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PEDIATRIC HIV TREATMENT TOOLKIT

A PRACTICAL GUIDE TO THE IMPLEMENTATION OF
THE 2009 WORLD HEALTH ORGANIZATION
PEDIATRIC HIV TREATMENT RECOMMENDATIONS

AIDSTAR-One
AIDS SUPPORT AND TECHNICAL ASSISTANCE RESOURCES

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AIDS Support and Technical Assistance Resources Project

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Abstract

The WHO regularly publishes guidelines to direct the efforts of pediatric HIV treatment programs. Many national governments adapt these guidelines and use them to update their existing policies. This document assists implementers by providing a logical and comprehensive methodology to identify key issues in designing their individualized implementation plans for the new WHO pediatric treatment recommendations. It divides these issues into two broad categories: those that create an environment that enables the recommendations to be effectively implemented and those that address operational issues involved in implementing the recommendations; and provides technical direction and tools and resources for implementation.

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ACRONYMS

ABC	activity-based costing
AIM	AIDS Impact Model
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
ATLAS	Assessment Tool for Laboratory Services
BASICS	Basic Support for Institutionalizing Child Survival
BCC	behavior change communication
BIPAI	Baylor International Pediatric AIDS Initiative
CBO	community-based organization
CD4	cluster of differentiation 4
CDC	Centers for Disease Control and Prevention
CEPA	Campaign to End Pediatric HIV/AIDS
CHW	community health worker
CI	confidence level
CSM	Clinical Systems Mentorship
CT	counseling and testing
DBS	dried blood spot
DH	district hospital
DNA	deoxyribonucleic acid
EID	early infant diagnosis
EIT	early infant treatment
EWA	Entebbe Women Association
FBO	faith-based organization
FHI	Family Health International
HBC	home-based care
HC	health center
HCW	health care workers
HCSP	HIV Clinical Services Program

ICAP	International Center for AIDS Care and Treatment Programs
IDID	infant diagnosis identifier
IEC	information, education, and counseling
IMCI	Integrate Management of Childhood Illness
JLICA	Joint Learning Initiative on Children and HIV/AIDS
LIAT	Logistics Indicators Assessment Tool
LMIS	logistics management information system
LSAT	Logistics System Assessment Tool
LTF	loss to follow-up
M&E	monitoring and evaluation
MCH	maternal and child health
MOC	model of care
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
MSH	Management Sciences for Health
MTCT	mother-to-child transmission
NACP	National AIDS Control Program
NASCOP	National AIDS/STDs Control Program
NAT	nucleic acid testing
NGO	nongovernmental organization
NNRTI	non-nucleoside reverse transcriptase inhibitor
OPD	outpatient department
PCR	polymerase chain reaction
PLWH	people living with HIV
PMTCT	prevention of mother-to-child transmission
QI	quality improvement
SE	side effect
SMS	short message service
SOC	standards of care
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
TBA	traditional birth attendant

UNAIDS	Joint U.N. Programme on HIV/AIDS
UNICEF	U.N. Children's Fund
USAID	U.S. Agency for International Development
UTH	university teaching hospital
VCT	voluntary counseling and testing
WHO	World Health Organization

INTRODUCTION

SCOPE AND URGENCY OF GLOBAL PEDIATRIC HIV

Despite ongoing efforts to address the specific challenges of pediatric HIV prevention and treatment, at the end of 2008, there were an estimated 2.1 million children under the age of 15 living with HIV. Children accounted for 6 percent of all people living with HIV (PLWH), 16 percent of the people newly infected, and 14 percent of all HIV-related mortality worldwide (Joint U.N. Programme on HIV/AIDS [UNAIDS] 2009). While data show that global under-five mortality has decreased steadily over the past two decades, 8.8 million children still die before their fifth birthday each year (U.N. Children’s Fund [UNICEF] 2009), and HIV has reversed many of the gains in those countries hardest hit by the epidemic.

In April 2008, in response to the high number of infants living with HIV and severe HIV-related pediatric mortality, the World Health Organization (WHO) Technical Reference Group for Paediatric HIV/Antiretroviral Therapy (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. These recommendations were revised in 2009, and additional changes were made in 2010. The latest changes to the WHO treatment guidelines are summarized below, in Table 1.

The goal of the WHO’s recommendations is to decrease mortality in infants living with HIV and universal access to prevention, care, and treatment of HIV infection in infants and children. The specific objectives are designed to provide a strategic framework focusing on 1) the appropriate time and effective technologies to identify and monitor HIV-infected or -exposed infants; 2) the right time to initiate ART; and 3) effective treatment and care regimens that save lives.

Table 1. Summary of WHO 2010 Changes to Pediatric Treatment Guidelines

Change			
1	Earlier, more accurate diagnosis of HIV	<ul style="list-style-type: none"> Establishing HIV exposure status at birth or soon after Testing HIV-exposed infants by four to six weeks of age with virological assays New standards for quality of serological and virological assays 	
2	Earlier initiation of ART	< 2 years of age	Start ART immediately on diagnosis
		> 2 years and < 5 years	< 25% cluster of differentiation 4 (CD4) or CD4 count < 750 mm ³
		> 5 years of age	CD4 count of < 350 mm ³
3	Simplified antiretrovirals for first- and second-line therapy	<ul style="list-style-type: none"> Continued encouragement for use of fixed-dose combinations Protease inhibitors for infants with non-nucleoside reverse transcriptase inhibitor (NNRTI) exposure 	

		• Recommended preferred standard regimens
4	Expectations for first six months of therapy	Expected signs and symptoms of initial therapy
5	Focus on nutrition	<ul style="list-style-type: none"> • Importance of nutritional assessment • Nutritional requirements of infants and children on ART
6	Strategic monitoring for antiretroviral (ARV) efficacy and toxicity	<ul style="list-style-type: none"> • Lab monitoring should not be a barrier to treatment, but children likely to have better outcomes with better monitoring • Guide to routine clinical follow-up • Phased-in approach to viral load testing to improve identification of treatment failure
7	Strengthening of adherence	Review of important principles of adherence promotion

GOAL OF THE TOOLKIT

The primary goal of this toolkit is to provide technical guidance on the planning and implementation of the WHO recommendations through suggested activities, tools, and resources. A technical brief, which outlines practical programmatic and political considerations for implementing these recommendations, is currently available on the AIDSTAR-One website at <http://www.aidstar-one.com/treatment-documents>. This toolkit was developed as a detailed supplement to this technical brief and should be used in conjunction.

The specific objectives of the toolkit are as follows:

- To assist with the successful implementation of the new WHO recommendations within current national HIV and AIDS treatment frameworks for pediatrics
- To help with the integration of these new WHO recommendations into existing pediatric program components, including service delivery, drug and supply procurement, and data management.

TARGET AUDIENCE OF THE TOOLKIT

The target audience for this toolkit includes program managers, designers, and implementers of pediatric HIV services, including those working within Ministries of Health, public sector health care facilities, academic institutions, nongovernmental organizations (NGOs), community-based organizations (CBOs), faith-based organizations (FBOs), and privately operated treatment programs.

The content within the toolkit is based on the assumption that national governments actively support the enhancement and expansion of early infant diagnosis (EID) and early infant treatment (EIT) through adoption of the WHO guidelines and recommendations to reduce infant mortality. It also assumes that there are existing pediatric HIV diagnostic and care programs in place. Therefore, this toolkit serves as a resource for those who are involved in the modification of existing pediatric HIV care and treatment programs in accordance with the WHO recommendations. For programs that are still in the process of implementing pediatric diagnostic and treatment services, a number of available tools and resources are listed in Box 1.

Box 1. Tools and Resources for Programs Initiating Pediatric Diagnostic and Treatment Services

For those policymakers and program designers who are seeking to initiate comprehensive HIV clinical care and treatment programs for infants and children in resource-limited settings, the following resources are available for reference.

Tool 1: Baylor International Pediatric AIDS Initiative Toolkit, Baylor International (2008). The purpose of this toolkit is to provide a practical step-by-step guide for any group looking to plan, implement, monitor, and evaluate programs specifically addressing the needs of children and their families who are infected and affected by HIV and are living in resource-limited settings. <http://bayloraids.org/toolkit/>

Tool 2: A Public Health Approach to Scaling Up Antiretroviral Treatment: A Toolkit for Programme Managers, WHO (2003). The aim of this toolkit is to address issues arising from planning and implementing ART programs in and to provide user-friendly technical guidance on planning and implementing ART programs in resource-limited settings. There is specific guidance regarding design, implementation, monitoring, and evaluation of pediatric treatment initiatives. http://www.who.int/hiv/pub/toolkits/arv_toolkit/en/index.html

Resource 1: WHO Report on Antiretroviral Therapy of HIV Infection in Infants and Children in Resource-limited Settings: Towards Universal Access: Recommendations for a Public Health Approach, WHO (2006). This WHO document provides historical perspective on WHO's approach to reaching universal access for pediatric HIV treatment. <http://www.who.int/hiv/pub/guidelines/WHOPaediatric.pdf>

Resource 2: International Center for AIDS Care and Treatment Programs (ICAP) Pediatric Resources (2009). ICAP has developed an extensive library of pediatrics HIV clinical tools and resources for clinicians in resource-limited settings, including training materials and case studies on pediatric testing and treatment. <http://www.columbia-icap.org/resources/peds/index.html>

Resource 3: From the Ground Up: Building Comprehensive HIV/AIDS Care Programs in Resource-Limited Settings, Elizabeth Glaser Pediatric AIDS Foundation (2009). This resource is recommended reading for international HIV professionals, students, and others who wish to learn more about the current state of the global HIV response. Over 320 distinguished authors have contributed to this collection, which features best practices and lessons learned from HIV programs around the globe, with a special focus on sub-Saharan Africa. <https://ftgu.pedaids.org/index.php>

STRUCTURE OF THE TOOLKIT

The toolkit is structured according to the framework developed in the technical brief, represented by the graphic in Figure 1. The purpose of this framework is to assist implementers by providing a logical and comprehensive methodology to identify key issues in designing their individualized implementation plans for the new WHO pediatric treatment 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 operational issues involved in implementing the recommendations.

Since the development of the technical brief in 2008, the WHO has revised their guidelines several times. Keeping these updates in consideration, this toolkit facilitates the development of a strong foundation for service delivery, which is essential for successful implementation of the highest international standards of treatment for HIV.

Figure 1. Implementation Framework



These considerations assume that decision makers have access to up-to-date assessments of HIV epidemiological data and service availability in their country or locality. Technical guidance on how to conduct a situational analysis and program assessment specific to the operational areas targeted by the recommendations prior to implementation of changes can be found in the “Creating an Enabling Environment” section.

Each section contains a number of suggested activities to address key issues raised within the technical brief and is followed by a selection of tools and resources to help carry out these activities¹. Tools are defined as instruments that can be directly used to perform specific tasks, whereas resources are documents to be used for additional information and support when performing suggested activities.

¹ Descriptions provided for the tools and resources in this toolkit were, in some cases, compiled and quoted directly from the hosting organizations' website.

Tools will be indicated throughout with the following symbol:



Resources will be identified with this symbol:



Many of the tools and resources cited were developed for adult programs, but can be utilized or adapted for issues specific to pediatric programs.

USE OF THE TOOLKIT

This toolkit is designed to provide an overview of the implementation issues that might need to be considered by program planners, implementers, and policymakers seeking to ensure their pediatric HIV treatment efforts align with the WHO's latest guidelines. The toolkit can be used as a whole; if followed from start to finish, it should help the user assess the need for, plan, and implement any changes to their current programs. Alternatively, specific modules of the toolkit can be used on their own to help address questions around a particular element of guideline revision.

CONDUCTING A SITUATIONAL ANALYSIS AND RESOURCE ASSESSMENT

The starting point for pediatric treatment program modification should focus on the creation of a detailed implementation plan that incorporates the new guidelines into the existing program according to the national framework. This plan should build on existing knowledge of current epidemiologic data, and service delivery should be based on a baseline situational analysis and rapid assessment of existing resources for pediatric diagnosis, care, and treatment.

CONDUCTING A SITUATIONAL ANALYSIS ON THE CURRENT PEDIATRIC HIV ENVIRONMENT

A situational analysis should define the local epidemic and identify situational factors contributing to current gaps in HIV pediatric care and the steps required to adapt systems and services to meet the new WHO recommendations. Data and descriptions should be collected on the following as they relate to the new recommendations and their potential impact on the existing health care and supporting systems:

- **Current regulatory and political environment**, including existing national health policies and treatment regulations related to pediatric HIV prevention, care, and treatment (e.g., prevention of mother-to-child transmission [PMTCT], voluntary counseling and testing [VCT], maternal and child health [MCH], antenatal care [ANC], etc.). This should include details relevant to the updated recommendations including regimens in use, pediatric ARV formulations certified for use, cadres permitted to do testing, treatment initiation, and routine monitoring and follow-up, including prescription refills. The political and financial commitment of local government agencies and major stakeholders in the prevention and treatment of infants and children living with HIV should also be assessed.
- **Demographic and epidemiological data**, including mother-to-child transmission (MTCT) rates, HIV antenatal statistics, clinical manifestations, and morbidities of pediatric HIV, as well as infant and child mortality due to the epidemic. If available, any data on current in-country prevalence of viral resistance to nevirapine-based therapy should also be assessed to ensure effectiveness of WHO recommended treatments. Collection efforts should be designed to identify the marginalized populations and communities most immediately vulnerable to pediatric HIV.
- **Behavioral data**, including common modes of MTCT in vulnerable populations and health-seeking behavior of the community (i.e., ANC, home-based vs. facility-based deliveries, and infant immunization rates). Data on perceptions about pediatric HIV care and treatment and the overall level of utilization of the current services should also be collected.

- **Socioeconomic and cultural data**, including the nature of community support structures, income, literacy rates, mobility, and gender roles. This should include factors affecting access to pediatric health services, including geography, financial constraints, knowledge, and stigma.
- **Health systems data**, including availability of trained pediatric health care workers (HCWs) and coverage of pediatric care, treatment, and support services, such as PMTCT uptake, percentage of infants tested, age of pediatric treatment initiation, availability of appropriate pediatric adherence and support services, and retention of exposed infants.

