SCALE UP OF HIV-RELATED PREVENTION, DIAGNOSIS, CARE AND TREATMENT FOR INFANTS AND CHILDREN

A Programming Framework



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This paper is written with technical and editorial contribution from the following members of the Expanded Inter-Agency Task Team (IATT) on Prevention of HIV Infection in Pregnant Women, Mothers and their Children:









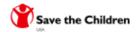
















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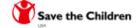
















ABBREVIATIONS AND ACRONYMS

AFASS affordable, feasible, acceptable sustainable and safe

AIDS acquired immunodeficiency syndrome
AMDS AIDS Medicines and Diagnostics Service

DBS dried blood spot

DNA deoxyribonucleic acid

G8 group of 8 countries

HIV human immunodeficiency virus

IMAI Integrated Management of Adolescent and Adult Illness

IMCI Integrated Management of Childhood Illness

PCP pneumocystis pneumonia
PCR polymerase chain reaction

PITC provider initiated testing and counselling

RNA ribonucleic acid
TB tuberculosis

UNAIDS Joint United Nations Programme on HIV/AIDS

UNICEF United Nations Children's Fund WHO World Health Organization

EXECUTIVE SUMMARY

HIV is increasingly affecting the health and welfare of children and undermining hard-won gains in child survival in some of the highly affected countries. Recent estimates from UNAIDS suggest that, globally, about 2.1 million children younger than 15 years of age have HIV, 90% of whom live in sub-Saharan Africa. In 2007 alone, an estimated 420 000 children were newly infected, mainly through mother-to-child transmission, of whom perhaps half will die without early interventions. Many of the 290 000 children who died in 2007 never received an HIV diagnosis or entered into HIV care.

To help address this significant public health issue for children, UNICEF and WHO initiated a process to develop a programming framework designed to assist national health managers and implementing partners in resource-constrained settings with a high HIV burden to scale up HIV prevention, diagnosis, care and treatment for children who are exposed to or who have HIV within the context of broader child survival and HIV programmes. This framework was developed following an international consultation held in New York in 2006 that included more than 100 participants from the global paediatric HIV and child survival community.

Underpinning the guidance in this framework is evidence regarding the importance of early HIV diagnosis, co-trimoxazole preventive treatment for children who are exposed to or who have HIV and timely entry to care and treatment. Studies also confirm that children in high-income, medium-income and low-income countries respond well to HIV treatment. Programmatic direction contained within the framework is based on lessons learned as resource-constrained settings have navigated the process of scaling up.

Despite evidence regarding the ability to deliver high-quality care to children who have HIV as well as documented progress in some countries, national responses in many resource-constrained settings remain limited. The following seven strategies have been identified as key to scaling up national responses.

Strategies for scaling up

- Government leadership, ownership and accountability evidenced by established management and coordination structures, national targets and budgeted plans for national scale-up directed to reach all children in need.
- 2. Integrated and decentralized delivery of HIV prevention, diagnosis, care and treatment services to children, building on existing health delivery mechanisms.
- Enhanced early identification of infants who are exposed to or have HIV through increased providerinitiated HIV testing and counselling at all levels of the health system.
- **4.** Reliable procurement and supply management mechanisms that ensure a consistent supply of medicines and commodities that meet the needs of infants and children.
- 5. Laboratory capacity to support HIV diagnosis, care and treatment for children.
- **6. Community-based capacity** to support the early identification of children who are exposed to or have HIV for referral to testing, care, support and treatment as appropriate and to provide follow-up care and support to children and families closer to where they live.
- 7. Strengthened monitoring and evaluation systems that enhance the provision of high-quality care for children who are exposed to or have HIV.

This framework outlines actions required to incorporate these strategies into efforts to scale up national programmes.

1. BACKGROUND

HIV burden among children

The number of children who have HIV continues to grow. Recent estimates from UNAIDS (1) suggest that globally about 2.1 million [1.9 million – 2.4 million] children younger than 15 years of age have HIV, about 90% of whom live in sub-Saharan Africa. In 2007 alone, an estimated 420 000 [350 000–540 000] children were newly infected with HIV, mainly through mother-to-child transmission. Sub-Saharan Africa remains the region most affected, followed by Asia (1). Almost all of these infections in infants could be avoided by timely delivery of known effective interventions to prevent mother-to-child transmission.

In certain parts of the world, HIV infection has significantly affected child survival. The World Health Report 2005 (2) estimated that HIV infection contributed 3% to the global mortality among children younger than 5 years of age in 2005. The proportion of mortality among children younger than 5 years of age attributable to HIV was about 7% in Africa as a whole but was estimated to exceed 50% in some of the most severely affected countries (3). The mortality rate of children born to seropositive mothers is higher than that of children of seronegative mothers and the incidence of prematurity and intrauterine growth retardation are also higher, irrespective of infant HIV infection status (4). In addition, women with more advanced HIV infection are not only more likely to transmit HIV to their infants than women with less advanced HIV, but their infected infants are more likely to die by 6 months of age (5).

HIV infection follows a more aggressive course among infants and children than among adults, with 30% dying by age 1 year and 50% by age 2 years without access to life-saving drugs, including antiretroviral therapy and preventive interventions such as co-trimoxazole (trimethoprim-sulfamethoxazole) (6). In 2007, WHO/UNAIDS estimated that 690 000 [580 000–860 000] children needed antiretroviral therapy (7). About 290 000 [270 000–320 000] children younger than 15 years died related to HIV in 2007, the vast majority in sub-Saharan Africa (1), death being most frequent among infants acquiring HIV infection earlier in the pregnancy. Most of these deaths in children who have HIV could have been avoided through early diagnosis of HIV and timely provision of effective care and treatment for common childhood illnesses, opportunistic infections and antiretroviral therapy.

Children surviving the first year of life are more likely to die from common childhood illnesses. The commonest causes of death in infants and children who have HIV are respiratory infections, diarrhoea and tuberculosis, which commonly result from several risk factors, including opportunistic infections and undernutrition (8), with all-cause mortality being greatest among those with low weight (9). Poor nutritional status makes children who have HIV more susceptible to morbidity and mortality, even while they are receiving antiretroviral therapy (10). Strengthened child survival and HIV programmes will therefore benefit all children, including those who are HIV-infected.

Scaling up programmes

The availability of services for preventing mother-to-child transmission, diagnosis, HIV care and antiretroviral therapy for children in well-resourced countries has resulted in fewer children being born infected with HIV and those being born with HIV living healthy and productive lives into their teenage years and beyond. Children respond as well to antiretroviral therapy in low- and medium-income countries as in high-income countries (11–14). Good evidence also indicates that using co-trimoxazole preventive therapy benefits infants and children who have HIV (15).

During the past few years, low- and middle-income countries have made good progress in building the capacity to provide care, support and treatment for children. By the end of 2006, more than 125 000 children in these countries were receiving treatment, a substantial increase over the estimated 75 000 children receiving treatment in 2005.

Nevertheless, challenges remain to scaling up services more comprehensively. Despite the known benefits of cotrimoxazole preventive treatment and updated recommendations from WHO, only 4% of the estimated 4 million children needing co-trimoxazole preventive treatment (who are exposed to or have HIV) are currently receiving it (7). Diagnostic protocols for HIV testing in younger infants have also been difficult to operationalize because of cost, lack of technical competence, little provider confidence in caring for infants and young children, underdeveloped laboratory systems and weak systems for transporting specimens and results.

International agreements and goals

The international community has issued several declarations in support of HIV prevention, diagnosis, care and treatment, many of which reference children. The most important HIV-related declarations are the following.

- Millennium Development Goals 4 and 6 call for a two thirds reduction in the mortality rate for children younger than 5 years and halting and beginning to reverse the spread of HIV/AIDS – by the target date of 2015.
- In the **Declaration of Commitment on HIV/AIDS** of the United Nations General Assembly Special Session in 2001, Member States agreed to reduce the proportion of infants infected with HIV by 20% by 2005 and by 50% by 2010. The Declaration of Commitment on HIV/AIDS also called upon governments to improve access to highquality HIV care, support and treatment to individuals, families and communities affected by HIV and AIDS.
- 'A World Fit for Children' (16) emerged from the first United Nations General Assembly Special Session on Children in 2002 that included more than 70 heads of state and government. It issued a strong call to improve the lives of children. HIV/AIDS is one of the four key priority areas for action.
- The "3 by 5" initiative launched by WHO, UNAIDS, UNICEF and other partners in 2003 played a major role in increasing access to HIV treatment for many people in low- and medium-income countries.
- The commitment on universal access adopted at the G8 Gleneagles Summit in 2005 (17) called for addressing HIV/AIDS through the whole continuum of care from prevention through treatment and care as well as for universal access to HIV services by 2010.

Guiding principles for HIV care and treatment for children

The needs of children who have HIV should be at the centre of programming approaches and guide the recommendations contained within this framework. The following principles underpin the seven strategies for scaling up articulated in this framework.

- **Urgency**. HIV prevention, diagnosis, care and treatment must be immediately scaled up to avert hundreds of thousands of deaths among children who are exposed to or have HIV.
- Universal access. All children in need should have access to HIV prevention, diagnosis, care and treatment services.
- **Life-long care**. HIV disease is a chronic disease and requires ongoing care and treatment; national governments have a responsibility to ensure uninterrupted care and treatment.
- **Family-centred care**. Family members should receive care in a manner that recognizes and responds to the family as a unit.
- **High-quality care**. Care provided should be of the highest quality possible and should be monitored and improved through a system of improvement.

A public health approach

HIV care and treatment for children should be scaled up in accordance with a public health approach. WHO has outlined key aspects of this approach (18), including:

- · selecting interventions based on the best available evidence and the burden of disease;
- optimizing the use of the available human resources;
- implementing standardized treatment protocols and simplified clinical monitoring, simplifying clinical decisionmaking and facilitating the provision of care by more types of health care workers;

- involving community members and people living with HIV in managing and designing programmes and delivering services; and
- using strategies to minimize costs, including the use of generic medicines and alternative laboratory technologies.

To reach the goal of universal access, interventions need to be delivered at scale, which urgently requires that service delivery be better integrated and decentralized. Given the significant mortality among children younger than 5 years attributable to HIV in certain parts of the world and the existing high infant and child mortality rates from other causes, HIV care for children needs to be integrated into existing and strengthened child health services. In addition, HIV care for children should be an integral part of all HIV care and treatment programming.

Differing approaches: high-burden versus low-burden countries

Guidance in this publication focuses largely on the needs of countries with a high HIV burden, defined as HIV prevalence in antenatal care settings exceeding 5%. The guidance may also be relevant, however, to specific states or provinces in countries with concentrated epidemics even if the entire country has lower HIV prevalence. Although not all components included will be applicable to lower-prevalence settings, national programme managers should review the guidance carefully to see which they may wish to adapt to their particular situations.

Development and organization of the framework for scaling up

WHO and UNICEF in collaboration with other partners have conducted several technical missions on scaling up the responses to HIV prevention, diagnosis, care and treatment for children. During these missions, policy-makers have expressed a desire for guidance on how best to scale up their responses, especially in resource-constrained settings. UNICEF and WHO are responding to this request by developing this programming framework, which is based on programme experience and lessons learned as well as experiences shared during the UNICEF-WHO Consultation: Development of a Programming Guide for Scaling Up Treatment, Care and Support for HIV-infected and Exposed Children in Resource-constrained Settings held in New York in 2006 (19).

The framework has four major sections. The first section provides background information to put the issue of HIV care and treatment for children into context. The second section describes the full package of interventions for infants and other children who are exposed to or have HIV. The third section describes the seven recommended strategies for ensuring their delivery. The fourth and final section describes and contains links to key resources.

2. COMPONENTS OF THE CARE PACKAGE FOR CHILDREN WHO ARE EXPOSED TO OR HAVE HIV

Background

Preventable communicable diseases including pneumonia, diarrhoea, malaria, measles and HIV infection account for more than half of all childhood deaths. Undernutrition is estimated to be an underlying cause of approximately a third of the deaths among children younger than 5 years of age (20). Underweight status and micronutrient deficiencies also impair immune and non-immune host defences and are related to infectious diseases that lead to death. In low- and middle-income countries, serious illnesses commonly occur sequentially or concurrently before death and are more frequent among the children who have HIV or whose family members have HIV.

Deaths reported among infants who have HIV are largely caused by infectious diseases, most frequently pneumonia and diarrhoea (21–24). Children who have HIV have a 3- to 13-fold greater risk of non-specific HIV-related conditions and an increased likelihood of more severe or recurrent conditions (25). A robust evidence base confirms that a range of interventions provided to mothers and children are effective in reducing child mortality by at least 60% irrespective of HIV infection status (26–28). Appropriate care and treatment for children who have HIV therefore includes, at a minimum, the interventions required to address infant and child mortality.

A first critical step for countries is to define their essential package of child health interventions, which includes HIV prevention, diagnosis, care and treatment. Child health interventions must also include preventive measures that may reduce the likelihood of exposure leading to disease. This component of the package is particularly important for children who are exposed to or have HIV, who are already more susceptible to childhood illness. The package should be based on local needs and epidemiology (such as high or low HIV prevalence, tuberculosis (TB), malaria, diarrhoea and other risk factors) and be reflected in national strategic, operational and implementation plans.

Expanded access to key child health interventions can help secure HIV care for children. The *Lancet* series on child survival (29) further describes the preventive and curative child health interventions. In particular, programme planning needs to ensure:

- · country health systems for immunization;
- essential nutrition interventions;
- · care for newborn infants; and
- · care for sick children.

Essential child survival interventions

The following essential child survival interventions need to be ensured for all infants or children.

Newborn care interventions include:

- ✓ skilled care at birth;
- ✓ thermal care;
- ✓ hygienic cord care;
- ✓ extra care for low-birth-weight or premature infants:
- ✓ early initiation of exclusive breastfeeding (ideally within the first hour); and
- ✓ early postnatal visit (optimally within the first 48 hours).

Prevention interventions include:

- exclusive breastfeeding up to 6 months of age;
- ✓ safe complementary feeding from 6 months of age;
- ✓ good maternal nutrition;

- complete and timely immunization: BCG, hepatitis B, DPT (diphtheria, pertussis, tetanus), oral polio vaccine, measles and Haemophilus influenzae type B;
- ✓ vitamin A supplementation;
- ✓ regular growth monitoring and developmental assessment;
- ✓ improved water, sanitation and hygiene; and
- ✓ insecticide-treated bed nets.

Treatment interventions include:

- ✓ oral rehydration therapy for diarrhoea (30);
- ✓ prompt care-seeking;
- ✓ zinc to reduce diarrhoea and pneumonia deaths;
- ✓ prompt antibiotic treatment for pneumonia and dysentery;
- ✓ prompt antimalarial treatment; and
- management of severe malnutrition.

Essential interventions for infants and children who are exposed to or have HIV

In addition, the following interventions are required for the children who are exposed to or have HIV:

- ✓ antiretroviral prophylaxis for mother and infant;
- ✓ early and regular clinical assessment;
- ✓ provider-initiated HIV testing, including laboratory tests for HIV in infants;
- counselling and support for optimizing nutrition and infant and young child feeding;
- ✓ co-trimoxazole preventive treatment;
- ✓ screening, prevention (including isoniazid prophylaxis) and management of TB;
- early antiretroviral therapy;
- ✓ treatment adherence support;
- regular clinical and laboratory monitoring;
- ✓ psychosocial support; and
- care, treatment and support for their family members.

Further detailed recommendations on key child survival interventions are available at the WHO, UNICEF and Basic Support for Institutionalizing Child Survival (BASICS) web sites, and the subsequent section focuses on where these interventions require modification for the children who are exposed to or have HIV or where additional interventions are required due to the presence of or exposure to HIV infection.

Additional information on the life-cycle approach to child survival and development is also available at the WHO web page on child and adolescent health and development (31).

