Technical Guidance for Global Fund HIV Proposals	
Broad Area	**TREATMENT**
Intervention Area	**Paediatric HIV Care and Treatment**

Working Document

Updated -February 2009

Table of Contents

A. Objective of this Technical Guide

The objective of this technical guide is to provide key information for the development of quality proposals to the Global Fund which integrate essential aspects related to the care and treatment of children exposed to and with HIV infection.

B. Introduction

Most resource-constrained countries provide at least limited access to paediatric HIV treatment and are in the process of scaling up more comprehensive and geographically widespread care, support and treatment for infants and children exposed to and infected with HIV.

The challenge for the majority of these countries is to move from pilot initiatives and projects, often funded and implemented by partners, to ensuring national programmes take into account the needs of children and their families.

Taking into consideration the current context

1. Most countries have paediatric HIV care and treatment services in place; they are at different stages of evolution
2. Most countries are in the process of scaling up paediatric HIV service provision
3. The majority of countries already benefit from financing outside of the Global Fund.
4. Most countries receive implementation funding from a cross-section of partners
5. Determining the level of national scale up, as well as programming and financial gaps is therefore critical

Many countries already benefit from previous financing from the Global Fund for HIV care and treatment, but the beneficiaries of these funds have been largely adults. In addition, numerous

partners have been dedicating increasing levels of support for national scale up of paediatric HIV care and treatment (e.g. PEPFAR, UNITAID, and Clinton Foundation).

It is therefore essential in the development of applications to the Global Fund to determine the level of national paediatric HIV scale up, and to identify programmatic and financial needs and gaps. An analysis of these areas is essential to ensure that activities that will be put in place as a result of anticipated financing will support and build upon existing initiatives and opportunities including existing financing.

C. Justification for the inclusion of paediatric HIV care and treatment within Global Fund requests

Globally

- Globally, according to the most recent estimates from UNAIDS, there are 2.0 million children with HIV. There were 370,000 new infections in children in 2007 (almost 17% of all new infections globally).

- Sub-Saharan Africa remains the region most affected, representing approximately 90% of all cases, followed by Asia.

- 270,000 infants and children died in 2007 of HIV/AIDS-related causes (the majority of whom live in Sub-Saharan Africa).

- In 2007 it was estimated that about 690,000 infants and children were in need of ART; however, these numbers are expected to increase with the release of new guidelines from WHO calling for immediate initiation of ART for all infants under the age of 1 diagnosed with HIV. New estimates should be available in mid to late 2009. At the end of 2007, there were approximately 200,000 infants and children receiving ART.

- More than 90% of new infections in infants and children are a result of mother-to-child transmission. It should be noted that in the absence of any intervention, between 20% and 45% of infants born to HIV-infected mothers could be infected themselves. The risk of transmission can be reduced to under 2% with use of proven efficacious PMTCT interventions.

At national level

- HIV-related disease is a major cause of morbidity and mortality in infants and children in countries with generalized epidemics, particularly in Southern African countries.

- Scale up of PMTCT and paediatric HIV care and treatment programmes represents an opportunity to improve overall health, wellbeing and survival of mothers and their infants and children (prevention of new infections including transmission of HIV from mother to child, prevention of opportunistic infections, treatment for mothers and children, reduction of maternal morbidity and mortality which also correlates with improved survival of their children and reduced orphaning).

- Infants infected in pregnancy or at the time of delivery usually have a very rapid progression, without ART over 80% will progress to severe disease, early diagnosis and initiation of ART before progression dramatically reduces mortality and morbidity. Revised WHO treatment guidelines (2008) recommend that ALL HIV infected infants should start ART as soon as they

are diagnosed. If they have been exposed to nevirapine through maternal or infant ARV prophylaxis, more costly Lopinavi/ritonavir regimens are recommended.

