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IMPLEMENTATION OF WORLD HEALTH ORGANIZATION'S 2008 PEDIATRIC HIV TREATMENT GUIDELINES

TECHNICAL BRIEF

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BACKGROUND

Despite ongoing efforts to address the specific challenges of pediatric HIV prevention and treatment, in 2007, there were an estimated 2.1 million children under the age of 15 living with HIV. HIV and AIDS contributed to three percent of the global mortality among children younger than 5 years of age in 2005, and the mortality among younger children attributable to HIV exceeded 50% in the most severely affected regions and countries (WHO 2008b).

In April 2008, in response to the high number of HIV-infected infants and severe HIV-related pediatric mortality, the WHO Technical Reference Group for Pediatric HIV/ART and Care released a series of nine updated recommendations for diagnostic testing, initiation of treatment, and appropriate treatment regimens for HIV-exposed and infected infants (WHO 2008b).

The goal of the WHO's recommendations is to decrease HIV mortality in infants. The specific objectives are designed to provide a strategic framework focusing on: 1) the appropriate time and effective technologies to identify HIV infected or exposed infants; 2) the right time to initiate antiretroviral (ARV) treatment; and 3) the effective treatment regimens that save lives. The purpose of this technical brief is to outline practical implementation considerations for program planners, country-level policy makers, and program staff working to incorporate these recommendations into their local efforts. A companion document currently under development will provide more detailed information and tools for implementation of specific activities in accordance with the guidelines.

WHO RECOMMENDATIONS

The WHO recommendations were issued in response to data from recent studies confirming that for in-

Quick Facts (Leshabari et al. 2006; WHO 2008)

- 700,000 infants infected with HIV every year
- Eighty percent of infants living with HIV require ART within 6 months

Without ART:

- Thirty percent of infants living with HIV die by age 1
- Fifty percent die by age 2

With ART:

- Seventy five percent mortality reduction in asymptomatic infants started on ART

fants who acquire HIV at or around delivery, disease progresses very rapidly in the following months, and often leads to death (Predergast et al. 2008; Violari et al. 2007). These studies demonstrated that starting antiretroviral therapy (ART) for infants as soon as possible after diagnosis of HIV led to a significant reduction in their mortality; others found that exposure to nevirapine (NVP) through infant or maternal treatment may compromise infants' response to NVP first line treatment regimens, or yield demonstrable viral resistance (Arrive et al. 2007; Barlow-Mosha et al. 2008; Church et al. 2008; Eshleman et al. 2008; Jourdain et al. 2004; Lockman et al. 2007; Micek et al. 2007; Moorthy et al. 2008; Shapiro et al. 2006; Thomas et al. 2008).

The WHO recommendations can be broadly defined as addressing three key issues for infants:

1. When and how to test
2. When to initiate ART
3. What ART regimens to use.

Table 1, on the next page, lists the nine new WHO recommendations. For full details, please see WHO's 2008 report of the Technical Reference Group on ART for infants and children (WHO 2008b).

Table 1. WHO Recommendations					
Recommendation					
1	Infants known to be exposed to HIV should have a virological test (HIV nucleic acid test) at 4–6 weeks of age or at the earliest opportunity for infants seen after 4–6 weeks.				
2	Urgent HIV testing is recommended for any infant presenting to health facilities with signs, symptoms, or medical conditions that could indicate HIV.				
3	All infants should have their HIV exposure status established at their first contact with the health system, ideally before 6 weeks of age.				
4	Infants under 6 weeks of age, of unknown HIV exposure status, and in settings where local or national antenatal HIV seroprevalence is greater than 1% should be offered maternal or infant HIV antibody testing and counseling in order to establish exposure status.				
5	All infants under 12 months of age with confirmed HIV infection should be started on ART, irrespective of clinical or immunological stage.				
6	Where virological testing is not available, infants under 12 months of age with clinically diagnosed presumptive severe HIV should start ART. Confirmation of HIV infection should be obtained as soon as possible.				
7	For children age 12 months or older, clinical and immunological thresholds should be used to identify those who need to start ART.				
	Criteria to start ART				
	Age	Infants <12 months	12–35 months	36–59 months	5 years or over
	% CD4	All	<20	<20	<15
Absolute CD4	<750 mm ³		<350 mm ³	As in adults (<200)	
8	For infants living with HIV with no exposure to maternal or infant non-nucleoside reverse transcriptase inhibitors, or whose exposure to maternal or infant ARVs is unknown, standard NVP-containing triple therapy should be started.				
9	For infants living with HIV with a history of exposure to single dose NVP or non-nucleoside reverse transcriptase inhibitor containing maternal ART or preventive ARV regimens, a protease inhibitor (PI)-based triple ART regimen should be started. Where PIs are not available, affordable or feasible, NVP-based therapy should be used.				