Child health interventions requiring additional components for infants and children who are exposed to or have HIV

Nutrition, infant and young child feeding. Without intervention, an estimated 5–20% of infants born to women living with HIV become infected through breastfeeding. Multiple studies have demonstrated the risk of transmission of HIV through breast-milk, with increasing rates of infection associated with prolonged duration of breastfeeding and mixed feeding. A recent study from South Africa (32), however, demonstrated that exclusive breastfeeding by mothers living with HIV may substantially reduce breastfeeding-associated HIV transmission compared with mixed feeding. In addition, studies are ongoing to examine the effects of antiretroviral therapy in mothers living with HIV during breastfeeding to reduce transmission, as well as studies on the efficacy of providing antiretroviral drugs to the infant during the breastfeeding period to reduce transmission.

Appropriate feeding of infant and young children is central to optimizing the health and development of all children. Given the significant benefits of breastfeeding for children's health, early initiation and exclusive breastfeeding until six months of age is recommended as an essential chid survival intervention. Women living with HIV are also recommended to exclusively breastfeed their child for the first 6 months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS) for them and their infants. Continued breastfeeding is recommended for infants who are already known to be HIV infected. For all infants, gradual introduction of nutritious complementary foods is recommended after 6 months of age. The WHO web site (33) presents the most recent consensus statement and specific criteria for replacement feeding that is AFASS. The United Nations has comprehensive recommendations regarding infant feeding (34). The WHO web site (35) presents a comprehensive overview of tools and resources on HIV and infant feeding.

Macronutritional support. Resting energy expenditure is increased by about 10% among asymptomatic children who have HIV, and the energy needs of both adults and children increase an additional 20–50% during the convalescent catch-up period after a severe infection. There is no evidence for increased protein requirement exceeding that required in a balanced diet to satisfy the total energy requirements; thus, all children should have a balanced diet in which protein contributes about 10–15% of energy intake (36).

Nutritional targets should be achieved through food-based approaches whenever possible; malnourished children may need supplementary or therapeutic feeding depending on the degree of malnutrition.

Micronutrient supplementation. Regular supplementation with vitamin A starting at age 6 months is recommended for all children younger than 5 years (37). Iron and folic acid supplementation should be targeted to those who are anaemic and at risk of iron deficiency. One recommended daily allowance (RDA) for all micronutrients is recommended for all children regardless of HIV status (38,39).

Regular monitoring of growth and development. Children's growth reflects their health and nutritional status well. Growth failure, however, is common among children who have HIV. Children who have HIV merit special attention as they have additional needs to ensure growth and development and depend on adults for adequate care. New WHO guidelines have been developed recently to assist in assessing the nutritional status of children who are exposed to or have HIV (40). Regular, ongoing follow-up and monitoring of growth, particularly weight gain (but also including height, head circumference and other measures of growth) are essential to document the progression of HIV and the response to treatment, including antiretroviral therapy (41). Mid-upper-arm circumference when used in combination with other clinical signs (bilateral pitting oedema) has been found to be a useful and highly practical indicator of wasting-associated mortality risk (42) and is particularly effective when infection is an underlying or contributing cause of undernutrition. The WHO Child Growth Standards for children younger than 5 years (43) provide more detail.

Management of severe malnutrition. All infants and children with severe malnutrition are at risk of several life-threatening problems and urgently require standard treatment, including vitamin and mineral supplementation as part of their therapeutic management. For HIV-exposed infants, access to virological testing is crucial to detect HIV early and optimize the management of malnutrition. HIV-exposed children with uncomplicated forms of severe acute malnutrition should be treated in the community using ready-to-use therapeutic foods (44). HIV-exposed children with severe malnutrition should be managed according to WHO guidelines (44) or other appropriate national guidelines. Poor response to therapeutic feeding in a child with HIV is usually an indication for initiating antiretroviral therapy. All infants who have HIV need ART, but stabilization of severe acute malnutrition is required prior to starting antiretrovirals.

Prevention, active early detection and management of common and opportunistic infections. Specific common childhood illnesses recognized to be more common and associated with adverse outcomes in children who have HIV are highlighted below. Adapted WHO and UNICEF Integrated Management of Childhood Illness (IMCI) guidelines or relevant national guidelines should be followed.

Pneumonia. Although effective interventions to reduce pneumonia deaths are available, they reach too few children, resulting in more than 2 million deaths among children each year: almost one fifth of deaths among children younger than 5 years worldwide. Undernutrition among children aged 0–4 years contributes to more than 1 million pneumonia deaths each year, and infants 6–11 months old who are not breastfed are also at an increased risk of dying from pneumonia compared with those who are breastfed. Children who have HIV and children who lack sufficient amounts of specific micronutrients, particularly zinc, face additional risks of developing and dying from pneumonia. Children who have HIV have higher rates of pneumonia and mortality in both resource-constrained and high-income settings (45–47). In African countries, pneumonia is the leading cause of hospital admission and the commonest cause of death among children younger than 5 years who have HIV. Infants who have HIV are at particular risk of pneumocystis pneumonia (*Pneumocystis jiroveci*, formerly *carinii*, often referred to as PCP), which is prevented by co-trimoxazole.

Essential interventions to reduce deaths among children who are exposed to or who have HIV and who have pneumonia include (48):

- early recognition of the sick child by family and caregivers;
- · appropriate care-seeking;
- improved case detection by health care workers;
- · early appropriate treatment with antibiotics; and
- · co-trimoxazole prophylaxis for children who are exposed to or who have HIV (also see below).

Diarrhoea. Acute and chronic diarrhoea is a common clinical presentation of HIV infection worldwide and is a major cause of mortality in cohorts of African children who have HIV. Compared with uninfected infants, infants who have HIV have higher incidence rates for acute diarrhoea and persistent diarrhoea, and death due to diarrhoea is more common among children who have HIV (49,50).

Appropriate case management includes (30,51–54):

- administering suitable available home fluids and use of new oral rehydration salt solution;
- increased feeding, including breastfeeding, during the diarrhoeal episode and for two weeks afterwards;
- · using antibiotics appropriately; and
- providing zinc supplementation for 10–14 days (10 mg per day for infants younger than 6 months and 20 mg per day for others).

Malaria. Children who have HIV are at increased risk of symptomatic parasitaemia, clinical malaria or severe or complicated malaria, and effective prevention and treatment interventions are therefore critical. WHO now recommends artemisinin-based combination therapy for the treatment of *Plasmodium falciparum* malaria (55–57).

Interventions include the following:

- prevention through the use of insecticide-treated nets and other locally appropriate preventive measures;
- prompt recognition and treatment of fever in malaria-endemic areas;
- · co-trimoxazole prophylaxis to prevent malaria among women and children who have HIV; and
- use of artemisinin-based combination therapy for treating *P. falciparum* malaria.

Immunization. All HIV-exposed infants and children should receive all Expanded Programme for Immunization vaccines, including *Haemophilus influenzae* type B and pneumococcal vaccine, as early in life as possible, according to the recommended national schedules (58–60). Programmes need to ensure that all infants and children who are exposed to or have HIV receive immunization for vaccine-preventable diseases to maximize impact. The following usual immunization schedules should be adjusted.

Measles

Because of the increased risk of early and severe measles infection, HIV-exposed infants should receive a dose of standard measles vaccine at 6 months of age with a second dose as soon after age 9 months as possible unless they are severely immunocompromised at that time (61).

Pneumococcal conjugate vaccine

Three doses of pneumococcal conjugate vaccine are safe and immunogenic in both HIV- and non-HIV-infected children younger than 2 years and should be given at 2, 4, 6 and 12–15 months of age. Pneumococcal conjugate vaccine, however, should be delayed if the child is severely immunocompromised (62,63).

Bacille Calmette-Guérin (BCG)

New findings indicate a high risk of disseminated BCG disease developing in infants who have HIV, and BCG vaccine should therefore not be given to children known to have HIV. However, infants cannot usually be identified as infected with HIV at birth, and so BCG vaccination should usually be given at birth to all infants regardless of HIV exposure in areas with high endemicity of TB and populations with high HIV prevalence (64,65).

Haemophilus influenzae type b vaccine

Haemophilus influenzae type b has been shown to be an important cause of childhood meningitis and a major cause of bacterial pneumonia in children. HIV appears to be a risk factor for developing invasive disease due to *H. influenzae* type b, especially bacteraemic pneumonia. Co-trimoxazole prophylaxis may reduce risk of community-acquired pneumonia. Children who are exposed to or who have HIV should receive *H. influenzae* type b conjugate vaccine. This requires three immunizations (usually given at 2, 4 and 6 months of age). A booster dose is recommended in most countries at 12–18 months of age but may not be necessary, especially in low- and medium-income countries, where most of the *H. influenzae* type b disease occurs before this age. Immunization should be delayed if the child is severely immunocompromised.

In some countries, other vaccinations are recommended as part of routine vaccination notably hepatitis B (66,67).

HIV testing. Early recognition of HIV exposure among infants and early diagnosis of HIV are crucial to enable the early initiation of life-saving care, including antiretroviral therapy. Many opportunities to diagnose HIV infection in infants and children, including through services for preventing mother-to-child transmission, are currently being

missed, resulting in increased mortality and/or late initiation of antiretroviral therapy when children are at an advanced stage of disease. WHO recommends that provider-initiated HIV testing and counselling for infants and children be implemented within health care services to facilitate diagnosis and access to HIV-related services. Health care providers should therefore recommend HIV testing and counselling as part of the normal standard of care provided to infants or children if they show signs and symptoms suggesting HIV infection or if they are known to be HIV exposed (68).

HIV testing is required to reliably identify HIV infection among infants and children. Standard HIV antibody testing, however (either rapid or laboratory based), identifies HIV antibody, which is made in response to infection with HIV. Because maternal HIV antibody is passively transferred to the infant during pregnancy and may persist during the first year of life (and exceptionally beyond), interpreting positive HIV antibody test results in infants during this time is difficult. HIV infection in the first year of life is therefore most reliably diagnosed by detecting the presence of components of the HIV virus itself, usually nucleic acid (HIV DNA or HIV RNA) or viral antigens (p24); these are referred to as virological tests.

Currently available virological assays for early infant HIV diagnosis include HIV DNA (polymerase chain reaction (PCR), HIV RNA (PCR and other methods of detection of RNA) and ultra-sensitive P24 antigen testing. The tests to be used in specific circumstances should be determined in discussion with national laboratory services. Use of dried blood spot (DBS) filter paper can facilitate the decentralization of access to HIV DNA virological HIV testing (69).

Breastfeeding infants remain at risk of acquiring HIV infection throughout the breastfeeding period. Breastfeeding does not have to be stopped before performing virological testing, but interpreting negative test results is difficult, and mothers whose babies have negative virological results in this situation need extra counselling to consider whether replacement feeding is acceptable, feasible, affordable, sustainable and safe (see section on infant feeding above). Positive results should be considered to reflect HIV infection, and the usual confirmatory algorithms should be followed. Based on expert opinion, WHO advises that a period of six weeks is required before negative virological test results can be assumed to reliably exclude HIV infection after breastfeeding ends. For children who have continued to breastfeed into the first year of life, the same six-week period is suggested before negative serological HIV antibody test results reliably exclude HIV infection.

HIV testing interventions

- 1 All HIV-exposed infants should have early virological testing at or around 4-6 weeks of age. Infants testing positive for HIV should be assumed to be HIV infected and started on antiretroviral therapy.
- 2 Provider-initiated age-appropriate HIV testing should be recommended for all infants and children where HIV is possible, suspected or HIV exposure is recognized.
- 3 If virological testing is not available, then infants who are suspected to be HIV infected or are HIV seropositive and are not well with signs and symptoms suggesting HIV need to be managed as if HIV infection may be the cause. CD4 testing, where available, should be performed to assess immunodeficiency and facilitate recognition of presumptive severe HIV disease requiring immediate antiretroviral therapy.
- 4 HIV testing should be recommended for all family members of infants and children known to be exposed or infected with HIV.
- 5 Infants or children with suspected TB should be offered an HIV test.
- 6 If HIV antibody testing is negative in a child younger than 18 months who is no longer breastfeeding and has not breastfed in the last 6 weeks, the child is presumed to be uninfected, and virological testing is only indicated if clinical signs or subsequent events suggest HIV infection.
- 7 Confirmatory HIV antibody testing at or around 18 months is recommended for all HIV-exposed children.

Interventions required for infants and children who are exposed to or have HIV

Provider-initiated HIV testing including virological testing for infants (see above and figure in annex 4).

Co-trimoxazole preventive therapy. Co-trimoxazole is an antibiotic. Data from randomized clinical trials and observational studies demonstrate the effectiveness of co-trimoxazole preventive treatment in preventing pneumocystis pneumonia (*Pneumocystis jiroveci* (formerly *carinii*, commonly referred to as PCP) and other infections among infants who have HIV and cost-effectiveness in reducing morbidity and mortality.

As death and PCP are most likely in the first 6 months of life, before the diagnosis of HIV is reliably assured, cotrimoxazole preventive treatment is recommended by WHO for all exposed infants until HIV status can be confirmed. All HIV-exposed children born to mothers living with HIV should start co-trimoxazole preventive treatment at 4–6 weeks after birth and continue until HIV infection has been excluded <u>and</u> the infant is no longer at risk of acquiring HIV through breastfeeding. Infants confirmed to be HIV uninfected who are no longer breastfeeding and therefore no longer at risk of acquiring HIV can discontinue co-trimoxazole preventive treatment (70).

WHO guidelines also recommend co-trimoxazole for infants and children who have HIV. All infants with HIV should continue co-trimoxazole preventive treatment up to the age of 5 years, at which point they may be reassessed (70).

Co-trimoxazole should be provided free of user charges.

Antiretroviral therapy and follow-up care. Infants and children respond well to antiretroviral therapy, and numerous potent antiretroviral drugs are available. If HIV infection is detected in infancy, early antiretroviral therapy is particularly crucial, but currently most children presenting to treatment programmes are older. The pattern and presentation of HIV varies by age, with younger infants and children usually presenting with acute infection (notably PCP in the first 3–6 months of life) and with chronic impairment of growth and development being more likely in older children. The United States Food and Drug Administration has approved, and WHO has prequalified, a fixed-dose combination antiretroviral drug for children, and additional fixed-dose combinations for children are in the pipeline. WHO has published technical guidelines outlining antiretroviral therapy care for infants and children, which have been recently updated (71), and has training modules for HIV care (72). As HIV testing for infants is expanded, programmes will increasingly need to ensure that antiretroviral therapy is available for them, requiring infant antiretroviral medicines and dosing guidance. Antiretroviral therapy should be provided free of user charges for infants and children.

National HIV treatment and care guidelines should include:

- ✓ criteria for enrolment into care;
- criteria for initiating antiretroviral therapy;
- ✓ pre-antiretroviral therapy care;
- ✓ standard first- and second-line treatment regimens;
- ✓ required national formularies;
- ✓ criteria for which types of health workers may initiate antiretroviral therapy;
- clinical and laboratory monitoring;
- ✓ criteria for and actions required for treatment failure;
- ✓ special consideration for different age groups, particularly infants and adolescents;
- special considerations for TB coinfection and other locally relevant conditions, including substance abuse;
- ✓ nutritional support;

- ✓ adherence support; and
- ✓ simplified standardized dosing instructions for antiretroviral drugs for all levels of service delivery (73).

Adherence and treatment support. The efficacy and durability of antiretroviral therapy regimens depend on optimizing adherence to antiretroviral therapy. Adherence means taking the correct dose of medicines, at the correct time and in the correct way (for example, with the right type of food or fluid and before or after a meal) according to the treatment plan. At the household level, this requires looking after medicines to ensure that they are stored properly and safely. For infants and young children frequent dose adjustments may be required to accommodate rapid catch up growth.

