:

- Stocks must be kept in high-security storage areas.
- A single person (at any one time) should be responsible for receipts and issues.
- Normal stock records must be kept for all receipts and issues, ledgers must be maintained for each item and a running balance must be kept.
- At the end of each month, the responsible individual must check the physical stock against the stock records.

Forecasting is the process of planning for the future supply needs of the programme by estimating requirements (i.e., HIV tests); see Table 4.1 for a sample forecasting formula. Procure supplies after the forecast is reconciled with the funds available. Procurement is the process of buying supplies by adhering to the appropriate national procedures.

**Table 4.1: Sample forecasting formula**

Formula for ordering

Quantity to order (QO) = Average monthly consumption (AMC) x 5 (number of months stock expected to last) – stock in hand (SI)

**QO=5(AMC)-SI**

**5 in the formula takes into consideration lead time (one month) and buffer stock of one month.*

Facilities must order commodities on a routine rather than an ad hoc basis. Orders should be made well in advance of the anticipated need to allow supplies to reach the facilities in time. Adequate buffer stock must be kept at all times and must be closely monitored to avoid stock outs.

## Conduct Pre-test Session

Individual or group pre-test session is required before testing to explain the rationale for testing, risks, benefits, confidentiality and right of refusal (Table 4.2). Group pre-test sessions can be very helpful because they provide information to a number of caregivers at one time, allowing healthcare workers more time to see patients and reducing wait times. Additionally, group sessions provide opportunity for mutual support and peer education.

Individual pre-test counselling is appropriate if the situation warrants it, for example, if requested by the caregiver, if the child is too ill for the caregiver to leave the bedside or in small facilities where the volume of clients is not large enough to warrant group pre-test sessions. Every effort should be made to provide privacy for individual sessions. Pre-test counselling must be conducted by a lay or professional healthcare worker trained to provide this service.

**Table 4.2: Pre-test session content**

The following content should be included in the pre-test session:

- *Introduce yourself and the session*
- *Ask what they may already know about HIV or PMTCT.*
  - *Can one of you tell the group what HIV is?*
  - *What is AIDS?*
  - *How is HIV passed from one person to another?*
  - *How can HIV be prevented?*
- *Discuss the reasons why HIV testing and counselling is recommended for children.*
  - *HIV testing for children is routine.*
  - *If a mother has HIV infection, the infection can be passed on to her child during pregnancy, during childbirth and after delivery by breastfeeding.*
- *Discuss the benefits of testing and counselling.*
- *Discuss confidentiality.*
- *Describe how the test is done.*
- *Describe the meaning of test results.*
- *Discuss availability of care and treatment.*
- *Discuss the right to decline the test.*
- *Close the session.*
  - *Are there any questions?*
  - *If you have a question or information you would like to share privately, you will be able to do so before the test is conducted.*

Pre-test sessions may be incorporated into routine services within the clinic or facility. For example, group pre-test sessions can be routinely scheduled at an Under-Five clinic or at certain times of the day in malnutrition wards. Because some caregivers may not be comfortable in a group setting, counsellors should respect requests for individual pre-test counselling. Tips on facilitating group education sessions and general counselling skills are included in Appendices 12 and 13.

## Obtain Informed Consent

Written informed consent for HIV testing is not required in Zambia. However, the counsellor must ensure that the elements of informed consent — benefits/risks of testing, right to confidentiality, right to decline testing — and the opportunity to decline testing are included in the counselling process.

The counsellor must ensure that the caregiver understands that the test will be conducted unless she or he explicitly declines to have the child tested, for

example, opt-out testing. This is distinct from voluntary testing and counselling (VCT), which is initiated only client request (opt-in). The counsellor should emphasize that testing is routine — recommended for all children in Zambia — because of the proven benefit of providing access to treatment as early as possible.

The counsellor and healthcare team must respect the caregiver's decision about whether or not to provide consent for testing. If the caregiver refuses testing, counsellors should follow the procedures listed in Table 4.3, to encourage the caregiver to reconsider the decision.

As minors, children cannot legally provide informed consent. Consent to HIV testing for children less than 16 years of age must be provided by an adult caregiver or guardian. However, young people under the age of 16 who are considered "mature minors" may consent for their own testing and care. Mature minors are defined as those who are:

- Married
- Pregnant
- Caregivers
- Heads of household
- Engaged in behaviour that puts them at risk for HIV (for example, unprotected sex)
- Child sex workers

**Table 4.3: Steps to follow if testing is declined**

Caregivers are entitled to decline HIV testing for themselves or for their child. Although HIV testing is strongly recommended, the caregivers' decision should be respected. If the HIV test is declined, the counsellor should provide additional, individual counselling to:

- Further explore concerns about testing.
- Clarify the importance of knowing the child's status to provide the best healthcare.
- Encourage the caregiver to reconsider testing.

Exploratory questions to consider include:

- *"Would you be willing to share your reasons for deciding not to have your child tested today?"*
- *"What do you know about the benefits of knowing your child's HIV status?"*
- *"What would have to change before you allowed your child to have the test?"*

Continue with pre-test counselling. If HIV testing is still declined:

- Let the caregiver know your door is open and that she or he can decide to have the child tested anytime.
- If available, provide the caregiver with a take home flyer.
- Arrange for further individual (or couple) pre-test counselling at the next visit (for outpatients) or the next day (for hospitalised patients).

The decision not to test should be noted on the *Under-Five Card* and in the medical record so that healthcare workers can follow up during subsequent clinic visits.