MAJOR CONCLUSIONS

Overview

We have created a framework to guide those involved in the implementation of the WHO recommendations at the country level. The purpose of this framework is to assist implementers by providing a

logical and comprehensive methodology to identify key issues they will need to address in their implementation planning and approach for each of the nine recommendations. The framework divides these issues into two broad categories: those that create an environment that enables the recommendations to be effectively implemented; and those that address

Table 2. Implementation Framework	
Environmental Focus Areas	Operational Focus Areas
• Policy and regulations	• Supply chain and pharmacy
• Cost	• Laboratory services
• Quality	• Human resources
• Socio-cultural implications	• Information, education, and communication (IEC) and community promotion
• Legal framework	• Treatment literacy and adherence
	• Integration with existing platforms (e.g. maternal and child health [MCH], prevention of mother-to-child transmission [PMTCT], adult ART)
	• Data management
	• Patient tracking

operational issues involved in implementing the recommendations.

We have applied this implementation framework to each of the nine WHO recommendations to articulate the key questions and issues involved in the implementation of each one. Based on our analyses, some common themes apply to all nine recommendations. For example, for all nine recommendations, implementers must consider the key questions around cost and sustainability. We have labeled these common themes as “Cross-Cutting Implementation Considerations” and have detailed these in the next section. Additionally, some, but not all, of the recommendations required more specific, tailored implementation considerations applicable only to that particular recommendation. We have labeled these as “Recommendation-Specific Considerations,” and they are outlined in the subsequent section. Please note that not all focus areas required recommendation-specific considerations.

The planning for implementation of these recommendations should engage key stakeholders. Depending on the country, the usual key stakeholders who could be involved throughout the process might include:

- Host country government representatives such as focal points from the Ministry of Health, National AIDS Control Program, Child Health division, Food and Drug Board, District or Regional Health teams, and other relevant departments
- Community groups and people living with HIV/AIDS (PLWHA)
- Representatives from the WHO, the United Nations Children’s Fund (UNICEF), and other agencies
- PEPFAR, Global Fund, Clinton Foundation, and other donors supporting pediatric HIV efforts
- Implementing partners.

Finally, please note that while our analyses provide high-level approaches and structured guidelines to

key implementation considerations, the implementation of the WHO recommendations will need to be tailored to country epidemiological data, the nature of the health system in a particular geographic area (e.g., who are the service providers, what are the roles of the public and private/nongovernmental organization [NGO], how are they financed, etc.), cultural traditions and social attitudes, political initiative, requirements for staff skill development, facility infrastructure, equipment and supplies, costs, and available sources of financing.

Cross-Cutting Implementation Considerations

Policy makers and program designers will need to consider the following considerations in designing their individualized implementation plans for the new WHO pediatric treatment recommendations. Addressing these questions is essential for establishing the foundation for proper implementation of all nine of WHO's new recommendations. These considerations assume that decision makers have access to up-to-date assessments of epidemiological data and service availability mapping of existing systems (such as health facilities, laboratories, referral systems, etc.). In the absence of these assessments, one of the first steps should be to conduct a rapid assessment.

Creating an Enabling Environment

Policy:

- What are the relevant current policies and regulations, if any, related to pediatric HIV?
- Have the current policies been updated to reflect these WHO recommendations?
- Do the current policies or regulations support implementation of the WHO recommendations?
- Who has the authority and responsibility to enact the policy changes necessary for successful implementation of the WHO recommendations?