TOOLS AND RESOURCES

Much of the data required for the national or provincial situational analysis may be available in existing reports and documents from the country-specific Ministry of Health (MOH) and/or National AIDS Secretariat. Engaging individuals from disciplines relevant to ART, program management, policymaking bodies, PLWH, and community members is also critical. For individual programs, this list should be prioritized to focus mainly on the regulatory environment, the current health system, as well as community behavioral data which will impact on local implementation on the recommendations.



Tool 3: Scale up of HIV-Related Prevention Diagnosis, Care and Treatment for Infants and Children: A Programming Framework, UNICEF/WHO (2008).

This framework is 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 are living with HIV within the context of broader child survival and HIV programs.

http://www.unicef.org/aids/files/OMS_PAEDS_Programming_Frameworks_WEB.pdf



Tool 4: Conducting a Situation Analysis of Orphans Vulnerable Children Affected by HIV/AIDS, U.S. Agency for International Development (USAID) Bureau for Africa, Office of Sustainable Development (2004).

This guide provides information on planning, executing, and analyzing a situational survey for orphans and vulnerable children.

http://pdf.usaid.gov/pdf_docs/Pnacx649.pdf



Tool 5: Behavioral Surveillance Surveys: Guidelines for Repeated Behavioral Surveys in Populations at Risk of HIV, USAID (2000).

This document is designed to provide a one-stop reference to help public health officials setup and manage systems that reliably document trends in HIV risk behaviors including general attitudes about HIV infection and transmission.

<http://www.fhi.org/NR/rdonlyres/ezsxcathgcvhxzmxwjlfgkl4mezcmep6ogzqty3lbyf5ighmb6k2swbgar32xup6yh5sykj6ii2kwp/bssguidelinesfullenhv.pdf>



Resource 4: Demographic and Health Surveys, MEASURE Demographic and Health Surveys (2009).

This program has collected, analyzed, and disseminated accurate and representative data on population, health, HIV, and nutrition through more than 200 surveys in over 75 countries. Indicators include HIV prevalence, fertility patterns, and knowledge of PMTCT of HIV during pregnancy, during birth, and after birth. <http://www.measuredhs.com/>

ADMINISTERING A RAPID ASSESSMENT OF CURRENT SITE RESOURCES

The purpose of a site assessment is to determine where existing health services and community resources can be enhanced and strengthened for successful implementation of new services. A strong assessment will identify current strengths that can be leveraged to address the existing needs and gaps (Box 2). Data and descriptions should be collected on the categories shown in Table 2.

Box 2. Report of a Pediatric HIV Care and Treatment Assessment in the Kilimanjaro, Iringa, and Mbeya Regions of Tanzania. Basic Support for Institutionalizing Child Survival (Resource 6)

Background of intervention: The Tanzanian Ministry of Health and Social Welfare (MOHSW) has committed itself to ensuring that 20 percent of those on ART will be infants and children. It is in this context that the U.S. Government and the National AIDS Control Program (NACP) in Tanzania conducted an assessment in 2006 of current pediatric identification, testing, and care and treatment services in the Kilimanjaro, Iringa, and Mbeya regions.

Objectives: The main objectives of the assessment were to 1) assess and document the current status of pediatric HIV care and treatment services at the facility and community levels in the three regions of Tanzania; 2) document missed opportunities for identification and care and treatment of infants and children exposed and/or living with HIV; and 3) make recommendations to increase access to pediatric HIV care and treatment services.

Details of the assessment: The assessment utilized several approaches to gain a clear understanding of the current status of services—the challenges, gaps, and prospects for solutions. The methods and samples include the following:

- Interviews with MOHSW staff members; NACP management and care and treatment program technical staff; the Integrate Management of Childhood Illness (IMCI) coordinator; WHO/Tanzania ART technical staff, regional and district level health team medical officers, and HCWs
- Site visits and review of documents, including policies, guidelines, and reports at referral and regional hospitals, district facilities, health centers (HCs), and dispensaries
- Stakeholder meetings of health facility, regional and district management, NGOs, and people living with HIV and AIDS.

The three assessment tools that were piloted and then revised include the following:

- Pediatric services at the regional/district level, including sections on general management such as planning, coordination, supervision, and referral; human resources and training; logistics management; and health information systems
- Health facility survey, including site organization, guidelines, services available, staff and staff training, laboratory monitoring, clinical practice, and patient records and management
- Pediatric HIV case identification, referral, and care at the community level

Key findings:

- MCH services are the most accessible health services in Tanzania. The units are accessible, free, attended by most mothers and children, and provide a variety of services (family planning, ANC, immunization, outpatient department [OPD], labor and delivery, PMTCT, and VCT).
- Laboratory capacity is adequate at the regional and referral levels to do HIV tests and to monitor patients on ART using biochemistry measures and CD4 counts.
- Few staff members are trained in pediatric HIV and most HCWs lack confidence in pediatric care in general, and more so with pediatric HIV.
- Infants and children known to be exposed and even those with signs and symptoms suggestive of HIV infection are not being tested on inpatient wards, at MCH visits, in OPD, etc.

Lessons learned:

- Maximize opportunities to identify and refer infants and children with HIV, including MCH visits for growth monitoring, immunization, and outpatient services, during hospitalization in pediatric inpatient wards, and following deliveries by mothers who have attended/not attended PMTCT programs.
- Train more HCWs at all levels in pediatric HIV and AIDS care and treatment.
- Improve linkages and systematize referrals between all services that see mothers and children.

Table 2. Categories, Metrics, and Tools for a Rapid Assessment of Site Resources

<i>Category</i>	<i>Metrics</i>	<i>Tool</i>
Facility infrastructure	<ul style="list-style-type: none"> • Conditions of inpatient and outpatient pediatric facilities • Pharmacy storage and security • Laboratory conditions • Location and capacity of current maternity and pre-/postnatal care clinics 	<ul style="list-style-type: none"> • Tool 6 • Tool 7 • Tool 8
Service delivery	<ul style="list-style-type: none"> • Current HIV pediatric testing and treatment protocols and their utilization • Range and availability of PMTCT services • Support and adherence counseling • Strength of referral systems between departments (e.g., PMTCT and MCH) and facilities • Retention rates and availability of outreach for retention and follow-up • Home-based care (HBC) services, including home deliveries 	<ul style="list-style-type: none"> • Tool 6 • Tool 7 • Tool 8
Human resources	<ul style="list-style-type: none"> • Availability of adequately trained physicians, nurses, counselors, pharmacists, laboratory technicians • Staff turnover rates 	<ul style="list-style-type: none"> • Tool 6 • Tool 9

Pharmacy and laboratory systems	<ul style="list-style-type: none"> • Current inventory • Logistics management information systems • Current laboratory capabilities • Procurement systems • Specimen and supply transport systems 	<ul style="list-style-type: none"> • Tool 6 • Tool 7 • Tool 8
Administration and health management information systems	<ul style="list-style-type: none"> • Use of a health management information system for routine data collection related to pediatric services • Case management for pediatric HIV care and treatment programs • Longitudinal medical record system 	<ul style="list-style-type: none"> • Tool 10
Monitoring and evaluation (M&E) and quality management systems	<ul style="list-style-type: none"> • Reporting systems to assess progress and impact of current activities and planned changes 	<ul style="list-style-type: none"> • Tool 11
Community services	<ul style="list-style-type: none"> • Linkages with CBOs, NGOs, FBOs, and associations for PLWH with capacity to provide care and support services, including home-based care 	<ul style="list-style-type: none"> • Tool 12
Funding sources	<ul style="list-style-type: none"> • International and domestic funding sources and their partners/subcontractors 	<ul style="list-style-type: none"> • Tool 6

TOOLS AND RESOURCES

Some of the data required for the assessment may be available in existing facility reports and documents, such as the annual district health planning reports, local CBO/FBO/NGO association membership listings, etc. Local service delivery data, such as available services, referral systems, and laboratory and pharmacy capacity will need to be collected in a reliable fashion during this stage. The following resources can be utilized or adapted for issues specific to pediatric programs.



Tool 6: Health Facility Assessment Methods, USAID MEASURE Evaluation (2008).

These tools increase utilization of facility-based information for decision making about investments in health systems and services.

<http://www.cpc.unc.edu/measure/tools/monitoring-evaluation-systems/hfa-methods>



Tool 7: HIV/AIDS Rapid Assessment Guide, USAID (2001). This guide includes a site inventory tool on enumeration of population, employment, infrastructure, transport routes, and health and social services.

<http://www.fhi.org/en/HIVAIDS/pub/guide/RapidAssessmentGuide/index.htm>



Tool 8: Assessment of Site Readiness for Initiating Pediatric Antiretroviral Therapy (ART), John Snow, Inc. (2007).

The goals of this tool are to assist sites and programs in rapidly assessing the critical elements for effective care system and delivery, and identifying those elements that need implementing or further strengthening or development. The tool focuses on adult ART, but a pediatric addendum to be used as a companion tool has also been developed.

Adult:

http://www.jsi.com/JSIInternet/Resources/Publications/DownloadDocument.cfm?DBLDOCID=10329&DBLLANGID=3&DOC=art_stages_of_readiness_tool_v1-3.pdf

Pediatric addendum:

<http://www.jsi.com/JSIIInternet/Resources/Publications/DownloadDocument.cfm?DBLDOCID=10670&DBLLANGID=3&DOC=Tool%20to%20Assess%20Site%20Readiness%20for%20Initiating%20Pediatric%20Antiretroviral%20Therapy.pdf>



Tool 9: A Guide to Rapid Assessment of Human Resources for Health, WHO (2004). This guide is designed to help users assess current human resources for health constraints and challenges to scaling up health interventions.

http://www.who.int/hrh/tools/en/Rapid_Assessment_guide.pdf



Tool 10: Developing Health Management Information Systems: A Practical Guide for Developing Countries, WHO (2004). This manual is designed to be a quick-and-easy, user-friendly reference for the development of health management information systems, with materials on how to assess an existing system.

http://www.wpro.who.int/NR/rdonlyres/3A34C50D-C035-425A-8155-65E8AD3CB906/0/Health_manage.pdf



Tool 11: Monitoring and Evaluation Systems Strengthening Tool, USAID (2007). This tool can be used at the national level, within groups of projects, and within individual projects or organizations that are seeking to assess M&E data collection and reporting systems, and to implement action plans for strengthening M&E to measure success of implemented activities. http://gametlibrary.worldbank.org/files/132_MESS%20tool%20guidelines.pdf



Tool 12: Questionnaire for the Evaluation of CBOs, NGOs and FBOs, Secure the Future (2007). This tool assists program managers in the assessment of local organizations for partnership in service delivery and community mobilization efforts.

http://www.bms.com/Documents/foundation/STF_manual_first_edition.pdf



Resource 5: Report of a Pediatric HIV/AIDS Care and Treatment Assessment in the Kilimanjaro, Iringa, and Mbeya Regions of Tanzania, USAID Tanzania, Basic Support for Institutionalizing Child Survival (BASICS), Centers for Disease Control and Prevention (CDC), and Elizabeth Glaser Pediatric AIDS Foundation (2006). This report provides findings from an assessment of the current status of pediatric HIV care and treatment services at the facilities and community levels in three regions of Tanzania. This report includes all tools that were used for the assessment and subsequently revised based on the experience presented.

http://www.basics.org/about_basics/countries/pdf/tanzania_ped_HIV_assessment_Final.pdf



Resource 6: Chapter 6: Towards Universal Access: Scaling up Priority HIV/AIDS Interventions in the Health Sector, Scaling up HIV Services for Women and Children, WHO (2009). Chapter 6 of this key document discusses the importance of leveraging international funding for HIV treatment services in order to strengthen the primary health care system in a low-resource setting, and the impact of integrating HIV treatment services into that system. http://www.who.int/entity/hiv/pub/taapr_2009_c6_en.pdf

CREATING AN ENABLING ENVIRONMENT

It is critical to establish an environment that facilitates implementation and integration of the latest WHO pediatric HIV treatment recommendations. Crucial elements of the environment include public and program policy, costing and financing, quality assurance, sociocultural implications, and the legal framework within which the program will operate. The following section describes these environmental issues in greater detail and provides a framework for how to use information from preimplementation assessment exercises to ensure that identified strengths are optimally utilized and relevant shortcomings are appropriately addressed.

POLICY AND REGULATIONS

Under the assumption that national governments have approved adoption of the new WHO recommendations, data from the situational analysis and program assessment should indicate which program policies, protocols, and regulations are in need of modification. Program planners and implementers must make preliminary decisions on where infant HIV testing will be performed and which pediatric regimens will be offered. In addition, it must be determined:

- How the current program policies and protocols on infant testing and treatment support/hinder implementation of the WHO HIV pediatric recommendations, including related policies on PMTCT, MCH, and VCT.
- Which agencies, departments, and persons have the authority and responsibility to enact the policy changes necessary for successful implementation.
- Which mechanism will disseminate and implement policy changes.
- Which policies or regulatory requirements will be used for selection, approval, registration, and use of new laboratory testing technologies and pediatric ARV formulations.

Obtaining this information will require close consultation with key stakeholders from health, social services, and other relevant government departments (e.g., laboratory services, pharmaceutical services, social welfare department, etc.), as well as careful review of program reports and government documents. Based on this information, program-level bottlenecks related to implementation should be clearly identified. For example, bottlenecks that program planners may strive to overcome in the implementation of the WHO pediatric recommendations may include the following:

- Insufficient infrastructure for diagnosis and treatment of infants and children living with HIV, resulting in gaps in coverage and late diagnosis (e.g., urgent need to scale-up laboratory capacity and utilize innovative strategies, including dried blood spot [DBS] testing)

- Operational barriers such as the lengthy turnaround time between drawing blood samples and reporting results
- Late initiation of infant HIV treatment due to poor access to EID or through loss to follow-up (LTF) of exposed infants
- Difficulty retaining children in the continuum of care after diagnosis and treatment initiation
- Lack of availability of appropriate pediatric ARV formulations and other essential drugs
- Lack of HCWs trained in pediatric HIV treatment and support according to the WHO recommendations, including clinical management of pediatric HIV and the use of pediatric diagnostic technologies, such as DBS testing.

Once key bottlenecks are identified, they must be prioritized to identify those that are most critical to overcome in order to implement the recommendations and achieve a long-term reduction in infant mortality. Tool 13, from the Campaign to End Pediatric HIV/AIDS (CEPA), contains a four-metric system to identify those bottlenecks that are both critical to overcome for successful implementation and also feasible in the context of the national HIV treatment framework. After individual programmatic bottlenecks are identified and prioritized, it is important to determine the mechanisms for addressing these issues for successful implementation of the WHO recommendations (Box 3). Resources 9 to 13 are available to assist program planners in the scale-up of HIV diagnosis, care, and treatment for children exposed to HIV within the context of broader child survival and HIV programs.