## Conduct Testing

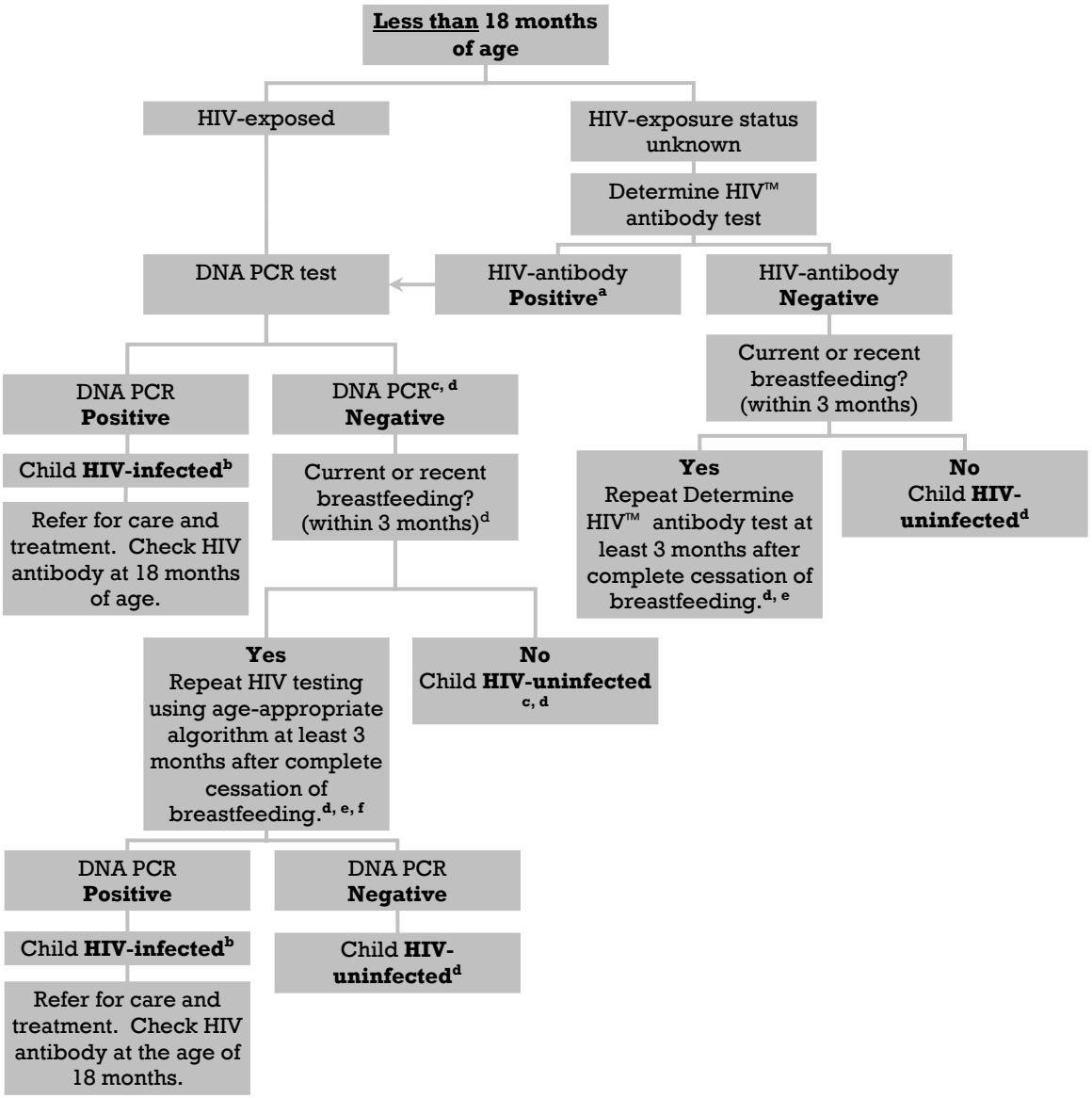
Once consent has been given, conduct the rapid HIV-antibody test according to manufacturer's directions. These tests use a specimen of blood, usually collected from a heel or toe stick (infants) or finger-prick (older children), and can be conducted in the clinic or in the hospital ward. The finger prick procedure is described in Appendix 14.

Rapid HIV antibody tests are relatively simple to conduct, provided that trained personnel and necessary supplies are available. Test results are available within minutes. The first-line rapid HIV antibody test used in Zambia is the Determine HIV 1/2 Test™. Positive tests must be confirmed with a second antibody test; if results conflict, a third test is conducted. Instructions for conducting antibody tests are included in Appendices 15-17. Follow up testing for infants less than 18 months of age is described below.

Because maternal HIV antibody is transferred across the placenta during pregnancy, ALL children born to mothers living with HIV will test HIV antibody positive in the first months of life. Maternal antibodies may remain detectable in the child's blood for as long as 18 months, but if the child is not HIV-infected, the HIV antibodies from the mother will fade away during the first 6-18 months of life. Due to the presence of maternal antibodies, a positive HIV-antibody test in children less than 18 months of age indicates *HIV-exposure* (and indicates that the mother is HIV-infected). It is not possible to determine whether or not the infant is infected with HIV without further evaluation.

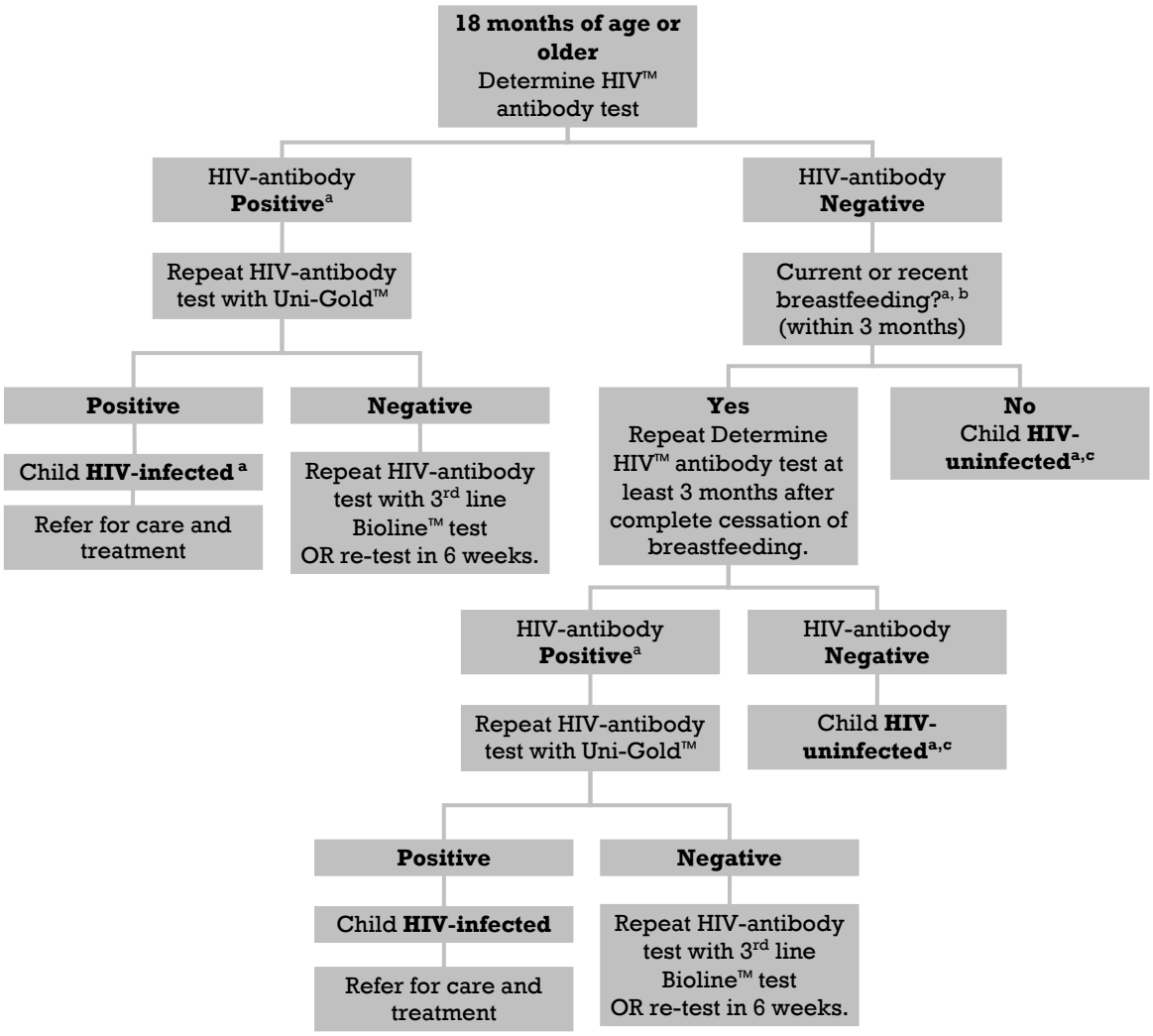
Age-specific algorithms illustrating the step-wise approach to determining HIV status are shown below in Figures 4.4 and 4.5.