Adherence among infants and children is a special challenge because of factors relating to children, caregivers, medicines, the environment and the interrelationships of these factors. Poor palatability, high pill burden or liquid volume, frequent dosing requirements, dietary restrictions and side effects may hamper the regular intake of required medication. Further, successfully treating a child requires the commitment and involvement of a responsible and consistent caregiver. Adequate treatment preparedness, frequent assessment and anticipation of adherence difficulties, and targeted support are key interventions to support effective antiretroviral therapy (74). Expedited treatment preparedness is necessary to accompany early initiation of ART in infants diagnosed in the first few months of life; this should include intensified efforts to achieve an understanding of the importance of treatment adherence.

Clinical and laboratory monitoring. All children who are diagnosed with HIV infection should undergo baseline clinical and laboratory assessment to determine the clinical stage of HIV disease and, where available, CD4 testing to determine eligibility for antiretroviral therapy. Infants under one year diagnosed with HIV should start antiretroviral therapy as soon as possible, so while CD4 testing is useful as a baseline, it is not a prerequisite for starting antiretroviral therapy. Developing laboratory capacity for monitoring is highly desirable to improve the efficacy of therapeutic interventions and to ensure the safe and timely initiation of antiretroviral therapy. In the absence of laboratory capacity, clinical parameters can be used for monitoring antiretroviral therapy (75–77).

Psychosocial support. Families, caregivers and children who have HIV also need access to other essential services that are usually available outside of health facilities, such as:

- ✓ age-specific counselling for children;
- ✓ recognition of needs, counselling and support for caregivers;
- ✓ support for disclosure and informing of children;
- mitigation of stigma;
- ✓ recognition and support to mitigate grief and overcome trauma;
- recognition of and recommendations for addressing depression, developmental delays and other issues; and
- ✓ support for improved family care practices that directly affect early childhood development (such as parenting support and education, play and stimulation).

These services, where provided, are often supported by nongovernmental organizations or implementing partners.

TB. TB represents a significant threat to children's health. HIV infection increases susceptibility to infection with *Mycobacterium tuberculosis* and the risk of rapid progression to TB disease and, in older children with latent TB, reactivation. Increasing levels of coinfection with TB and HIV in children have been reported from resource-constrained countries, the prevalence of HIV among children with TB ranging from 10% to 60%. TB should always be considered in symptomatic children who have HIV.

Interventions include the following (78-80).

- 1 Isoniazid preventive therapy is recommended for children who have HIV who live in areas with high TB prevalence or are household contacts of people with TB following exclusion of active TB disease.
- 2 Contact tracing and family history for children at risk.
- 3 Household contacts or children exposed to an adult diagnosed with active TB or smear-positive pulmonary TB require investigation and exclusion of active TB disease.
- 4 TB treatment should follow guidelines from the national TB programme. Directly observed therapy should be followed.
- 5 Antiretroviral therapy recommendations for children coinfected with TB should follow the national antiretroviral therapy guidelines.

WHO has additional resources on the clinical management of children with HIV that can be accessed through the web site (70,71,81–84). For instructions on how to register free of charge for access for all the IMAI tools, including training materials for the above clinical guideline modules and district management tools, go to http://www.who.int/hiv/capacity/Access_Sharepoint.pdf. This includes an IMAI briefing document that summarizes all the available IMAI, IMCI and Integrated Management of Pregnancy and Childbirth tools.

3. KEY STRATEGIES FOR SCALING UP HIV DIAGNOSIS, CARE, SUPPORT AND TREATMENT FOR CHILDREN

Seven key strategies are essential for scaling up HIV care, support and treatment programmes for children. The action steps needed to incorporate these into national programmes are outlined below.

Strategy 1: Enhance government leadership, ownership and accountability by strengthening established management and coordination structures to ensure appropriate response to the needs of children who are exposed to or have HIV by developing supportive policies, setting national targets and developing budgeted national plans for scaling up directed towards reaching all children in need.

Background

Effective leadership, ownership, programme management and coordination capacity are needed at the national and subnational levels (such as districts) to promote and support the scaling up of HIV programmes for children and to ensure that high-quality care is provided. Although management and coordination structures focused on the overall health needs of children often exist, the focus within these on the needs of children who are exposed to or have HIV is often weak and insufficient. In addition, HIV units often focus more on the needs of adults and have neglected the needs of infants and young children. Management structures within health ministries must ensure that key entry points into HIV care as well as core service delivery points for children, including maternal, newborn and child health programmes, are coordinated in their approach in identifying HIV-exposed infants, identifying children who have HIV and linking children to care and treatment where necessary. Management and coordination structures will be more effective in their efforts to integrate programme activities when they can access adequate human and financial resources to permit both national and subnational management and coordination, delegation of authority and appropriate allocation of funds across programmes and flexibility of resource flows and allocation at all levels.

Having a high-level advocate for HIV care and treatment for children in the health ministry or higher is often helpful. These champions can provide commitment for programme implementation and ensure accountability among the mid-level managers responsible for day-to-day activities and facilitate important policy changes.

Relevant actions

Situational analysis. An initial rapid but systematic situational analysis should be performed to assess current programming, including key health system bottlenecks, and used to guide the national strategic and implementation plan that addresses child health and HIV (see Annex 1). Core elements of the situational analysis include assessments of where children who are exposed to or who have HIV are being identified, the interventions they are receiving (Box 1) and the respective roles and interactions between health care facilities and the community in HIV care and treatment for children. The initial rapid analysis may need to be followed by more detailed functional area-specific analysis but should not slow the scaling up of programme activities. Health impact and health outcomes for children and child survival (such as demographic and health surveys or multiple indicator cluster surveys) are regularly evaluated every 3–5 years, and this can be used to inform and modify national strategic and/or implementation plans.

Box 1. Intervention assessment for HIV care and treatment programmes for children

Assess whether the following interventions are articulated in updated policy and practice guidelines and implemented within activities related to HIV, services for preventing mother-to-child transmission and maternal, newborn and child health programmes:

- ✓ provider-initiated HIV testing and counselling;
- ✓ early infant testing for HIV-exposed infants (early infant diagnosis);
- counselling on and support for infant feeding;
- ✓ co-trimoxazole preventive therapy;

- intensified growth monitoring, developmental assessment and support for children who are exposed to and who have HIV;
- ✓ modified immunization schedules;
- intensified prevention (including isoniazid prophylaxis for M. tuberculosis) and optimized management of HIV/TB;
- ✓ prevention of malaria, including provision of insecticide-treated nets;
- ✓ antiretroviral therapy for children, including those younger than 5 years;
- ✓ clinical and laboratory monitoring, with specific focus on the needs of children;
- functional referral networks and patient tracking mechanisms between facilities and communities and within facilities; and
- ✓ HIV services for infants and children, including HIV testing, clinical monitoring and antiretroviral therapy are provided at no charge to the affected family.
- 1.1. Targets. Based on the lessons from the "3 by 5" Initiative, national treatment targets for children are essential to scale-up. Time-bound targets based on need are particularly important for antiretroviral therapy and co-trimoxazole prophylaxis, as both of these interventions significantly reduce morbidity and mortality, and current levels of uptake are low in most low- and middle-income countries. Time-bound targets help ensure urgency and drive among national programme managers. Population-based or geographically-based targets can also be used locally to drive planning: for example, the treatment targets for urban areas will probably differ from the targets for rural areas. Setting district-level targets is also important, since it assigns expectations and accountability and assists in coordinating supportive technical assistance, including targeting training for health care providers and ensuring that appropriate quantities of supplies reach sites in need.
- 1.2. Ensure that management and coordination structures address HIV care and treatment for children. Management structures should provide programme direction for services for HIV programmes for children, ensure coordination among and across stakeholders and oversee programme planning, implementation, monitoring and quality at the national and subnational levels. They should be supported by advisory bodies or technical working groups that include all key national technical resources, major funders and partners implementing programmes. Management structures should ensure that national budgets incorporate the items required for national scale-up. Governments should provide management structures with sufficient resources to ensure that the management, coordination and supervision activities can be carried out.

The essential functions of the management and coordinating body should include the following.

a. Development of an implementation plan for scaling up HIV treatment for children congruent with national and district-level HIV and child survival plans that integrate community activities and that include human resource planning and development (such as training needs and identifying opportunities for task-shifting and -sharing). This plan should take into account existing HIV programming for women and children in the country. The Inter-Agency Task Team on Prevention of HIV Infection in Pregnant Women, Mothers and their Children has developed guidelines for scale-up (85). A new guide on managing programmes to improve child health is being developed to assist programme managers responsible for children's health and is undergoing field testing. Once it is available, it will be on the WHO web site at http://www.who.int/child-adolescent-health.

Gain consensus regarding the essential intervention package for children who are exposed to or who have HIV.

The essential intervention package must include key child survival interventions, modified immunization schedules and interventions designed to address common childhood illnesses.

c. Develop appropriate policies to facilitate the implementation of core programme activities for children. Examples of such policies include but are not limited to:

- provider-initiated HIV testing recommended for pregnant women, with women testing positive given priority for assessment for prophylaxis or treatment;
- provider-initiated HIV testing recommended for sick children in sites likely to have large numbers of children who have HIV such as paediatric wards or malnutrition clinics;
- ✓ implementing follow-up testing for infants known to be exposed to HIV;
- using mechanisms to communicate a child's HIV exposure or infection status, such as child health cards with HIV exposure status documented and adult antiretroviral therapy cards that request information on children's HIV status;
- ✓ providing a package of HIV diagnosis, care and treatment free of user charges, including antiretroviral therapy for children;
- ✓ ensuring legal and social protection for children who have HIV;
- ✓ using developmentally appropriate modes of consent for HIV testing; and
- revising national scopes of practice to permit additional types of health workers to perform healthrelated tasks related to HIV care and treatment for children.

These policies should be incorporated into site preparation processes and personnel expectations and actively disseminated so that they are implemented.

d. Review and adapt existing guidelines pertinent to delivering HIV care and treatment for children

WHO has developed and/or updated guidelines that can be adapted at the country level:

- ✓ provider-initiated HIV testing and counselling and infant diagnosis (68);
- ✓ services for preventing mother-to-child transmission (86);
- ✓ antiretroviral therapy for children (71);
- ✓ patient monitoring guidelines (77);
- ✓ co-trimoxazole prophylaxis (70); and
- ✓ infant and young child feeding (35,87).

e. Coordinate the training of health care workers

As governments move to decentralize the delivery of HIV health care for children, the related need to strengthen the capacity of existing health care workers to manage HIV care not only of adults but also of children will necessitate coordinated national training. District-level coordination is essential to ensure that the training is applied consistently across sites and that it reaches all the providers who need it.

Examples of key training-related activities include:

 identifying specific skills, knowledge and competencies needed by providers at each level to deliver the essential package of services (or elements thereof);

- developing a national training plan taking into consideration the training needs of all types of health care workers, focusing on training first those in areas of highest HIV burden, and including evaluation of the effect of training within the national training plan;
- ✓ developing district-level capability to implement training; and
- developing or adapting existing curricula for both in-service and pre-service training such as those from the WHO IMAI and IMCI, the African Network for Care of Children Affected by HIV/AIDS, the International Center for AIDS Care and Treatment Programs and the Baylor International Pediatric AIDS Initiative (see Annex 2).

Several training curricula have now been developed or are in the process of being completed. Annex 2 provides more information on these.

f. Develop site preparedness, site readiness and standard operating procedures related to providing high-quality HIV diagnosis, care and treatment for children

As care for children is decentralized, it will be important to ensure that sites providing this care have the necessary capacity (human and physical) to provide care and that the quality of care being provided is acceptable. Readiness criteria should be established for facilities preparing to provide HIV care and treatment for children.

g. Integrate the commodity needs of infants and children who are exposed to or have HIV into national procurement and supply management systems

Ensure that national procurement and supply management systems address HIV-related medicines, diagnostics and commodities for children (see the section on supply management).

h. Integrate indicators on HIV services for children into monitoring and evaluation systems (see the section on monitoring and evaluation).

Strategy 2: Integrate service delivery of HIV prevention, diagnosis, care, treatment and support for children into existing services such as HIV and maternal and child health and decentralize the provision of core components of the HIV care and treatment package for children to the lowest appropriate and feasible level of health care delivery

Background

Traditionally, HIV infection among children has been seen as the realm of the specialist and remains limited in most cases to tertiary care centres. Decentralized delivery of care through an integrated package of services for the child and family offers several advantages:

- delivering care for all family members, including male partners and older siblings, at the same time and place;
- minimizing costly and time-consuming transport to and from tertiary centres;
- ✓ facilitating the continuity of care between the home, the community, and the health centre; and
- maximizing efforts to improve adherence and overcoming barriers to long-term engagement in care.

Relevant actions

2.1 Integrate HIV diagnosis, care, treatment and support for children into existing HIV care and treatment services

Existing antiretroviral therapy sites provide an excellent platform for expanding diagnosis, care, treatment and support for children who are exposed to or have HIV, as many of the challenges of scaling up HIV services such as training in HIV clinical management, supply, procurement and laboratory capacity have already been addressed. However, specific training sessions related to children may be needed to overcome the "fear" of treating children among some clinicians, to provide the special skill needed to draw blood from children, to provide psychosocial support to children and to ensure that someone on every clinical team is trained in counselling on and support for infant feeding. As many countries have already made significant progress in rolling out antiretroviral therapy services, the opportunity for expanding HIV care for children and access to antiretroviral therapy is significant (Box 2).

Malawi provides an excellent example of scaling up access to HIV services for children. Primarily through a concerted plan to integrate HIV care and treatment for children into existing sites, the number of sites providing antiretroviral therapy for children increased from 22 in mid-2005 to 83 by the end of 2006 (18 months later). The number of children placed on treatment increased correspondingly during the same period from slightly more than 1000 to more than 5000.

Box 2. Guidelines on chronic HIV care

Revision 2 of the WHO IMAI/IMCI guideline module on chronic HIV care with antiretroviral therapy and prevention with its clinical training courses and mentoring and management support materials integrates the care of children with the care of adolescents and adults. The basic training for clinical staff and people living with HIV on antiretroviral therapy counselling training provides a solid foundation in family-based care and preparation for managing chronic HIV care and antiretroviral therapy for children. Based on initial country experience in 10 countries, the section of the guidelines related to children has been expanded to include age-specific recommendations for informing and disclosing to children and psychosocial support. By integrating care for children into simplified, operational guidelines and tools that support task-shifting and decentralized care, the IMAI and IMCI approach can support the rapid expansion of HIV care for children.

Source: Chronic HIV care with ARV therapy and prevention: guidelines for health workers at health centre or district hospital outpatient clinic (88).

2.2 Integrate HIV diagnosis, care and treatment for children into existing maternal, newborn and child health programmes

Existing maternal, newborn and child health programmes including specific services such as immunization are often underutilized for scaling up HIV services for children, even though these programmes are well established, well attended and have high penetration into the very communities being targeted (see also early diagnosis, strategy 3).

Antenatal care. Antenatal care provides an opportunity for testing and counselling pregnant women. For HIV-negative women, it is an opportunity to gain information and the skills needed to remain HIV-negative. For women living with HIV, it is an opportunity to be informed about the importance of measures to reduce transmission to the infant and an entry point to assessing their own need for antiretroviral therapy or prophylaxis. Pregnant women should also be educated during antenatal care on the importance of safer infant feeding, HIV testing, co-trimoxazole preventive treatment for the newborn and the need for early initiation of antiretroviral therapy if the infant is found to have HIV.

Child health care. Health care workers need to know how to support and manage infants who are exposed to or who have HIV. Health care workers should be able to recognize when infants and children need HIV testing and co-trimoxazole preventive treatment (which can be done more effectively if the child health card includes information related to services for preventing mother-to-child transmission) and support mothers on infant feeding. Providing routine follow-up of children receiving antiretroviral therapy, including appropriate treatment of common illnesses among children who have HIV, is an important skill to acquire. Providers also need to be able to recognize when they need to refer children to HIV care and antiretroviral therapy sites for more complicated conditions, including toxicity or treatment failure.