Box 3. CEPA, Priority Technologies to Address Major Bottlenecks, Kenya 2009

Background: The Kenyan CEPA country team identified a number of high-priority bottlenecks to EID and EIT including long turnaround time (2–6 weeks) for deoxyribonucleic acid (DNA) polymerase chain reaction (PCR) testing of DBSs. Local facilities used paper-based tracking of laboratory samples and test results, requiring transportation of results via courier services or conventional mail.

Intervention:

- Key informants in Kenya have reported on early efforts to implement a national email-based reporting system for EID results.
- Central PCR laboratories send test results via email to regional or subregional distribution locations, where designated personnel print and distribute results to the peripheral facilities that provide testing.
- Limited internet access has so far prevented larger scale-up, but options like general packet radio service modems, which can transmit email and other data through short message service (SMS) texting networks, create the possibility of electronic results reporting at any facility with cellular network access.

Results and lessons learned:

- Given the rapid progression of HIV infection in infants and the short window in which children living with HIV must be started on treatment, governments, programs, and partners should make every effort to decrease the amount of time it takes to test DBS samples and return results.
- If designed appropriately, electronic results reporting systems of this kind could have enormous impact beyond EID programs, as they would enable rapid reporting of a wide range of other laboratory information, such as CD4 counts or tuberculosis (TB) cultures.

TOOLS AND RESOURCES



Tool 13: On the Road to Developing a CEPA National-Level Advocacy Action Plan, CEPA (2009). This guide was developed to assist country teams in the development of strong national-level advocacy action plans to advance the CEPA.

http://aidsalliance.3cdn.net/3ceccf6de7fd6541bc_0em6byj93.pdf



Resource 7: Scale up of HIV-Related Prevention, Diagnosis, Care and Treatment for Infants and Children: A Programming Framework, UNICEF and WHO (2008). This framework is 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 programs.

Full guide: http://www.unicef.org/aids/files/OMS_PAEDS_Programming_Frameworks_WEB.pdf

Condensed guide:

[http://www.unicef.org/aids/files/Condensed_Guide_Prog_Framework_\(final3\).pdf](http://www.unicef.org/aids/files/Condensed_Guide_Prog_Framework_(final3).pdf)

Slide set:

http://www.unicef.org/aids/images/PaedS_Programming_Framework_Slides_Aug_28_2009.ppt



Resource 8: Diagnosis of HIV Infection in Infants: A Comprehensive Implementation and Clinical Manual, ICAP and Columbia University Mailman School of Public Health (2007). This manual provides guidance for designing and implementing infant diagnosis programs at ICAP-supported programs. The manual is intended to provide guidance at the site level for nurses, physicians, counselors, and other health care providers caring for children exposed to HIV; in addition, it targets HIV program managers, health planners, laboratory technicians, and organizations responsible for program design, implementation, and M&E. <http://www.columbia-icap.org/resources/peds/files/Infantdx050307.pdf>



Resource 9: Handbook on Paediatric AIDS in Africa, African Network for the Care of Children Affected by HIV/AIDS (2006). This handbook is intended to provide a simple, accessible, and practical resource for health professionals involved in preventing infection and caring for children infected and affected by HIV. The primary targets are medical students and their lecturers, nurses, clinicians, community health workers (CHWs), and other service providers in resource-limited settings where there is a significant HIV burden. The handbook may be adapted by users in various countries to meet their specific needs.

<http://www.searchitech.org/pdf/p06-db/db-50966.pdf>



Resource 10: Co-trimoxazole Prophylaxis for HIV-exposed and HIV-infected Infants and Children: Practical Approaches to Implementation and Scale Up, UNICEF and WHO (2009).

This document provides a brief review of evidence supporting the use of co-trimoxazole prophylaxis in children and summarizes common barriers to implementation. It proposes specific actions and strategies needed for scaling up co-trimoxazole prophylaxis. http://www.unicef.org/aids/files/CotrimoxazoleGuide_2009.pdf



Resource 11: Taking Every Opportunity: Ensuring Infant Access to Early HIV Diagnosis, Care and Treatment, BASICS and USAID (2008).

A presentation by USAID and BASICS containing background on the epidemic, findings from the field, and recommended actions to ensure access to early HIV diagnosis, care, and treatment. http://www.basics.org/documents/Taking-Every-Opportunity_Pediatric-HIV.pdf

BUILDING AND MAINTAINING POLITICAL PARTNERSHIPS

Even in countries that have adopted EID and EIT into national guidelines, significant support is necessary to ensure site-level practice changes. Some infrastructure barriers can be overcome by a political and financial commitment by both donor and implementing national governments to make the necessary changes. For example, the creation of a national antenatal seroprevalence surveillance system may help to identify infants in need of testing early on. In addition, the capacity of national reference laboratories may need to be expanded to handle infant testing and result dissemination. This level of commitment will be underscored by an accurate understanding of the nature of the epidemic and its impact on country development.

Information regarding the following should be described and, when needed, collected and analyzed:

- The current scope and urgency of national/regional and local pediatric HIV and projections about its likely future course without intervention
- The impact of the epidemic on health as well as the social and economic well-being of the nation or region in question
- The proven WHO diagnostic and treatment interventions that reduce infant mortality and improve the lives of those who are either infected or affected by HIV as cited in the WHO recommendations and other sources
- The current bottlenecks that would need to be addressed in order to successfully implement the new WHO recommendations for pediatric HIV testing and treatment.

Using Tools 14 to 17, this information should be presented to key political gatekeepers who have influence and decision-making capacity to change local service delivery (Box 4). It is important to know which level(s) of government and agencies are appropriate for partnership based on their responsibility for public health policies and resources (i.e., national, regional, district, or local level partnership or a combination).

Box 4. Use of the AIDS Impact Model (AIM) in the Fight Against AIDS in Kenya, POLICY Project (Tool 14)

Background: The Kenyan National AIDS/Sexually Transmitted Infection (STI) Control Program (NAS COP) implemented the AIM activity with technical assistance from the RAPID IV and POLICY Projects of USAID. The purpose of the AIM activity in Kenya was to increase awareness and knowledge about the AIDS epidemic in order to build a broad consensus in support of effective AIDS interventions. One of their main objectives was to secure financial support for key activities surrounding care and treatment.

Intervention:

- Initial target audience included the most influential leaders from the public, private, NGO, and community sectors.
- NAS COP trained presenters, including a number of consultants, and provided them with equipment, materials, booklets on “AIDS in Kenya,” travel support, and a small allowance.
- A formal program of reporting for the hundreds of presentations that were required to reach the target audiences was established.
- A one-page report format that included information on the presenter, the audience, questions that were raised, and topics that were discussed was developed.

Results and lessons learned:

- Booklets produced using the AIM were later published in the national newspaper and called to the attention of the president.
- Budget allocations by the government increased markedly with the support of ministries (other than the MOH), partly as a result of AIM presentations and training for those ministries.
- High levels of political commitment from all sectors were secured allowing for successful implementation of HIV testing and counseling programs throughout the country.

TOOLS AND RESOURCES



Tool 14: The AIDS Impact Model (AIM), USAID POLICY Project (2000). AIM is a computer program and information dissemination tool with an objective to build political support for HIV programs. AIM and the associated activities are designed to analyze the HIV situation in a country, produce accurate information about the likely course and impact of the epidemic, package that information in a media presentation, and reach out to leaders at all levels of society. <http://www.policyproject.com/pubs/bookgreen.pdf>



Tool 15: HIV Advocacy from the Ground Up: A Toolkit for Strengthening Local Responses, Asia Pacific Council of AIDS Service Organizations (2005). This toolkit has been developed for HIV-related NGOs and CBOs working on the ground directly with most affected communities. Operating at the frontline of HIV responses, the experiences and

knowledge of these organizations are critical in the development of policy and programs that reflect community needs and concerns. This resource will provide CBOs and NGOs with the necessary knowledge and skills to effectively influence policymakers at the local, national, and regional levels. <http://www.hivpolicy.org/Library/HPP001526.pdf>



Tool 16: Advocacy in Action: A Toolkit to Support NGOs and CBOs responding to HIV/AIDS, International HIV/AIDS Alliance (2002). This toolkit aims to support NGOs and CBOs in their advocacy efforts in the field of HIV by providing useful information on advocacy, including advice on building practical advocacy skills such as analyzing legislation, lobbying, and writing persuasive educational dramatic presentations. http://www.comminit.com/redirect.cgi?r=http%3A%2F%2Fwww.aidsalliance.org%2Fincludes%2FPublication%2Fadv0602_Advocacy_toolkit_eng.pdf



Tool 17: HIV/AIDS Toolkit: Building Political Commitment, USAID POLICY Project (2000). The toolkit contains six modules to assist activists interested in increasing political commitment at international, national, and local levels for effective HIV policies and programs. The toolkit reviews political commitment, its importance, and describes actions to build political commitment as a key step in combating HIV in sub-Saharan Africa by reviewing approaches that have proven to be effective. <http://www.policyproject.com/pubs/bookorange.pdf>

INVOLVING A RANGE OF STAKEHOLDERS AT ALL LEVELS OF SOCIETY

National leaders include not only those in politics and government but also leaders from the civil and private sector, including business, education, CBOs, FBOs, and NGOs. These stakeholders are an important part of change. Their support for the implementation of the new treatment protocols will contribute to increased momentum in the acceptance of the new recommendations, as well as to the establishment of the requisite enabling environment. For example, an advocacy campaign by these sectors and organizations may be helpful in establishing protocols for identifying infants exposed to HIV who are not seen by health care providers prior to six weeks of age. Likewise, engaging the community at large, including PLWH, is critical to ensure acceptance of and access to new and existing pediatric HIV services and is discussed more fully in the “Information, Education, and Counseling and Community Promotion” section.

The assessment of community resources performed in the planning period may help to ensure access to all services by identifying potential partners to provide the community-based components of care (Box 5). The partners selected should be intimately familiar with the community’s circumstances and needs and be well accepted by community members. Tool 18 can be used to identify the community support needed in the implementation of the recommendations as well as to perform a comprehensive assessment of local CBOs and NGOs.

Box 5. Implementation of a Comprehensive Program to Improve Adherence to HIV Care and Treatment for a Pediatric Population in Kenya

Background: Ensuring adherence to HIV care and treatment amongst the pediatric population has been a great challenge to health programs. Care of children mainly relies on the abilities of the caregivers who more often may not be the parents. To improve adherence and follow-up, Eastern Deanery AIDS Relief Program, an indigenous FBO that provides integrated HIV/tuberculosis (TB) prevention and care in the eastern slums of Nairobi, adopted a community approach to HIV care and treatment.

Intervention:

- All patients seeking treatment are linked to a CHW for follow-up and continuum of care.
- CHWs (including those living with HIV) are selected and nominated by their communities for intense training over a 6- to 8-month period.
- CHWs who are deemed able are appointed as *Muangalizi* (kiswahili for the one who cares) for children. Monitoring tasks include three home visits per week, assessment of nutritional status, pill counts, and assessment of physical health and emotional health; they also remind primary caregivers to accompany children to the clinic, refer children for HIV testing, and bring children to the clinic when the caregiver is unavailable or unable.

Results and lessons learned:

- After one year, ART enrollment increased by 75 percent, patient retention increased from 82 to 90 percent, fewer patients died, and 89 percent of caregivers were retained in care (compared with 76 percent before Muangalizi).
- Engaging the local communities improves service delivery and treatment outcomes for care and treatment for adult and pediatric populations.
- Patients receiving care alongside other members of the family are more likely to remain in care.
- Muangalizi improved pediatric enrollment and retention rates as well as caregiver retention rates.

(Owiso et al. 2009)

TOOLS AND RESOURCES



Tool 18: Child Health in the Community - "Community IMCI": Briefing Package for Facilitators, WHO (2004). This briefing package proposes a process for bringing principal partners together for planning and implementation at the national, intermediary, district, and community levels. This process will enable development of coherent strategic and operational plans at various levels; facilitate the sharing of experiences, resources, and expertise among projects and geographical areas; and help ensure consistency. The process is best carried out with the assistance of a facilitator.

http://www.who.int/child_adolescent_health/documents/9241591951/en/



Tool 19: Building Political Commitment at Subnational Levels, Policy Project (2008). This component of the Policy Project toolkit describes different approaches for enhancing the participation of all sectors, including the local community.

<http://www.policyproject.com/pubs/bookred.pdf>



Tool 20: Tool No. 5 Criteria for Choosing Community Services, Baylor International (2008). A list of specific criteria to consider when choosing community-based partners for assistance in service delivery, community outreach, and education.

http://bayloraids.org/toolkit/tools/Tool_No_5.pdf



Tool 21: New Initiative to Train India's People Living with HIV on AIDS Advocacy in the Workplace, International Labour Organization and the India Network of People living with HIV/AIDS (2009). A unique training video and handbook package aimed at guiding those living with the virus in AIDS advocacy in the workplace.

http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2009/20091007_ILO_India.asp

COSTING AND FINANCING

When planning for the implementation of the WHO recommendations, it is essential to have accurate cost estimates for each of the program modifications to determine if there is sufficient funding to both implement and sustain the proposed programmatic changes. Management Sciences for Health (MSH) has developed cost modeling framework (Tool 22) based on the following components:

- Setting out quantified, time-bound measurable goals and objectives
 - Program implementers should consider a phased approach when implementing the WHO recommendations, enabling rapid expansion and coverage of new pediatric services among vulnerable and high-risk populations.
- Describing and quantifying the activities needed to achieve the goals and objectives
 - Careful consideration should be given to:
 - The expected demand of testing and treatment services (i.e., number of sites).
 - Community-based activities required to support adherence and retention.
 - Related programs (PMTCT, VCT, etc.) that need strengthening to support new pediatric services.
- Showing the resources required to carry out the activities
 - Careful consideration should be given to:
 - On- or off-site laboratory infrastructure and transport.
 - Cost, storage, and distribution of new pediatric formulations.
 - HCW recruitment, training, and retention.
 - IEC materials and activities to increase demand for new services.