- Children infected through breastfeeding as well as those infected earlier but who survive through infancy usually have less rapid disease progression but also benefit from early detection and management of HIV

- HIV-infected infants and children respond well to treatment, currently in most countries children are staring ART late are therefore more complex to manage, and have less than optimal responses to ART

D. Technical working group on Paediatric HIV Care and Treatment

Existing PMTCT and/or Paediatric HIV technical working groups in country, which include representation from the national paediatric HIV and PMTCT programmes, as well as from laboratory, nutrition, civil society, NGOs, and implementing partners, can be instrumental for ensuring that portions of the proposal focused on PMTCT and paediatric HIV care and treatment are well developed. Through a consultative and participatory approach, such groups are well equipped to identify programmatic and financing gaps that should be addressed in the proposal. In addition, by including all relevant partners, it will be possible to ensure that financed activities will support and build upon what is already in place financed by existing partners. Where technical working groups focused on PMTCT and paediatric HIV care and treatment do not exist, countries may wish to constitute one to assist in guiding future programming direction.

E. Situational Analysis

The situational analysis should include considerations of children and family HIV care in addition to analysis of the current composition and functioning of the CCM, performance levels for interventions already supported by Global Fund, the epidemiological context of paediatric HIV, and the national response to scaling up paediatric HIV care and treatment.

The principal objectives of the situational analysis are:

- Review the comments of the TRP on previous proposals/grants related to the composition and functioning of the CCM as well as the level of implementation.
- Define the extent of the epidemic with respect to women and children
- Describe the level of implementation and scale up of the paediatric HIV care and treatment programme including development of supportive policies and clinical guidelines and other aspects related to service delivery
- Identify programming and financial constraints
- Develop a catalogue of different partners supporting the national programme including a description of their different contributions
- Guide the process of proposal development, including assisting in defining goals, objectives, and strategies to be included in the proposal

The following should be included in the situational analysis:

1. Epidemiological and demographic data [*Section 4.2.2- Epidemiologic data for targeted population]*

- Number and proportion of people living with HIV who are infants and children
- The number and proportion of people living with HIV and in need of treatment who are infants and children

- The number and proportion of people living with HIV and on treatment who are infants or children
- The estimated number of HIV-infected pregnant women giving birth per year (to determine the annual expected number of HIV-exposed infants).
- The level of coverage of PMTCT services
- Rates of HIV transmission from mother to infant in the absence of any interventions
- Proportion of HIV-infected mothers practicing exclusive breastfeeding

2. Review of the programme

a. **What is the situation nationally with respect to paediatric HIV care and treatment (See *Section 4.2-Epidemiological background – 4.2.1- Geographical reach of this proposal)***

- Number of infants and children exposed? Infected?
- Number of regions, provinces districts with paediatric HIV treatment capacity?
- Total number of health centres (could be divided along the lines of the health pyramid)? Number of health structures with ART services? Total number of health structures offering paediatric HIV care and treatment?
- Number of health centres offering early infant diagnosis services?
- Number and location of laboratories with NAT and DBS capacity?
- Proportion of infants and children exposed to HIV who have received an early HIV diagnosis (i.e. virological test before two months of age)?
- Proportion of infants and children exposed to HIV who have been initiated on cotrimoxazole prophylaxis?
- Proportion and number of infants and children with HIV who initiate isoniazid prophylaxis?
- Proportion of HIV-infected infants (under 1 year of age) receiving ART?
- Linkages between PMTCT and ART programmes?

b. **Norms, standards and policies supporting paediatric HIV care and treatment. Mention national policies, guides, and protocols with respect to**:

- PMTCT, paediatric care and treatment in general and ART in particular (including elements related to no cost care and treatment for women and children)
- Testing and counselling for HIV within the context of PMTCT and paediatric HIV care and treatment (particularly with respect to provider initiated HIV testing and counselling within hospitals, nutritional centres and child health clinics)
- Appropriate follow up of the infant including provision of cotrimoxazole prophylaxis and early infant diagnosis
- Infant feeding and nutrition for the young child
- Integration of services, particularly with respect to HIV care and treatment and child health
- Intensified case finding, infection prevention and isoniazid prophylaxis for children