**Figure 4.4: HIV testing algorithm for children less than 18 months of age**




[a] A positive antibody test in this age group indicates HIV *exposure (mother is HIV-infected)*.
[b] A positive virological test at any age indicates HIV infection. Infants 12 months and younger should receive treatment immediately, regardless of CD4 count. HIV antibody testing is done at the age of 18 months as a confirmatory test.
[c] DNA PCR testing is maximally sensitive after the age of 4-6 weeks. A negative DNA PCR test conducted before the age of four weeks should be repeated 1) immediately if the child is symptomatic; or 2) after the age of four weeks.
[d] If a child experiences symptoms suggestive of HIV, HIV testing should be repeated (even if child has not stopped breastfeeding).
[e] A breastfeeding child remains at risk of HIV infection if the mother is HIV-infected or becomes HIV-infected during the breastfeeding period. It is recommended that breastfeeding children be re-tested for HIV three months after complete cessation of breastfeeding.
[f] Use DNA PCR if less than 18 months of age and HIV antibody test if 18 months of age or older.

**Figure 4.5: HIV testing algorithm for children 18 months of age or older**




[a] A positive antibody test for a child 18 months or older should be confirmed with a second HIV antibody test. A positive confirmatory test indicates HIV-infection. A single negative antibody test for a child 18 months or older *who has not breastfed in the past three months* excludes HIV infection.

[b] A breastfeeding child remains at risk of HIV-infection if the mother is HIV-infected or becomes HIV-infected during the breastfeeding period. It is recommended that breastfeeding children be re-tested for HIV at least three months after complete cessation of breastfeeding.

[c] If a child experiences symptoms suggestive of HIV, testing should be repeated (even if child has not stopped breastfeeding).

## DNA PCR testing

Because an HIV antibody test cannot definitively diagnose infection in children less than 18 months, laboratory testing for evidence of the virus or virus particles is needed to determine HIV status of children who test HIV antibody positive. The

HIV DNA PCR test detects presence of the virus or virus particles; a positive DNA PCR indicates that the child is HIV-infected.

Unlike antibody tests, DNA PCR can detect HIV (the actual virus) in a child's blood. By the time a baby is four weeks old, the DNA PCR test is 98%+ accurate in detecting HIV in an infected child if the child was infected during pregnancy or at delivery. Because the virus is not always detectable in the first weeks after birth, the MoH recommends initial DNA PCR testing for HIV-exposed children at 6 weeks of age or as soon thereafter. Six weeks is a convenient age, as this is when most children return to the clinic for their first immunisations. DNA PCR is used to diagnose HIV infection in children up to the age of 18 months.

Both children who test HIV-positive and those who test HIV-negative should return for re-testing by HIV antibody at the age of 18 months. In this age group (0–18 months), an HIV-positive antibody test is not required to start ART. Children 12 months of age or younger who are determined to be HIV-infected should start HIV treatment as soon as possible because of the high risk of rapid disease progression.

### DBS specimen collection

DNA PCR has been used for infant diagnosis for a number of years and was introduced in Zambia in 2006; its use is currently being scaled up nationally with the introduction of a methodology of specimen collection referred to as dried blood spot (DBS). DBS simplifies the collection, storage and transport of specimens for analysis.

DBS specimen collection involves taking small drops of whole blood that are collected on strips of special filter paper card and then dried. The procedure for taking a DBS specimen involves obtaining blood from a child's heel, toe or finger and applying it directly onto filter paper card, bypassing the need for needles, syringes, whole blood collection and separation of blood into plasma.

The amount of blood required is small (usually 100 μL). If properly dried and stored, specimens remain stable for an extended period at room temperature. Even though studies have suggested that specimens are stable for 1–3 months — even as long as one year, depending on the temperature at which they are stored — all specimens should be sent to the laboratory for testing as soon as possible. Dried specimens can be transported with minimal special handling to a central laboratory.

Detailed instructions for collecting, packaging and shipping DBS specimens are described in *Dried Blood Spot for DNA PCR Testing: Health Facility Handbook.* Appendix 18 describes the steps to conduct the DBS procedure.

## HIV testing and breastfeeding

HIV infection cannot be excluded in breastfeeding children (of any age) because they continue to be at risk of acquiring HIV infection through breast milk if the mother is herself living with HIV. Therefore, HIV-exposed breastfeeding infants, even if they previously tested HIV-negative, should be re-tested at least three months after complete cessation of breastfeeding — using the appropriate test for age (see Figures 4.4 and 4.5) — to determine final HIV-infection status. The three months wait after complete cessation assures that the child will be outside of the window period. The "window period" is the time from initial infection with HIV until the immune system has produced enough antibodies to be measurable by an antibody test.

Tables 4.4 and 4.5 summarise the interpretation of HIV test results in children.

**Table 4.4: Interpreting HIV antibody test results**
**If the child is less than 18 months:**

| Result (breastfeeding status) | Meaning |
|---|---|
| **A negative antibody test (if all breastfeeding stopped at least three months ago)** | The child is not HIV-exposed or HIV-infected. |
| **A negative antibody test (if child is currently breastfeeding or stopped breastfeeding within the past three months)** | The child is either HIV-uninfected or is in the window period due to recent (i.e., within the past three months) exposure to HIV through breastfeeding. |

| | |
|---|---|
| | Ask the caregiver and child to return three months after complete cessation of breastfeeding for re-testing. |
| **A positive antibody test** | The child is HIV-exposed, the child was born to a woman living with HIV. Conduct a virological test (DNA PCR) to determine HIV diagnosis. For a child less than 18 months of age, the HIV antibody test cannot distinguish between HIV-exposure and HIV-infection. |
| **If the child is 18 months or older:** | |
| **Result (breastfeeding status)** | **Meaning** |
| **A negative antibody test (if all breastfeeding stopped at least three months ago)** | The child is not HIV-infected. |
| **A negative antibody test (if child is currently breastfeeding or stopped breastfeeding within the past three months)** | The child is either HIV-uninfected or is in the window period due to recent (i.e., within the past three months) exposure to HIV through breastfeeding.<br><br>Ask the caregiver and child to return three months after complete cessation of breastfeeding for re-testing. |
| **A positive antibody test** | The child is HIV-infected. Confirmatory testing should be conducted to validate the first test. |

| **Table 4.5: Interpreting DNA PCR test results** | |
|---|---|
| **Result (breastfeeding status)** | **Meaning** |
| **A positive DNA PCR test (regardless of breastfeeding status)** | The child is HIV-infected. |
| **A negative DNA PCR test (if the child was never breastfed or if all breastfeeding stopped at least three months ago)** | The child is HIV-uninfected.<br><br>If the test was done before four weeks of age, it should be repeated after the age of four weeks (or immediately if the child is symptomatic). |
| **A negative DNA PCR test (if child is currently breastfeeding or stopped breastfeeding within the past three months)** | The child is either HIV-uninfected or is in the window period due to recent (i.e., within the past three months) exposure to HIV through breastfeeding.<br><br>Children who remain asymptomatic can be re-tested at the age of 18 months using HIV antibody testing OR three months after complete cessation of breastfeeding (whichever is later). Children who are symptomatic should be re-tested immediately.<br><br>If the test was done before four weeks of age, it should be repeated after the age of four weeks (or immediately if the child is symptomatic). |