HIV care and treatment. In high-burden countries, more complicated HIV care and treatment interventions may have to be integrated into the same maternal, newborn and child health programmes, allowing the same health workers to identify, diagnose, care and treat children exposed to and infected with HIV. Infant feeding must be supported and growth monitored systematically, whether the mother has chosen exclusive breastfeeding or replacement feeding. The skills of IMCI-trained health workers can be expanded to accomplish this using the IMCI complementary course on HIV/AIDS (82); IMAI training supports skills to prepare the clinical team to deliver chronic HIV care and first-line antiretroviral therapy to children (Box 3).

Box 3. An IMCI approach to HIV diagnosis, care, support and treatment

Several countries (Botswana, Ethiopia, Kenya, Lesotho, Namibia, Rwanda, South Africa, Swaziland, Uganda, Zambia and Zimbabwe) have adapted their IMCI materials to include HIV and AIDS. The IMCI HIV guidelines are similar to the existing syndromic guidelines for common childhood illnesses, since they provide health care workers with a checklist to determine whether a child might be either exposed to or infected with HIV. The first question during the child assessment is whether the mother received an HIV test during antenatal care. Depending on the answer received and the presence or absence of other symptoms including pneumonia, persistent diarrhoea or severe malnutrition, the health care worker can classify the child into different HIV exposure and infection categories and determine the next steps to follow in the child's care plan. The IMCI HIV complementary training course (82) addresses HIV testing in newborns and infants and provides an introduction to counselling on infant feeding.

Decentralization

2.3 Decide which interventions for HIV care and treatment for children can be decentralized to which existing health delivery points

The important decision of which interventions should be decentralized to lower-level health systems depends on the complexity of the intervention, the burden of disease and the proximity to communities. The benefits of decentralization to people receiving services must be balanced with the ability of the health care system to provide high-quality services. In low-burden countries, decentralizing the initiation of antiretroviral therapy for children to a more peripheral level may not be practical, as the number of children who have HIV each health provider sees will drop below the level necessary to maintain clinical skills. The provision of co-trimoxazole preventive treatment or referral of symptomatic children, however, can usually be decentralized to the lowest levels of the health system (Box 4).

Box 4. Decentralizing HIV care and treatment for children

Decentralizing HIV care and treatment for children requires capacity-building at first- and second-level health facilities so they can provide services that previously had been restricted to specialized referral centres. This will require shifting tasks from more specialized to less specialized health care workers – for example, from specialized paediatricians to multi-purpose physicians, medical officers and general practitioners, from these basic physicians to nurses and clinical officers and from nurses to trained and paid people living with HIV and other lay providers and community-based workers and organizations. Experience in many countries has shown that non-specialist physicians, clinical officers and nurses can effectively deliver HIV-related clinical services, including antiretroviral therapy, to adults. Shifting tasks related to care and treatment for children can have special challenges if personnel have only managed adult cases during their professional career; but this may be overcome by adequate training, supportive supervision and clinical mentoring.

2.4 Improve referral mechanisms and care for children

Some proportion of children with HIV needs to be referred to a higher level of care for managing complicated opportunistic infections or antiretroviral therapy. To effectively decentralize HIV care and treatment for children, adequate systems for referral care must be in place. This includes the availability and accessibility of transport and mechanisms for adequate communication between the referring clinical team, the centre providing guidance and the child's caregiver and family. Systems must be in place as well to effectively transfer the results from tests and accompanying guidance back to the referring clinical provider. Warmlines (where telephone calls for consultation are returned within a short period of time, in contrast to hotlines, where someone is immediately available) can provide answers to questions on antiretroviral therapy and HIV care.

2.5 Utilize communities for early identification and provision of care, including delivery of the basic package of services, such as co-trimoxazole preventive treatment and antiretroviral therapy adherence

Early identification and referral will happen in the community for most children. In addition, decentralization into the community may be helpful in delivering some essential interventions to children. For example, health care workers with minimal clinical background or experience in HIV care and treatment can effectively deliver co-trimoxazole prophylaxis. Community leaders and health care workers need to understand that (1) children who have HIV are likely to die before age 2 years without treatment, (2) children who have HIV can survive and thrive, (3) co-trimoxazole preventive treatment is a low-cost and easy-to-deliver intervention that can dramatically reduce morbidity and mortality and (4) antiretroviral therapy is available for children in addition to adults. By using community-based channels or health outreach services, essential services for children who are exposed to or who have HIV can be delivered much closer to where the children live. Treatment support at home for children receiving antiretroviral therapy or TB treatment is particularly important. If possible, every family should have a treatment supporter. In some communities, trained community health workers are also already providing community newborn care, which includes support for exclusive breastfeeding and treatment for sepsis and/or referral. In addition to training in providing basic clinical care and support, community health workers should receive training in how to address stigma, fear and worries about abandonment among children who are exposed to or who have HIV.

Table 1 provides information regarding which interventions for children can be effectively delivered at a more peripheral level and which interventions are more appropriately delivered at a higher level of health care delivery.

Table 1. Interventions for children by level of the health system

Strategy 3: Governments should promote the enhanced early identification of infants and young children who are exposed to or who have HIV

This should be accomplished by:

- providing policy and technical guidance supporting follow-up of infants known to be exposed to HIV who are identified through services for preventing mother-to-child transmission;
- using health cards held by children and mothers documenting information on receipt of services for preventing mother-to-child transmission;
- using DBS filter paper to facilitate early virological diagnosis among HIV-exposed infants;
- implementing provider-initiated testing and counselling for HIV in acute and chronic child health facilities;
- · implementing a family-centred approach to HIV testing;
- implementing IMCI and IMAI approaches to identify infants and children at peripheral sites and refer them for HIV testing;
- identifying settings and situations in which recommended HIV antibody testing for well children should be undertaken; and
- training existing outreach and home care providers to identify and assist in referral for provider-initiated HIV testing and counselling.

Background

Programmatic success to institutionalize the early diagnosis of HIV infection in infants and children hinges on links with child health programmes, health care worker training, finalization of guidelines and tools and the development of laboratory capacity and systems to decentralize the performance of virological HIV testing for infants (or rapid antibody testing for older children). Although many countries are moving towards national coverage of services for preventing mother-to-child transmission, most children born to women known to be living with HIV are not being systematically monitored and followed up during the postpartum period. Experience from South Africa reveals that, without a systematic and structured care plan that includes early testing at six weeks, up to 85% of HIV-exposed infants are lost to follow-up from clinics providing services for preventing mother-to-child transmission at 1 year of age, with 75–80% already lost to followup at 6 months of age (89).

HIV-exposed children must be followed up to avoid postpartum HIV transmission, improve infant health outcomes and identify early the infants who have HIV so that they can access care and treatment in a timely fashion. The following actions are required to improve the follow-up of infants known to be exposed to HIV identified through services for preventing mother-to-child transmission.

Relevant actions

3.1 Ensure updated policy and technical guidance supporting the follow-up of known HIV-exposed infants identified through services for preventing mother-to-child transmission

National policies and guidelines on the follow-up of HIV-exposed infants should be either newly developed or adapted for the prevailing national epidemic and resource situation. Budgets for HIV-related expenditures should include line items for developing and disseminating policy revisions. Efforts should be made to ensure that guidance is harmonized across documents (such as eligibility for co-trimoxazole prophylaxis). Policies and guidelines should address:

✓ why follow-up should take place, such as starting care and treatment in a timely fashion;

- where follow-up should take place, such as maternal, newborn and child health centres and associated services including immunization and growth monitoring;
- ✓ what follow-up interventions are required for HIV-exposed infants such as virological testing, clinical examination, provision of co-trimoxazole prophylaxis and counselling on infant feeding;
- the timing and frequency of the recommended HIV testing of HIV-exposed infants and associated requirements for consent, confidentiality, best interests and counselling in relation to provider-initiated HIV testing and counselling;
- ✓ early antiretroviral therapy for infants diagnosed with HIV;
- ✓ what resources are available to ensure the availability of follow-up services; and
- ✓ who oversees the implementation of these policies.

3.2 Document information on receipt of services for preventing mother-to-child transmission on maternal and child health cards

Health care workers providing care to either the mother or the infant can use health cards with HIV exposure and infection status to facilitate follow-up of the infant. Health cards can contain some or all of the following information:

- HIV status of the mother:
- ✓ antiretroviral drugs provided to the mother and/or infant;
- ✓ HIV testing status for the infant; and
- ✓ whether the mother or infant initiated co-trimoxazole preventive treatment.

This approach has been used successfully in several countries, including Zambia and Zimbabwe. Health care workers who are made aware by looking at either the mother's or child's health card that the child has been exposed to HIV are prompted to ensure that important interventions including providing co-trimoxazole preventive treatment and early diagnostic testing are implemented and that both the mother and the child are followed more carefully to monitor for any signs suggesting symptomatic HIV infection. For this mechanism to work, however, at a minimum the following must be in place.

- ✓ Information on services for preventing mother-to-child transmission, including the child's HIV exposure status, must be documented on the child's health card and included on the mother's health card (Fig. 1).
- Child health cards must be distributed in a timely fashion at or around delivery: some countries now provide the pregnant woman living with HIV with a child health card documenting HIV exposure status at the time she receives her result.
- Information on the card must be standardized nationally and follow nationally agreed guidance.
- Health care workers must be oriented to and vested in the utility of this information.
- Health care workers must be skilled in delivering specific interventions (such as testing and counselling, collecting samples for virological testing and providing co-trimoxazole preventive treatment) or be able to appropriately refer.

Fig. 1. Child health card used in Zimbabwe

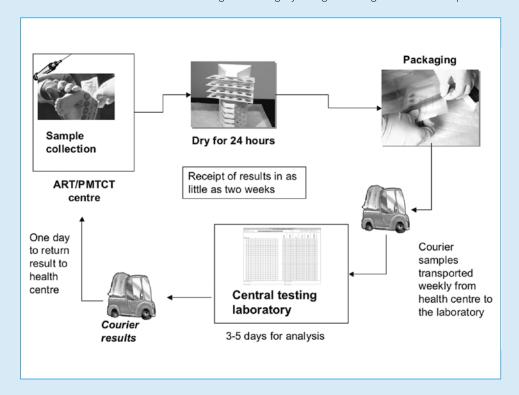
MINISTRY OF HEALTH CHILD HEALTH	INFAI	ITI	FEE	DIN	IG		
	2.00						
CARD	Follow-up time	Birth	10D 6	N 2N	1 3M	4M	5M
ZIMBABWE	Infant feeding code						
	Follow-up time	6M	7M 9	VI 12	M 15	и 18N	24M
	Infant feeding code						
NT FEEDING PRACTICE	INFANT FEEDING C 1. Exclusive Breast F 2. Exclusive Heat Tre 3. Exclusive Commer 4. Exclusive Modified 5. Mixed Feeding 6. Other Specify	eedin ated l cial Ir	g Breast Ifant Fo		а		
reast milk for the first 6 months. blids and liquids from 6 months. ast feeding up to 24 months or beyond	CARE						
inseled otherwise by a health worker. AKANAKA KWEMWANA	NVP/Other ARVs give (Circle Yes or No)	en at l	oirth?			NO	YES
na mukaka wezamu chete pamwedzi vekutanga.	Follow-up time		6	W 21	и зм	4M	5M
dya kana kunwa kubva pamwedzi	Cotrimoxazole (suppl	ied)					
iyamwisa kusvika pamakore maviri	Follow-up time		6	M 91	1 121	4 15N	18M
kunze kwekuti makataurirwa	Cotrimoxazole (suppl	ied)					
neve utano.	Parent/Caregiver pre-	test o	nunsel	led fr	ır		
KUNGABANGELI INGOZI	child test (Circle Yes			100 10		NO	YES
e yakho okwenyanga eziyisithupha okunye okudliwayo lo kunathwayo	Child tested date:						
a eziyisithupha. nunvisa ingane vakho ize ifike iminyaka	Test Number:	. Tes	t Used	(Spe	cify)		
ukwedlula, ngaphandle uma ucetshisiwe a kahle ukuba ungamunyisi.	Date Parent/Caregiver po counselled for child's						
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OTHER:			۵.				
DRESS:	CARE COMMENTS:						
H:							
ENTRE:							
re information on infant feeding, contact your nearest Health Worker.							

3.3 Use DBS filter paper to facilitate early virological diagnosis

DBS filter paper has been used for transporting specimens to a centralized laboratory for HIV DNA testing in several countries in sub-Saharan Africa (Botswana, Côte d'Ivoire, Kenya (Box 5), Rwanda, South Africa, Zambia and others). This approach is relatively easy to implement and use, samples are easy to store and transport and the specimens are not infectious once dry. However, specimens must be kept dry at all times. Preliminary data from Botswana, Rwanda and South Africa show a significant increase in the numbers of HIV-exposed infants being tested as a result of this intervention.

Box 5. Use of DBS for PCR testing in Kenya

The Government of Kenya has piloted a mechanism for early diagnosis of HIV-exposed infants to enable selected health care facilities to access virological testing by using DBS. Fig. 2 outlines the process.



Steps

- 1. Samples are collected from the infant and placed on filter paper.
- 2. Samples are placed in drying racks for a day to fully dry. They are placed in individual envelopes with desiccant and then placed in a larger airtight zip-lock bag with humidity indicators for transport.
- 3. Samples are sent via courier to a laboratory where PCR testing capacity is in place.
- 4. The adequateness of samples is assessed upon arrival at the laboratory; adequate samples are analysed for the presence of HIV and determined to have a positive or negative result.
- 5. Results are sent back to the centres via courier or e-mail for quickest turnaround. In addition, all results sent via e-mail are also sent via courier to ensure good records.
- 6. Results are provided to the caregiver of the infant at the next clinic visit, and follow-up continues in accordance with the national algorithm for early infant diagnosis.

Source: personal communication from Jackson Hungu, Clinton Foundation HIV/AIDS Initiative.

Identifying infants and children who have HIV

As indicated above, the vast majority of infants who have HIV are currently not identified through services for preventing mother-to-child transmission but when they present for inpatient and outpatient health services because of signs and symptoms suggesting HIV infection. Significant numbers of children who have HIV have been identified in many countries through PITC in acute care settings, including Cameroon and Uganda (90), Zambia (91) and others.

A recent and particularly striking example comes from a study of referral patterns for HIV care and treatment for children in Malawi, which found that only 1% of the children referred to antiretroviral therapy come from services for preventing mother-to-child transmission. The vast majority, 80%, come from children's wards or nutritional rehabilitation units (Fig. 2).

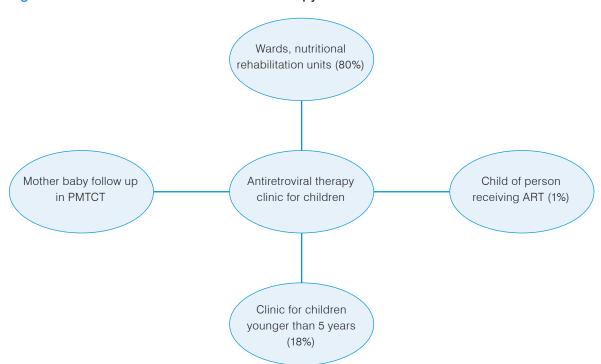


Fig. 2. Referral sources for antiretroviral therapy for children in Malawi

Source: HIV Unit, Department of Clinical Services, Ministry of Health; National TB Control Program; Lighthouse Trust, Lilongwe; and United States Centers for Disease Control and Prevention, Malawi (92).

3.4 Implement provider-initiated testing and counselling at sites likely to yield a high volume of positive test results

Protocols should be established for testing hospitalized children, children in malnutrition clinics, children with TB and children younger than 5 years with other signs and symptoms suggesting HIV infection, such as severe pneumonia, severe persistent diarrhoea, ear discharge or very low weight for age. Protocols for counselling and obtaining consent should be established. For younger infants, virological testing is required.