- Which policies that pertain to pediatric treatment are contained in other related policies (e.g., PMTCT, HIV counseling and testing, or MCH policies)?
- What is the mechanism for disseminating and implementing policy changes?
- Are there any policies or regulatory requirements for selection, approval, registration, and use of new laboratory testing technologies, and pediatric ARV formulations that will need to be addressed?

Cost:

- Has the cost of implementing the recommendations been considered? Has a cost modeling exercise been performed to help inform decision making?
- Is there sufficient funding to implement and sustain the recommendations? If not, how will adequate funding be secured?

Quality:

- How will standardization of pediatric services be ensured?
- How will program efforts be integrated into any ongoing continuous quality improvement and supervision?
- How will integration be encouraged?
- How will retention be monitored?
- How is appropriate counseling, as a complement to all HIV testing, going to be made available, and how will its availability and quality be measured?
- Is there a quality assurance scheme for all health care services involved in pediatric treatment—from laboratories to pharmacy to patient care—and if not, how and when will it be developed?

Socio-cultural implications:

- Will stigma affect the willingness of parents to permit pediatric HIV testing, and their treatment-seeking behavior? How is it currently addressed or, if not addressed, how will it be?
- How will the new pediatric services address issues of multiple family members needing testing, treatment, and care (i.e., the family-centered care model)?

Legal framework:

- Will testing of infants be opt-in, opt-out, or mandatory?
- If infant testing is not mandatory, who can give consent?
- Do the WHO recommendations conflict with the country's current legal framework?

Operational Implications

Supply chain and pharmacy:

- What is the strategy for using the data management system to quantify and forecast product demand?
- How will systems take into account HIV prevalence and incidence, mandatory versus opt-out testing, potential impact of more effective PMTCT, etc.?
- How will financing for commodity procurement be structured? How will inventory control be managed?

Human resources:

- What are the human resource needs to implement the new pediatric recommendations at the:
 - National
 - Provincial/district
 - Health facility

– Community level?

- How are the roles and responsibilities of staff and facilities at different levels of the health care system delineated?
- How will decentralization of pediatric testing and care be managed?
- Are there policies or guidelines on task-sharing that can accommodate human resource needs for pediatric HIV testing and care?
- How will the needed support and supervision be provided, both pre- and in-service?
- What will the role of community health workers be?

IEC and community promotion:

- How will the audiences be segmented in order to target messages and programs effectively?
- How will demand for the product or service be generated?
- How will parents and caregivers be educated about the disease, its treatment, and prevention of transmission?
- How will young patients be educated about their disease, its treatment, and prevention of transmission as they age?

What is task sharing (WHO 2008)?

A process of delegation whereby tasks are moved to less specialized health workers.

Improves health care coverage by:

- Using available human resources efficiently
- Quickly increasing capacity

Example:

- In Malawi and Uganda, the basic care package for PLWHA has been designed to be delivered by non-specialists or nurses supported by community health workers.

Data management:

- How will patient confidentiality be ensured?
- How will data systems be adapted or designed to support patient follow-up?
- What data systems will be needed to support the integration of services?

Patient tracking:

- How will follow-up be ensured in integrated services?
- How will functional referral networks be established to ensure all pediatric HIV patient needs are met and follow-up maximized?
- What is the best strategy for utilizing data management systems to support patient tracking?
- What is the strategy for managing patients in the public sector, in the private sector, and patients who move between the two?
- How will essential tools, such as infant medical information cards and longitudinal pediatric patient records, be introduced and utilized?
- What is the system for early-infant diagnostic testing that guarantees that results are effectively and promptly delivered?

Recommendation-Specific Strategies

Some recommendations require more specific, tailored implementation considerations. These recommendation-specific considerations are outlined in this section.

Recommendation 1: Provide HIV nucleic acid test¹ for HIV-exposed infants at 4–6 weeks of age, or as soon as possible thereafter

Policy and regulations:

- Does the country's national testing policy currently specify:

1) Nucleic acid testing (or NAT) is a method of testing blood for the presence of the HIV virus that is more sensitive than conventional tests that require the presence of antibodies to trigger a positive test result. NAT identifies the presence of the HIV virus itself, rather than testing for the antibodies that the body will eventually produce in response to the virus. This allows the test to identify patients with HIV at an earlier disease stage. (Canadian Blood Services n.d.).