### Presumptive diagnosis

**Less than 18 months**: If a child less than 18 months of age has symptoms that are suggestive of advanced HIV infection and DNA PCR testing is not available, a presumptive clinical diagnosis of HIV infection may be necessary. This diagnosis will permit decision-making on the need for the initiation of potentially life-saving ART. Antibody testing must be repeated anytime after 18 months of age to confirm infection status. (See Zambian *Guidelines for Antiretroviral Therapy of HIV Infection in Infants and Children* and Appendix 3.)

**18 Months or older**: For children 18 months of age or older with signs and symptoms suggestive of HIV, the use of antibody testing is strongly recommended. Some clinical conditions are very unusual without HIV infection (for example, pneumocystis pneumonia, oesophageal candidiasis, Kaposi's sarcoma and cryptococcal meningitis), and the diagnosis of these conditions would suggest HIV infection and indicate a need to conduct an HIV antibody test for a definitive diagnosis.

In the absence of virologic testing, asymptomatic HIV-exposed children should be tested for HIV using antibody testing at the age of 18 months OR three months after complete cessation of breastfeeding — whichever is later. After 18 months, antibody testing can confirm the child's infection status.

## Conduct Individual Post-test Counselling

Post-test counselling is critical for planning next steps with the caregiver and ensuring on-going care and treatment for the child. Group sessions are not appropriate for post-test counselling. Test results are confidential; the post-test session should take place in an area or room that is private. Messages in post-testing counselling must be tailored to the caregiver's needs, the test result and the interpretation of the test result, given the child's age and breastfeeding status (see Tables 4.4 and 4.5). See Appendix 19 for infant and young child feeding counselling and recommendations.

Caregivers should be given the opportunity to ask questions and enough time to ensure that they understand the information they have received. Once the healthcare worker has ascertained that the caregivers understand the meaning of the test results and have no more questions, the healthcare worker should discuss next steps in the child's care. The recommended care plan is tailored according to child's healthcare needs and available care, treatment and support systems. It is critical that the caregiver understand the rationale for, and urgency of, ongoing care and how and where they can seek care.

A summary of the post-test counselling content follows (the scripts for the post-test counselling session can be found in Appendix 20):

### Post-test Counselling for Negative HIV Antibody Test

- Introduce yourself and the session.
- Provide the test result.
  - Discuss the meaning of the test result for the child according to age and breastfeeding status.
- Discuss IYCF.
  - Discuss IYCF according to breastfeeding status and age of child.
- Plan child's follow-up care.
  - HIV testing (if needed)
  - Under-Five clinic
  - How to cancel/change appointments
  - What to do if child is sick
- Review care and treatment for the mother and other family members.
- Assess caregiver's understanding of the results and the follow-up plan. Address questions or concerns.

### Post-test Counselling for Positive HIV Antibody Test 18 Months or Older

- Introduce yourself and the session.
- Provide test result.
  - Discuss the meaning of test result for the child.
  - Offer support and allow time for processing the information and discussing feelings.
  - Ensure understanding that HIV is a treatable, lifelong disease.
  - Discuss availability of treatment for the child.
- Find out more about the support system and provide support for the caregiver.
- Discuss continuing CTX.
- Discuss young child feeding.

- Discuss the meaning of a positive test for the mother.
- Discuss meaning of test for other family members.
- Make appropriate referrals for HIV care and treatment for the child, the mother, and any other family members as needed. Explain what to expect at the visits.
  - Date, place, time of appointments
  - What to expect at the appointments
  - How to change the appointments
  - What to do if the child or mother is ill
- Review care and treatment for the mother and other family members.
- Assess caregiver's understanding of the results and the follow-up plan. Address questions or concerns.

### Post-test Counselling for Positive HIV Antibody Test Less Than 18 Months of Age

- Introduce yourself and the session.
- Provide the test result.
  - Discuss the meaning of test result for the child.
  - Offer support and allow time for processing the information and discussing feelings.
- Discuss the process of determining HIV status:
  - DNA PCR testing
- Find out more about the support system and provide support for the caregiver.
- Discuss starting CTX.
- Discuss IYCF according to breastfeeding status and age of child.
- Discuss the meaning of a positive test for the mother.
- Briefly discuss HIV care and treatment.
- Discuss the meaning of test for other family members.
- Make appropriate referrals for HIV care and treatment for the child. Explain what to expect at the next visit.
  - Date, place, time of appointment
  - What to expect at the appointment
  - How to change the appointment
  - What to do if the child is ill
- Assess caregiver's understanding of the results and the follow-up plan. Address questions or concerns.

### Post-test Counselling for Positive DNA PCR Test

- Introduce yourself and the session.
- Provide the test result.
  - Discuss the meaning of test result for the child.
  - Offer support and allow time for processing the information and discussing feelings.
  - Ensure understanding that HIV is a treatable, lifelong disease.
- Find out more about the support system and provide support for the caregiver.

- Discuss continuing CTX.
- Discuss IYCF according to breastfeeding status and age of child.
- Discuss care and treatment for the mother.
- Discuss the meaning of test for other family members.
- Make appropriate referrals for HIV care and treatment for the child and the mother (if needed). Explain what to expect at the next visit.
  - Date, place, time of appointment
  - What to expect at the appointment
  - How to change the appointment
  - What to do if the child is ill
- Review care and treatment for the mother and other family members.
- Assess caregiver's understanding of the results and the follow-up plan. Address questions or concerns.

### Post-test Counselling for Negative DNA PCR Test

- Introduce yourself and the session.
- Provide the test result. Discuss the meaning of test result for the child. Interpret test results by category:
  - For breastfeeding children
  - For an infant less than four weeks of age (at the time of testing)
  - For a child more than four weeks of age and not breastfed
- Find out more about the support system and provide support for the caregiver.
- Discuss IYCF according to breastfeeding status and age of child.
- Plan child's follow-up care.
  - HIV testing
  - EPI/Under 5 clinic
  - How to cancel/change appointments
  - What to do if child is sick
- Review care and treatment for the mother and other family members.
- Assess caregiver's understanding of the results and the follow-up plan. Address questions or concerns.

## Record Data

Testing and counselling must be carefully documented, as record keeping is integral to program monitoring, evaluation, reporting and continuous QA.