Identify potential policy barriers to the utilization of available services for HIV-exposed and infected children. They include among others:

- Cost of and lack of capacity of laboratory services
- Legal issues related to consent for testing and counselling of infants and young children
- Issues related to confidentiality within the context of HIV testing
- Use of non-medical personnel in the provision of services within the health care setting

- Issues related to delegation of tasks (task shifting)
- Lack of national policy directives (e.g. isoniazid prophylaxis).

c. Service provision

- What is the capacity of healthcare workers with respect to provision of ART to infants? To prevent and treat opportunistic infections in infants and young children?
- What capacity do health centres have to:
    - Ensure identification of exposed infants,
    - Provide PITC for infants and children
    - Utilize DBS to access virological testing for HIV-exposed infants?
    - Provide cotrimoxazole prophylaxis to infants and children
    - Initiate and monitor response to ART in infants and children?
    - Provide isoniazid prophylaxis?
- What are the entry points to care and treatment for HIV-exposed and infected infants and children? What is the level of utilization of these entry points?
- What is the minimum package of care for paediatric HIV care and treatment at the different levels of health care delivery (Note: At a minimum, take into account HIV testing, cotrimoxazole prophylaxis, and early infant diagnosis, and ART)
    - Is cotrimoxazole prophylaxis for exposed and infected infants currently being implemented? Are guidelines regarding prophylaxis available? Are paediatric formulations available?
    - What mechanisms are in place for referral with respect to paediatric ART?
- How is nutritional support for HIV-infected mothers and their infants provided?
- Is isoniazid available outside TB programmes?
- What is the level of integration between PMTCT, EPI, ART, and child health?

d. Laboratory

What capacity is in place for early infant diagnosis in infants and young children (including laboratory capacity for virological diagnosis utilizing DBS and HIV NAT)?

e. Laboratory reagents and equipment

The analysis should focus on:

- The availability of reagents and necessary equipment for early infant diagnosis (e.g. laboratory kits, DBS, NAT machines). What is the cost for reagents and maintenance of machines? Are these costs addressed in leasing arrangements?
- Which paediatric ART medicines are available within the country? What is their cost? Are they among the WHO list of recommended ARVs for children? Are they registered or licensed in country?

Are mechanisms for procurement and supply management for ART, prophylaxis, and child health integrated within existing supply management systems?

F. Defining and estimating the target population

It is important to determine the specific populations that should receive the different aspects of paediatric HIV care and treatment, specifically:

- Antiretroviral therapy (ART)
- HIV testing and counselling
- Co-trimoxazole prophylaxis
- Isoniazid prophylaxis

Targets for Paediatric HIV Care and Treatment

Targets for Paediatric HIV Care and Treatment	
Target population for ART	All HIV-infected infants under the age of one, and children with clinical or immunological criteria to start ART (usually stage 3 and 4 or any stage and CD4 below age specific thresholds: 1-4 years: %CD4 < 20 12 months -35 months: <750mm^3 36 months -59 months: <350mm^3 ≥ 5 years: % CD4 < 15 or absolute count as in adults- usually < 200mm^3

Target population for HIV testing and counselling	• All infants born to mothers with HIV (virological test at 4 - 6 weeks)
	• All infants born to mothers with HIV at 18 months (antibody test)
	• Children presenting sick:
	  ◦ In countries with generalized epidemics, health officials may wish to consider testing all sick children admitted to acute care facilities such as paediatric wards and malnutrition clinics.
	  ◦ In countries with concentrated or low-level epidemics, health officials may consider only testing those infants and children with signs or symptoms of advanced HIV infection.
	
	It is important to note for planning purposes that at least 30% of all estimated under 5s will have some sickness and present to a health facility over a one year period and so estimates of numbers of children to be tested need to consider this.
	• Other populations (patients in TB clinics, malnutrition clinics, relatives of those in ART centres, etc.)