- At what age patients should be tested?
 - Specify which tests should be used at each age?
 - At which level of the laboratory system early infant diagnosis can be provided?
 - What kind of health care worker is allowed to provide each of the different kinds of tests?
- How will infants who are not seen by health care providers at 4–6 weeks of age be identified for testing?

Laboratories:

- What level of the health care system will offer this testing?
- Are existing infrastructure and personnel capacity sufficient to support implementation of viral load testing for infants at 4–6 weeks of age?
- Will the testing and sample handling protocols, equipment, and reagents be standardized?
- How will timely and accurate reporting of test results to patients and providers be ensured?
- What modifications to current laboratory procedures and data management systems will be needed to ensure a continuous supply of the required lab reagents and supplies to support infant HIV testing?
- Will new lab equipment need to be purchased?

Human resources and training:

- Who are the relevant health staff that should be trained in the new testing and sampling protocols? Lab technicians? Clinical health care workers, such as doctors and nurses? Counselors? Community health workers?

Treatment literacy and adherence:

- How will mothers living with HIV and other caregivers be made aware of the need for follow-up testing for their infant in case of exposure during breastfeeding?

Integration:

- Is it possible to conduct a system-wide assessment of where infants make contact with the health system? What will the strategy be for developing and enacting testing or referral to testing? How will testing services be integrated with post-test counseling, care, and treatment services?

Recommendation 2: Provide urgent testing for any infant presenting with possible HIV signs or symptoms**Policy and regulations:**

- How does the national HIV policy define HIV signs, symptoms, and testing protocols?
- Does the national HIV policy define protocols that are specific to each different health facility level? What is appropriate protocol for national level hospitals? What is appropriate for community clinics?
- What are the current protocols for age-specific consent for testing?

Supply chain management and pharmacy:

- This recommendation, when implemented, will likely result in a large increase in the number of infants requiring HIV testing. How will quantification and procurement procedures be designed and tailored to ensure accurate forecasting and sufficient materials and resources, taking into account the country's HIV context (high versus low prevalence, for example)?

Laboratories:

- What are the implications of implementing these recommendations for the nation's laboratory system?
- How will the laboratories handle the increased demand placed on them, immediately and long-term?
- What is the best way to initiate implementation of this recommendation?

- How will the immediate implementation plans transition to a long-term strategy?

Human resources and training:

- How will health services personnel be trained to screen infants for likely exposure, as well as in infant testing procedures?
- How will the training for different types of personnel (i.e., doctors, nurses, and counselors) differ?
- How will current health programs be instructed to adapt their current algorithms for forecasting and procurement?
- How might task-sharing help alleviate some of the additional burden that implementing this recommendation might impose? For example, how might training nurses to identify infants with HIV signs and symptoms reduce the burden on doctors?

Integration:

- How will the capacity for referral at all points of the health care system be strengthened? Can testing be built into MCH programs, and integrated with post-test counseling, care, and treatment services?

Data management:

- How will patient data regarding signs and symptoms be captured, collected, and tracked?
- How will data be linked back into the supply chain management mechanism, in order to help strengthen forecasting and procurement?

Recommendation 3: Establish HIV exposure status of all infants at their first contact with the health system**Policy and regulations:**

- What will be the policies regarding gaining consent from a mother or caregiver in order to determine an infant's exposure status?

- How will the country define exposure status?
- How will the policies on consent be harmonized with the national PMTCT policy?
- How will consent policies address births that take place in health facilities as well as those that occur at home?

Integration:

- How will testing services be integrated with post-test counseling, care, and treatment services, as well as with immunization and MCH?

Data management:

- Does the country use health cards that an individual carries with them as a record of their previous health care and health issues when visiting a health care provider?
- If so, how will health care workers be alerted to the need to record an infant's exposure status on the card, once it has been determined?
- If not, how will the infant's exposure status be recorded in a way that will be transferable within the healthcare system?

