

**AFRICAN NETWORK FOR THE CARE OF  
CHILDREN  
AFFECTED BY HIV/AIDS (ANECCA)**

**Early Diagnosis and Care of HIV  
Infected Children**

**Workshop Report**

**31 March – 1 April 2003  
Kampala UGANDA**



# PROCEEDINGS OF THE ANECCA REGIONAL WORKSHOP ON EARLY DIAGNOSIS AND CARE OF HIV-INFECTED CHILDREN HELD MARCH 31-APRIL 1, 2003, HOTEL AFICANA, KAMPALA, UGANDA

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## 1. 0 INTRODUCTION

The African Network for the Care of Children Affected by HIV/AIDS (ANECCA) in conjunction with the Department of Paediatrics and Child Health, Makerere University, Kampala organized a two-day regional workshop on *Early Diagnosis and Care of HIV-infected Children* from March 31-April 1, 2003 at the Hotel Africana, Kampala, Uganda. Participants were mainly paediatricians, and a few counselors and social scientists from Kenya, Tanzania, Uganda, Zambia and Zimbabwe.

The workshop was funded by USAID's Regional Economic Development Service Office (REDSO) through the Regional Centre for Quality of Health Care (RCQHC) based in Kampala, which hosts ANECCA.

As a background to the introduction of the workshop objectives, the convener of the workshop, Dr Denis Tindyebwa noted that:

- ❑ There is a high burden and mortality of HIV related-disease in children in Africa
- ❑ PMCTCT coverage in the African region in 2001 was 1 % on average (range 0-37)
- ❑ Coverage of cotrimoxazole in children in Africa was 1 % (adults 6)

Accordingly, measures to reduce the burden of HIV in children have to include primary prevention in young women, PMTCT, and early identification of infected children to improve the quality of their lives.

## 2.0 Workshop objectives

A major goal of the workshop was that a greater number of children would be offered testing for HIV infection and that PCP prophylaxis would be provided for those infected and exposed.

Workshop recommendations were to be used to influence a change in policies and practice in PMTCT and VCT programs in order to increase access to testing for HIV and provision of cotrimoxazole for children infected or exposed according to WHO/UNAIDS guidelines.

The objectives of the workshop were outlined as:

- 2.1 To sensitize health policy makers, program managers and implementers of VCT and PMTCT programs on the need for early diagnosis of HIV infected children, and PCP prophylaxis for the HIV exposed and infected children
- 2.2 To identify factors that prevent testing children for HIV infection in VCT programs
- 2.3 To identify factors that prevent PCP prophylaxis for HIV exposed-children in PMTCT programs in the countries of the sub-region, and
- 2.4 To identify practical approaches for including children in VCT programs, and implementing PCP prophylaxis for exposed and infected children in these countries.

### **3.0 Expected Outputs and outcome**

The workshop was expected to produce the following outputs:

- 3.1 A statement from participants on the urgency of improving diagnosis and early treatment of children to be used as an advocacy tool for improving the care of HIV infected children
- 3.2 Increased commitment of participants to introducing prophylaxis for HIV exposed and infected children within services they manage, and to advocate for its integration into child health programs in their respective countries.
- 3.3 Dissemination of workshop report to strengthen the role ANECCA will play in advocating for early diagnosis and PCP prophylaxis throughout the region.

## **4. SUMMARY OF PROCEEDINGS**

### **4.1 DAY 1: OPENING SESSION**

The session Chairperson, **Dr. Janet Kayita**, welcomed the participants, noting with satisfaction the wealth of experiences represented by the delegates present. She noted, with concern, however, the under-representation of health professionals from the provincial/regional/district level.

**Dr Denis Tindyebwa**, the workshop coordinator, likewise warmly welcomed the delegates and urged them to use the workshop to exchange experiences and views on how best to improve the quality of care for children infected or

affected by HIV/AIDS. He highlighted the currently high burden of disease and high mortality rates among HIV infected children and challenged both policy makers and implementers present to effectively address these concerns. Dr. Tindyebwa reviewed the workshop objectives and expected outputs before inviting **Dr. Joel Okullo** the RCQHC director, to officially open the workshop.

**Welcome address: Dr Joel Okullo, Director RCQHC.**

**Dr. Okullo** warmly welcomed the delegates and briefed them on the objectives and operational highlights of the RCQHC and of ANECCA.