For patient tracking and reporting purposes, information is recorded in the *General HIV Counselling and Testing Register* (Appendix 11). This register is used to record client number, date of visit, patient's name, age and other identifying information. It also includes columns for couple counselling, partner testing, reason for seeking service, date of HIV testing, result, post-test counselled,

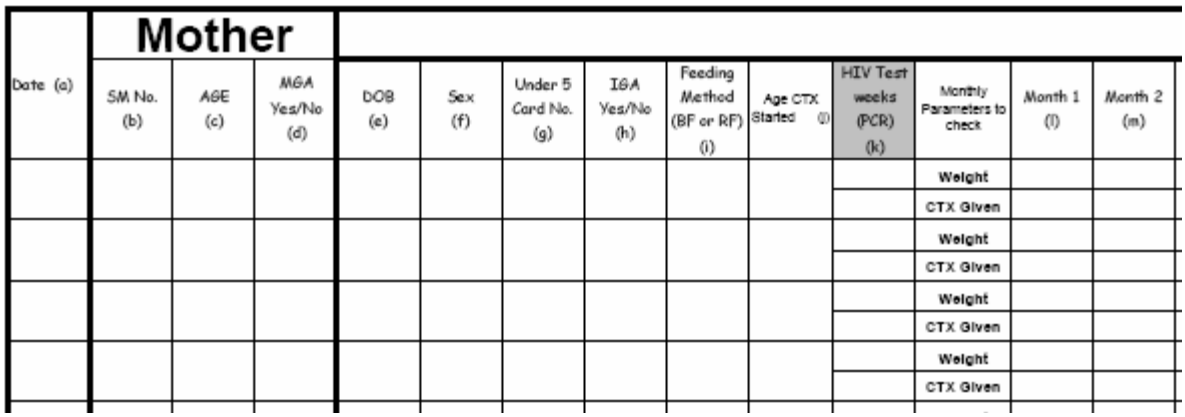
assessed/referred for ART. There is also space for other notes specific to the child or family; these might be useful as a tool for tracking patient attendance at follow-up testing or other services. The same register is used for adults and children; therefore, there are some data points requested that are not applicable to paediatric testing (for example, marital status).

The *General HIV Counselling and Testing Register* is usually kept in the room used for counselling and is completed by the counsellor. Data from the *General HIV Counselling and Testing Registers* are collated by a supervisor or designee to create monthly aggregate reports on the number of individuals who received pre-test counselling; number of individuals tested; number of HIV-positive test results (by age group); number of individuals who received test results and the number of individuals referred to ART. These form the basis for regional and national reports, evaluation and action planning for commodities and services.

The *Clinic (or Ward) Register*: This register is used to record patients admitted (hospital) or scheduled to be seen (outpatient clinic) each day. The register includes information about the child (for example, name, contact information and date of birth) and simplifies the task of identifying the care (related to testing and counselling) needed at any given visit because the status of testing can be identified quickly. See Figure 4.6.

The *Clinic Register* can be adapted for the specific context, but usually includes: date, clinic number or name, age, gender, DOB. The clinic register for antenatal and/or PMTCT care may also include information about the client's baby, PMTCT intervention received, CTX, breastfeeding status, date last breastfed, ART status, referral to treatment and other relevant comments.

**Figure 4.6: Sample Clinic Register**



| Date (a) | Mother | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | SM No. (b) | AGE (c) | MGA Yes/No (d) | DOB (e) | Sex (f) | Under 5 Card No. (g) | IGA Yes/No (h) | Feeding Method (BF or RF) (i) | Age CTX Started (j) | HIV Test weeks (PCR) (k) | Monthly Parameters to check | Month 1 (l) | Month 2 (m) |
| | | | | | | | | | | | Weight | | |
| | | | | | | | | | | | CTX Given | | |
| | | | | | | | | | | | Weight | | |
| | | | | | | | | | | | CTX Given | | |
| | | | | | | | | | | | Weight | | |
| | | | | | | | | | | | CTX Given | | |
| | | | | | | | | | | | Weight | | |
| | | | | | | | | | | | CTX Given | | |

The *Under-Five Card* (Appendix 21), carried by the caregiver, provides an information bridge between antenatal or maternity services and the children's clinic, and continues to link the child's care from one visit to the next. It also supports the continuity of care when patients move or seek care at another clinic. HIV testing information is recorded on this card (date, test done and the test result).

## Specimen Tracking

When a DBS specimen is collected for DNA PCR testing, the following steps are used to ensure specimens can be correctly identified and tracked:

1. Complete the *DNA PCR Test — Laboratory Requisition Form* (Appendix 22). The requisition form requests clinic details, site code, patient details, specimen details, clinical information and information about the requesting clinician. It should be kept with the specimen while it is drying and when it is sent to the laboratory. Keep a copy as a record.
2. Label the DBS specimen filter paper card: Label with patient's initials & ID number, date of collection, DOB, facility name, & district as seen in Appendix 18.
3. Complete the DNA PCR *Specimen Delivery Checklist* (Appendix 23). This is a checklist to verify that the DBS specimen and the *DNA PCR Test — Laboratory Requisition Form* are sent to the laboratory together. One form is used for each batch of specimens sent to the district laboratory. This form is filled in after the blood specimen is taken.
   - The checklist should be included in the envelope containing DBS bags sent to sent to the regional hub and designated referral laboratory

- At the laboratory, the technician handling the samples will indicate on the checklist that each patient sample has been received
- Before sending the *Specimen Delivery Checklist*, the clinic should keep a copy for their records.

When results are returned from the laboratory, they should be recorded in the *General HIV Counselling and Testing Register* (Appendix 11) as soon as possible. The Register should be reviewed every week to determine if any test results are missing (results should be received within one month).

## Linkages to HIV Care, Treatment and Support

The primary purpose of paediatric PITC is to enhance the health and wellbeing of the child and family by providing access to care and treatment. Paediatric PITC is not limited to providing the result of the HIV test — the goal is to indentify HIV-infected children and enrol them in care and treatment. In this regard, PITC must be strongly linked to the provision of care and treatment for the child and for other members of the family who may need HIV services. Care and treatment services must have:

- Necessary systems and capacity to provide care and treatment
- Referral system coupled with the ability to track patients who are referred for other services
- Follow-up system to contact patients who have not returned for results or treatment. See Appendix 24 for more information on referrals for the child and family members.

A follow-up system and protocol is particularly important for children because HIV progresses rapidly in this population; initiation of care and treatment, particularly ART, prevents HIV-related complications and gives the best chance of long-term survival. A follow-up system requires:

- A working appointment system whereby healthcare workers can readily track missed appointments related to testing and counselling, and a system for regularly contacting patients who miss appointments to bring them back to the clinic.
- Weekly follow up of patients who miss their appointments. In urban areas, contact may involve the use of cell phones (calling, SMS), while in rural areas, community workers, NGOs, peer educators, family members or friend networks may serve this purpose. Contacting families when appointments are missed, either by telephone or by home visit, requires the consent of the

caregiver; therefore, a system should be in place to both obtain contact information and to routinely request consent to follow up missed appointments.