Recommendation 4: Offer maternal and infant antibody counseling and testing for infants under 6 weeks of age of unknown exposure status and in settings with greater than 1% antenatal HIV

Policy and regulations:

- Is it possible to implement an antenatal seroprevalence surveillance system in the country? If so, how will it be implemented? If one already exists, how can its reporting be sped up so actions on pediatric HIV status can occur as soon as possible?
- How can surveillance protocols be integrated into the national MCH guidelines, along with testing for mothers during pregnancy and infants after birth?

- How and where will prevalence be measured? Will it be measured nationally, regionally, or at a facility-level?
- What are the programmatic implications for implementation of both data collection and management, and antibody counseling and testing?

Human resources and training:

- How will MCH workers be trained on integration of the antibody counseling and testing into existing MCH protocols?
- How will MCH workers be made aware of the mother's health and HIV status?
- Will support and training be offered to nurses and other health care workers, who will be implementing the counseling and testing, in order to help alleviate the additional burden placed on them?
- How will this support fit into or enhance established systems of supervision and quality improvement?

Integration:

- How can antibody counseling and testing for infants be integrated into all MCH programs to ensure maximum leveraging of resources while reaching as many mothers and children as possible?

Data management:

- Does the country use health cards that individuals carry with them as a record of their previous health care and health issues when visiting a health care provider?
- If so, once the antibody test has been performed and the infant's status is known, will the information be recorded on their health card and the card given to the infant's caregiver for safekeeping?
- If not, how will the information be recorded and tracked?

Recommendation 5: All confirmed infants Living with HIV under 12 months of age should be started on ART

Policy and regulations:

- Where will pediatric HIV treatment initiation and monitoring services be provided?
- How will implementing this recommendation impact the number of infants receiving ART in the country? What will that mean for drug supply, and human and facility capacity?
- How can the stresses on the health care system that implementing this recommendation will cause be mitigated?
- What is the national policy regarding who can initiate treatment?
- Can policies be developed to increase access for patients to ART treatment?
- Will operational guidelines and standard operating procedures be developed for each level of the service delivery system, from testing centers to laboratories to pharmacies, and covering ART initiation as well as regimen switching due to toxicity or resistance?

Supply chain management and pharmacy:

- Which pediatric ART formulations are available in-country?
- How will the ART regimens for infants and small children, which may include liquid medications that must be kept cool, be transported and stored?
- How will pediatric dosing schedules and wastage be accounted for by forecasting?
- What equipment will be needed to facilitate accurate mixing and dosing of pediatric formulations?
- What procedures exist to facilitate and ensure timely and accurate procurement and distribution?

- Can an assessment of the scalability of pediatric monitoring be conducted?
- What changes can be implemented if an assessment of the current pediatric monitoring system determines that the efforts are not reasonably scalable?
- How will pharmacists be trained to consider an infant's other medications and any other contraindications before starting an infant on ART?

Laboratories:

- How will strategies be tailored to address the expected increase in demand for CD4 count tests and toxicity screenings, and the attendant equipment and reagents?
- How will staffing, medical equipment, and other resources be appropriately allocated?

Human resources and training:

- Can increasing the size of the health care corps, or training for existing health care workers, help mitigate the effects of the increased demand on the health care system that will result from implementing this recommendation?
- Are there materials and trainings available with the appropriate focus, such as the importance of adherence, teaching dosing and swallowing to patients or caregivers of patients, or the counseling of caregivers, mothers, and couples?
- How will training address immune reconstitution syndrome (IRS), which occurs when a reconstituted immune system overreacts to the various pathogens in the body and causes health risks of its own?

Treatment literacy and adherence:

- How will the health care providers and caregivers of patients be trained on the meaning and importance of adherence, as well as on dosing and swallowing of medications for infants?

- How will the fact that many caregivers might be illiterate, or innumerate, be accommodated?

Integration:

- How will parents and caregivers of infants living with HIV be linked to support groups for PLWHA, especially those groups with a pediatric element, to offer them ongoing support and assistance?
- Will parents of infants living with HIV be referred to counseling and testing services for themselves?
- Will coordinated family care be made available to families in which the caregivers and one or more children are living with HIV?
- Is coordinating family care a task that can be addressed by community-based organizations, in order to reduce the burden on the public health care system?