- Calculating the costs of the resources and the unit cost per patient
 - Particular attention should be focused on testing strategies including DBS collection as these collection and testing materials are not currently available in kits and must be purchased separately (Box 6 and Tool 38).
- Showing the sources of funding and estimating financing gaps
 - Programs must ensure multiple sources of funding for procurement of ARV drugs and HIV test kits as well as a long-term plan for sustainability of financing for new commodity procurement to support scale-up.
- Producing a detailed budget.

Box 6. Costing Exercise on EID using PCR of DBS, Botswana

Background: To accurately estimate the cost of testing infants using DBS collection and subsequent PCR, a Botswana team compiled all of the materials involved in the proper collection, drying, and packaging of DBS in a rural clinic.

Intervention: The following materials were identified in the process and individually costed to come up with an annual cost of implementing DBS PCR for EID:

- Collection of DBSs from infants for PCR testing: gloves, blood collection card (filter paper), lancet (2 mm) (the Botswana study used a self-springing lancet), 70 percent spirit or alcohol, gauze or cotton wool, and lab forms
- DBS samples: large drying rack and a clean, dry, protected area
- Packaging DBS: glassine paper, special sealable plastic bag (10 samples per bag), desiccant packets (1 per sample), humidity card (1 per bag), and a large mailing envelope (1 bag and 10 lab forms per envelope)
- Processing of DBS: Roche Amplicor HIV DNA PCR kit

Results and lessons learned:

- The total cost per test in Botswana's national reference laboratory is \$19.60 (including \$8.00 for the PCR kit), and it is estimated that the ongoing yearly cost of testing Botswana's 13,300 infants who are exposed to HIV will be approximately \$300,000.
- At a 7 percent HIV transmission rate, this represents \$321 per infant diagnosed with HIV or \$24 per infant demonstrated to be uninfected.
- Estimate includes the cost of test kits, laboratory and clinic consumable products, technician time, machine maintenance, and repeat testing after weaning for infants exposed to HIV who are breastfed.

(Creek et al. 2008)

TOOLS AND RESOURCES

The following tools and resources are available for those program implementers who would like additional information on costing and financing of HIV programs and can be adapted for components specific to pediatric programs.



Tool 22: The Planning, Costing and Budgeting Framework, MSH (2007). This is an Excel spreadsheet workbook designed to allow users to clearly identify the linkages between all elements of a plan—the activities, strategies, objectives, and goals, and the budget that would be required to achieve these goals and objectives. The workbook consists of an example plan and a blank template plan.

http://erc.msh.org/toolkit/toolkitfiles/file/PCB_Workbook.xls

The framework is also accompanied by a user's manual that explains the layout of the spreadsheet and provides instructions on how to use it.

http://erc.msh.org/toolkit/toolkitfiles/file/PCB_Manual2.pdf



Tool 23: Design and Application of a Costing Framework to Improve Planning and Management of HIV/AIDS Programs (With Case Study), Abt Associates (2000).

This is a validated activity-based costing (ABC) methodology, including a standardized list of activities by major intervention, a list of “activity lines,” a standardized cost classification system, a set of cost drivers to trace indirect costs to activity centers, and a program management agenda that can be addressed with cost information generated by ABC.

<http://www.abtassociates.com/reports/sir29fin.pdf>



Tool 24: Financial Management Assessment Tool, MSH (2000). This tool allows managers to assess the current capacity of their organizations, to manage their finances, and identify steps that they can take to improve that capacity. The tool includes an instrument that one can use for collecting and summarizing technical information, and a process for applying the instrument. <http://erc.msh.org/toolkit/Tool.cfm?lang=1&CID=3&TID=134>



Resource 12: Chapter 16: “Guidelines for Assessing the Economic and Financial Costs of HIV/AIDS Prevention and Care Programs”, Evaluating Programs for HIV Prevention and Care, FHI (2006). This chapter provides guidelines for assessing the economic and financial costs of HIV/AIDS interventions. In turn, policymakers will use this information to assure that fully informed decisions are made regarding the cost-effective use of limited resources for HIV/AIDS care and prevention.

<http://www.fhi.org/NR/rdonlyres/ez7svgsmatlnljiupck35ipxkbfwqr43tmidspsesufm2ptudeudeithei2ufzfwfbcsebjilt4ca/31776textR1enhv.pdf>



Resource 13: Logistics Fact Sheets: ARV Drugs, USAID | DELIVER PROJECT (2008). This resource provides information on brand names, manufacturers, strength/form, packaging and shipping information, shelf life, storage conditions, and prices for commonly used ARVs.

http://deliver.jsi.com/dlvr_content/resources/allpubs/factsheets/LogiFactShee_ARV_Comp.pdf



Resource 14: Logistics Fact Sheets: HIV Test Kits, USAID | DELIVER PROJECT (2008). This resource includes information critical to the selection, forecasting, procurement, and inventory management of 16 brands of HIV tests.

http://deliver.jsi.com/dlvr_content/resources/allpubs/factsheets/LogiFactShee_HIIVT_Comp.pdf

ENSURING QUALITY

To ensure the quality of the enhanced pediatric HIV testing and treatment services, all national protocols must be standardized, required tasks must be supported through training and supervision, and performance of HCWs must be measured according to these standards. Improvements can then be made so that the highest quality of care possible is provided. A quality measurement and improvement scheme should be developed for any new pediatric services delivered through implementation of the recommendations and should be integrated into current quality assurance efforts.

DEVELOPING STANDARD OPERATING PROCEDURES

The WHO recommendations and current guidelines should be used to update and expand existing standards for pediatric HIV diagnosis, care, and treatment. In order to be considered valid, credible, and able to be surveyed, standards should clearly identify the performance/service compliance expected; should be specific, measurable, and time-bound; and should permit a valid measuring process (Tool 25). Standard operating procedures (SOPs) can then be developed from the agreed on standards. SOPs describe processes and provide specific instructions to maximize pediatric HIV service delivery at health facilities in accordance with national guidelines. They will serve to guide clinicians in testing for HIV and providing ART to infants and children living with HIV as well as in evaluating performance, thereby serving as a quality assurance tool for management (Tool 26 and Resource 17).

Treating infants and children living with HIV with ART is complex, given the changes in dosing as the child develops, the dependence of the child on other caregivers, and the rapid evolution of scientific evidence. SOPs are “working” documents that must be updated regularly to incorporate new or revised procedures to ensure quality pediatric HIV service delivery. SOPs are intended for all health facility staff, including medical doctors, registered clinical officers, nurses, counselors, health facility management, receptionists, and maintenance staff.

TOOLS AND RESOURCES



Tool 25: Standards of Care for HIV-Exposed and Infected Infants and Children, WHO and UNICEF (2008). This poster outlines the standards of care presented in the 2008 Scale up of HIV-Related Prevention, Diagnosis, Care and Treatment for Infants and Children: A Programming Framework (Resource 9).
http://www.unicef.org/aids/files/StandardsofCareChildren_Final.pdf



Tool 26: Standards for Quality HIV Care: A Tool for Quality Assessment, Improvement, and Accreditation, WHO (2004). This publication and the proposed standards are intended for WHO member states and their authorizing bodies in developing their own framework of accreditation as a guiding principle to improve the quality of HIV care at all levels of health care facilities of the country, with a special focus on ART.
http://www.who.int/entity/hiv/pub/prev_care/en/standardsquality.pdf



Resource 15: Defining Quality, The Quality Assurance Project (2009). The project provides technical support in applying modern quality assurance strategies on a large scale as an integral component of the system of health care at the national, regional, or local

levels. Major areas of assistance include development of quality standards, improving compliance with standards, quality improvement (QI), quality monitoring, accreditation and other regulatory strategies, and redesign of systems of care. <http://www.qaproject.org/methods/resdefin.html>



Resource 16: HIVQUAL International, U.S. Health Resources and Services

Administration (2009). The project works with national governments to implement a systematic strategy to build capacity to measure and improve the quality of HIV care for adults and children. The website also provides access to additional QI resources including links to the U.S.-based National Quality Center, which offers access to a range of online and downloadable resources for training and implementation of quality measurement and improvement.

<http://www.hivqual.org/>

PROVIDING APPROPRIATE TRAINING AND SUPPORTIVE SUPERVISION FOR ALL HEALTH CARE WORKERS

Once SOPs are developed and updated for all aspects of pediatric HIV care, all individuals that will be implementing these procedures must be fully trained and receive ongoing supportive supervision. HCWs must be able to understand all aspects of the expected performances/services according to the SOPs and have a clear idea of the division of labor.

HCWs can be trained with existing pediatric training resources as well as newer resources on infant diagnosis and treatment as they become available (for a full list of available training tools and resources, see the “Human Resources” section). Because the recommendations call for the testing and treatment of very young infants, program implementers must ensure that training and supervision on doing so is strong and consistent. In addition to treatment protocols, laboratory and pharmacy service quality must also be ensured. Training resources for performing DBS collection is available as well as other information regarding laboratory and supply chain quality assurance can be found in the following sections: “Supply Chain and Laboratory,” “Supply Chain and Pharmacy,” and “Human Resources.”

Efforts to integrate preservice training in pediatric care and treatment for HCWs will help in the long-term sustainability of these efforts, including incorporation of updated pediatric HIV curriculum within local medical education. However, in-service continuing medical education will still be required given the rapidly changing nature of the field. Indicators to assess progress in this area should be chosen, including the proportion of HCWs trained and competent in relevant areas as well as geographic coverage of these workers and the targeted services. These might include:

- Percent of targeted health workers trained in DBS sample collection and percent of sites with adequate staffing
- Percent of targeted HCWs trained in recognition of HIV illness among infants and children and percent of sites with adequate staffing.

STRENGTHEN THE EXISTING QUALITY MANAGEMENT PROGRAM

All new and existing program efforts should be integrated into any ongoing performance measurement and QI activities and supervision. Program planners should ensure that any existing QI indicators are updated in accordance with the recommendations and that all staff and supervisors are notified of any changes and additions. New indicators may need to be developed if implementing

new services and operating procedures, such as DBS testing and infant testing counseling services. For example, QI indicators may include:

- Percentage of infants exposed to HIV who are linked into follow-up
- Percentage of infants and families exposed to HIV who received appropriate counseling and DNA PCR testing by 6 weeks of age
- Percentage of infants diagnosed as living with HIV in a timely manner (determined by DNA PCR)
- Percentage of families who receive test results
- Number/percentage of infants living with HIV initiated on ART
- Number/percentage of pediatric patients receiving ART
- Percentage of infants (exposed to and living with HIV) LTF.

It is imperative that a strong supervision structure must exist for all components of the health system and delivery of care, including supply chain, laboratory services, psychosocial support, and counseling, as well as clinical care to ensure quality patient care at all levels. Clear and appropriate testing and treatment algorithms supported by the quality management programs should be instituted to ensure that the test results and treatment plans are of the highest quality and being implemented as planned. Laboratory procedures and quality assurance should draw on existing knowledge and practices. For example, performing DNA PCR on a second disc from the same DBS sample has been shown to confirm the initial result and reduce error as well as retesting a subset of all negative samples (see the “Supply Chain and Pharmacy” section). Similarly, all components of the counseling process should be reinforced through in-service training and counseling aids and measured through exit and follow-up interviews (see Box 7, below).

Box 7. Improving Quality in a Decentralized Pediatric HIV Care and Treatment Program: The ICAP Experience in Rwanda

Background: Ensuring high quality clinical services is a challenge to the decentralization of pediatric HIV care and treatment in resource-limited settings. ICAP designed the Clinical Systems Mentorship (CSM) as an approach to QI including three steps: 1) supporting implementation of a model of care (MOC) for HIV using a standardized tool; 2) evaluating the quality of existing services based on available site data and improving on the standards of care (SOC); 3) and maintaining high quality of the SOC over time. In collaboration with district health teams, ICAP trained and mentored site staff to implement a pediatric HIV MOC and routinely evaluated program performance using predefined pediatric SOC indicators. They implemented CSM at 13 sites including two university teaching hospitals (UTHs), nine district hospitals (DHs), and two HCs in Rwanda.

Intervention:

- Site staff randomly selected a sample of 10 to 20 percent of charts from pediatric patients in care to assess SOC indicators.
- Each indicator was compared to a threshold score of 80 percent and poorly performed (< 80 percent) indicators were further investigated through root causes analysis, followed by mentorship of site staff to implement a specific action plan to address them.
- We report on trends of specific SOC indicators and impact on routine program outcomes (enrollment into care, ART initiation, and LTF).

Results and lessons learned:

- Between September 2007 and September 2008, at UTHs, DHs, and HCs respectively, the proportion of children who had WHO staging increased from 83 percent, 12 percent, and 76 percent to 100 percent, 97 percent, and 95 percent.
- CD4 assessment rate was 95 percent at UTHs and increased from 46 percent and 58 percent to 85 percent and 89 percent at DHs and HCs, respectively.
- Routine program outcomes showed the LTF rate decreasing from 14 percent to 7 percent ($p = 0.003$); child enrollment and ART initiation rates increased over time in all settings: from 41 percent, 40 percent, and 20 percent to 69 percent, 85 percent, and 57 percent, but were significantly higher at UTHs and DHs than at HCs ($p < 0.001$).
- The CSM approach contributed to improve quality of pediatric HIV services at selected health facilities. Performance improvement was higher at UTHs and DHs than at HCs.
- Further poor performance investigation and staff mentoring reaching all levels of the health system will better improve quality of services for children.

(Tene et al. 2008)

TOOLS AND RESOURCES

The following tools are available to assist program managers in designing interventions to increase adherence to standards as well as other QI activities.



Tool 27: Quality Academy Online, The National Quality Center (2009). This is an online, modular learning program designed to increase understanding of QI in HIV care that features 20 content-rich tutorials, which are accessible at all times on any Internet-connected computer. <http://nationalqualitycenter.org/index.cfm/5847/8860>



Tool 28: Helping Healthcare Providers Perform According to Standards, Quality Assurance Project (2004). This paper examines the principles for designing interventions to increase adherence to standards. It describes the main approaches and interventions that have helped providers meet clinical and administrative standards and summarizes the findings of studies evaluating the effectiveness of those interventions. <http://www.qaproject.org/pubs/PDFs/helphcpro3.pdf>



Tool 29: How Can Self-Assessment Improve the Quality of Healthcare?, Quality Assurance Project (2001). Many health care providers in developing countries work without supervision. This paper reviews several studies of various kinds of self-assessment interventions and can help policymakers decide what kind of self-assessment program to implement and how to do so. <http://www.qaproject.org/pubs/PDFs/selfassess402.pdf>



Tool 30: Quality Assurance Measures for Voluntary Counseling and Testing Services: Counselor Quality Assurance Tool, WHO (2006). These documents provide means and measures for assessing staff performance, client satisfaction, and adequacy of both counseling and testing (CT) protocols. The checklists/forms included are Approaches for Assessing Staff Competency, Counselor Skills, Client Satisfaction and Counseling Protocol and Laboratory Testing Adequacy; Counselor Quality Assurance Tool; VCT Site Instrument; Counselor Reflection Form; and the VCT Client Exit Survey Form.