In Malawi, 4492 children in health centres and hospitals were tested for HIV during a three-month period in late 2006, almost all of whom were sick and required diagnostic testing. Slightly more than one third of those tested received positive results and were referred for antiretroviral therapy (93).

3.5 Institutionalize a family-centred approach and secure HIV testing for all additional family members once an index case is identified

If one family member is identified as having HIV, recommending HIV testing and counselling for other family members is very important. Many families have more than one person who has HIV. Programmes can help ensure that all family members are tested by incorporating information on the person's health card that requests information on all other family members, including whether they have been tested for HIV and the results of these tests.

3.6 Use IMCI and IMAI approaches to identify infants and children at peripheral sites and refer them for HIV testing

IMCI has a modified assessment algorithm for assessing children presenting to primary health facilities that is designed to recognize when to recommend HIV testing. For the HIV-exposed child, health care workers are guided to ensure that the child receives appropriate interventions including co-trimoxazole preventive treatment and early testing and that the mother receives information about infant feeding options and the importance of regular follow-up for the HIV-exposed child. First-level health care workers should be trained to improve their recognition of a child who may have HIV (as in the HIV-adapted IMCI approach). This involves training health workers to recognize signs and symptoms common in children who have HIV and in providing basic care and appropriate referrals. Fig. 1 in Annex 2 presents the generic IMCI HIV algorithm.

3.7 Use community health workers to facilitate entry to diagnosis and care services

Ensure that the community health workers who are providing community-based case management or treatment for common childhood infections such as diarrhoea, pneumonia, malaria and fever are able to recognize and refer when HIV testing is recommended or symptoms suggest that antiretroviral therapy may be required (see also the section on community-based strategies-strategy 6).

3.8 Consider whether health care sites caring for infants and young children should implement interventions to determine a child's HIV exposure status

Some high-prevalence countries have debated the utility of determining the HIV infection status of mothers postpartum and corresponding exposure status of their infant or young child in situations in which the mother did not receive interventions for preventing mother-to-child transmission, including HIV testing, during pregnancy. The benefits of this approach include opportunities for preventing future infections among women who test negative, earlier links to HIV care and treatment for mothers who do test positive, earlier access to care including referral for virological testing for the infants and young children determined to be exposed and opportunities for positive prevention activities for mothers living with HIV. Testing should be offered first to the mother, clearly explaining the potential benefits of knowing her status. If the mother declines, rapid antibody testing may be proposed for the infant, followed by virological testing at 6 weeks of age or as soon as possible thereafter if the child tests positive. Although this approach may be considered in settings with a high burden of HIV or in populations considered to be especially at risk, it is generally not recommended in lower-prevalence settings.

Strategy 4: Governments should develop reliable procurement and supply management mechanisms that ensure a consistent supply of medicines and commodities that meet the needs of children

Supply management is an essential component of scaling up activities. Key factors that should be taken into consideration include:

- ensuring adequate coordination among stakeholders and linking to the overall implementation plan;
- building on what already exists;
- ✓ facilitating rapid scale-up and the accommodation of new technologies; and
- ✓ including children in national or programme plans for scaling up supply.

In the context of HIV diagnosis, care, support and treatment for children, a well-functioning supply system is critically important to ensure that people who need antiretroviral therapy, prophylaxis against and management of common opportunistic infections and other commodities for routine care can access them when and where they need them. Similar to all health care commodities, the steps to establish a functioning supply management system can be structured according to the processes in the supply cycle: selection, procurement (including quantification), distribution (including inventory management), use and the organizational and managerial functions underpinning them (Annex 3). However, rapidly scaling up care, support and treatment for children requires some special consideration in formulating supply management strategies.

- ✓ The package of services and activities offered at different levels of the health care system varies and may change over time. Supply planning needs to be aligned with the decentralization and scale-up of interventions to ensure the availability of medicines and commodities appropriate to each level.
- Rapid increases in the numbers of children starting and in care require a flexible, well-informed supply system to keep up with changes in demand.
- ✓ Easy-to-use products, including fixed-dose combinations appropriate for children, are not always available or appropriate for large-scale interventions. Mechanisms for storing, refrigerating and transporting syrups may need to be planned for in the context of earlier diagnosis and the scale-up of treatment.
- ✓ Health workers may need special training to use the commodities and equipment correctly.
- Diagnostic tests and equipment and treatment options are evolving rapidly, and the adoption of new technology may need to be anticipated.
- ✓ Building on existing supply management systems that support child health and/or HIV programmes is recommended rather than creating vertical supply lines for implementing child-focused HIV care, support and treatment programmes. Decisions to integrate into existing systems should be based on assessment of capacity and the strengthening of existing supply mechanisms.
- ✓ Appropriate coordination at all levels mitigates against the threats that the proliferation of stakeholders and resources can create for supply mechanisms.

Medicines and commodities for care, support and treatment programmes

The commodities to be supplied to the various levels of care are identified by reviewing the package of care at the national or subnational level. Depending on what exists in the country, equipment and commodities needed to provide an essential package of care and treatment to children who are exposed to or who have HIV can be provided through various systems:

✓ items supplied through laboratory services: test kits, reagents and consumables (e.g. filter paper, lancets, desiccant, envelopes) for establishing HIV exposure or infection and monitoring disease progression and the response to antiretroviral therapy;

- items supplied through the pharmaceutical sector: basic essential medicines such as products used for IMCI, antibiotics for treating infections, antiretroviral medicines and vaccines in accordance with the immunization schedule;
- medical equipment, medical consumables and other supplies needed for universal precautions and waste disposal;
- ✓ nutritional support including weighing scales, nutritional and micronutrient supplementation and breast-milk substitutes when appropriate; and
- ✓ general supplies for dispensing medicines, record-keeping, stock management and patient monitoring.

Relevant actions

4.1 Ensure that supply management is appropriately coordinated among supply stakeholders and also linked to the overall implementation plan

- 4.1.1 Given the wide range of medicines and commodities that are needed to support the implementation of an essential package of care and treatment, joint work planning and budgeting between partners and across all involved government departments are essential to secure the programming capacity and necessary financial resources for scale-up.
- 4.1.2 Identify a person, ideally within the health ministry, who will be the focal point responsible for coordinating supply management to support care and treatment for children.
- 4.1.3 Where a working group on procurement and supply management exists for HIV, integrate care, support and treatment for children into the existing mechanism. A subcommittee or team may be needed to develop, implement and monitor the procurement and supply management plan for care and treatment for children. Membership of the working group will depend on the programmes, disciplines and initiatives involved but should, in addition to key stakeholders, include a child health specialist.
- 4.1.4 Link procurement and distribution to treatment targets and the opening of new sites. Update procurement and distribution plans regularly to match revised treatment targets and new sites.

4.2 Foster the integration of supply systems by ensuring that programmes are introduced and scaled up based on what exists and build capacity where it is lacking

- 4.2.1 Analyse the situation of supply systems underpinning programming for children in the country; supply management considerations can be incorporated into the initial situational analysis conducted for programme planning purposes. Include an assessment of site capacity to manage and coordinate supplies to support programme scale-up.
- 4.2.2 Develop a supply management capacity-building plan to support programming for children that is linked to the procurement and supply management plan. If needed, use a phased approach to building capacity, introducing supplies and integrating into existing systems. If capacity-building strategies already exist at the national or local level, coordinate and integrate efforts.
- 4.2.3 Address supply to community-based workers and ensure that decentralized supply systems reach the community levels.

4.3 Supply planning processes of medicines and commodities should facilitate rapid start-up and accommodate new technological developments

- 4.3.1 Treatment for infants and children needing antiretroviral therapy should not be delayed because ideal preparations are not available; develop approaches to mitigate complexities. Both liquid and low-dose solid formulations of medicines will usually be required. Use of liquid formulations may require planning to address storage and refrigeration. Practical solutions to facilitate scale-up include providing antiretroviral therapy dosing tables based on WHO recommendations and providing guidelines to facilitate dispensing.
- 4.3.2 Ensure that the national selection and regulation processes allow for the speedy introduction of more appropriate formulations such as fixed-dose combinations as they become available. Assess existing regulatory processes and plan for measures to allow the fast-track registration of new products. Procurement and supply management should support the rapid phase-in and phase-out of supplies.
- 4.3.3 The national strategic plan should quantify the overall equipment and commodity needs for laboratory services to support care, support and treatment for children. Procurement should be phased to allow new technologies to be introduced as they become available.
- 4.3.4 Ensure that the selection and specifications of laboratory equipment address the needs of infants and children: for example, provide CD4 percentage readings and have the capacity to analyse small-volume samples.
- 4.3.5 Consider additional supply implications, especially for new technologies. For example, certain test kits require additional reagents and equipment, techniques such as DBS require drying devices and packaging for transport and some equipment may require unique and often costly commercial brands of testing reagents or kits.

4.4 Foster efficient and responsive supply chains to support the introduction and scaling up of programmes for children

- 4.4.1 Establish a dynamic and accurate pharmaceutical management information system to provide upto-date data to inform demand forecasting and supply management, particularly to provide early warning of potential oversupply or stock-outs. Provide simple tools and where necessary, staff to assist sites in collecting, analysing and reporting data. The WHO AIDS Medicines and Diagnostics Service (AMDS) web site (94) provides useful tools and links to procurement and supply management partners specializing in technical assistance for procurement and supply management (procurement and supply management toolbox project).
- 4.4.2 Quantifying the needs for commodities at the national level, particularly antiretroviral medicines for children, can be complex, especially during programme start-up. Set up a mechanism that includes all active players to regularly review stock levels and uptake of antiretroviral medicines, reschedule allocations as needed and track future product and funding requirements (Box 6).
- 4.4.3 The team responsible for quantification and forecasting in analysing data, developing assumptions and calculating needs may need to build capacity. Estimate the initial product volume using the targeted number of children per regimen, add a safety margin and then adjust for product consumption and the rate of scaling up. Setting monthly targets for scaling up at the site level will assist in quantifying needs and programme planning. A "push" system of resupply, in which the procurement unit or warehouse determines the quantity of antiretroviral medicines to issue, can be helpful when the programme starts and facilities lack the data and experience needed to calculate requirements accurately. However, to avoid over- or understocks, facility staff should quickly be

- trained and receive the tools that they need to operate a "pull" system, in which they calculate and requisition antiretroviral medicines and other supplies based on expected use.
- 4.4.4 Introduce flexibility in the supply and distribution chain that will allow redistribution of excess supplies and filling of non-routine orders, especially in the early phases of scaling up. Site reporting forms should allow sites to feed back on the quantities of supplies that need to be redistributed and the expiry dates of products in stock.
- 4.4.5 Manage the costs of stock-holding and buffer stocks through innovative storage and distribution strategies such as direct delivery mechanisms, higher frequency of deliveries and negotiated safety stocks held by suppliers.
- 4.4.6 Establish clear contingency and back-up provisions for laboratory equipment breakdown and supply shortages, particularly for antiretroviral medicines; options include collaborating with nongovernmental organizations and the private sector and interregional cooperation.
- 4.4.7 Interventions to increase access to treatment and/or to strengthen supply mechanisms should consider other providers involved in providing services, such as faith-based organizations or accredited private providers providing services on behalf of government.
- 4.4.8 Countries that adopt strategies such as public-private partnerships or contracting out selected core functions will require strengthening of management and oversight mechanisms in government. Considering the implications of these decisions early in the planning and budgeting cycles is important in maximizing success, for example by employing additional and/or expert staff on a contractual basis to assist in managing contracts.

Box 6. Case study - supply management in Kenya

In Kenya, the National AIDS and Sexually Transmitted Diseases Control Programme (NASCOP) is responsible for coordinating the commodity supplies for children to support the scaling up of antiretroviral therapy and services for preventing mother-to-child transmission. The working committee established under NASCOP to manage procurement and supply management issues for scaling up antiretroviral therapy services for children includes a wide range of stakeholders and partners. NASCOP informs and draws on the national HIV/ AIDS strategic plan developed by the National AIDS Control Council and its partners and the national health sector strategic plan of the Ministry of Health to develop targets for scaling up. Inputs from implementing partners are incorporated into the overall national planning process to build consensus on the targets set, avoid duplication and optimize the use of the limited resources available for procurement.

At the national level, the method used to forecast the antiretroviral medicines needed for infants and children is similar to that used for adults. However, more detailed data are required, including disaggregated data by weight, age, comorbidity and the proportion of children using solid versus liquid formulations. The monthly ordering and reporting system allows managers to routinely monitor the rate of uptake for the various antiretroviral formulations and adjust the deliveries accordingly. As the antiretroviral therapy supply chain is demand driven (a "pull" system), a well-functioning antiretroviral therapy pharmaceutical management information system is critical to provide the necessary data for forecasting. Both manual and electronic tools are used to assist sites in collecting, analysing and reporting data. The monthly reporting system enables early warning of potential overstock or undersupply of products, and sites have been encouraged to strengthen links with other facilities to facilitate the borrowing of antiretroviral medicine products as an interim measure to avoid stock-outs. To support the phasing in of new formulations, NASCOP drafts circulars and organizes stakeholder forums to inform stakeholders and partners of impending changes. Most antiretroviral medicine formulations for children are currently procured through donor systems that use phased deliveries to facilitate the smooth phasing in of the new formulations to avoid wasting old formulations.

Supply management of antiretroviral medicines and other products for children has been integrated into existing supply systems to minimize the proliferation of parallel systems and to build on the capacity of well-established systems. To facilitate rapid scale-up, checklists are used to quickly assess the pharmaceutical management capacity at sites to identify needs prior to initiating antiretroviral therapy services for infants and children. Simplified worksheets have been developed to assist new sites in using regimens and weight bands to quickly estimate the initial requirements for antiretroviral medicine formulations. NASCOP has also developed simplified charts to assist health workers in calculating dosage. Initial experiences with "push" systems resulted in significant overstocks of formulations for children at sites, as many of them fell short in meeting their assigned targets. Consequently a "pull" system is now used both for start-up and for routine resupply of antiretroviral medicines for infants and children, and facilities use previous consumption patterns to calculate resupply quantities.

Sources: personal communications, NASCOP, Ministry of Health, Kenya and Management Sciences for Health, Rational Pharmaceutical Management Plus (MSH/RPM Plus) Kenya office.

Strategy 5: Governments should ensure laboratory capacity for early diagnosis of HIV infection among infants and children and routine monitoring for HIV care and treatment

Background

National programmes need to extend the capacity of existing laboratory services to be able to provide early infant virological testing for HIV and ensure services for CD4 determination to aid in clinical decision-making on initiating treatment and/or prophylaxis for infants and children. Numerous assays and diagnostic platforms are now available, and health ministry programmes need to consider the most appropriate technology given existing capacity, infrastructure, equipment and predicted need.

Virological diagnosis can be undertaken using appropriate, continually externally validated commercially and non-commercially available tests for HIV DNA (PCR) or HIV RNA. For CD4 determination among children younger than 6 years, machines capable of measuring CD4 percentage are preferred to machines that only provide absolute numbers.

As with all laboratory services, effective systems for ensuring that results are transmitted to facilities and communicated to families are essential. Delays in delivering positive test results to health care workers and affected families can lead to unnecessary death and morbidity. National programmes and regional and or district networks need to monitor and evaluate how long it takes for results to be delivered and acted on at the site level.

Key actions

5.1 Plan for laboratory service expansion to accommodate early infant testing for HIV and routine immunological monitoring

- 5.1.1 Review national laboratory capacity-building plans and ensure that they reflect the HIV diagnosis, monitoring and care requirements for children. Ensure that national plans include capacity-building, including training and supportive supervision of existing staff in new technologies.
- 5.1.2 Identify all geographical sites where HIV testing will be needed and match this to existing and planned laboratory capacity. Based on this, update or review plans for introducing and decentralizing services.