- The *Clinic (or Ward) Register*, as seen in Figure 4.6 can utilised for appointment tracking and follow-up with patients and caregivers. In settings with a high volume of exposed and infected children (such as tertiary hospitals), specific staff may need to be assigned to this task on a full-time basis to assure testing procedures are completed and that the linkages between testing and subsequent care are maintained.

### Patient tracking

Linkages between services — especially between the facility where the patient is tested (such as the hospital or the Under-Five clinic) and the facility where the patient will receive follow up HIV-related services, such as the ARV clinic — should be cross-checked. On a monthly basis, the clinic should cross-check its referral records with the ARV clinic records to verify that patients who have been referred have presented for treatment. The ARV clinic should attempt to contact the family to bring them (back) into care. It is best to assign one person to take responsibility for maintaining the relationship with the ARV (and other) clinics, to cross-check the records and follow-up with the clinic to see if the family was successfully tracked and brought back into care. In some areas, the clinic can alert the public health nurse if any patients have not presented.

### Referral networks

In addition to referrals for HIV care, the child or family may require other services, including specialty healthcare services, psychosocial services or community-based services. The healthcare worker should assess the patient's needs, plan the referral, assist patients to access referral services by, for example, helping the patient make the appointment, discussing transportation or other possible barriers to attendance and identify solutions, document the referral and follow up to ensure that the patient attends the appointment. If the patient does not attend appointments, she or he should be contacted according to their agreed upon follow-up plan and barriers to access should be re-evaluated and support offered.

**Results indicating HIV-exposure:** HIV-exposed infants are linked to the Under-Five clinic for ongoing testing and monitoring until HIV status is determined. Under-Five clinic visits also include growth monitoring, developmental monitoring, provision of CTX preventive therapy, infant feeding counselling and general assessment of health, including assessment for possible HIV-related signs or symptoms. Information is recorded on the *Under-Five Card* to facilitate continuity of care between clinics and facilities.

**It is critical that healthcare workers follow-up with children and families until the final HIV-infection status is determined. Unlike in adults, final determination of HIV status in infants and children can take months.**

**Results indicating HIV-infection:** If the scheduled follow-up date is several weeks away, a healthcare worker should attempt to contact the caregivers of children testing positive by DNA PCR and ask them to come to the clinic at their earliest convenience. Although all children and caregivers must be encouraged to return for results and for post-test counselling, return of those who test DNA PCR-positive should be expedited to facilitate referral into care, treatment and support. Because HIV can progress rapidly in infants and children, delaying ART even a few weeks can make a difference to an infant's chances of survival. HIV-infected infants and children must be referred to the ART clinic immediately for clinical, laboratory evaluation, treatment and psychosocial support. Children will undergo a baseline clinical and laboratory assessment to determine the clinical stage of HIV disease (Appendix 3), immunological status (if CD4 testing is available at the site) and eligibility for treatment and other interventions according to the *Zambia Guidelines for ART of HIV-infection in Infants and Children*. Ongoing clinical and laboratory assessments are required to monitor clinical and immunological status, determine eligibility for treatment (if not yet treated) and monitor response to treatment.

**Indeterminate results:** If the lab requests another specimen because of an inconclusive test result, find out the reason for the request, i.e., if the test was borderline or if the specimen was collected incorrectly. Contact parents or caregivers and ask them to return with their child for re-testing. Explain the reason for the repeat test, reassure them of the benefits of early HIV testing and

make an appointment for the return visit. CTX should be continued for infants or children with indeterminate results and parents or caregivers should continue to receive counselling on safer infant feeding.

**Negative DNA PCR results**: Children who test DNA PCR-negative should be counselled and encouraged to return to the health facility for all routine immunisation visits and three months after complete cessation of breastfeeding for final determination of infection status.

# Chapter V: Quality Assurance and Programme Supervision

**Chapter overview**
- **Quality assurance in paediatric PITC services**
- **Quality assurance measures**
- **QA methodology (including supportive supervision)**

QA is important for the continuous evaluation of paediatric PITC services to ensure compliance with guidelines and SOPs, to identify problems and, ultimately, to improve services for children and their families. Prior to implementation of paediatric PITC services, the facility should adapt QA protocols to meet the specific needs of the facility, include protocols in staff training activities and ensure that protocols are available to all staff providing PITC services.

Implementation of QA activities will help to ensure effective rollout of paediatric PITC. Reports from central laboratory staff suggest that one of the primary challenges has been the number of indeterminate DNA PCR test results, because the specimen samples were contaminated or incorrectly collected. This feedback provide rationale for additional training on DBS specimen collection.

## QA Measures

QA activities examine and evaluate:

- General
  - Patient flow: (smooth, efficient, attentive to the needs of families)

- Compliance with national guidelines, standard operating procedures and protocols, including
  - Identification of children who require PITC services
  - Content of pre- and post-test counselling, informed consent
  - Procedures related to confidentiality
  - Adherence to universal precautions
  - HIV testing procedures following appropriate algorithms for the child's age
  - Referrals and linkages to care and treatment; tracking and supporting adherence to follow-up

- Documentation of all services (ensure data collection is accurate, complete and according to standard procedures)
- Tracking and follow-up of DNA PCR test results
- Logistics management: supplies are adequate, not out of date, secure, forecasts are accurate

- Quality of testing and counselling procedures
  - Accurate identification of all children who require PITC services according to national guidelines
  - Quality of general counselling skills
  - Pre- and post-test counselling content
  - Protection of confidentiality
  - Informed consent procedure
  - Accurate interpretation of HIV testing algorithms
  - Consistent use of universal precautions
  - Proper collection and accurate interpretation of rapid HIV-antibody test
  - Proper collection of DBS specimens
  - Accurate and complete data collection and forms completion
  - Tracking and follow-up of DNA PCR test results
  - Accurate and complete completion of logs and data collection tools and forms

- Physical space: adequacy of space and attention to privacy

- Linkages to care and treatment:
  - Provision of referrals and linkages to HIV care and treatment for the mother, child and other family members as needed
  - Responsiveness to the priority needs expressed by the family
  - Tracking, follow-up and documentation of missed appointments
  - Meeting national standards for follow-up care and treatment

## QA Methodology

QA activities are most useful when more than one methodology is employed. This allows for the broadest and most comprehensive review of services. A well-designed QA programme is one that simplifies the evaluation process and becomes a meaningful, interesting and participatory activity that reduces the burden placed on any one particular staff member and allows input from staff involved in service implementation.

The best methodologies are often interactive and may include any of the methods listed below.[30] Also, an often overlooked component of QA is the incorporation of a feedback mechanism that will lead to the improvement of systems based on

lessons learnt. Clinic managers and supervisory staff should be assisted in setting up these systems.

**Records review:** Periodic reviews of records, with staff feedback, should be part of the comprehensive QA plan. The reviewer should check for accuracy, completeness and consistency of entries in the *General HIV Counselling and Testing Register,* patient medical record, *Voluntary Counselling and Testing Activity Sheet, DNA PCR Laboratory Requisition Form* and the combined monthly data sheets.