Target population for co-trimoxazole prophylaxis	• All infants born to mothers with HIV infection until HIV infection and risk are ruled out • All infected infants diagnosed under one year of age until at least the age of 5
Target population for isoniazid prophylaxis	▪ TB preventive therapy should be provided to infants and children with HIV and who are HIV exposed who are household contacts of TB cases who do not have active TB disease.

G. Minimum package of care for infants born to mothers with HIV *

The table below details what different populations of children affected by HIV should receive:

Target population	Interventions
1. All infants born to mothers with HIV	• Routine care (vaccination, weight and growth monitoring, nutrition) • ARV prophylaxis • Co-trimoxazole prophylaxis • Early infant diagnosis • Follow-up testing • Infant feeding counselling and support
2. All HIV-infected infants	• Routine care (vaccination, weight and growth monitoring, nutrition) • Co-trimoxazole prophylaxis • ART • Infant feeding counselling and support • Treatment adherence support • Psycho-social support • TB case finding and INH prophylaxis • OI prevention and management • Palliative care

* Countries may wish to consider including pneumococcal, hepatitis B, and *haemophilus influenzae* vaccines into the package of care if these are not already covered through other funding mechanisms.

H. Essential Programmatic Considerations to Include in the Proposal

Questions to bear in mind in proposal development

1. Why? (Magnitude of the problem – programmatic and financial gaps)
2. Who? (Targeted populations/beneficiaries – e.g. women, infants and children)
3. When? (When services should be provided – on time)
4. Where? (geographical coverage with district-level implementation)
5. How? (Strategies that address identified gaps)

1. **Integration of paediatric HIV care and treatment into existing ART sites as well routine child health services.**

   Most countries providing paediatric HIV care and treatment are in the process of integrating these services into existing HIV treatment sites formerly largely benefiting adults. Integration of paediatric HIV services into existing treatment and child health services is essential for ensuring wide geographical coverage.

2. **Introduction of provider-initiated HIV testing and counselling (PITC) within health services where HIV-infected children are more likely to be identified**

   Sites where children with HIV are likely to be identified include paediatric wards, ART centres, tuberculosis clinics, and nutritional care centres.

3. **Tools to address early HIV infant diagnosis**

   Most children in need of ART are only identified at very advanced stages of disease when they are already symptomatic and often hospitalized. Only a very small proportion of infants

needing ART are identified either through PMTCT services or through services for sick children.

Due to the fact that maternal HIV antibodies cross the placenta and can be detected in the infant's blood for up to 12-18 months, only virological tests from 4 – 6 weeks can be used to confirm presence of infection in the HIV-exposed infant. Early HIV diagnosis is usually done through PCR or nucleic acid (NAT) testing which can only be done in specialized laboratories (usually at national level). For follow up of HIV exposed infants, who are usually seen away from urban centres and larger hospitals, DBS is the optimum way to get specimens to these central labs. Virological testing is more costly and requires robust QA, therefore it cannot be integrated within all laboratories in the country. It is recommended that access to virological testing for peripheral sites be achieved through use of DBS to one or more central recognized and appraised laboratories. Specimens from children who are inpatients, may not be required to be performed on DBS, but all NAT requires standardization and validation before use within diagnostic algorithms. Early identification of HIV allows for early initiation of ART which has been associated with significant decreased mortality in infants.

4. **Policies and mechanisms for sharing of information between relevant health care providers and clinics regarding a child's HIV exposure status and HIV-related services received**

   Revision of maternal and child health cards to include information regarding receipt of PMTCT-related services (HIV exposure/infection status, co-trimoxazole prophylaxis, early infant diagnosis, infant feeding method, etc.) is essential to ensure that mothers and their HIV-exposed infants access available interventions and that they are effectively used, and should be anticipated to lead to considerable improvement in follow up of HIV-exposed infants maternal and child health clinics.