<http://www.who.int/hiv/topics/vct/toolkit/components/service/en/index5.html>

SOCIOCULTURAL IMPLICATIONS AND COMMUNITY ENGAGEMENT

In many resource-limited settings, knowledge among the general population of the prevention and treatment of pediatric HIV is limited and sometimes inaccurate or distorted by local beliefs and myths. Those living with HIV are subject to stigma and discrimination and may be afraid to seek medical care for themselves and their children. Other barriers to access may include patient-related factors, such as depression, and health system-related factors, such as distance. For those caregivers and children who overcome these barriers and enter into care, maintaining high levels of adherence to treatment and care remains a challenge due to uncoordinated HIV services among family members.

IDENTIFYING AND ADDRESSING BARRIERS TO ACCESS FOR PEDIATRIC HIV SERVICES

Research in resource-limited settings has shown that there are a number of barriers to accessing critical treatment and care services, many of which may affect the willingness and ability of caregivers to permit pediatric HIV testing and treatment (Box 8). Barriers to testing and treatment must be identified for each setting and unique targeted strategies employed to overcome these challenges to access. A number of strategies have been used or recommended, including psychosocial assessment and treatment, peer counseling and education through home visits, mobile clinics, transport reimbursement, and other incentives such as nutritional support (see Resources 19 and 20). Many of the fear and stigma-related barriers can be addressed through community mobilization and involvement of PLWH.

Box 8. Sociocultural Insights from an EID Stakeholder Meeting on Pediatric HIV, Iringa Region of Tanzania (Resource 7)

Background: In 2006, the BASICS project assessed the status of pediatric HIV treatment and care services in three regions in Tanzania. The objective of the assessment was to find missed opportunities for identification or initiation into care and treatment of children exposed to or living with HIV, with the goal of increasing pediatric access to HIV treatment.

Intervention:

- Thirty-five district and regional medical officers, HCWs from local hospitals, NGOs, and community members including mothers with children living with HIV attended a stakeholder meeting to discuss pediatric HIV care and treatment in the Iringa region of Tanzania.
- The meeting objective was to elicit insights into common barriers to access of pediatric HIV services experienced by families with infants exposed to HIV.

Results and lessons learned: Community members cited a number of barriers to women not taking an infant for testing, whether the baby was sick or well. These included:

- *Personal barriers*, such as lack of money for transport or medication, economic dependency of women on men and thus fear of marital rejection, or depression and despair
- *Knowledge-related barriers*, including a belief that children cannot get HIV, that healthy children do not need care, and that traditional medicines are effective in treating HIV, as well as not understanding the importance of learning the HIV status of a child or not wanting to know their status
- *Fear-/ stigma-related barriers*, including fear of a husband's reaction to an infant being diagnosed with HIV, of exposing her own HIV status to her husband, of what will happen in the future, or of her test result, as well as fear of exposure to the community
- *Facility-related barriers*, including distance to the facility or the condescending or judgmental attitude of HCWs.

These findings indicated several important lessons for EID program managers:

- Programs must devote adequate resources to community education and mobilization around the issues of infants and children exposed to HIV.
- Unique strategies must be employed to help families overcome barriers, such as the use of CHWs and peer educators trained to engage families and provide psychosocial support and education to those in need.

MOBILIZING THE COMMUNITY AND INVOLVING PEOPLE LIVING WITH HIV

Mobilizing the community to access the enhanced pediatric HIV services, prior to implementation of the new guidelines as well as on an ongoing basis after implementation, is crucial to attaining the defined goals (see Tools 31 and 32). Objectives of community mobilization include the following:

- Raising awareness and fostering commitment to the provision of basic HIV prevention, care, and treatment services for children
- Strengthening community capacity by facilitating dialogue around newborn care practices including infant HIV testing and initiation of ART according to the WHO recommendations
- Addressing underlying causes of inequitable access and care as a result of physical, social, cultural, and political factors that stigmatize and discriminate against and marginalize women and minority groups.

Community members living with HIV are an important part of advocacy for better management of HIV-related issues and problems. Though many of them may not be in key decision-making positions, their empathy and personal experiences with the disease gives them the ability to influence caregivers of children living with HIV, as well as public officials. PLWH have been shown to effectively provide education, adherence counseling, and psychosocial support to patients living with HIV, including mothers and their infants. Program implementers should support the creation and strengthening of PLWH organizations to better address community needs, knowledge, and access to pediatric HIV services.

Program implementers should work with local advocacy organizations and journalists to develop targeted campaigns and education materials for all stakeholders, including radio messages, community events (such as dramas), as well as door-to-door campaigns to emphasize the importance of early testing and treatment of infants and children (Box 9).

Box 9. HIV Awareness Campaigns by the Entebbe Women Association (EWA) in Gulu, Uganda

Background: With the help of the World Association of Christian Communication, EWA carried out HIV sensitization sessions designed to increase HIV awareness by highlighting issues surrounding stigma, the care and support of PLWH, and the community's role in HIV prevention. EWA hoped to encourage PLWH to adopt and maintain positive living practices, increase the disclosure of HIV status among sexual partners, and improve community involvement in HIV services.

Intervention: Interventions included the following:

- Drama and music sessions highlighting issues surrounding stigmatization and support of PLWH
- Training and advocacy for PLWH in positive living, positive prevention, and drug adherence
- Radio programs focusing on reducing stigma and increasing care and support of PLWH.

Lessons learned:

- An increase in the number of referral cases for integrated HIV support through advocacy
- An increase in testing and disclosure rates
- Requests for additional information through radio calls and letters were also observed.

TOOLS AND RESOURCES



Tool 31: The String Game, UNICEF (2009). This activity was created to educate low literacy community members and patients on the routes of HIV transmission. Educators carry a stand-up display to the clients' homes. Cardboard cut-out figures of men, women, and children are applied to the board and connected by strings to indicate particular modes of transmission. http://bayloraid.org/toolkit/tools/Tool_No_12.pdf



Tool 32: Secure the Future Manual: Seven Steps to Involve the Community in HIV/AIDS Treatment Support Programmes, Bristol-Myers Squibb (2009). The purpose of this manual is to guide any group in how to integrate community mobilization and supportive services provided by CBOs (including FBOs and NGOs) to patients in their homes and communities. <http://www.bms.com/documents/STF/manual/print.pdf>



Resource 17: “If you build it, will they come?” Kenya Healthy Start Pediatric HIV Study: A Diagnostic Study Investigating Barriers to HIV Treatment and Care Among Children, Horizons Program (2008). This study aimed to examine barriers to uptake of pediatric HIV care and treatment services, including community perceptions and service quality, to derive lessons for increasing uptake of existing services. http://www.popcouncil.org/pdfs/horizons/Kenya_PediatricHIVTreatment.pdf



Resource 18: A Chance for Children: Overcoming Barriers to Pediatric HIV Care and Treatment Services, USAID and BASICS (2009). This poster reviews the common barriers to pediatric HIV care and treatment services and proven strategies to overcome these barriers in resource-limited settings, with particular emphasis on experiences in Rwanda. http://www.basics.org/documents/pdf/Pediatric_HIV_A_Chance_for_Children.pdf



Resource 19: Demystifying Community Mobilization: An Effective Strategy to Improve Maternal and Newborn Health, USAID (2009). This document describes the use of community mobilization as a primary strategy to reduce maternal and newborn mortality in communities, while building civil society capacity to achieve and sustain further positive health and community development results. <http://www.comunit.com/redirect.cgi?m=7e32243c5974bcbb8ae3e08a1b0377dc>



Resource 20: The Great Involvement of People Living with HIV/AIDS (GIPA), UNAIDS (2007). A brief detailing actions for governments, organization of PLWH, wider civil society and private sector, and international partners to involve PLWH in obtaining universal access. http://data.unaids.org/pub/Report/2007/JC1299-PolicyBrief-GIPA_en.pdf



Resource 21: Involving People Living with HIV: Support to PLWH Organizations in Cameroon, Gesellschaft fur Technische Zusammenarbeit (GTZ) (2007). This is a report describing establishment of the Cameroon Network of PLWH organizations, RéCAP+, which coordinates the activities of its member organizations, aims at building their institutional capacities, and aims at ensuring the representation of PLWH in political decision-making bodies at local and national levels. <http://www.gtz.de/de/dokumente/en-produktblatt-plwh-2008.pdf>

ADOPTING A FAMILY-CENTERED MODEL OF CARE

Families affected by HIV have multiple needs, and when services are not coordinated, care can become more complicated, costly, and fractured. By contrast, family-centered care provides comprehensive care in the same facility for parents, caregivers, and children living with and affected

by HIV, at the same time and by the same staff. It includes treatment, management of opportunistic infections, palliative care, nutrition support, and child protection and prevention programs. Any new or enhanced pediatric care and treatment services should be integrated into a family-centered model to increase uptake of services and adherence to care and treatment (Box 10). Family-centered approaches include referring parents of HIV-positive infants to CT services for themselves and coordinating routine appointments, counseling sessions, pharmacy pickups, and laboratory testing for families in which the caregivers and one or more children are HIV-positive.

Family-care case managers can be appointed and trained to assess, support, and coordinate HIV and primary care as well as psychosocial needs for children and families, including linkage with community-based services, in order to reduce the burden on the public health care system. Child HBC teams can support case managers in providing follow-up care in the home for the whole family, referring them to the health facility when necessary through established referral systems between facilities and from the community (see Box 16).

Box 10. Promoting a Family-Centered Approach in Scaling-Up Care and Treatment Services for Children in Rwanda

Background: IntraHealth's HIV Clinical Services Program (HCSP) in Rwanda supports HIV service integration. Children's HIV testing rates are often low due to the lack of a children's testing program and providers' discomfort delivering HIV testing results to children. HCSP sought to scale-up care and treatment services via a family-centered approach.

Intervention:

- In 14 HCs, HCSP-trained providers in a family-centered CT approach targeting families of women identified as living with HIV during ANC.
- CT sessions were held on weekends and holidays and all families in the area were invited so as not to draw attention to or stigmatize the target population.
- Children were invited through youth groups to ensure confidentiality.

Results and lessons learned:

- At the end of the first year of (September 2008) there was a seven-fold increase in children tested, to more than 22,000.
- In rural areas, there was a doubling of numbers of children tested.
- Before, children accounted for only 9 percent of all HIV-tested individuals in HCSP-supported sites. With the new approach, the number increased to 30 percent (16,494).
- Of the 1,371 clients living with HIV identified, 134 (10 percent) were children.
- Services for the entire family are thus provided in a single visit, reducing costs and facilitating care and treatment.
- Challenges included the follow-up of identified students living with HIV when children returned to school; identifying information for parents as well as their role in compliance and follow-up of infected children; and parent fears that children cannot cope with their positive status or that children will inform the community that their parents infected them.

(Ngendahimana et al. 2009)

RESOURCES



Resource 22: Family-centered Models of Care and Support for Orphans and Other Vulnerable Children Affected by HIV/AIDS, Joint Learning Initiative on Children and HIV/AIDS (JLICA) (2010). This literature review provides an overview of family-centered support models for children and families affected by HIV.

<http://www.jlica.org/userfiles/file/Wakhwaya%20JLICA%20LG1%20Paper%20Brief.pdf>



Resource 23: Expanding Access to Services and Protecting Human Rights, JLICA (2010). This report provides a synthesis of the lessons learned and recommendations of Joint Learning Initiative on Children and HIV/AIDS's "Expanding Access to Services and Protecting Human Rights" group.

[http://www.jlica.org/userfiles/file/JLICA_LG3_FINAL\(1\).pdf](http://www.jlica.org/userfiles/file/JLICA_LG3_FINAL(1).pdf)



Resource 24: Embracing a Family-centred Response to the HIV/AIDS Epidemic for the Elimination of Pediatric AIDS. DeGennaro, V., and P. Zeitz (2009). This paper reviews the arguments for family-centered pediatric HIV treatment, including strengthening the general health care system's ability to respond quickly to illnesses in the population and concludes that family-centered programs should be the gold-standard for prevention and treatment of HIV/AIDS.

http://aidsalliance.3cdn.net/3dcceac2a703f320d7_orm6bxifw.pdf

LEGAL FRAMEWORK

It should be established early on whether testing of infants will be opt-in, opt-out, or mandatory according to national legislation and international legal instruments, declarations, and guidelines. Implementation of planned activities should be adapted accordingly. Because no major international agencies are advocating mandatory testing for infants and children, issues surrounding informed consent should be clarified and standardized (see Resource 27).

ASSESSING CURRENT LEGISLATION ON HIV TESTING

In light of the need for infants and children to have earlier access to treatment, care, support, and prevention, UNAIDS and WHO are supporting a major expansion of access to HIV CT through the scaling up of client-initiated and provider-initiated CT services using an opt-out approach. With an opt-out approach, an HIV test will be performed routinely unless it is specifically declined. In high HIV prevalence settings, this approach is preferable as it rapidly expands the scope of people who can access prevention (Box 11).

All testing, whether client- or provider-initiated, should be conducted under the conditions of the "Three Cs": involve informed consent, be confidential, and include counseling. The 2004 UNAIDS/WHO *Policy Statement on HIV Testing* recommends that traditional VCT be supplemented by provider-initiated testing in all health settings in generalized HIV epidemics, and in selected health facilities (such ANC clinics) in areas with low or concentrated HIV epidemics.

Box 11. Universal HIV Testing of Infants at Immunization Clinics: An Approach for EID in High HIV Prevalence Settings in South Africa

Background: In the South African province of KwaZulu Natal, 39 percent of women receiving ANC are living with HIV. To try and increase the detection of HIV infection in infants, investigators undertook a study to see how feasible and acceptable opt-out HIV testing was at infant immunization clinics to achieve early diagnosis of HIV and referral for HIV treatment and care services.