Overview of ANECCA

ANECCA was established in 2001 in response to the growing recognition that the needs of children infected and affected by HIV/AIDS have largely been neglected. To address this need, ANECCA brings together clinicians and social scientists to find ways of improving quality of clinical and non-clinical care for children in Africa.

He underscored the importance of the workshop in identifying solutions to problems that affect a very large and vulnerable constituency—the children. He called for the adoption of a holistic approach involving multi-disciplinary skills--clinical, psychological and sociological to formulate children-friendly policies and programs. He also urged the delegates to identify barriers to effective implementation of programs as well as practical solutions to the constraints identified. He continued support for the initiatives that seek to enhance quality assurance in the health sector.

**Following this, the delegates were also welcomed by Dr. Philippa Musoke** the Head of Department of Paediatrics and Child Health at Makerere University as a co-host, and hailed them for giving priority to the issues on the workshop agenda. She called for concerted action and commitment by African health professionals to the articulation of the voices of the children.

## 4.2 HIGHLIGHTS OF THE PAPERS PRESENTED AND SUBSEQUENT DISCUSSIONS

### 4.2.1 Chairperson: Dr. Janet Kayita

**Presenter: Dr. D. Tindyebwa**

**Topic: *Morbidity and Mortality of HIV infected Children***

Dr. Tindyebwa's presentation highlighted the following issues:

- ❑ The poor state of children's health in Africa where up to 2.6 million children under 15 years old are living with HIV/AIDS, compared to the global total of 3 million.
- ❑ The heavy magnitude of HIV infection among children estimated at 700,000 new infections in 2001 for sub-Saharan Africa, and up to 500,000 deaths in that year alone.
- ❑ The similarity of the spectrum of disease in HIV infected children with those that are not infected, in terms of the symptoms relating to respiratory infections, malnutrition, diarrhea and malaria. That there was early growth failure/stunting among HIV infected children.
- ❑ The bimodal nature of disease progression and the results of some natural history studies in Africa; the high mortality (one study in Uganda established that 66 % of perinatally HIV infected children had died by the age of 3 years); the infant mortality rate among children born by infected mothers stood at 163 per 1000. He noted that in most sub-Saharan Africa, HIV attributable under- 5 mortality has been rising during the last 10 yrs.

In one of the studies among perinatally infected children in Uganda

- Mean age of AIDS-related onset of symptoms was 5 months
- 66% children had died before their 3<sup>rd</sup> birth day
- Of those who had died, 45% were asymptomatic or mildly symptomatic 2 weeks before their death.

- The need to care for the mothers as well as their children as maternal mortality had a negative impact childhood morbidity and mortality.
- To address the problem of HIV infected children requires a 3 prolonged approach:
  - Prevent primary infection among young women,
  - Prevent mother to child transmission using available technology
  - Identify HIV infected children early in their lives, and provide them with care including cotrimoxazole for prophylaxis against opportunistic infections according to existing guidelines.

#### **4.2.2 Presenter: Dr. P. Musoke**

##### ***Topic: Management of Paediatric HIV***

Dr. Musoke presented a 10-Point approach for management of children infected by HIV:

1. Early diagnosis - the two common approaches include:
  - a. Clinical methods - based on WHO staging I-III, and CDC classification: A, B, C; and
  - b. Laboratory method - based on antibody tests for over 18 months, and DNA/RNA tests for younger children.
 She pointed out the advantages and shortcomings of each approach.
2. PCP Prophylaxis
3. Growth monitoring
4. Nutritional Supplementation
5. Treatment of Acute Illnesses
6. Treatment of Opportunistic Infections—bacterial, TB, oral & esophageal candida and demotophytes
7. The need and importance of psychosocial support and adolescent care including the issue of timely disclosure to the HIV infected adolescents
8. Immunizations
9. Anti-retroviral therapy that was becoming increasingly accessible to the poor (currently the cheapest cost using generics is about \$30 a month in Uganda)

## 10. Care for HIV/AIDS infected mothers

The plenary discussion that followed raised the following issues:

- The need to engender child transmission and all it more appropriately parent-to-child transmission (delegates were informed that a congress of Medical Women International Association, MWIA Near East & Africa Region) held the previous week in Kampala had indeed emphasized this same point). Although there was no consensus on the actual name to be used (parent or mother to child transmission, delegates were agreed to greater involvement of both parents in PMTCT programs and not to apportion blame to either party.
- The currently inadequate sensitization of medical personnel
- The need for doctors to be transparent when completing the “cause of death” forms in cases of HIV/AIDS as this would facilitate the process of de-stigmatizing the disease
- The absence of counseling knowledge and skills in current medical curriculum. It was noted that in some countries, the curriculum for nursing training addresses counseling skills. Counseling and communication skills need to be built amongst the doctors.
- An HIV infected child may be the first indicator of HIV infection in the family and may be the entry point for counseling the parents for HIV Infection.
- That studies conducted at Kenyatta National Hospital in Nairobi, Kenya, show that over 90 % of patients would welcome getting information on their sero-status

### 4.2.3 Chair: Dr Elizabeth Obimbo

**1<sup>st</sup> Presenter: Dr Sabrina Bakeera Kitaka**

**Topic: *Prevention and Outcome of Pneumocystis Carini Pneumonia in children Admitted with Severe Pneumonia at Mulago Hospital, Uganda***

Dr. Bakeera presented the findings, conclusions and recommendations of a cross-sectional follow up study on prevalence of PCP in Ugandan children.

The study had been undertaken against a background of limited available information on the incidence of PCP in HIV-infected infants and children in Africa and difficulties in diagnosis, geographic variations and a common presence of Ois in developed countries.

The study sampled 121 children (42.1 % male and 57.9 % female) that had satisfied the WHO criteria for severe pneumonia and came up with the following conclusions:

- Prevalence of PCP was 16.5 %
- Immediate outcome PCPP was poor, CFR=40 %
- Radiological findings PCP, most common was Multi segmental infiltrates MSI (45.5 %), Lobar consolidation LC (19.5 %) and Normal chest x-ray (14.2 %), Ground glass appearance (10 %)
- PCP presentation: <6 months, clear chest, with AIDS according to WHO or CCD
- Strongest predictors: HIV +ve & clear chest.

The study recommended as follows:

1. PCP has a high mortality and should be treated as an emergency, using the standard protocol
2. The diagnosis of PCP should be considered in infants < 6 months, with severe pneumonia and signs of paediatric AIDS; every attempt should be made to have a confirmatory laboratory diagnosis using locally available stains after sputum induction and naso-pharyngeal aspiration
3. Cotrimoxazole chemoprophylaxis should be prescribed in all infants born to HIV positive mothers, those with confirmed HIV infection, and those who have had a previous episode of PCP.

**2<sup>nd</sup> Presenter: Dr: Janet Kayita**

***Topic: PMTCT Programs and PCP Prophylaxis for Exposed Infants***

Dr Kayita reviewed various PMTCT interventions in the Region that include the following:

- Improving MCH services
- Offering voluntary counseling and testing for HIV
- Providing antiretroviral drugs to HIV-infected mothers and their babies
- Offering HIV-infected mothers counseling and support for optimal infant feeding
- Promoting optimal delivery practices, and
- Follow-up services

She discussed the challenges to, and opportunities for implementation of PCP prophylaxis for HIV-exposed infants in PMTCT programs, using a parallel example of linking PMTCT with FP services. Primary to the challenge is the very poor follow-up rates that PMTCT programs are recording. This in part reflects the interrelatedness of uptake of interventions, and poor follow-up planning and infrastructure. There are severe staffing constraints at many PMTCT sites, and especially at health center level, leading to over-reliance on minimally trained staff (usually nurse aides/vaccinators) to conduct follow-up clinics for infants. Finally there is lack of awareness among health providers of the concept of, and efficacy of PCP prophylaxis for HIV-exposed infants.

Dr. Kayita called for the following strategies and actions:

- Linking of various child health programs and training (Safe motherhood, PMTCT, BFHI, & IMCI)
- Involvement of child care staff in PMTCT planning and training
- Training in paediatric HIV primary care down to sub-district level service providers
- Explicit endorsement by Health Ministries of cotrimoxazole (CTX) prophylaxis recommendations for infants

- ❑ Availability of requisite resources (human, drugs and supplies) as well as adherence support mechanisms
- ❑ Proactive implementation of CTX prophylaxis recommendations by paediatricians and child care staff
- ❑ Training, training and more training!