**Supervisor observation and immediate feedback:** Direct observation of procedures — such as DBS blood sample collection, the pre-test session, the post-test session (with permission of the client), HIV-antibody testing of a blood specimen, interpretation of HIV test results (both DNA PCR and antibody) and correct storage, packing and shipping of DBS specimens — can increase the delivery of high quality services and decrease mistakes and misuse of materials. For example, direct observation of testing and counselling sessions can help ensure that the content of counselling is complete, that counselling messages are accurate and that the quality of the counselling interactions meets expected standards.

Observation and feedback should be structured (for example, utilising a standard checklist) and the outcome should be constructive rather than punitive. Supervisors should support the positive elements of the activity under observation and provide specific, constructive comments regarding areas needing improvement. Many healthcare workers report that such sessions are useful in enhancing skills. Healthcare worker discomfort with observation typically wanes over time.[31] A suggested time frame for routine, direct observation of testing and counselling by the supervisor is twice monthly for the first 6 months, monthly for the second 6 months and quarterly for counsellors with more than one year of experience.

In general, supportive supervision should be a component of supervisors' interaction with staff and refers to working with staff to establish goals, monitor performance, recognise good worker practices, identify and correct problems and proactively improve the quality of services. Mentoring, as an important element of supervision, should also be an integral component of the supervisory relationship, particularly for new staff or for staff with newly learnt skills. Together, the supervisor and workers identify and address weaknesses regularly, thus preventing poor practices from becoming routine. Programme supervision and QA are closely linked, as the aims of supportive supervision closely follow the goals of QA.

**Case conferences:** Regularly scheduled meetings with counsellors and other members of the multidisciplinary team give supervisors an opportunity to understand the current skills being utilised and areas that need improvement, and help all members of staff share techniques with their colleagues. Case conferences are an opportunity for counsellors to discuss a particularly problematic or complex client or family. Attendance by other healthcare workers gives them the opportunity to better understand the concerns facing families. In addition, case conferences can help offset staff fatigue and burnout by providing a positive outlet for dealing with difficult situations.

The case conference format may be used as a guide for multidisciplinary team meetings. These meetings may serve as a forum to coordinate care, highlight current challenges, discuss systems that are working and those that need improvement, and provide a forum for proposing solutions.

In the face of continuing human resource challenges, particular attention should be paid to providing the necessary training, supervision and continuing mentorship for staff. Feedback, in the form of supportive recommendations, recognition of their contributions and systemic attempts to reduce staff burden, will further enhance the ability of a facility to provide appropriate and high-quality service for paediatric patients.

**Community feedback:** As discussed in Chapter III, it is important to keep community stakeholders informed of the progress of paediatric PITC service implementation. Likewise, it is critical to receive feedback from stakeholders on their experiences with the programme as well as any feedback they have received from community members. Though formal meetings with the stakeholders should be held at least annually (more often at the initiation of the programme), valuable opportunities for feedback may also arise informally or in the course of other meetings or activities.

**Evaluation of client satisfaction:** Evaluations of caregiver satisfaction through private, voluntary exit interviews ensures that counselling meets the needs of the caregiver and of the family. These evaluations can also provide important feedback to counsellors who might otherwise not see the benefits of their work. These evaluations should be brief and should address the quality of the interaction and whether specific counselling goals were met. Linking caregiver feedback with the perspective of the counsellor can provide a more comprehensive view of the quality of services. Ideally, these evaluations are to be conducted once or twice each year.

**Periodic evaluation of physical space, patient flow and time concerns:** Ideally, counselling sessions are conducted in a private space where the discussion cannot be overheard or seen. Caregivers and children should not wait for long periods, especially between the rapid test procedure and post-test counselling. Voluntary client and staff surveys or interviews are useful to obtain feedback on the adequacy of space and client flow; waiting periods can be periodically measured. Additionally, structured observations of client flow and facility's space usage can be equally beneficial evaluation tools.

**Periodic reviews of supply chain management** should be conducted to determine if supply forecasts are accurate: Are there too few supplies on hand and frequent stock-outs? Are too many supplies ordered so that HIV test kits are frequently discarded because they are out of date?

**Meet with stakeholders to elicit feedback.** For example, meet with staff in the services where families are referred to ask them about client needs, gaps in services and feedback on services.

# Chapter VI: Monitoring and Evaluation

**Chapter overview**
- **Monitoring and evaluation of PITC services**
- **Paediatric PITC indicators**
- **Supervision of monitoring and evaluation activities**

Monitoring and evaluation involves continuous assessment of the quality and effectiveness of a service or programme through the review of programme data (information). QA activities are one component of monitoring and evaluation, since QA activities form part of the feedback for continuous quality improvement of systems.

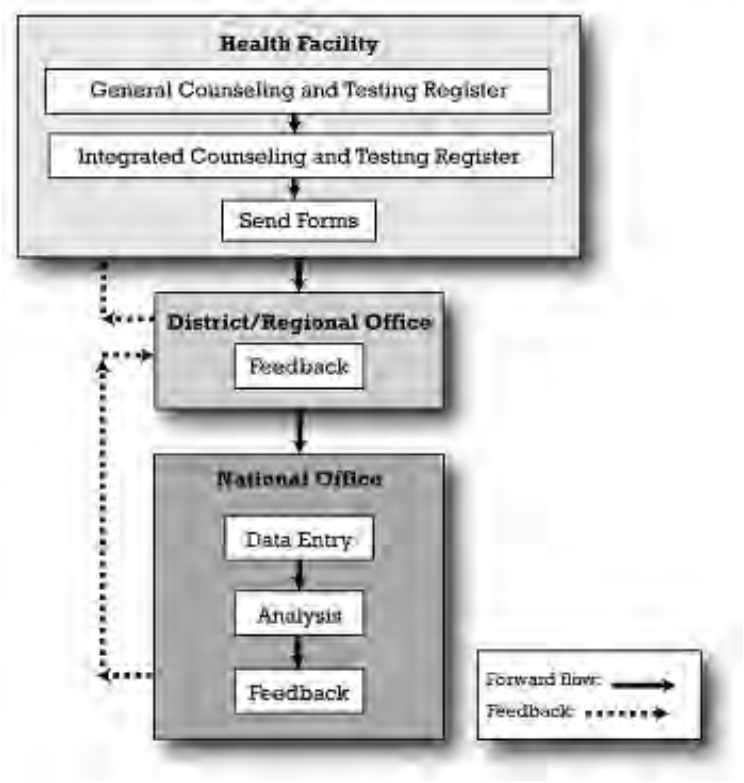
Paediatric PITC programme monitoring and evaluation involves the routine collection and analysis of data related to PITC implementation and delivery. Data collection is standardised, beginning with the identification of children for HIV testing and counselling through to the enrolment of children and families in HIV care and treatment services. Each facility should have a routine monitoring system in place, including:

**Indicators are measures chosen to represent progress in service delivery and can be used to assess progress in meeting programme objectives. Indicators used for programme monitoring reflect key service interventions and provide information about activities and results.**

- Forms
- Registers
- Records
- Procedures for collection and reporting information on specified *indicators*.