- 5.1.3 Estimate the numbers of virological and serological HIV tests required. This needs to include virological tests needed as part of follow-up for HIV-exposed infants (usually done at 4-6 weeks), serological tests as part of follow up of the exposed infant (usually done at 12-18 months), and both serological and virological testing required for provider initiated HIV testing in acute or chronic child health services.
- 5.1.4 Establish laboratory capacity to perform virological testing using HIV DNA (PCR) and/or HIV RNA at one central or tertiary laboratory and plan for national coverage by additional laboratory testing capacity through the use of DBS and/or referral. For larger throughput, more than one laboratory may be necessary.
- 5.1.5 Ensure the development of robust, reliable systems for transporting specimens and reporting results back to the facility level and infants or children being tested in a timely fashion.
- 5.1.6 Ensure that serological assays are widely used for HIV testing of infants of unknown exposure status and sick children.
- 5.1.7 Ensure the standardization of laboratory equipment and procedures, including testing algorithms, across sites. Implement laboratory quality control systems to ensure accurate results.
- 5.1.8 Plan for decentralizing CD4 enumeration services and providing services to determine the CD4 percentage.

5.2 Select assays for virological diagnosis with the involvement of key staff from the national reference laboratory and officials in the health ministry working on HIV care and treatment for children

Factors differing between assays include assay performance, specimen throughput, volume requirements, limit of detection, ease of execution, instrument work space and the costs of equipment and disposal. Key considerations in selecting an appropriate assay should include:

- ✓ the ability to identify the common HIV subtypes in the country;
- the cost of the assay, kits, reagents and supplies and equipment maintenance (see sources and prices (95));
- ✓ the time and labour cost for each testing platform;
- the results from clinical validation studies to determine the sensitivity, specificity, precision and reproducibility of the results;
- ✓ in country regulatory or registration requirements; and
- ✓ infrastructure requirements (such as space, electricity and water).

Table 2 provides a very brief overview of possible platforms for virological diagnosis.

Table 2. Assays available for early infant diagnosis

Assay	Specimen	Advantages	Disadvantages
DNA One major platform currently available	0.5ml of whole blood	 ✓ Widely used and validated ✓ Not affected by exposure to ARVs ✓ Standardized reagents and kits ✓ Proven to be stable in DBS specimens 	 Not useful in predicting the need for antiretroviral therapy Not licensed or approved for diagnostic purposes Not yet fully automated
RNA Range of assays available	Most use Plasma, serum and require 0.2-1.0 ml recent studies using DBS suggest potential for false negatives below HIV RNA 2000 copies	 ✓ Useful in assessing the likelihood of disease progression ✓ Some use automated systems that combine all amplification and reading steps in one instrument ✓ Some have high throughput and short turnaround time ✓ Used for most types of HIV ✓ Can be used for other diseases ✓ One is approved by the FDA for surveillance 	 Potential for amplification errors Concern that where infant is exposed to ARV (MTCT or maternal ART) low levels of RNA may result RNA less stable in DBS specimens No standardized reagents and kits for diagnosis Most are not licensed or approved for diagnostic purposes Concern about accuracy where low level RNA for DBS

5.3 Develop systems for the timely and reliable use of laboratory results

For DBS or other specimens collected and transported to the diagnostic laboratory by mail, courier or other means, the promptness and reliability of the systems should be evaluated at each point in the chain of events (collection, mailing in, testing and reporting back). Delays at any point in the chain of events can result in significant increases in morbidity and mortality. Systems to track positive results and the ensuing actions should be developed. Simple standardized reporting and recording formats should be developed nationally to facilitate site-level and national-level evaluation of the systems. The basic information required for all specimens collected should be agreed on and reporting standardized.

5.4 Provide staff with appropriate education and training to ensure high-quality diagnostic services

High-quality diagnostic services require staff with appropriate education and training. Currently, few countries with high HIV prevalence have enough technicians, administrators, maintenance workers and others to fully support a scaled-up diagnostics network. For this reason, provision should be made for training (and retraining) such valuable human resources through a detailed plan and budget based on realistic objectives.

Additional considerations for scaling up laboratory capacity

I. Location of testing facilities

Deciding where and how many testing sites are required to perform optimum virological and CD4 determination depends partly on the national burden of HIV, required coverage and capacity. The optimum configuration depends on the factors outlined below and differs in each country.

II. Procurement, supply and maintenance

Several factors regarding the procurement of commercially available assays must be taken into account.

Technology. For most resource-constrained settings, the technology chosen should support the use of DBS samples, supported by standardized and validated protocols (see the section on sample collection and transport below). Laboratory managers should take a long-term view in their platform selected and in managing the procurement and storage of consumables. Some commercially available PCR platforms permit measurement of hepatitis C and hepatitis B, other sexually transmitted infections and *M. tuberculosis*. PCR methods are becoming automated, thus reducing the potential for error and increasing the reliability of results while simultaneously decreasing procedure time, thereby permitting greater throughput. However, they remain expensive.

Procurement, supply and maintenance. A favourable price or leasing agreement can often be negotiated through service contracts, and price negotiations should be carried out at the national level. Suppliers must be able to guarantee the timely provision of test kits and associated reagents and consumables with an adequate shelf life. The negotiated package should include technical support by the supplier, initial training in the use of the reagents and equipment (including routine equipment maintenance tasks to be completed by the staff of the testing facility) and regular scheduled maintenance and emergency repair by specialists of any associated equipment supplied. Ordering should ensure sufficient stocks so that any interruption of supplies will not result in interrupted service.

IV. Workload and sample throughput

Predicting workload and the frequency and number of samples to be tested in a given period is crucial to assessing the cost-effectiveness and suitability of any given technology. Some assays are better suited to larger throughput and may lead to waste if not fully used. Consideration needs to be given to the immediate situation and the estimation of needs over the longer term (such as 2–5 years). Unless the test is performed regularly, maintaining the required level of competence among technicians will be difficult, and more equipment-associated problems are likely to occur.

V. Sample collection and transport

Viral nucleic acids may degrade over time, and so the type of specimen and time between sample collection and testing is important, particularly if it is stored at high ambient temperature (such as during transport to the laboratory) for extended periods of time. Samples can be protected if transported rapidly at a cool temperature (2–10°C). However, where transport and refrigeration are problematic such as in remote or rural areas, DBS or plasma spots may be the best solution. Not all assays can be used on dried blood specimens, and some require greater sample volume.

The advantages of DBS include:

- low sample volume for infants;
- · the sample is safe and sterile;
- once dried and if kept dry, the sample is stable;
- easy storage (dry and at room temperature);

- inexpensive and easy transport (no dry ice required and no biological hazard);
- DBS spots can be cut out of the filter paper using scissors, punch-machines (manual and pneumatic)
 and automated cutters:
- · compatible with various nucleic acid isolation technologies; and
- plasma and whole blood generate accurate and reproducible results.

Currently only DNA assays are standardized for use with DBS for diagnostic purposes.

Additional resources

Information is available about:

- evaluated assays, bulk procurement, quality assurance and training (96);
- quality control for HIV rapid testing (97);
- HIV rapid testing training tools (98);
- laboratory monitoring (75);
- CD4 enumeration technologies (99); and
- shipping DBS (100).

In the resources listed in annex 2 additional training and standard operating procedures are provided.

Strategy 6: Strengthen community-based capacity to identify possible cases of HIV and refer for testing and to provide follow-up care and support for infants and children who have HIV

Community-based strategies provide an important way of optimizing continued care, support and treatment for children who are exposed to or who have HIV, particularly for families living far from health centres. Interventions in the community are particularly important for children who depend on caregivers within the community to access services that benefit these children. Interventions that are based in the community and use community resources can not only aid in case-finding, improve basic care and provide support for treatment adherence but can also play a vital role in addressing stigma, incorporating the voice of people living with HIV in programming and improving treatment literacy.

Relevant actions

6.1 Integrate community-based approaches into child health and HIV programming strategies

For community-based strategies in child health, including HIV care, to be effective, several components must be in place. These include:

- ✓ including community strategies in national treatment and care plans;
- establishing policies that support the roles of community health care workers in HIV-related care and focus on maintaining the quality of care and performance;
- ✓ developing core content for use at the community level;
- ✓ paying attention to sustainable systems of incentives;
- developing systems of communication and coordination between levels of care that include community workers;

- ✓ investing in community health care worker recruitment and training; and
- ensuring adequate supervision structures.

In planning for community-based strategies, however, the time commitment and caseloads of community health workers, particularly those who work as volunteers or receive a small stipend, cannot be expected to be the same as for full-time workers who may also earn more substantial financial compensation for their efforts. For community health workers to be effective, their workload must be manageable and fit within their other responsibilities. Limited literacy among volunteers can also affect their ability to perform certain tasks. Specific tasks that community health workers can appropriately provide should be selected and training provided to support them in delivering these services.

6.2 Accelerate case-finding through integration into community health programmes

Identifying infants and young children with HIV is important so that they can be given appropriate care and benefit from life-saving antiretroviral therapy. Community options for case-finding can be built on existing community health services such as regularly scheduled outreach maternal and child health services and delivering integrated services through child health days (vitamin A supplementation, immunization and deworming as core interventions, distributing or re-treating insecticide-treated nets free of charge, growth monitoring and IMCI and health education and promotion as additional interventions), community IMCI, home-based care and community nutrition programmes and other child care activities driven by nongovernmental and community-based organizations. A structured approach to case-finding should be encouraged, with community health workers focusing on areas likely to result in the highest yields rather than attempting to focus on all areas at once. Attention to consent and confidentiality should be stressed during training, supporting and supervising community case finding.

- 6.2.1 Where community IMCI is in place, integrate HIV case-finding and case follow-up into protocols, training and referral processes.
- 6.2.2 Harmonize essential community newborn care and essential care for HIV-exposed newborns. Community newborn care is delivered through two or three home visits during the first week and can improve case follow-up and provide a mechanism for reinforcing safer infant feeding practices and the use of co-trimoxazole prophylaxis while decreasing the potential for stigmatization, as home visits would be provided regardless of HIV status.
- 6.2.3 Assess local care-seeking practices to determine where caregivers are most likely to bring sick children. This should include mapping formal services as well as community volunteers, birth attendants and traditional health providers. Community health and nutrition workers, committees for orphans and vulnerable children and other HIV-related supports are likely points of contact with sick and HIV-exposed children and can be excellent referral sources for HIV testing. Develop district-specific plans based on local care-seeking and use patterns.
- 6.2.4 Based on local understanding of care-seeking and local mapping of formal as well as traditional health services, orient community workers, volunteers and traditional practitioners to HIV signs and symptoms and the importance of timely referral for services.

6.3 Improve case follow-up and essential care for HIV-exposed newborns and their families

6.3.1 Promote community-level follow-up and support for infants and young children who are exposed to or who have HIV through community-based services and groups. With direct support to community-based organizations and nongovernmental organizations, governments can ensure continued and sustained provision of co-trimoxazole prophylaxis, nutritional counselling, psychosocial support and adherence counselling and the management of simple, common side effects.

- 6.3.2 Where newborns whose mothers have received services for preventing mother-to-child transmission are commonly lost in follow-up, community strategies should be developed to improve case follow-up through the period where testing determines the child's HIV status. This could include developing a planned agreement for a home visit if the mother does not return for follow-up.
- 6.3.3 Children and their caregivers who access services for managing severe malnutrition should be counselled on HIV testing. As the use of community therapeutic care expands, the possibility of linking HIV testing to nutritional interventions, particularly in settings with high HIV prevalence, will become more relevant
- 6.3.4 Both primary and secondary prevention should be reinforced through community-level interventions. This includes support for safer feeding practices for infants and young children and basic disease prevention measures to protect health and delay disease progression.

6.4 Enhance community capacity to provide care and support

Community health workers can play an instrumental role in sustaining long-term delivery of co-trimoxazole preventive treatment and antiretroviral therapy, counselling for infant feeding choices and the timely referral of sick infants (Box 7). The use of peer-to-peer approaches, maternal support groups and community health workers can help support adherence to treatment by re-supplying pharmacotherapy and routinely reviewing the health plans with caregivers. Community health workers currently doing community case management for pneumonia and malaria are an excellent source for providing follow-up services for infants and young children who are exposed to or who have HIV. Mapping community groups and the types of service provided is important, as is ensuring that some group or individual covers all households, especially those with HIV and infants. Specifically, community health workers can enhance community capacity to provide care and support in the following ways.

- 6.4.1 Improve treatment literacy and support for adherence. Improved understanding among caregivers and children of treatment regimens, side effects and the importance of adherence, with age-appropriate information, can improve clinical outcomes for children.
- 6.4.2 Improve access to co-trimoxazole preventive treatment through community child health programmes. Community health workers can raise community awareness of the benefits of co-trimoxazole preventive treatment for children exposed to or infected with HIV and provide families with simple advice to ensure that children get the appropriate daily dose. Where community health workers already deliver medicines as part of their work, feasible mechanisms may already exist for delivering co-trimoxazole preventive treatment and ensuring adherence.
- 6.4.3 Make sure that children who are exposed to or have HIV are immunized. Community health workers can explain to families about the importance of immunization. Community health workers should advise families to keep children's health cards in a safe place and ensure that health records are passed to future guardians as part of the preparation when a parent is terminally ill.

6.5 Promote good nutrition

- 6.5.1 Promote safe infant feeding. Community health workers should reinforce messages that ensure the consistent use of safer feeding practices. Where possible, refer women living with HIV for counselling about infant feeding or, if counselling is not available, provide clear advice about infant feeding in their circumstances.
- 6.5.2 Raise awareness about malnutrition and how to prevent it. Community health workers can advise families about how to care for a child who has a sore mouth and to seek help if a child is not eating well or has signs of malnutrition.

6.5.3 Use community-based nutrition programmes to improve health outcomes for children who have HIV who need higher nutritional intake, both before and during treatment (Box 8).

6.6 Give vitamin A supplementation

6.7 Protect children from malaria and TB

Community health workers can advise families to make sure all young children sleep under an insecticide-treated net and find out where families can obtain insecticide-treated nets free of charge or subsidized. Community health workers can also help ensure that TB screening, isoniazid prevention and TB treatment are offered to children and to adults.

6.8 Promote safe water and good hygiene

Community health workers can advise families on the use of clean water for drinking and preparing food. They can also provide families with practical information about good hygiene practices that can help to prevent and care for diarrhoea and other infections and distribute soap and other preventive materials.

6.9 Norms for confidentiality and disclosure should be adapted specific to community settings

Mothers living with HIV should be consulted in developing and tailoring local approaches to ensure confidentiality. Accountability mechanisms for volunteers and for paid community workers must also be established.

Box 7. Examples of community-based care and treatment programmes for children *Uganda*

With support from Save the Children, the nongovernmental organization Health Alert Uganda works in Gulu District in northern Uganda to promote access to treatment and care for children who have HIV. Specific activities include:

- raising awareness in the community of the importance of testing children and providing treatment for children who need it;
- giving families basic information about antiretroviral therapy, including how to give medicines to children and how to manage side effects;
- · training children as treatment adherence peer educators;
- supporting children with HIV to communicate their needs to a wider audience through radio programmes; and
- establishing peer support clubs for children regardless of HIV status.

The project has shown that increasing access to treatment for children and home management of children on antiretroviral therapy are feasible in resource-constrained settings. Communities better understand the importance of testing and treatment for children, and parents and children appreciate the importance of taking their medicines. Peer support clubs have been very effective in helping parents to tell children that they have HIV, promoting adherence and reducing stigma towards children with HIV.

Source: Building Blocks Development Group - provided by Timothy Ahimbisibwe, Save the Children (UK) Uganda.

Thailand

Tools developed by Médecins Sans Frontières in Thailand to help support adherence in children include: fairy tales and dolls used to explain how the HIV multiplies in the body and how taking medicine helps to stop this; a medicine weekly wall planner with morning and evening doses in small bags attached to it; a medicine box that looks like a small apartment block with medicines for each day on a different floor; and a medicine card with different stickers representing each medicine and showing when they need to be taken. Médecins Sans Frontières invites children and their caregivers to meet every three months so they can talk to each other about their problems.

Source: Poinnet (101).