5. **Capacity for clinical (staging) and immunological evaluation of infants and children with HIV**

   Clinical evaluation (staging) and immunological monitoring are important components of paediatric HIV care and treatment to determine eligibility and document response to treatment. For younger children, it is preferable to have machines with the capacity to calculate CD4 percentages in addition to absolute numbers. Infants do not need CD4 assessment prior to starting ART and lack of immunological assessment capacity should not be used to deter access to ART.

6. **Integration of cotrimoxazole prophylaxis into routine service delivery for all infants born to mothers infected with HIV**

   Co-trimoxazole prophylaxis for infants exposed to HIV and infants and children with HIV is essential for reducing morbidity and mortality. Implementation of this approach, in terms of integration with maternal, newborn, and child health services, requires strengthening of linkages with child survival services, including immunization, growth monitoring, infant feeding and nutrition.

7. **Integration of isoniazid prophylaxis into HIV and TB service delivery for all infants and children with HIV**

I. Principal activities to include

Principal activities to consider within the context of a comprehensive/holistic approach	
Elements	**Principal activities to consider**
Decentralized delivery of paediatric HIV prevention, care, support and treatment, integrated within existing health care services.	○ Integrate HIV diagnosis, care, treatment and support into existing HIV care and treatment services ○ Integrate HIV diagnosis, care, treatment, and support for children into existing maternal, newborn, and child health programmes ○ Decide which interventions for HIV care and treatment for children can be decentralized to which existing health delivery points ○ 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
Enhance early identification of infants and young children who are exposed to or who have HIV	○ Ensure updated policy and technical guidance supporting the follow-up of known HIV-exposed infants identified through services for preventing mother-to-child transmission (PMTCT) ○ Document information on receipt of services for prevention mother-to-child transmission on maternal and child health cards(e.g. HIV status of the mother, ARVs administered to the mother and infant, early infant diagnosis, HIV status of the infant, co-trimoxazole prophylaxis, INH prophylaxis) ○ Use DBS filter paper and NAT testing to facilitate early virological diagnosis ○ Implement provider-initiated testing and counselling at sites likely to yield a high volume of positive test results (e.g. paediatric wards, malnutrition clinics, ART centres) ○ Institutionalize a family-centred approach and secure HIV testing for all additional family members once an index case is identified ○ Utilize approaches such as IMCI and IMAI to identify infants and children at peripheral sites and refer them for HIV testing ○ Utilize community-based organizations (see below)
Develop reliable procurement and supply systems that ensure a consistent supply of medicines and commodities that meet the needs of children	○ Ensure that supply management is appropriately coordinated among stakeholders and also linked to the overall implementation plan.
Ensure laboratory capacity for early diagnosis of HIV infection among infants and children and routine monitoring for HIV care and treatment	○ Plan for laboratory expansion to accommodate early infant testing for HIV and routine immunological monitoring ○ Select assays for virological 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 ○ Develop systems for the timely and reliable use of laboratory results ○ Provide staff with appropriate education and training to ensure high-quality diagnostic services ○ In scaling up laboratory capacity, consider ▪ Location of testing facilities ▪ Procurement, supply and maintenance ▪ Workload and sample throughput ▪ Quality assessment for NAT technologies ○ Sample collection and transport

Principal activities to consider within the context of a comprehensive/holistic approach	
Elements	**Principal activities to consider**
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	○ Integrate community-based approaches into child health and HIV programming strategies ○ Accelerate case-finding through integration into community health programmes ○ Improve case follow-up and essential care for HIV-exposed newborns and their families ○ Enhance community capacity to provide essential care and support to children born with HIV and their families

J. Principal Indicators for Monitoring and Evaluation

WHO and UNICEF in collaboration with other agencies within the United Nations have developed a National Guide for Monitoring and Evaluation of Programmes for the Prevention of HIV in Women and Children. This guide contains a list of global indicators as well as other indicators. The following is a listing of indicators pertaining to PMTCT and paediatric HIV care and treatment and should be considered for reporting associated with funding from GFATM.