She concluded by calling for making PMTCT as a springboard to care, treat and support mothers and infants a reality—from inception, planning and implementation of PMTCT programs.

**3<sup>rd</sup> Presenter: Dr Tindyebwa (on behalf Dr Mary Pat Kieffer (USAID/RESDO, Nairobi, Kenya)**

**Topic: *PCP Prophylaxis for Pregnant Women –The Thai Experience***

The paper discussed the findings and conclusions of a study on the safety and efficacy of PCP prophylaxis among Thai women.

The major conclusion of the study was that it is safe and effective to give cotrimoxazole to pregnant mothers at risk of PCP.

Delegates then addressed the following issues in the subsequent plenary:

- ❑ That some pharmacies don't fully comply with doctors' prescriptions for some conditions in HIV infected children. For example, because the dose for cotrimoxazole for PCP is higher than for ordinary prescriptions, some pharmacies may take it to be a mistake and advise the mothers/caregivers otherwise. There is therefore a need to educate pharmacists on treatment of various conditions in HIV infected children.
- ❑ The low uptake rates of PMTCT services due to inadequate information, myths and negative traditions. These require deliberate efforts to educate and mobilize communities for PMTCT programs.
- ❑ The low or almost non-existent use of cotrimoxazole for PCP prophylaxis for HIV exposed children in PMTCT programs, despite explicit guidelines from WHO/UNAIDS. The reasons for this were briefly discussed and are highlighted in the next session during group work.

- ❑ The role of Traditional Birth Attendants (TBAs) and the possibilities for building partnerships in PMTCT programs. Participants were not equivocal on this, as most of them said they did not have adequate information or experience. However there was consensus that this is a partnership whose potential should be explored.
- ❑ The effectiveness of using intravenous cotrimoxazole. This was mainly with regards to efficacy of intravenous as opposed to oral cotrimoxazole in treatment of PCP. There were no controlled studies cited for African children, but participants felt the intravenous route should be the preferred mode of treatment for PCP, despite the limited data and experience.
- ❑ Timing and duration of PCP prophylaxis. Participants discussed the timing and duration of PCP prophylaxis in light of existing guidelines and ability to diagnose HIV infection in children.
- ❑ It was agreed that all HIV exposed children identified in pregnancy or at birth should be started on PCP prophylaxis at 6 weeks (the time for routine immunization in most settings) until the age of 18 months when it is possible to exclude HIV infection. The few centers that are able to confirm HIV infection at an earlier age using DNA PCR, can discontinue cotrimoxazole as soon as they are able to exclude HIV.
- ❑ Participants could implement this as soon they get back to their stations.

❑ Growth monitoring and immunization cards or discharge notes that are normally given at birth should be marked with the correct dose (per kg) of cotrimoxazole for the child to receive at 6 weeks at her primary care facility.

- ❑ Children identified to be HIV infected at any age should receive cotrimoxazole (and ARV's if possible) according to WHO/UNAIDS guidelines.

Staffing constraints appear to be common to most countries. However the few available staff at primary level where the majority of HIV infected children are seen, should be trained in management of HIV infection.

- ❑ Efforts should made to link the care of HIV infected children in health facilities to other non-clinical support services that may be available in

the locality of the child. This may require that health workers to be re-oriented to existing support in their neighborhood.

### **4.3 Day 1: Afternoon Sessions**

Delegates broke into three groups to discuss the following issues:

- **Constraints to implementation of PCP prophylaxis**
- **Opportunities for implementing PCP prophylaxis**
- **Practical steps to implement PCP prophylaxis at policy and operational level**
- **Individual actions to improve implementation of PCP prophylaxis in your clinic, country Ministry of Health.**
- **What next? --- Training, policy, way forward**

The groups identified the following:

#### **1.0 Constraints:**

- 1.1 How to diagnose children
- 1.2 Lack of clear national policy and guidelines
- 1.3 Lack of local/national data & evidence on PCP
- 1.4 Gender issue—lack of partner involvement - who decides for the mother & child—and d to adopt a holistic family-centred approach
- 1.5 Lack of Community mobilization and involvement—which perpetuates stigma and gender insensitivity
- 1.6 Poverty - affected people can ill - afford the cost and the logistics involved. leads to low uptake/coverage among pregnant mothers. Voluntary nature of VCT and PMTCT forces health centers to 'facilitate' i.e. pay mothers to patronize the service
- 1.7 Lack of country policy & clear guidelines to facilitate implementation in some countries.