Data management:

- How will patients' medical records be linked to dispensed medications in order to strengthen forecasting and resupply, and to monitor quality control and adherence?
- Will the patients' medical records be able to track their health and medical care over time?

Recommendation 6: Infants under 12 months of age with clinically diagnosed presumptive severe HIV should start ART; HIV status should be confirmed as soon as possible thereafter

Policy and regulations:

- Is the timing of the different stages of the process of confirming the HIV status of an infant made clear to all relevant parties?

Supply chain management and pharmacy:

- How will pharmacists be trained to consider an infant's other medications and any other contraindications before starting an infant on ART?

- How will health facilities/pharmacies ensure continuous supply and availability of pediatric formulations for infants who need to start ART immediately?

Human resources and training:

- Will health care providers be provided with the training and additional supervision to help reduce or avoid staff burn-out from the additional case load?
- What special efforts can be made to support staff in remote areas?
- How will training address IRS?
- How training address handling the uncertainty inherent in prescribing ART to a patient without confirmed HIV?

Integration:

- How will staff at the various sites and programs that see infant patients be trained to identify infants with potential cases of HIV?
- How will patients at these various sites and programs be cross-referred to sites offering HIV care?
- Are there programs offering care for health concerns closely associated with HIV (e.g., care for tuberculosis) that would offer clear opportunities for integration?

Recommendation 7: Use clinical and immunologic thresholds to identify infants over 12 months of age who need to start ART

Policy and regulations:

- What are the country's guidelines addressing initiation of ART for infants over 12 months of age?
- Are relevant policies, including standard operating procedures, systems for implementation, supply chain management, and training of health care workers and patients, needed?

Laboratories:

- How will the specific reagents and equipment needed for the tests to identify clinical and immunologic threshold for initiating ART be forecasted, procured, and distributed?
- How will the ongoing supply of these commodities be maintained?
- How will the procedures for testing the clinical and immunologic thresholds be standardized?
- How will referral systems be developed for identifying patients for CD4 testing, and for providing support to those found to need ART?

Human resources and training:

- How will health care workers be informed of these policies, and how will it be ensured that the policies are being implemented?

Treatment literacy and adherence:

- As children grow, how will they be educated about and involved in their own ART? How will they be educated about prevention of transmission?
- What kind of outreach and education is necessary to ensure parents know that treatment is available and lifesaving, and that testing is necessary?

Recommendations 8 and 9: Start standard NVP-containing triple therapy; and start PI-based triple ART regimens and NVP-based therapy

Policy and regulations:

- What is the current in-country viral resistance to the medication specified in recommendations 8 and 9 (NVP-containing triple therapy and PI-based triple ART regimens and NVP-based therapy)? Resistance prevalence should be ascertained to determine if implementing the treatment recommendations will be widely effective.
- What PMTCT regimens and any in-country variability in protocols exist?

- Is there a standard regimen in the country currently? If not, what is the best option, given the country's scenario?

Treatment literacy and adherence:

- How will treatment literacy and adherence materials be tailored to address possible side effects, triggers for seeking clinical follow-up, and where to go for clinical follow-up for side effects?

Integration:

- How will linkages be established with PMTCT, MCH, and other child health programs, as well as to adult HIV treatment programs, to identify potential patients and provide them with support once initiating ART?

Data management:

- How can the mother's treatment history and breastfeeding status be linked to each child's health records? (Does the country utilize health cards?)
- How will demand for NVP- versus PI-based triple ARV regimens be forecasted, procured, and distributed to ensure continuous availability?

SUMMARY

The purpose of this technical brief is to outline practical implementation considerations for U.S. government and other program planners, country-level policy makers, and program staff working to incorporate the WHO's recommendations into their local efforts. Implementation of these recommendations must be based on up-to-date assessments, and take into consideration local conditions, including current policies and the state of the epidemic in the country, as well as current and future resources. As such, the implementation of the recommendations may follow a different course or timeline from one country to the next. The recommendations will have the greatest

impact in countries in which they are implemented by people with an understanding of the needs and aspirations of their country.

RESOURCES

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