Intervention: Mothers attending three immunization clinics with infants aged 6, 10, and 14 weeks were offered opt-out tests by trained counselors. Blood samples were collected by heel prick onto filter paper. DBSs were tested for HIV antibodies and, if present, were tested for HIV DNA by PCR. Testing at the immunization clinics allowed both mothers and infants to be linked into ART programs. Exit interviews were requested of all mothers irrespective of whether they had agreed to infant testing or not.

Results and lessons learned: A total of 646 mothers of infants attending the immunization clinics were offered opt-out HIV tests by the counselors. The median age of the infants was a little under eight weeks. Findings included the following:

- Most (584, 90 percent) mothers consented to their infant being tested for HIV.
- Of those 584 mothers, only 332 (57 percent) returned for the result.
- Among women who reported being HIV-negative, 7 percent of their infants were found to be infected.
- Most mothers (78 percent) reported that they were comfortable with the offer of an opt-out HIV test for their infant, 5 percent of mothers said that the offer frightened them, and 2 percent said that it caused anxiety.
- Only 2 percent of mothers refused the offer of an HIV test because they needed more time to decide.
- The main reasons for accepting a test were to confirm the HIV status of the infant (77 percent) and to gain access to ART (55 percent).
- Over a quarter of women also said that the test result would help inform their infant feeding practices.
- Screening of all infants at immunization clinics is acceptable and feasible as a means for early identification of infants living with HIV and referral for ART.

(Rollins et al. 2009)

ADDRESSING ISSUES OF CONSENT FOR INFANT TESTING

Protocols for acquiring written consent or documentation of verbal consent from parent or guardian, consistent with general requirements for consent for diagnosis and care of minors, should be established for births that take place at the health care facility and at patients' homes.

Documentation of at-home births will require maintaining strong linkages with traditional birth attendants (TBAs) as well as other CHWs to properly document and refer new mothers and their babies for testing at the nearest facility. In pediatric wards with high HIV prevalence and among children with TB, universal diagnostic HIV testing may be appropriate. If the parent or guardian is unable to give consent, appropriate protocols must be established in line with national legislation.

These efforts, however well-intentioned, may raise major concerns among caregivers around issues of confidentiality and informed consent. For a mother, the HIV test on her infant amounts to disclosure of her own status. Counselors and medical staff have the important task of ensuring that proper consent is being sought and that accidental disclosure of a woman's HIV status to her partner, relatives, or other community members is avoided. CHWs and other staff need to explain to mothers/caregivers the implications of refusing a test for their child. However, they must do so without undue pressure, rather aiming to educate the mother/caregiver of the benefits of HIV testing and the implications of a positive and negative test result so that he/she is able to make an informed decision and to provide appropriate support systems (see Resource 28).

A counseling script for explaining infant diagnostic testing to parents or caregivers is available in Tool 50.

RESOURCES



Resource 25: UNAIDS/WHO Policy Statement on HIV Testing, UNAIDS and WHO (2004). The cornerstones of HIV testing scale-up must include improved protection from stigma and discrimination as well as assured access to integrated prevention, treatment, and care services. The conditions under which people undergo HIV testing must be anchored in a human rights approach that protects their human rights and pays due respect to ethical principles. <http://www.who.int/entity/hiv/pub/vct/en/hivtestingpolicy04.pdf>



Resource 26: Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities, WHO and UNAIDS (2007). This document responds to growing need at the country level for basic operational guidance on provider-initiated HIV CT in health facilities. It is intended for a wide audience including policymakers, HIV program planners and coordinators, health care providers, civil society groups, and NGOs providing HIV services. http://whqlibdoc.who.int/publications/2007/9789241595568_eng.pdf

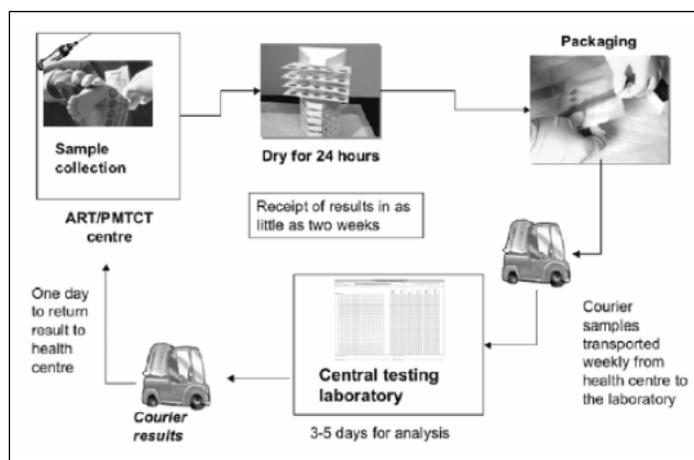
OPERATIONAL ISSUES AND CONSIDERATIONS

Once an enabling environment is created for implementation, a number of operational and system strengthening activities must be undertaken. Considerations surrounding the supply chain capacity and scalability of the laboratory and pharmacy systems to effectively and efficiently obtain, manage, and deliver the laboratory reagents and supplies, and the ARV formulations required for pediatric diagnosis and treatment should be addressed to ensure successful implementation of the recommendations. Similarly, other activities surrounding human resources, IEC and community promotion, treatment literacy and adherence, integration with existing platforms, data management, and patient tracking must be assessed and gaps in service addressed.

SUPPLY CHAIN AND LABORATORY

Challenges to implementation of EID and EIT to date include poorly equipped and understaffed reference laboratories, the lack of an established system for timely delivery of blood samples and reporting of laboratory results, and the need to strengthen linkages for referral to HIV care and treatment. Program implementers should assess current laboratory capacity to conduct HIV nucleic acid testing (NAT) for EID and determine at which level(s) of the laboratory system and at which specific laboratories NAT PCR testing can realistically be performed. In addition, program implementers should also conduct an assessment of the laboratory supply chain management functions to identify any issues related to financing, forecasting, procurement, and distribution of the specific laboratory reagents, supplies, and equipment that will be required to provide HIV NAT for EID according to the recommendations.

Figure 2. Example of PCR network using DBS, Kenya



The use of DBSs can overcome the blood sampling and logistical obstacles that limit access to infant diagnosis in low-resource settings. In DBS PCR, drops of blood from each infant are taken from a toe or heel prick on filter paper, then dried, packed with desiccant, and stored and/or sent to centralized laboratories for PCR testing. There are, however, a number of materials required for collection, storage, and transport of DBS specimens (see Box 7 and Table 3). Materials for collecting DBS samples are currently sold separately instead of as a premade kit. While this may seem like a minor detail, it is a reflection of the segmented purchasing system that

may drive up costs and slow down EID capabilities. See Figure 2 for an example of a PCR network using DBS.

Many infant diagnostic PCR test kits still require product approval from national and international regulatory bodies before countries will adopt the technologies. The Roche Amplicor DNA PCR v1.5 is currently being evaluated by WHO, but the process may not be officially completed for several years. In the meantime, WHO is advocating the use of Roche’s Amplicor DNA PCR based on significant data from several country programs, including South Africa (Creek et al. 2007). While PCR testing remains expensive, using a rapid HIV antibody test to screen out negative results could reduce the number of samples that need to be collected and sent for PCR.

SUPPLY CHAIN CONSIDERATIONS FOR IMPLEMENTATION OF HIV DEOXYRIBONUCLEIC ACID POLYMERASE CHAIN REACTION TESTING FOR INFANTS

Product Selection and Standardization

New laboratory testing technologies and equipment will need to be procured and incorporated into the existing laboratory system to be able to expand DNA PCR viral load testing for infants. Successful implementation of NAT will require a reliable supply of the specific laboratory reagents and consumable supplies needed to perform the testing. The laboratory testing techniques, equipment, and operating procedures for DNA PCR viral load testing should be standardized for the program (see Tool 35). Table 3 is an illustrative list of the different types of laboratory equipment and supplies required to support DNA PCR viral load testing.

Table 3. Supply Chain Management Systems Catalog for EID Procurement: Illustrative List of EID Equipment and Supplies

<i>PCR Test Kits</i>	
• DNA PCR Amplicor HIV-1 Monitor Test, 96 Tests, Roche	
<i>Equipment (One-time Order)</i>	
• Thermal Cycler, GeneAmp PCR System 9700, 220V	• Incubator and Refrigerator Thermometers
• Eppendorf Thermomixer 5350	• Refrigerator/Freezer
• Thermolyne Vari-Mix and Speci-Mix Tube Rockers	• Incubator 2.5 cubic feet 220V
• Vortex Genie 2® Laboratory Mixer	• ELx50™ Microplate Strip Washer
• Stratagene Stratalinker 1800 UV Crosslinker	• ELISA Reader, Absorbance Microplate,
• Pipet-Aid, Cordless, Rechargeable, Programmable	• Gen5 Data Analysis Software for Elisa Reader
• Laminar Flow PCR Workstation	• Eppendorf Microcentrifuge 5424, 230V
• Digital Count Down/Up Timer; Pocket size	• Microcentrifuge, personal benchtop for quick spin, 115–240V
<i>Tubes and Accessories</i>	
• Thin-wall PCR Plates	• Sarstedt rack 48 apertures
• PCR Plate Thermal Adhesive Sealing Film	• Tubes, 15/50 mL, Conical, Polypropylene
• Seal Film Applicator	• Tube racks 2mL
• ABI MicroAmp 96-Well Support Base	• Tube Racks, for multiple tube sizes, Inter-locking four-way rack
• Micro Tube, screw cap, sterile, 1.5 mL	• Cryo Boxes, Polycarbonate, Assorted Colors

Other Consumables	
• Disposable Gloves, Powder-Free, Nitrile	• Self-Adhering Label Tape 0.75 in
• Bag, Autoclave, Orange, 8½ × 11 in	• Absorbent Pad With Plastic Backing, 17 × 24 in
• Wire Bag Holder	• Basic Lab Coat, S/M/L, White, Kimberley Clark
• Biohazard Autoclave bags 24 × 36 in	• Paper Punch, 6 mm
• Lab Markers, Extra-Fine Tip, Black	• Sticky Mat for PCR Room, 25.5 × 45 in
DBS Consumables	
• 903 DBS Card, 5 × 1.5 in	• Drying Racks
• Weighing Paper, 76 × 76 mm	• Swab Alcohol WBCL
• Humidity Indicator Card	• Fisherbrand Adhesive Bandages, 0.75 × 3 in
• Bitran Long-Term Specimen Storage Bags, 7 × 8 in	• BD Microtainer™ GENIE™ Lancet
• Dessicant Packs	• Transport Packaging (if delivering off-site)
(CDC and Global AODS Program 2009)	

Laboratory Accreditation and Training of Laboratory Personnel for Early Infant Diagnosis

Criteria for the selection of laboratories and qualifications of the laboratory personnel to be trained to perform DNA PCR testing should be established to determine at what levels of the laboratory system EID testing will be provided and which laboratories may be accredited as EID testing sites. Laboratory personnel may also require training in the correct ordering, management, and distribution of laboratory reagents and supplies for DNA PCR testing.

Quantification of HIV Deoxyribonucleic Acid Polymerase Chain Reaction Testing Supplies

The program will need to establish a methodology for forecasting demand for EID using DNA PCR viral load technology; for collecting and monitoring data on the actual number of infants tested and consumption of laboratory supplies; and for quantifying the required laboratory reagents and supplies for procurement. Program implementers should consider the data sources and quality of the data on demand for EID for the program. Data on past EID services and consumption of DNA PCR testing supplies should be collected and reviewed if available, and program plans and targets should be taken into consideration in estimating future demand for EID and the quantities of DNA PCR testing supplies that will need to be procured.

Funding and Procurement of Laboratory Equipment and Supplies for HIV Deoxyribonucleic Acid Polymerase Chain Reaction Testing

The costs associated with the purchase, maintenance, repair, and replacement of DNA PCR equipment, as well as recurrent costs for resupply of the laboratory reagents and consumable supplies that will be needed to meet the increased demand for DNA PCR testing should be estimated. The sources of funding as well as the timing and amounts of funding commitments should be identified, and funding gaps should be addressed as part of the program planning and budgeting process. The suppliers, procurement mechanisms, and lead times will also need to be considered to be able to plan shipment delivery schedules and quantities to ensure a continuous supply of the products needed.

Inventory Management, Storage, and Distribution

In assessing the laboratory supply chain, it will be important to determine whether current inventory management procedures for ordering, distribution, stock monitoring, and management are sufficient to ensure continued availability of the laboratory reagents and supplies that will be needed for implementation of EID. SOPs should clearly establish how the supplies for DNA PCR testing will be ordered, distributed, used, and monitored. A key question to address is whether the DNA PCR testing supplies will be ordered, distributed, and stored together with other laboratory reagents and supplies through the existing laboratory supply chain, or whether these items will be managed separately.

TOOLS AND RESOURCES

The following tools and resources will assist program implementers in assessing current laboratory supply chain capacity and in identifying supply chain management procedures that will facilitate implementation of EID using DNA PCR testing technology in resource-constrained settings.



Tool 33: Laboratory Logistics Handbook: A Guide to Designing and Managing Laboratory Logistics Systems, USAID | DELIVER PROJECT (2009). This document provides basic information to logisticians on 1) the function and organization of laboratory services; 2) commodities for laboratory services—reagents, consumables, durables, and equipment; and 3) supply chain considerations for management of laboratory commodities. The appendices to this document include valuable reference materials.
pdf.usaid.gov/pdf_docs/PNADP082.pdf



Tool 34: Guide to Implementation of Services for Early Diagnosis of HIV in Infants in Resource-Limited Settings, CDC and Global AIDS Program (2009). This five-module training curriculum on EID can be used to teach staff how to collect, handle, and send DBS specimens for EID. The appendices include a complete list of all equipment and commodities needed to perform DBS PCR testing on infants.
<http://www.womenchildrenhiv.org/wchiv?page=ch-09-00-eid>



Tool 35: Laboratory Standardization: Lessons Learned and Practical Approaches, USAID | DELIVER PROJECT (2009). Based on the experience of the USAID | DELIVER PROJECT in supporting countries during the laboratory standardization process, this paper provides a detailed definition and description of laboratory standardization, outlines the benefits, and offers some suggested approaches for implementing standardization in-country. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LabStand.pdf



Tool 36: Lessons Learned in Managing National Laboratory Supply Chains, USAID | DELIVER PROJECT (2009). This document highlights some of the key lessons learned by the USAID | DELIVER PROJECT in strengthening laboratory logistics systems and implementing good supply chain practices to the laboratory setting.
http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/LessLearnManaLabSC.pdf



Tool 37: Guidelines for Managing the Laboratory Supply Chain (v.2), USAID | DELIVER PROJECT (2008). This paper describes the function and organization of laboratory services and the commodities needed for laboratory services, and it discusses supply chain considerations for management of laboratory commodities. Appendices include information on laboratory tests and the commodities needed to perform them and sample records and reports for a logistics management information system (LMIS) for laboratory commodities.
http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidManaLabSC_v2.pdf



Tool 38: Quantification of Health Commodities: HIV Test Kit Companion Guide, Forecasting Consumption of HIV Test Kits, USAID | DELIVER PROJECT (2009).