Box 8. Examples of community-based nutrition programmes integrating HIV care

Valid International in Malawi

In Malawi, Valid International studied the feasibility and outcomes of the use of community therapeutic care for managing severe acute malnutrition in children younger than 5 years of age for treating severely malnourished children who have HIV in the community. Ready-to-use therapeutic foods were used for nutritional rehabilitation, provided as weekly take-home rations. In addition, vitamin A, deworming, anaemia treatment, antibiotics for bacterial infections and malaria prophylaxis were provided according to standard community therapeutic care protocols (102). The approach demonstrated its potential to increase the uptake for HIV testing of malnourished children as well as caregivers (94% and 61% respectively). Fifty-nine per cent of the children who have HIV in a prospective cohort recovered their nutritional status using community therapeutic care protocols without the addition of antiretroviral medicines, and 86% of these children were not malnourished approximately 15 months after discharge.

Source: Bahwere et al. (103).

Swaziland

Community volunteers care for preschool children at neighbourhood care points in Swaziland. The aim is to improve young children's health and nutrition, give psychosocial support and enable older siblings to go to school. UNICEF provides cooking pots and the World Food Programme provides corn-soya blend.

Source: Neighbourhood care points: an advocacy and action strategy for realising the rights of orphans and vulnerable children in Swaziland (104).

More information is available about family and community practices that promote child survival, growth and development (105).

Strategy 7: Governments should promote strengthened monitoring and evaluation systems that enhance the provision of high-quality care for children who are exposed to or who have HIV

Background

As governments work toward scaling up national HIV care and treatment programmes for children, provision of quality care is often compromised in the rush to scale up. National-level efforts to monitor the performance of HIV treatment and care for children, however, are often hampered by weak monitoring and evaluation systems. To assist governments in better monitoring national progress toward eliminating HIV infection in infants during pregnancy, birth and postpartum and to ensure universal access to prevention, treatment, care and support for mothers and children, WHO and UNICEF recently reviewed and revised existing guidance on monitoring and evaluation of services for preventing mother-to-child transmission, antiretroviral therapy and HIV care and support. The guidance was revised to better reflect the recent technical revisions to recommendations on antiretroviral therapy and HIV care and support and the new global commitments that call for action to focus on the programme needs of children in HIV care and treatment.

7.1 Governments should include core indicators of services for preventing mother-to-child transmission and HIV care and treatment for children in national monitoring and evaluation frameworks (Table 3) to monitor and support national scale-up efforts

Table 3. Core national-level indicators for services for preventing mother-to-child transmission and HIV care and treatment for children

Domain	Indicator		
Core indicator 1: Existence of guidelines for the prevention of HIV infection among infants and young children	Existence of national guidelines (either approved or in draft form) for the prevention of HIV infection among infants and young children and the care of infants and young children in accordance with international or nationally agreed standards		
Core indicator 2: Number and percentage of health care workers newly trained or retrained	The number and percentage of health care workers newly trained or retrained in the minimum package ¹ during the preceding 12 months		
Core indicator 3: Prevention and care service points	The percentage of public, missionary and workplace venues (family-planning and primary health care clinics, antenatal care, maternal, newborn and child health and maternity hospitals) offering the minimum package of services for the prevention of HIV infection in infants and young children in the preceding 12 months		
Core indicator 4: Women completing the testing and counselling process	The percentage of pregnant women making at least one antenatal care visit who have received an HIV test result and post-test counselling		
Core indicator 5: Antiretroviral medicines for services for preventing mother-to-child transmission (UNGASS)	The percentage of pregnant women living with HIV receiving antiretroviral medicines for preventing mother-to-child transmission in accordance with a nationally approved treatment/prophylaxis protocol (or WHO/UNAIDS standards) in the preceding 12 months		

¹ The National guide to monitoring and evaluating programmes for the prevention of HIV in infants and young children (106) states that "the minimum package varies between different types of health care facilities". The minimum package for antenatal care and maternal and child health clinics is defined to include: counselling on risk reduction, counselling on infant feeding, and referring for or providing the following: HIV counselling and testing, antiretroviral prophylaxis, family planning (including counselling on dual protection), attended delivery in birth facilities with safe obstetric practices and long-term care. Staff members at family planning clinics, maternity hospitals and primary health care facilities are expected to be trained in a subset of the above, consistent with national expectations.

Domain	Indicator		
Core indicator 6: Infants with HIV born to mothers living with HIV	Percentage of HIV-infected infants born to mothers living with HIV		
Core indicator 7: Pregnant women living with HIV assessed for antiretroviral therapy	The percentage of pregnant women living with HIV attending services for preventing mother-to-child transmission who are assessed for eligibility for antiretroviral therapy prior to delivery either on site or by referral		
Core indicator 8: HIV-exposed infants receiving co- trimoxazole prophylaxis	Percentage of infants born to women living with HIV started on co-trimoxazole prophylaxis before 2 months of age		
Core indicator 9: HIV-exposed children tested for HIV by 12 months	The percentage of infants born to women living with HIV receiving a virological test for HIV diagnosis before 2 months of age or antibody testing before 12 months of age		
Core indicator 10: Antiretroviral therapy for children	The number of infants with HIV under 1 year of age receiving antiretroviral therapy, and number of children 0-14 years who have advanced HIV disease who are receiving antiretroviral therapy		
	Distribution of infant feeding practices of HIV-exposed infants at 3 months of age using 24-hour recall.		
	Number of HIV-exposed infants who were exclusively breastfeeding at or around 3 months of age		
Core indicator 11: Infant feeding	 Number of HIV-exposed infants who were replacement feeding (no breast-milk) at or around 3 months of age 		
	Number of HIV-exposed infants who were mixed feeding at or around 3 months of age		
	It is measured at or around the third vaccination for diphtheria-pertussis-tetanus (DPT3), which takes place between 14 and 16 weeks of age		

7.2 Efforts to systematically monitor programme effectiveness and quality should be strengthened and expanded

- 7.2.1 A quality improvement focal point within the health ministry should be tasked with site selection and performance measurement, introduce quality improvement concepts to new sites and facilitate quality improvement activities in HIV care and treatment for children. The focal point can also assist in aggregating data at various levels of government infrastructure, including the district, province and national levels.
- 7.2.2 To achieve success in the area of quality improvement and to promote sustainability, quality improvement champions should be identified at the health facility level who believe in the possibility of change and can motivate the staff to achieve the desired results.
- 7.2.3 Performance indicators should ideally be chosen by national stakeholders and reflect stakeholders' understanding of the essential intervention package. Indicators should be based on nationally recognized information such as clinical guidelines, and be SMART (specific, measurable, achievable, relevant and timely). Indicators that impact decision-making should be used.

Performance measurement indicators (Box 9) can assist service providers and programme managers at the local, district and national levels in determining whether essential health services are being provided to everyone who should receive them and on schedule. An indicator essentially measures the proportion of people who should receive a service who actually do.

Box 9. Examples of indicators to measure the quality of care

- Proportion of HIV-exposed children provided with early HIV diagnosis
- Proportion of children 2 years of age provided all recommended immunizations
- Proportion of children 5 years or younger who have been assessed for weight for height during the past six months
- Proportion of children 5 years or younger who were provided a bed net as malaria prophylaxis
- Proportion of children 5 years or younger who were provided mebendazole for deworming in the past six months
- Proportion of children with HIV who had CD4 assessed within the past six months
- · Proportion of children receiving antiretroviral therapy who were assessed for adherence at last clinic visit

Process indicators are those that measure the provision of interventions that are linked to good clinical outcomes. Outcome indicators measure areas such as morbidity and mortality for an affected population. Outcome indicators are attractive because programmes are ultimately interested in improving outcomes, but determining whether the interventions conducted or not conducted by a health service provider or facility were responsible for the improved or worsened outcome is often difficult. Other factors beyond the control of the health care provider may have had a role in modifying the outcome.

- 7.2.4 Limit the number of indicators being measured to balance obtaining useful information with limiting the burden on the health care workers responsible for collecting the data.
- 7.2.5 Data must be analysed and reported back to the sites where it was collected in a timely manner. Old data may no longer reflect the current situation, making analysing bottlenecks and system weaknesses and subsequent improvements in care delivery more difficult.

7.3 Quality improvement activities need to quickly follow performance measurement

Quality improvement activities should quickly follow data collection and analysis. Data should be used to identify areas for improvement that can be achieved with the available staff and resources of the health centre. Quality improvement projects should be focused on areas that will result in significant improvements in health status for significant numbers of children. Successful experiences as well as challenges in implementing quality improvement projects should be shared among staff from different health centres in the region.

Problems with the quality of care being delivered are often linked to systems. In most situations individuals are interested in providing high-quality care, but because of systemic issues such as lack of documentation tools or easily visible guidance documents, or insufficient training, appropriate care does not get delivered.

A number of quality improvement models suitable to resource-limited environments exist. These include plan-do-study-act (PDSA) cycles; rapid assessment interdisciplinary teams that include community members to champion change; and formalized learning collaboration within and among health facilities. More information about improving quality is available from the New York State Department of Health AIDS

Institute (107), Institute for Healthcare Improvement (108), University Research Corporation (109), John Snow, Inc. and JSI Research & Training Institute, Inc. (110) and the Electronic Resource Center of Management Sciences for Health (111,112).

The quality of HIV care for children can often be improved simply by introducing basic documentation tools. For example, introducing a basic checklist into a child's health chart can help remind health care providers when specific interventions such as immunization or testing of exposed infants are required.

Many facilities in a geographical area often experience similar challenges in a particular area of service delivery for children (such as early diagnosis). Sharing of experiences between different health facilities can lead to sharing of successful strategies and overall group learning, especially if formalized learning collaborations are established. Rather than one facility tackling a series of quality improvement problems linearly, multiple facilities can engage in quality improvement via plan—do—study—act cycles and share their findings, contributing to orchestrated quality improvement in a geographical area (Box 10).

Box 10. Improving the quality of HIV care for children in Thailand

The Government of Thailand, after successfully implementing performance measurement and quality improvement for adult HIV care, began similar activities focused on the needs of children in late 2006. Different clinics have focused on different areas for improvement, including assessment of antiretroviral therapy adherence among children, oral health care for children who have HIV and assessment of immunization history. By focusing on systemic reasons behind poor performance and developing tools to improve service delivery, sites were able to achieve the following during one year:

- the proportion of children who have HIV whose adherence to antiretroviral therapy was assessed rose from 66% to 85%;
- ✓ the proportion of children who have HIV whose immunization history was assessed rose from 8% to 100%; and
- ✓ the proportion of children who have HIV with abnormal oral health receiving oral
 health treatment rose from 41% to 100%.

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ANNEX 1.

SAMPLE SITUATIONAL ANALYSIS CHECKLIST

The following are some essential components to include in a situational analysis focused on HIV care and treatment for children.

✓ Management structure, including key national stakeholders such as government officials, bilateral institutions, nongovernmental organizations and donors

✓ Demographics. Estimates for:

- Number of pregnant women accessing antenatal care and number of these testing HIV positive
- Number of infants/children who are exposed to HIV
- Number of infants/children who have HIV
- Number of children with HIV receiving antiretroviral therapy

✓ Health care facilities and sources of support

- Number of maternal, newborn and child health facilities
- Number of antiretroviral therapy sites (with a breakdown of those providing services to children)
- Clinical capacity in HIV care and treatment for children and need for additional training
- Status of IMCI expansion

✓ Policies, programmes and materials related to preventing mother-to-child transmission

- National targets
- Technical working group to advise on programme direction and strategies
- Testing policy (such as provider-initiated HIV testing and counselling), including policies for pre- and post-test counselling
- Guidelines, including regimens for preventing mother-to-child transmission
- Mechanisms for following up HIV-exposed infants
- Training curriculum and plan
- Fee structure
- Consent policies
- Programme manual

✓ Antiretroviral therapy policy and programme implementation

- Existence of a national policy on antiretroviral therapy for infants and children
- Existence of national targets for infants and children
- Existence of a national strategy for scaling up antiretroviral therapy
- Funding sources and sources of technical assistance
- Existence of national guidelines specific to the treatment of children
- Specified standard first line antiretroviral therapy regimens for infants and children.
- Defined package of HIV-related clinical services for children and families
- Plans and tools for quality assessment and supervision
- Existence of a national training curriculum and plan

✓ Medicine and commodity supply

- Availability of generic antiretroviral medicines and co-trimoxazole in formulations for children
- Supply procurement and supply management mechanisms and integration within existing procurement and supply management mechanisms
- Other essential medicines (such as antibiotics, artemisinin-based combination therapies and fever and pain medicines)
- Essential diagnostic supplies

Laboratory

- Virological diagnostic capacity, including DBS
- Diagnostics: test kits, reagents and consumables
- monitoring capacity (%CD4)

✓ Community involvement

- Policies supportive of community involvement in HIV diagnosis, care, treatment and support for children
- Role of community organizations in identifying children needing HIV testing
- Providing HIV-related care and treatment at the community level

Monitoring and evaluation

- Agreed national strategy for monitoring services for preventing mother-to-child transmission and antiretroviral therapy for infants children and families
- standardized data elements and tools

✓ Child health

- Co-trimoxazole policy and implementation status
- IMCI implementation status
- Nutritional support interventions, including infant feeding policies, and practices and status of the International Code of Marketing of Breast-milk Substitutes

✓ Funding sources

ANNEX 2. TOOLS AND RESOURCES

Guidance documents

The following guidance documents are available for use and/or adaptation:

a. WHO guidelines

- Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access: recommendations for a public health approach – 2006 version. Geneva, World Health Organization, 2007 (http://www.who.int/hiv/pub/guidelines/pmtct/en/index.html, accessed 18 January 2008).
- Guidelines on co-trimoxazole prophylaxis for HIV-related infections among children, adolescents and adults: recommendations for a public health approach. Geneva, World Health Organization, 2006 (http://www.who.int/hiv/pub/guidelines/ctx/en/index.html, accessed 18 January 2008).
- 3. Antiretroviral therapy of HIV infection in infants and children in resource-limited settings: towards universal access. Recommendations for a public health approach. Geneva, World Health Organization, 2006 (http://www.who.int/hiv/pub/guidelines/art/en/index.html, accessed 18 January 2008). Note: To be updated in mid 2008.
- 4. IMCI: Integrated Management of Childhood Illness [web site]. Geneva, World Health Organization, 2008 (http://www.who.int/child-adolescent-health/integr.htm, accessed 18 January 2008).
- 5. HIV/AIDS: IMAI/IMCI publications [web site]. Geneva, World Health Organization, 2008 (http://www.who.int/hiv/pub/imai/en, accessed 18 January 2008).
- HIV and infant feeding [web site]. Geneva, World Health Organization, 2008 (http://www.who.int/child-adolescent-health/NUTRITION/HIV infant.htm, accessed 18 January 2008).
- IMAI course director and facilitator guides for the Basic ART Clinical Training and Acute Care Training Courses. Geneva, World Health Organization, 2005 (http://ftp.who.int/htm/IMAI/Firstlevel/Basic/BasicFacilitatorGuide.doc, accessed 18 January 2008).
- 8. WHO recommendations for clinical mentoring to support scale-up of HIV care, antiretroviral therapy and prevention in resource-constrained settings. Geneva, World Health Organization, 2006 (http://www.who.int/hiv/pub/meetingreports/clinicalmentoring/en/index.html, accessed 18 January 2008).
- 9. Guidelines for an integrated approach to the nutritional care of HIV-infected children (6 months 14 years): chart booklet. Geneva, World Health Organization (in press).
- 10. Guidelines for an integrated approach to the nutritional care of HIV-infected children (6 months 14 years): handbook. Geneva, World Health Organization (in press).
- 11. Guidelines for an integrated approach to the nutritional care of HIV-infected children (6 months 14 years): guide for local adaptation. Geneva, World Health Organization (in press).

b. African Network for Care of Children Affected by HIV/AIDS (ANNECA)

1. Tindyebwa D, et al., eds. *Handbook on paediatric AIDS in Africa*. Kampala, African Network for Care of Children Affected by HIV/AIDS (ANECCA), 2006 (http://www.anecca.org/index.php?option=com_downloads&Itemid=51, accessed 18 January 2008). Available in English and French.