Data are summarised and analysed at regular intervals at the facility, district and national levels to examine progress, identify gaps and improve service delivery. Paediatric PITC monitoring and evaluation does not operate parallel to the national PITC adult programme; rather, it is integrated within the national system. Standardised national forms and procedures are used. Data flow includes a feedback loop that is vital to assessment of, and improvements in, service delivery. The flow of data to and from the local, regional and national levels is shown in Figure 6.1.

**Figure 6.1: Data management flow**




The MoH began an overhaul of the routine health information system for monitoring and evaluation of health-related data in 2005 to allow for better responses to emerging health issues. Considerable effort has gone into this process to ensure that already over-burdened staff can collect data using existing forms, registers and procedures rather than creating separate, parallel systems as new health problems emerge or new services are introduced. New models of HIV testing and counselling have emerged, including PITC, but the standardised approach to data collection, monitoring and evaluation is used for all HIV testing and counselling not associated with PMTCT.[32] PMTCT data collection is kept separate, at the facility level, to reduce the possibility of duplication of data collection efforts which may lead to double-counting or under-reporting. However, all collected information is eventually aggregated into the Health Information Aggregation form (HIA2).

Standard tools are used for collecting and collating all (non-PMTCT) HIV testing and counselling services:

- Individual client data are recorded in the *General HIV Counselling and Testing Register* (Appendix 11).
- Selected data fields are then summarised on the *VCT Monthly Activity Sheet* (Appendix 25) and later aggregated for regional and national reporting.

Other forms — for example, a facility specimen registers and the *Specimen Delivery Checklist* (Appendix 23) — ensure that all procedures have been

followed but such forms may not be aggregated or reported to the district level. Regardless of how these data forms are used systems should be put in place to ensure that there is regular review and oversight of data collection efforts.

As noted previously, there are data collection tools and forms used for the purpose of monitoring and evaluation of HIV testing and counselling activities that will also be utilised for monitoring the implementation of paediatric PITC (see Appendices 22, 23, 25, 26 and 27). The information in these forms, collected at the facility, district and national levels, have differing schedules for collection, aggregation and reporting to the next level. For example, the *General HIV Counselling and Testing Register* collects information on the number of new clients tested for HIV as well as the number who test positive; these data are aggregated at the facility level before being sent to the district. The number of new clients is reported quarterly and annually; the number who test positive is reported monthly and annually to the district level. These differing levels of reporting requirements entail a high level of monitoring and follow-up to ensure that requirements are adhered to consistently.

## PITC Indicators

The standardised national indicators for monitoring and evaluation of all HIV testing and counselling services are noted in Table 6.1.

| Table 6.1: Standardised national indicators | | |
|---|---|---|
| **Indicator** | **What it means** | **Significance/Rationale** |
| The percentage of new clients tested for HIV at the first encounter | Indicator measures, of all new clients in a given time period, what proportion were tested at their first visit | Indirectly measures the quality and effectiveness of counselling services |
| Percentage of clients testing HIV-positive | Indicator measures the proportion of clients testing HIV-positive in a given period | Indicates level of HIV infection among the patient population at the health facility |
| Percentage of HIV-infected clients collecting results and percentage of clients referred for HIV treatment services | Indicator measures, of all HIV-positive clients within a given period, what proportion received their results and what proportion were referred for continuing services | Measure of the quality of follow-up and referral services at a facility |

The national scale-up of paediatric PITC services highlights a need to identify and track additional indicators for children and their families who receive testing and counselling services outside the realm of PMTCT or VCT service systems. Additional indicators to consider for monitoring and evaluation of PITC services are listed below; these are not currently measured in the standard national monitoring and evaluation system. The denominator is the number of children seen with unknown status.

- Number and percent of caregivers/children offered testing and counselling
- Number and percent of caregivers/children accepting testing and counselling
- Number and percent of HIV-antibody positive test results
  - Less than 18 months of age
  - 18 months of age and older
- Number and percent of HIV-exposed infants tested using DNA PCR
- Number and percent of HIV-exposed infants whose parent/caregiver refuses DNA PCR testing
- Number and percent of parents/caregivers who receive DNA PCR results
- Number and percent of positive DNA PCR test results
- Number and percent of HIV-exposed or -infected children started on CTX prophylaxis
- Number and percent of infants and children enrolled in follow-up HIV care and treatment services
- Number and percent of infants with an initial negative DNA PCR test result receiving follow-up HIV testing
- Number and percent of infants for whom final HIV status is determined

- Number and percent of children lost to follow-up (missing all visits for a period of 6 months)

These data are critical to assessing the progress of paediatric PITC services, identifying gaps and refining implementation strategies. They are also needed to determine performance (achievement of milestones and targets for specific indicators), to assess impact and effectiveness and can contribute to understanding the cost-effectiveness and sustainability of the programme. Facilities would need to first identify baseline parameters (for example, average number of infants and children seen per month with unknown HIV status i.e. "eligible for HIV testing") and then set milestones and targets for specific indicators.

## Supervision

To ensure that accurate data are available for programme monitoring, supervisors should regularly review the accuracy, completeness and quality of the data recorded in the *General HIV Counselling and Testing Register* and the *VCT Monthly Activity Sheet*. If the facility has elected to use a clinic (or ward) register, this should also be examined. During initial implementation, daily or weekly data checks allow immediate follow-up to correct problems. As services become well-established, data reviews should become routine, taking place at designated (monthly or quarterly) intervals. The completeness and accuracy of data should be assessed against standards. Measurements and data recording that reflect an acceptable level of accuracy might include the following:

- At least 80% of fields in the programme register are complete.
- At least 80% agreement between 2 sources of information (for example, registers and patient cards)
- At least 80% data within expected range (for example, date of visit has the correct year, infant date of birth is logical).
- 100% of clients are recorded in the *General HIV Counselling and Testing Register.*
- Selected data fields are then summarised on the *VCT Monthly Activity Sheet*.
- At least 90% of caregivers/clients accept HIV testing after counselling.
- 100% of DBS specimens for DNA PCR that are sent to the lab have either a test result or documentation of reason the test was not done.

Continuous, accurate and consistent monitoring and evaluation of paediatric PITC implementation underpins quality assurance measures and reporting of services. The accuracy of monitoring and evaluation efforts can be improved through staff training in data collection, close supervision of new staff undertaking monitoring activities, on-site mentoring followed by routine QA. The following general guidelines should be followed at every facility:

- Ensure that staff undertaking monitoring and evaluation activities are trained. In addition, all programme staff (not just those undertaking monitoring activities) should know the data to be collected, how it should be recorded and why it is recorded. Indicators must be clearly defined.
- Use standard registers to collect and document PITC monitoring information. Zambia national registers and forms are shown in Appendices 11, 21, 22, 23, 25, 26 and 27.
- Record accurately, completely and in a timely manner all testing, counselling, referral and enrolment data.
- Review monitoring data routinely to assure that PITC data are consistently and reliably recorded.
- Include in the monitoring and evaluation system a feedback loop that allows for improvement of procedures based on an evaluation of previously-collected information.

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