- 1.8 Limited skills of health workers - need for more training-to impart knowledge and change attitude, practices.
- 1.9 Inadequate research, publication and dissemination of research findings.
- 1.10 Poor drug availability and accessibility
- 1.11 Inadequate qualified staff – for example there are very few counselors
- 1.12 Perceived stigma due to negative attitudes among health providers.
- 1.13 Absence of a ‘full package’ of service
- 1.14 Absence of uniform standards.

## **2.0 Opportunities:**

- 2.1 At the clinics during immunization/well baby clinics and during anti-natal & Family planning MCH sessions
- 2.2 In-Patients and Outpatients facilities.
- 2.3 Use of TBAs/Community Health Workers/Traditional Healers for info dissemination
- 2.4 Use of relevant CBOs/non-medical agencies. For example Mothers Union, Youth Groups/Traditional Leaders, etc. for info dissemination at community level
- 2.5 PMTCT & VCT sites & Children’s clinics
- 2.6 Scaling up PMTCT services
- 2.7 IMCI, Homopack Community packages
- 2.8 Use existing IEC materials, Child Health Card and pool of experts
- 2.9 Availability of mass media-print, electronic
- 2.10 Political rallies

### **3.0 Practical steps to implement:**

- 3.1 Provide relevant information to Policy makers on the existence of guidelines, and impact of PCP prophylaxis. (Role of paediatricians, universities, medical research institutes)
- 3.2 Obtain more funding for more research – and translate research into action
- 3.3 Formalize PCP into government policy framework and include it in Essential Drug category
- 3.4 Increase drug supply
- 3.5 Establish follow up clinics
- 3.6 Engage in more effective advocacy in collaboration with child advocacy bodies, paediatric associations, local and traditional/cultural/religious leaders
- 3.7 Improve health information systems
- 3.8 Continue with research & disseminate findings
- 3.9 Recruit and train personnel
- 3.10 Implement awareness programs with health workers
- 3.11 Renew IMCI with emphasis on PCP
- 3.12 Conduct M & E

### **4.0 Individual actions:**

- 4.1 Provide feedback to colleagues/staff on the Kampala workshop
- 4.2 Identify HIV exposed children-pre-and-post exposure
- 4.3 Prescribe and ensure proper dispensation
- 4.4 Conduct seminars including for People Living With AIDS (PLWHAs)
- 4.5 Advocate and make input into policy formulation process
- 4.6 Train health workers at all levels—university teaching hospitals...incorporate in PMTCT, CME programs and curriculum,

develop training materials & clinical protocols/guidelines & display posters

- 4.7 Ensure effective supervision
- 4.8 Conduct research, publish and disseminate findings
- 4.9 Re-vitalize the professional associations to engage in effective advocacy, networking and program delivery
- 4.10 Provide financial & technical support for research & quality assurance (CDC)

**At institutional level:**

- Initiate policy change
- Lobby for global funds (WHO, UNICEF, etc)

**5.0 What next?**

- Make policy statement
- Discuss with policy makers
- Hold regular meetings
- Improve diagnostic facilities

**GROUP RECOMMENDATIONS FOR IMPROVEMENT OF PCP:**

1. Evaluate and plan infrastructure for PCP prophylaxis
2. Routinize HIV testing
3. PCP prophylaxis should be incorporated into PMTCT guidelines
4. Ensure effective and broad dissemination of policy and guidelines to users—thru user-friendly media and messages
5. Ensure effective implementation! —Start practicing in the clinics and develop clear implementation guidelines. Mark on immunization cards correct dosage per kg for child's next visit, wherever that might be.
6. Incorporate PCP training into existing pre-service training

7. Develop one simple dosing formula at national level instead of current wide options.
8. Have one comprehensive care package—under the child health clinic—practitioners should provide policy makers with reliable data and information to empower formulation process
9. Practitioners should document and disseminate their operational findings.
10. Improve home based care

## **DAY 2 SESSIONS**

**Presenter: Dr. J R. Lule**

**Topic: *Prevention of Diarrhea and other Opportunistic Infections among Persons with HIV in Eastern Uganda***

Dr. Lule shared on the experience of Centers for Disease Control (CDC) Uganda office in preventing Opportunistic Infections (OIs) among persons with HIV by providing an easy-to-use safe water system (SWS). The SWS has been successfully used in several countries including Pakistan (Karachi area), Guatemala, Guinea Bissau, Bolivia and Uzbekistan.