C. Columbia University International Center for AIDS Care and Treatment Programs (ICAP)

 Fayorsey R, Abrams EJ. Paediatric HIV/AIDS care and treatment pocket guide. New York, Columbia University International Center for AIDS Care and Treatment Programs, 2006 (http://www.columbia-icap.org/resources/peds/files/PediatricPocket06.pdf, accessed 18 January 2008).

- Abrams EJ, Fayorsey R, Gonzalez LF. Diagnosis of HIV infection in infants: a comprehensive implementation and clinical manual. New York, Columbia University International Center for AIDS Care and Treatment Programs, 2007 (http://www.columbia-icap.org/resources/peds/files/ Infantdx050307.pdf, accessed 18 January 2008).
- 3. WHO and the United States President's Emergency Plan for AIDS Relief. WHO and the United States President's Emergency Plan for AIDS Relief are collaborating to produce and implement operational guidance for providing HIV prevention, care and treatment services at primary health centres in resource-constrained settings with high HIV prevalence. They are developing two manuals, one on operations and one on basic HIV services, with input from 13 expert panels.
- 4. Centers for Disease Control and Prevention
 A range of resources to support implementation of infant diagnosis are available on request from CDC. These include written guidance on starting a programme; tools for supply projection, procurement information, suggested registers and forms, and a checklist for implementers. Training materials on infant dried blood spot collection for clinical staff include suggested testing algorithms, job aids for clinical staff, and a DVD on DBS collection. Tools for laboratorians include guidance on how to set up a PCR lab, equipment recommendations, standard operating procedures for testing, supply projection & procurement information, and job aids for laboratory staff. Contact: Shambavi Subbarao at sfs2@cdc.gov or Tracy Creek at tgc0@cdc.gov

Web sites

The following web sites may be useful for HIV and AIDS programming for children.

- **a. WHO HIV/AIDS**. This section of the WHO web site contains useful normative information related to clinical guidance (antiretroviral therapy, co-trimoxazole prophylaxis, early diagnosis, services for preventing mother-to-child transmission, infant feeding and nutrition) as well as global data related to HIV and AIDS: http://www.who.int/hiv/en.
- **b.** WHO Child and Adolescent Health and Development. This section of the WHO web site contains useful information on these topics, including information related to child survival. The page also contains links to other WHO web pages, including IMCI: http://www.who.int/child-adolescent-health.
- c. WHO AIDS Medicines and Diagnostics Service (AMDS). The AMDS is a network for supply management of HIV commodities and facilitates cooperation between technical partners, funding agencies, manufacturing companies and other organizations. Information is available on specific HIV-related products, prequalification/quality assurance, and procurement supply management including forecasting, logistics management, and patents and registration: http://www.who.int/hiv/amds/en.
- **d. WHO HIV/AIDS Toolkit**. WHO has developed a toolkit for programme managers, implementers and their partners in the public and private sectors with the aim of providing technical guidance on planning and implementing antiretroviral therapy programmes in resource-constrained settings: http://who.arvkit.net/arv/en/index.jsp.
- e. WHO guidance on scaling up voluntary counselling and testing: http://www.who.int/hiv/topics/vct/en/index.html.
- **f. UNICEF.** The UNICEF web site contains a variety of information on children and HIV including services for preventing mother-to-child transmission, infant diagnostics, HIV care and treatment for children, primary prevention and children affected by HIV: http://www.unicef.org.

- g. International Center for AIDS Care and Treatment Programs, Columbia University. The web site contains a variety of resources including training modules, technical updates, and general resources on HIV care and treatment for children and adults, including services for preventing mother-to-child transmission, HIV/TB and prevention: http://www.columbia-icap.org/whatwedo/mtctplus/index.html.
- h. Baylor International Pediatric AIDS Initiative. The web site contains a variety of information related to HIV treatment for children, including a training curriculum, guidance on adherence and pill swallowing for children and a pictorial atlas of common manifestations of HIV infection among children: http://bayloraids.org.
- i. African Network for Care of Children Affected by HIV/AIDS (ANECCA): ANECCA has developed a useful handbook for the care and treatment of children who have HIV with a special focus on care and treatment in the African setting: Tindyebwa D, et al., eds. Handbook on paediatric AIDS in Africa (http://www.anecca.org/index.php?option=com_downloads&Itemid=51). Available in English and French.
- j. Mothers2Mothers (m2m). This is an innovative mentoring programme offering comprehensive support for pregnant women living with HIV and new mothers. m2m trains and employs mothers living with HIV who have themselves benefited from their services to become mentor mothers. These mentors comprise a team of caregivers and educators for other mothers living with HIV and become an integral element of clinical care for preventing mother-to-child transmission: http://www.m2m.org.
- k. International HIV/AIDS Alliance. The International HIV/AIDS Alliance has many useful publications and toolkits on community action for HIV and AIDS. Of particular interest is the online collection of resources concerning orphans and vulnerable children: http://www.ovcsupport.net. This is jointly produced by the Alliance and Family Health International and contains more than 500 annotated resources on children affected by HIV, with a dedicated section on health and nutrition: http://www.aidsalliance.org.
- I. United States Centers for Disease Control and Prevention. The web site contains useful information on programme implementation in HIV. Of particular interest to many implementers will be information on laboratory considerations within the context of HIV and AIDS: http://www.cdc.gov/hiv.
- **m. UNITAID**. UNITAID is an international drug purchasing facility dedicated to scaling up access to treatment for HIV, malaria and TB for people in low- and medium-income countries through innovative financing mechanisms: http://www.unitaid.eu.
- n. HIVQUAL International. HIVQUAL International is a quality improvement initiative that was developed in New York State and has now been successfully implemented across the United States as well as in Africa, Asia and Latin America. The goal of the initiative is to improve the quality of care delivered to people living with HIV. Participants are coached to develop specific skills in measurement, sampling, identifying opportunities for improvement and conducting projects to improve performance: http://www.hivqual.org.
- o. Elizabeth Glaser Pediatric AIDS Foundation. The web site describes its programmes, advocacy documents for treatment of children, global data and technical publications and links to other sites for more information: http://www.pedaids.org.
- p. BASICS. The Basic Support for Institutionalizing Child Survival (BASICS) web site contains useful information on proven child survival interventions. Technical publications are available on acute respiratory infections, malaria, diarrhoeal diseases, HIV, immunization, nutrition and other areas: http://www.basics.org.

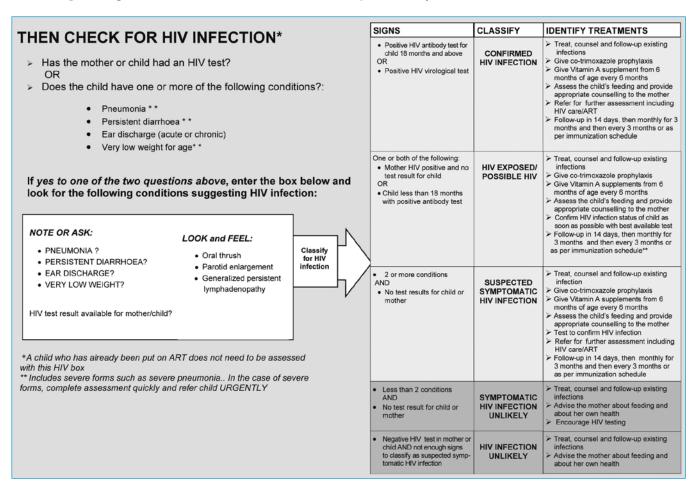
q. Institute for Healthcare Improvement: The chronic care model for quality improvement used by the Institute for Healthcare Improvement highlights six general components for improving productive interactions between patients and providers to produce better outcomes: community resources, decision-support (such as guidelines and algorithms), effective self-management, delivery system design, information systems and health care organization. Much attention is given to community resources and decision support for HIV-related scale-up: http://www.ihi.org/IHI/Topics/ChronicConditions.

Training curricula

Several training curricula have now been developed or are in the process of being completed. The following curricula are in more advanced stages of development.

- **IMAI/IMCI**. WHO and UNICEF have developed a training curriculum for lower-level health care workers to enable them to more effectively identify children who have HIV and provide routine HIV care for children: *Integrated Management of Childhood Illness complementary course on HIV/AIDS*. Geneva, World Health Organization, 2007 (http://www.who.int/child-adolescent-health/publications/IMCI/ISBN_92_4_159437_3.htm).
- IMCI complementary course on HIV/AIDS (chart booklet). The page in Fig. 1 is one of six similar pages in the chart booklet of the IMCI complementary course on HIV/AIDS focused on different conditions. This specific page, and other related pages in the chart booklet, were designed to assist in health care workers assessing and classifying young infants and children for HIV infection as well as associated opportunistic infections. This tool is also intended to assist health care workers in preventing illnesses among young infants and children who have HIV, communicate with mothers regarding infant feeding options and appropriately follow up with infants who are exposed to or who have HIV in terms of chronic care, clinical staging and initiation of antiretroviral therapy: WHO and UNICEF. Integrated Management of Childhood Illness complementary course on HIV/AIDS. Geneva, World Health Organization, 2007 (http://www.who.int/child-adolescent-health/publications/IMCI/ISBN 92 4 159437 3.htm).

Fig. 1. Page from chart booklet of the IMCI complementary course on HIV/AIDS



ART: antiretroviral therapy.

Source: WHO and UNICEF. Integrated Management of Childhood Illness complementary course on HIV/AIDS. Geneva, World Health Organization, 2007 (http://www.who.int/child-adolescent-health/publications/IMCI/ISBN_92_4_159437_3.htm).

- Infant and young child feeding counselling: an integrated course. This course, developed by WHO and
 UNICEF, prepares health and lay workers to counsel and support mothers, including women living with HIV, to
 carry out recommended feeding practices for their infants and young children from birth up to 24 months of
 age: http://www.who.int/nutrition/iycf_intergrated_course/en/index.html.
- African Network for the Care of Children affected by HIV/AIDS (ANECCA): An HIV care training curriculum, originally developed in English and now translated into French, is available for use in both Anglophone and Francophone countries in Africa: http://www.anecca.org/index.php?option=com_downloads&Itemid=51.

ANECCA has also developed curricula for a training course on psychosocial care and counselling for children and adolescents who have HIV. The course is meant for front-line health care providers involved in day-to-day care, treatment and support for children and families affected by HIV and AIDS. Presented in 14 modules, the course covers various aspects in the area of HIV counselling for children including: practical techniques of communicating with and counselling children of different age groups; HIV testing and disclosure of HIV status to children and families; adherence to antiretroviral therapy and other aspects of care; adolescent support; palliative care and grief and bereavement counselling. The course includes a series of practical sessions, role plays, video demonstrations of selected vital skills, case studies as well as classroom discussions: http://www.anecca.org/index.php?option=com_downloads&Itemid=51&func=selectfolder&filecatid=10.

Tools

Spectrum

Spectrum is a software package developed by UNAIDS that can be used to determine the consequences of current trends and future programme interventions with respect to the HIV epidemic, including the number of people living with HIV by age and sex, the number of AIDS deaths and the number of orphans as a result of AIDS as well as other demographic indicators of interest, such as life expectancy and mortality of children younger than 5 years of age. The software package uses projections of adult HIV prevalence over time as well as assumptions about the local epidemiology of HIV, including the ratio of female-male prevalence, the distribution of infection by age, the distribution of the time from infection until AIDS death and the effect of HIV on fertility. More information about SPECTRUM is available at http://www.unaids.org/en/KnowledgeCentre/HIVData/Methodology.

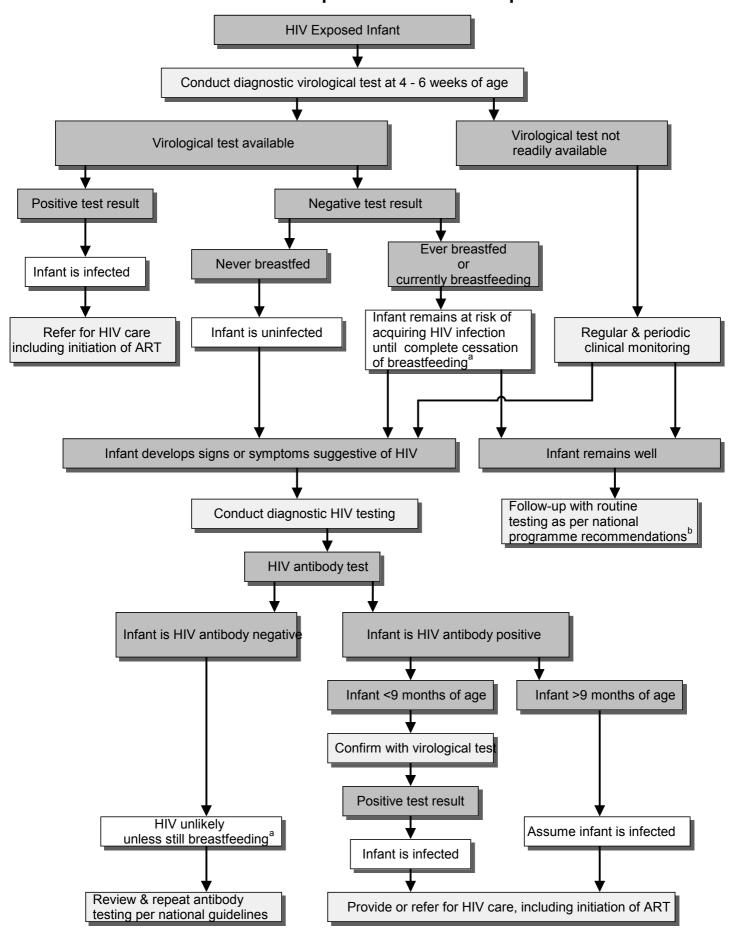
ANNEX 3. PROCUREMENT AND SUPPLY MANAGEMENT CHECKLIST

Checklist for a stepwise approach to introducing new products

Has a procurement strategy (who will buy what) been defined for both the initiation and the expanded phase of the project? How will this strategy for children be integrated into existing procurement methods?	O Yes	O In preparation	O No
Are there minimum quality criteria for the commodities to be supplied?	O Yes	O In preparation	O No
Is there a list of prequalified potential suppliers for all equipment and consumables? How is local and international competition ensured?	O Yes	O In preparation	O No
Have the regulatory requirements for procuring these items been considered, such as the registration status of medicines?	O Yes	O In preparation	O No
Have the legal implications been considered, such as patent situation, prescribing restrictions of certain medicines and/or loopholes in maintenance contracts for equipment?	O Yes	O In preparation	O No
Have the supply streams been assessed, with clearly documented strategies, timelines for addressing gaps and benchmarks for readiness for integration? Is the capacity-building strategy coordinated with the implementation strategy?	O Yes	O In preparation	O No
Was an orientation or training module developed for procurement staff and is there a schedule for implementing this training?	O Yes	O In preparation	O No
Is there a supply plan with quantities and delivery dates for initial orders, follow-up orders and emergency orders or contingency stocks?	O Yes	O In preparation	O No
Have new commodities been added to existing requisition forms and supply management tools? Are all the people involved trained in using it?	O Yes	O In preparation	O No
Is there a monitoring and evaluation strategy that includes monitoring the quantities procured and distributed and linking it to the number of clients enrolled in the intervention?	O Yes	O In preparation	O No

 $Source: adapted from the \verb|UNICEF/WHO| framework| for scaling up the prevention of mother-to-child transmission of HIV.$

Annex 4: Testing Sequence for Inital and Subsequent Visits of HIV Exposed Infant



- a The risk of HIV transmission remains as long as breastfeeding continues
- b Usually HIV antibody testing from 9-18 months of age