The purpose of this companion guide is to supplement the general guide on Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement by describing in detail the specific methodology for forecasting consumption of HIV test kits as a critical step in the overall quantification process.

http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuanHealtCommoHIVtestkit.pdf



Tool 39: Guide for Quantifying Laboratory Supplies, USAID | DELIVER PROJECT (2008).

The primary focus and purpose of this guide is to describe the quantification process, including estimating the quantities and the cost of products required to meet customer demand and to fill the pipeline with adequate stock levels, taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement.

http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LabQuantGuide.pdf



Tool 40: Logistics Indicators Assessment Tool for HIV Test Kits, USAID | DELIVER PROJECT (2009).

This is a quantitative data collection instrument developed by the USAID | DELIVER PROJECT and used to conduct a facility-based survey to assess health commodity logistics system performance and commodity availability at health facilities. This tool has been adapted from the original version, specifically to assess HIV tests logistics system performance and availability at health facilities.

<http://deliver.jsi.com/portal/page/portal/738F4DD2AE482725E04010AC6D2B315B>



Tool 41: Assessment Tool for Laboratory Services (ATLAS), USAID | DELIVER PROJECT (2006).

The ATLAS is a diagnostic and monitoring tool that can be used for a baseline survey to complete an annual assessment or as an integral part of the work planning process. The information collected when using the ATLAS is analyzed to identify issues and opportunities and to outline further assessments and/or appropriate interventions.

http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/AsseToolLab_ATLAS.pdf



Tool 42: ProQ: Quantification Software for HIV Tests, USAID | DELIVER PROJECT (2009).

ProQ is a software tool that quantifies HIV test requirements based on realistic forecast demand, assessment of existing supply chain capacity, and availability of resources for procurement.

www.deliver.jsi.com/dhome/resources/tools/softwaretools/proq



Resource 27: Retesting Same Dried Blood Spot (DBS) Card as a Quality Assurance Strategy for Early Infant Diagnosis Using Polymerase Chain Reaction in Nigeria, CDC (2008).

This document details a study of the reuse of dried blood spot cards for quality assurance in Nigeria.

http://www.hivimplementers.com/2008/pdf/E6/E6_1450_Jelpe.pdf



Resource 28: Critical Steps for Establishing Laboratory Capacity for Early Infant Diagnosis of HIV Infection, Malawi MOH and CDC (2008).

This presentation describes the need for EID and EIT, outlines the steps the Malawi MOH has taken to establish EID capacity, and reviews challenges encountered during implementation.

http://www.hivimplementers.com/2008/pdf/E6/E6_1708_NYIRENDA.pdf

SUPPLY CHAIN AND PHARMACY

A critical challenge for HIV care and treatment programs will be to meet the increased demand for pediatric ARV medicines in response to the revised WHO recommendations for initiation of

treatment and changes in the recommended treatment regimens for infants. Once regimens are selected, an assessment of the program’s supply chain capacity to finance, forecast, procure, and distribute pediatric ARV medicines at the pharmacy level should be conducted. This assessment should include an evaluation of the program’s capacity to correctly store, manage, and dispense the recommended pediatric ARV formulations

The objectives of these assessments should be:

- To identify supply chain and pharmacy level issues and challenges currently affecting the supply, availability, and use of pediatric ARV formulations that will need to be addressed to ensure successful implementation of the WHO recommendations
- To determine if the new policy guidelines, standard treatment guidelines, and procedures for diagnosing, prescribing, and dispensing the recommended treatment regimens and formulations have been adequately disseminated to service providers, and are ready to be put in to practice at the pharmacy level
- To estimate the number of infants that will require treatment and the demand for pediatric ARV medicines that will need to be financed and procured by the program
- To provide recommendations for strengthening supply chain performance and pharmacy management of pediatric ARV medicines to ensure successful implementation of the WHO recommendations.

Program managers and implementers need to prioritize the medicines required for implementation of the WHO recommendations and assess whether these products can be made available. This will depend on the regulatory environment, potential sources of supply, and available finances, some of which may need change as addressed in earlier sections of the toolkit. Table 4 shows the WHO recommended first-line pediatric therapies for children with and without exposure to NNRTIs followed by pediatric formulations currently available.

Table 4. WHO Recommended First-line Regimens and Currently Available Pediatric Formulations

<i>No or Unknown Exposure to NNRTIs</i>	<i>History of Any Exposure to Nevirapine</i>
• AZT + 3TC + NVP	• AZT + 3TC + LPV/r
• ABC + 3TC + NVP	• ABC + 3TC + LPV/r
• d4T + 3TC + NVP	• d4T + 3TC + LPV/r
<i>Available Pediatric Formulations</i>	
• AZT (also known as ZDV)	• Syrup, 10 mg/mL bottle
• ABC	• Oral solution, 20 mg/mL bottle
• d4T	• Oral solution, 1 mg/mL bottle
• 3TC	• Oral solution, 10 mg/mL bottle
• NVP	• Oral suspension, 10 mg/mL bottle
• LPV/r	• Oral solution, 80mg/mL and 20mg/mL bottle • Tablet, 100 mg/25 mg

Available Fixed-Dose Combination Drugs	
• Triviro-LNS kid (d4T + 3TC + NVP)	• d4T (5mg)/3TC (20mg)/NVP (35mg)
• Triviro-LNS kid Double Strength	• d4T (10mg)/3TC (40mg)/NVP (70mg)
• Triomune Baby (d4T + 3TC + NVP)	• d4T (6mg)/3TC (30mg)/NVP (50mg)
• Triomune Junior (d4T + 3TC + NVP)	• d4T (12mg)/3TC (60mg)/NVP (100mg)

Abbreviations: 3TC, lamivudine; ABC, abacavir; AZT, zidovudine; d4T, stavudine; LPV/r, lopinavir and ritonavir; NVP, nevirapine.

Fixed dose combination drugs not only reduce the total pill burden and thus improve adherence, but they also simplify the supply chain functions of forecasting, procurement, storage, and distribution, as well as dispensing, record keeping, and stock management at the pharmacy level. New formulations are being developed on a regular basis, and ensuring that information on availability is up-to-date is crucial. For example, Ranbaxy Laboratories have developed two new pediatric formulations of tablets for oral suspension designed to disintegrate quickly into a uniform suspension in a teaspoon of liquid media like water. The formulations are shown in Table 4.

SUPPLY CHAIN CONSIDERATIONS FOR IMPLEMENTATION OF WORLD HEALTH ORGANIZATION RECOMMENDATIONS FOR TREATMENT OF INFANTS EXPOSED TO AND LIVING WITH HIV

Coordinate Procurement and Distribution of Pediatric Antiretroviral Medicines with Dissemination of New Guidelines and Provider Training

Program managers and implementers should coordinate the timeframe for procurement and distribution of pediatric ARV medicines used for treatment of infants with 1) the dissemination of new policy guidelines and training of clinicians and pharmacists in prescribing, dispensing, and management of the ART regimens and 2) pediatric formulations that will be required to implement the new WHO recommendations. This will help to ensure availability of the required medicines when services are scheduled to begin, that providers have been trained to use the products correctly, and that overstocking and potential product expiration are avoided—if products were procured before guidelines were approved and disseminated and/or before providers were adequately trained.

Product Selection and Use

Treatment of infants (under 12 months of age) exposed to and living with HIV is limited to the use of liquid formulations and dispersible tablets. Not all the formulations required to complete the recommended regimens are available in easy-to-use, fixed-dose dispersible tablets. Liquid formulations must be individually calculated and dosed according to body weight (mg/kg of body weight) and body surface area measurements (mg/m² of body surface area). In addition, they must be continually adjusted over time as the infant gains weight. Once prescribing dosages have been determined, additional calculations are required to convert the number of milliliters of each drug needed in the treatment regimen to the number of bottles of each drug to be dispensed to the caregiver. This is further complicated by the different bottle sizes for liquid formulations, typically packaged in 100 mL, 200 mL, or 240 mL bottles (see Tool 48).

Quantification of Pediatric Antiretroviral Medicines

A major supply chain challenge for implementation of pediatric ART is forecasting the demand (the number of patients expected to initiate treatment and that will continue on treatment, and the distribution of patients by regimen) and estimating the quantities and the cost of the pediatric ARV formulations that will need to be procured according to the recommended regimens, dosing guidelines, and available supplier packaging. Quantification of pediatric ARV medicines is further complicated by changes in the selection and quantities of medicines needed over time as the child grows and responds to treatment. The quantification should also include an agreed on wastage rate to account for expiry of short-shelf-life products once opened and spillage expected during measuring and administering of liquid formulations.

The program will need to establish a methodology for forecasting the demand for treatment of infants exposed to and living with HIV, and for estimating the quantities of medicines that will need to be procured. The methodology should consider the program data sources and quality of the data on demand for infant ART. Data on past services and consumption of pediatric ARV medicines should be collected and reviewed if available, and program plans and targets should be taken into consideration in estimating future demand for infant ART and the quantities and cost of the pediatric ARV medicines that will need to be procured. Program managers and implementers should conduct a quantification of the pediatric ARV medicines that will be needed for treatment of those exposed to and living with HIV as a program planning activity to determine the funding needs and budget for procurement.

Funding and Procurement of Pediatric Antiretroviral Medicines

Implementation of the WHO recommendations for initiation of treatment and treatment regimens for infants exposed to and living with HIV may have significant cost implications given the relatively high cost of pediatric ARV medicines compared to adult ARV medicines. The results of the quantification will be critical in determining the funding needs and should be used to mobilize resources for procurement of pediatric ARV medicines to implement the new WHO recommendations. The sources of funding as well as the timing and amounts of funding commitments for procurement of pediatric ARV medicines should be identified, and funding gaps should be addressed as part of the program planning and budgeting process. The suppliers, procurement mechanisms, and lead times will also need to be considered to be able to plan shipment delivery schedules and quantities to ensure a continuous supply of the products needed.

Inventory Management, Storage, and Distribution of Pediatric Antiretroviral Medicines

Several requirements related to inventory management of pediatric ARV medicines should be considered during the supply chain assessment and in planning for implementation of the WHO recommendations. Storage and transport requirements will also have cost implications for the program. Some of those implications include the following:

- Liquid formulations have special storage and handling requirements
 - Sensitivity to temperature, light, and heat, therefore requiring cool chain and refrigeration in storage and transport and protection from sunlight and humidity
 - Packaging in fragile, glass bottles that requires careful handling and storage to avoid breakage
 - Increased product loss due to packaging in glass bottles

- Increased bulkiness and weight therefore requiring additional space in storage and transport.

TOOLS AND RESOURCES

The following tools and resources will assist program managers and implementers in assessing current supply chain capacity for financing, forecasting, procuring, distributing, and storing pediatric ARV medicines, and in identifying key supply chain management procedures that will facilitate implementation of the WHO recommendations for treatment for infants exposed to and living with HIV.



Tool 43: Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement, USAID | DELIVER PROJECT (2009). This guide is designed to assist users in applying a systematic, step-by-step approach to quantifying health commodity requirements and costs. The guide should be used when conducting a national-level quantification exercise and includes specific guidance on how to use the results of the quantification to identify the funding needs and gaps for procurement of the required commodities, coordinate procurements and shipment delivery schedules to ensure a sustained and effective supply of commodities, implement a process for reviewing, and updating the results of the quantification to maintain and improve the validity, accuracy, and usefulness of current and future quantifications.
http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuantHealthComm.pdf



Tool 44: Quantification of Health Commodities: ARV Companion Guide: Forecasting ARV Drugs Using the Morbidity Method, USAID | DELIVER PROJECT (2009). This companion guide is intended to complement information on the preparation and supply planning steps in the Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement (see Tool 43). The main guide provides information on how to conduct consumption-based forecasts for all commodity categories. This companion piece provides specific instructions for using the morbidity method to forecast ARV drug requirements and follows an actual ARV forecasting exercise using the morbidity method.
<http://deliver.jsi.com/portal/page/portal/6EAF4683D699615FE04010AC6E2B46E6>



Tool 45: Logistics System Assessment Tool (LSAT), USAID | DELIVER PROJECT (2009). Newly revised, the LSAT is a qualitative data collection instrument provides a comprehensive system-level assessment of logistics system performance for any program that manages a health commodity.
<http://deliver.jsi.com/portal/page/portal/44F65C7D4D0A01A3E040007F01001808>



Tool 46: Logistics Indicators Assessment Tool (LIAT) for ARV Drugs, USAID | DELIVER PROJECT (2009). The LIAT is a quantitative data collection instrument developed by the USAID | DELIVER PROJECT and used to conduct a facility-based survey to assess health commodity logistics system performance and commodity availability at health facilities. This tool has been adapted from the original version specifically to assess ARVs logistics system performance and availability at health facilities.
<http://deliver.jsi.com/portal/page/portal/738F4DD2AE0C2725E04010AC6D2B315B>



Tool 47: Building Blocks for Logistics System Design for HIV Tests and ARV Drugs: Inventory Control Systems, Logistics Management Information Systems, and Storage and Distribution, USAID | DELIVER PROJECT (2008). A logistics system that manages any health commodity must have the infrastructure to support the supply chain as a whole in order to manage and move commodities. This document focuses on four elements that require careful management in the context of HIV supply chains: 1) the inventory control

system, 2) the logistics management information system, 3) storage, and 4) distribution. It is designed to help logisticians design logistics systems that are appropriate for managing these commodities.

http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/BuilBlocLogiSystDesi.pdf



Tool 48: Summary of Simplified Dosing of ARVs for Infants and Children, WHO

(2008). This chart is provided to support infant treatment. The WHO has updated the dosing recommendations for ARVs in children contained in Annex E of the 2006 WHO Pediatric Guidelines. http://www.who.int/hiv/paediatric/Sum_WHO_ARV_Ped_ARV_dosing.pdf



Resource 29: Computerizing Logistics Management Information System (LMIS) for Managing HIV & AIDS Commodities, USAID | DELIVER PROJECT (2008).