The objective of the Uganda study that was undertaken between April 2001 and November 2002 was to measure the impact of SWS on diarrhea among persons with HIV and their family members as well as the added health impact of the SWS and Cotrimoxazole (CTX) prophylaxis when used concurrently by persons with HIV infection. The study covered 800 HIV-infected persons and 4700 family members.

The main conclusions of the study were that:

- ❑ Acceptance of CTX prophylaxis was very high
- ❑ Severe toxic reactions were very rare
- ❑ Prophylaxis among children with HIV require enhanced counseling and DOTS
- ❑ Reported assessment tended to overestimate drug-related CTX reactions.

**Presenter: Dr. Emmanuel Luyirika**

**Topic: Children's responses to Testing HIV positive in Uganda:  
The Mildmay experience**

Dr Luyirika presented preliminary results of a qualitative study on children's responses to their HIV status. He presented a summary of the children's "voices" on learning their status and how they have coped. The main responses were that children like adults get depressed, but generally cope well on learning their HIV status. Many will have known long before they are actually informed, and would wonder their parents never informed them earlier. The main lesson was that disclosure helps improve medication adherence, but perhaps more importantly living positively.

Providers, both clinical and social, should develop programs and policies to help children adopt positive living.

**Presenter: Dr. Hitimana-Lukanika**

**Topic: *Testing Children in VCT sites-the AIC Uganda Experience***

Dr. Lukanika shared the experience of the Aids Information Centre, Uganda, where despite the initial policy of not testing children have had to test children for HIV/AIDS, for a number of reasons. He highlighted the following issues:

- Children (under 18 years of age) are minors and are not authorized by Ugandan law to consent to sex or to being tested for HIV
- Many children aged 12-17 years are already sexually active as evidenced by the many pregnancies and STDs. They are therefore entitled to medical services including VCT services.
- A few guardians may want to know the HIV serostatus of their children but not in the interests of the child.
- Children with HIV/AIDS are entitled to support both in education and health care and knowing HIV status may be necessary.

- Child counseling skills are still insufficient in most facilities among service providers and even in communities.

The three presentations were followed by group discussions from which a number of issues and recommendations were generated as follows:

### **REASONS FOR HIV TESTING FOR CHILDREN**

1. Caregiver wants support for the child.
2. For education/counseling a child so that they do not pass on the infection as adolescents.
3. Children who have chronic illness and want to exclude HIV (i.e. diagnostic testing by health personnel.
4. Provide access to care to improve their quality/quantity of life.
5. For taking appropriate steps for policy development e.g. to supply adequate drugs.
6. For disclosure of positive HIV result to the child if old enough.
7. For legal purposes (eg after sexual assault).
8. Helps children to cope better with being HIV positive
9. For confirmation of a previous HIV test.
10. For post exposure prophylaxis.
11. To initiate ART and PCP prophylaxis.
12. For research purposes

### **WHERE CAN HIV TESTING FOR CHILDREN BE DONE?**

1. At diagnostic laboratory centers in public or private facilities.
2. At VCT sites.

Therefore:

- Testing centres should be readily available/accessible for children, and quality control observed.
- All MCH centres should be linked to VCT services diagnostic testing services and counseling services.

VCT sites should embrace HIV testing services for children, especially where they are the only available facilities in the locality where testing for HIV can be done.

## RECOMMENDATIONS

1. ALL children who need HIV testing should have access, either to antibody tests for children older than 18 months, or to PCR or antigen tests for those younger than 18 months.
2. Avail cheaper or free HIV tests for low/ poor resource countries
3. Protect child's rights
4. Make child and family counseling available and accessible.
5. Improve communication skills for all health workers and counselors. Involve other child caregivers in the counseling process e.g. teachers.
6. Provide psychosocial support to children about their parents' health status, loss of parent or social stigma.
7. Avail other support services to these children.

Participants then formulated and discussed a statement to be used as an advocacy tool for improving access to testing for HIV and prophylaxis for PCP for HIV infected and exposed children (see attached annex)