Monitoring indicators for scale up of PMTCT and Paediatric HIV care and treatment

Indicators	
Health facility indicators	Total number of health facilities offering paediatric ART
	Total number of health facilities that provide virological testing services (e.g. HIV DNA PCR) for infant diagnosis on site or through use of Dried Blood Spots (DBS)
	Total number of ANC facilities that also provide HIV testing and counselling and ARV prophylaxis with more efficacious regimens
	Total number of health facilities with CD4 capacity on site
Infants and Children: output	Number and proportion of infants born to mothers with HIV that received a virological test for HIV diagnosis within two months of birth; that received any HIV test within 12 months of birth
	Number and proportion of infants born to mothers with HIV that were initiated on co-trimoxazole prophylaxis before two months of age.
	Number and proportion of infants /children with HIV that were initiated on isoniazid prophylaxis
	Number of infected infants on treatment by age category
	Number of infants initiated on ART who were less than one year of age.
Infants and children: Outcome	Number and proportion of infants and children receiving ART who were maintained on treatment for at least 12 months
	Number of HIV-infected infants who died or were lost to follow up
Infants and children: Impact	HIV prevalence levels among children
	HIV-free survival rates
Service Provision	Number of service providers trained in paediatric ART management
	Number of peer educators/counsellors who have been trained

K. Techniques/Tools for quantification/budgeting of activities

Costs will be based on the specific estimates for the country and region. Essentially, there are categories of costs: *(See Report on the methods used to estimate costs of reaching the WHO target of "3 by 5").*

Patient-level costs (*non-exhaustive):*
Treatment of infants and children:

- The number of infants in need of treatment (disaggregated by age)
- Cost of first-line medicines (paediatric HIV formulations can be more expensive than for adults);
- Cost of second-line regimens in case of first-line regimen failure
- The number of infants in need of HIV testing (virologic and serologic) within the context of PMTCT, testing of sick children, and children belonging to families where at least one member of the family has tested HIV positive.
- The estimated number of infants and children to be placed on treatment per year
- The number of infants and children already on treatment who will continue to receive ARV treatment
- The number of children lost to follow up or who have died
- Prevention, diagnosis and treatment of opportunistic infections; cost of co-trimoxazole, isoniazid
- Laboratory testing and management of treatment side effects (particularly for patients presenting with signs of toxicity) and substitution of drugs in cases where toxicity is confirmed.
- Operational costs linked to CD4 monitoring and virological tests.
- Costs associated with palliative care.
- Psychosocial support
- Nutritional support (replacement feeding, nutritional supplements and ready to use therapeutic foods)
- Vaccines

Programme costs:

- Training of professional health care workers (doctors, nurses), peer educators, lay counsellors, and community health care workers
- Training of managers of ART services
- Recruitment, training and ongoing reimbursement for community healthcare workers and volunteers who provide treatment adherence support
- Supportive supervision and mentoring for paediatric and family care
- Supply management of paediatric HIV-related medicines and other commodities
- Commodities to observe universal precautions
- Medicines for post-exposure prophylaxis
- Purchase of vehicles
- Transport and communication to support EID
- Operational research

L. Additional Information

- For more detailed information on ***health system strengthening*** with respect to PMTCT and paediatric HIV care and treatment, please see technical guidance on Global Fund proposals for Prevention of Mother-to-Child Transmission of HIV (PMTCT).

- For more detailed information on ***clinical care and treatment*** of children exposed to or infected with HIV, and recent updates to ART recommendations for infants please refer to WHO guidelines available at www.who.int/hiv and http://www.who.int/hiv/pub/paediatric/WHO_Paediatric_ART_guideline_rev_mreport_2008.pdf

- For more detailed information on ***scale up strategies*** for paediatric HIV care and treatment, please refer to “Scaling up HIV-related Prevention, Care, Diagnosis, and

Treatment – A Programming Framework", available at www.unicef.org or www.who.int/hiv

- For more detailed information on any of the points above, please contact Robert Gass at UNICEF at rgass@unicef.org or Siobhan Crowley at crowleys@who.int or other members of the PMTCT and Paediatric HIV Interagency Task Team.