This poster explains what a computerized LMIS is and why it is useful, as well as providing options for computerizing and lessons learned from the computerization of Uganda's and Kenya's LMISs. <http://deliver.jsi.com/portal/page/portal/53697F5F58A4867DE040007F01005ED6>



Resource 30: What to Consider When Designing Supply Chains for Delivering Pediatric ARVs, USAID | DELIVER PROJECT (2006).

This poster provides information on pediatric ART, characteristics of pediatric ARV drugs, as well as supply chain implications, considerations, and recommendations when designing supply chains for delivery of pediatric ARVs.

<http://deliver.jsi.com/portal/page/portal/45E1159851B1393FE040007F01004968>

HUMAN RESOURCES

Implementation of the WHO recommendations will require not only an adequate number of staff—and appropriate types of staff—to provide care and treatment, but also staff to provide family counseling and infant testing, including trained laboratory staff. To ensure delivery of quality health services by HCWs, an assessment should be made to determine staffing needs at the targeted pediatric care sites and to evaluate staff capacity, stability, and willingness to expand and sustain infant diagnostic testing and treatment. Training needs, roles, and responsibilities of different individuals and relationships with managers of the testing and treatment program will need to be identified prior to implementation. The number and type of HCWs required will depend on anticipated case load, the geographic distribution of sites and target population, and task assignment.

Implementation-related challenges may include increased workloads for existing HCWs, including PMTCT and primary care nurses. These higher workloads resulting from increased demand of testing and treatment services may compromise workflow as well as quality of the services provided. To address the severe human resource shortage in many countries, WHO has strongly supported an integrated program of task-shifting among providers. Appropriate health care responsibilities have been transferred from physicians to midlevel clinicians (e.g., nurses and clinical officers) and from nurses to CHWs. The success of these programs has maximized the potential of health care providers, and allowed the continued expansion of these services in the face of severe resource constraints (Box 12). In addition, efforts to decentralize care to increase access and utilization will depend on an ability to ensure that training and supportive supervision is able to be decentralized as a parallel effort.

All personnel involved in pediatric and maternal clinical services at the sites should participate in an initial overview training (see Tools 40 to 47). The training should provide an overview of scientific issues related to infant diagnosis and pediatric HIV infection as well as an introduction to new

protocols and procedures regarding PMTCT and infant diagnosis. A number of EID and EIT training resources are listed below. Specific areas of training will need to include the following areas depending on the cadre being trained:

- Methods to identify infants exposed to HIV on hospital wards, outpatient care settings, MCH and vaccination clinics, including awareness of the mother's health and HIV status
- Care and follow-up of the child exposed to HIV with an emphasis on identifying infants who have not undergone appropriate testing in new settings (vaccination clinics, OPD) monitoring growth, prescribing cotrimoxazole, and identifying linkages with HIV care and treatment services
- Practical instruction on assigning patient identifiers or codes, completing registers, paper files, and summary reports
- Teaching the practical aspects of obtaining, labeling, and shipping DBS, including the programmatic aspects
- Discussions of follow-up methods and practical examples of language to use with parents when blood is obtained or results are given
- New systems for tracking and monitoring infants and children
- Recognition of immune reconstitution syndrome in children, which occurs when a reconstituted immune system overreacts to the various pathogens in the body
- Protocols for prescribing ART in the absence of confirmed HIV infection according to the new recommendations.

Depending on the setting, it is best to establish one or several stable training teams that can move from one site or setting to another for training sessions, and provide ongoing supportive supervision. If HCWs are not supported by the tools and supervision they need to take on these new tasks, service quality will likely suffer and task-shifting strategies may falter. Program implementers must take preemptive steps to avoid these problems by developing competency-based training, supportive supervision and clinical mentoring, and strong mechanisms for quality management as described above. In addition, improved working conditions and compensation to retain newly trained pediatric HCWs should be considered.

Box 12. Training HCWs on the Follow-up of Infants Exposed to HIV through EID by DNA PCR Testing of DBS Specimens, CDC (see Tool 40).

Background: The Infant Diagnosis Working Group at CDC developed training materials for EID programs using DNA PCR testing of DBS specimens. These materials were designed for adaptation and use by resource-limited countries. Nigeria was the first to adapt this training tool for its use and the results of this pilot are presented below.

Intervention:

- Training was provided to 50 HCWs, primarily physicians, nurses, and laboratory scientists
- Training lasted 1.5 days plus an additional day of hands-on training

- Five different training modules were used, including scripts, slides, case studies, role plays, and step-by-step photo/video guides on DBS collection.
- Training topics included strategies for early identification of infants exposed to and living with HIV within the context of well-child care, promotion of HIV testing of children presenting to health care settings with signs and symptoms of HIV, and protocols on DBS collection, drying, and packaging.
- Methods of evaluation included participant before and after questionnaires, trainer informal focus groups, and on-site supervision and training of DBS protocols.

Results and lessons learned: Trainers found the materials and organization of the training package to be useful, but required a substantial amount of adaptation for the Nigerian protocol. The findings are as follows:

- Knowledge pre-/post-tests completed by 46 participants showed a 23.6 percent increase in correct responses post-training, shifting the mean score from 56.9 percent to 80.4 percent.
- Objectives with the lowest pre-evaluation scores included ability to correctly collect a DBS specimen from an infant, ability to assess the quality of a DBS specimen, and ability to correctly pack and store DBS specimens.
- More than 80 percent of HCWs successfully drew blood with one prick for a DBS specimen. Over 99 percent of these DBS samples were testable at the lab.
- HCWs were able to effectively implement and integrate the skills to actual clinical settings in Nigeria.
- Involvement of various professionals provided a rounded approach and perspective to EID training and implementation.
- Orientation of all staff working in key areas must be included in follow-up activities.
- Involvement of state/regional coordinators is extremely important for commitment, networking between laboratory and collection site, roll-out, and quality assurance.
- Flexibility in model: sites are operationally unique and plans and procedures differed during implementation.
- On-site training is extremely important as concepts in theory differ from the practical experience; schedule on-site demonstration/training of small teams for non-clinic days.
- Staff members showing excellent standards of practice can serve as master trainers in scale-up.

TOOLS AND RESOURCES



Tool 49: Guide to Implementation of Services for Early Diagnosis of HIV in Infants in Resource-Limited Settings, CDC and Global AIDS Program (2009). This five-module training curriculum on EID and infant follow-up is intended for midwives, nurses, doctors, and other health care staff. Following the training, staff members will be able to identify infants in need of testing, counsel caregivers before testing, and provide appropriate follow-up care

for infants and young children exposed to and living with HIV. They will also learn how to collect, handle, and send DBS specimens for EID. The fifth module is an interactive group exercise that evaluates and reinforces skills gained from the training.

<http://www.womenchildrenhiv.org/wchiv?page=ch-09-00-eid>



Tool 50: Diagnosis of HIV Infection in Infants: A Comprehensive Implementation and Clinical Manual, ICAP and Columbia University Mailman School of Public Health (2007).

This manual provides guidance for designing and implementing infant diagnosis programs at ICAP-supported programs. The manual is intended to provide guidance at the site level for nurses, physicians, counselors, and other health care providers caring for children exposed to HIV; in addition, it targets HIV program managers, health planners, laboratory technicians, and organizations responsible for program design, implementation, and M&E. <http://www.columbia-icap.org/resources/peds/files/Infantdx050307.pdf>

Additional pediatric resources: <http://www.columbia-icap.org/resources/peds/index.html>



Tool 51: HIV Curriculum for the Health Professional, Baylor International Pediatric AIDS Initiative (BIPAI) (2009).

This training curriculum is comprehensive and adaptable for all cadres of personnel on both clinical and community levels to improve the care of children. BIPAI has successfully used the curriculum to train physicians, nurses, psychologists, social workers, CHWs, pharmacists, laboratory technicians, and volunteers.

<http://bayloraids.org/curriculum/>

Dosing Chart for common pediatric ARV formulation according to weight:

<http://bayloraids.org/curriculum/files/DosingChart.pdf>



Tool 52: Integrated Management of Childhood Illness complementary course on HIV/AIDS, WHO and UNICEF (2006).

This training curriculum was developed to enable lower-level HCWs to more effectively identify children who have HIV and provide routine HIV care for children.

http://www.who.int/child_adolescent_health/documents/9241594373/en/index.html



Tool 53: Pediatric HIV Toolkit, BASICS and USAID (2009). This comprehensive toolkit includes assessment tools in integrating pediatric HIV into child health programs, job aids and tools, and pediatric HIV orientation manuals for frontline workers.

<http://www.basics.org/pediatric-hiv-toolkit.htm>



Tool 54: Dried Blood Spot Specimen Collection for HIV DNA PCR Testing for Infants: Training for Health Care Workers, International Training and Education Center on HIV (2007).

The aim of this two-day course is to train HCWs how to perform DBS specimen collection for HIV DNA PCR testing for infants. The course provides background information on DBS testing in Namibia, methods for performing the procedure, pre- and post-test counseling skills, and a hands-on practice session in the clinic or hospital setting.

<http://www.searchitech.org/itech?page=ff-07-02>



Tool 55: Community Home-Based Care for People and Communities Affected by HIV/AIDS: A Comprehensive Training Course for Community Health Workers, Pathfinder International (2006).

This curriculum aims to provide CHWs with the knowledge and skills necessary to provide community HBC to all PLWH in their communities.

http://bayloraids.org/toolkit/resources/Resource_No_5.pdf



Tool 56: Accompagnateur Curriculum, Partners In Health (2008). Recognizing accompagnateurs (CHWs trained and employed to provide medical and psychosocial

support for their neighbors) as the bridge between health clinics and the community, this training curriculum has two overarching goals: to help accompagnateurs develop competence in active case finding for diseases and social needs, and to instill a sense of solidarity and social justice in supporting patients, households, and the community.

http://model.pih.org/accompagnateurs_curriculum



Resource 31: Task Shifting: Global Recommendations and Guidelines, WHO

(2008). These recommendations and guidelines are primarily intended for countries that are considering adopting or extending a task-shifting approach to strengthen and expand the health work force for the delivery of HIV services. Countries that are considering adopting or extending a task-shifting approach are likely to be, but need not be limited to, those that are experiencing a serious shortage of human resources for health alongside a high HIV burden.

<http://www.who.int/healthsystems/TTR-TaskShifting.pdf>



Resource 32: Retention of Health Care Workers in Low-Resource Settings: Challenges and Responses, Technical Brief, The Capacity Project (2006).

Based on an intensive literature review, this technical brief considers challenges and responses related to retention of HCWs, including the causes of turnover, actions to address turnover, and emerging evidence on retention approaches. The brief considers retention primarily in the context of sub-Saharan Africa. http://www.capacityproject.org/images/stories/files/techbrief_1.pdf

INFORMATION, EDUCATION, AND COUNSELING AND COMMUNITY PROMOTION

Community misconceptions surrounding the transmission, diagnosis, and treatment of HIV in children affects demand for testing and treatment services. While information is a very powerful tool for promoting behavioral change, appropriate information needs to reach the designated targets and be in a form that will be understood. High rates of poverty and illiteracy in many resource-limited settings calls for the need of specially tailored IEC methods. Information on HIV is best disseminated through the local community structures as well as in the health facility in forms appropriate to the local culture and tradition.

It is critical that all primary and secondary caregivers are informed about the need and availability of pediatric HIV services. With the help of all stakeholders, program implementers should design and launch an IEC strategy to target caregivers of children living with HIV, as well as the children themselves. The strategy should involve the creation of fact sheets, pamphlets, and posters as educational tools, as well as community activities such as dances, dramas, and peer education for these target populations. The materials and activities should be available free of charge at health facilities as well as within the community.

TARGETING PREGNANT WOMEN

Program implementers should employ mothers with experience managing their own or their child's treatment and others living with HIV to provide support to mothers of infants and children living with HIV and to do outreach and informational services. Peer mothers living with HIV can be trained to identify, educate, and refer pregnant women from PMTCT programs, antenatal clinics, and the community to pediatric HIV CT services. Engaging in collective dialogue with mothers-in-law, elder ladies of the community, and TBAs can have a profound effect on the health-seeking behavior of women (see Resource 38).

TARGETING MALE PARTNERS

Because male partners have been shown to inhibit mothers from bringing their child to a health facility for testing and treatment, the exclusion of male partners limits the impact of programs aimed at treating pediatric HIV infection. Interventions that might support the positive participation of males in pediatric HIV testing and treatment include utilizing male HCWs and counselors and establishing “fathers’ clinics,” and other similar male-centered activities as an opportunity for education and peer support.

TARGETING INFANTS AND CHILDREN

In order to target exposed infants and children, programs should expand the use of all entry points to test infants and children. By using the existing child health programs and platforms, HCWs and CHWs should seek out children where they are (e.g., at home, at immunization visits, through orphans and vulnerable children programs, and HBC programs). Assessment of additional exposed siblings of the infant should also be done according to existing pediatric diagnostic algorithms to identify undiagnosed older children living with HIV.

The following resources are available to help programs implement, strengthen existing, or develop and promote new IEC materials for pediatric HIV services as well as guide counselors and peer educators in providing information for mothers, children, and families.

RESOURCES



Resource 33: Behavior Change Communication (BCC) Handbooks, Family Health International (FHI) (1994). This collection of eight handbooks, produced by FHI’s AIDSCAP project in 1994, introduces important concepts in BCC in simple, clear language. The booklets address policy and advocacy, partnership with media, preventing and treating STIs, using mass communication, creating effective communication projects, conducting effective pre-tests, creating effective peer education projects, and assessing and monitoring BCC interventions. <http://www.fhi.org/en/HIVAIDS/pub/guide/BCC+Handbooks/index.htm>



Resource 34: Lessons Learnt from IEC Programme Experiences, WHO (2005). Countries in Southeast Asia can benefit from the experiences gained within as well as outside the region. Learning from others allows program managers to initiate more effective strategies and communication approaches to assist behavioral change. Such lessons illustrate the importance of selecting appropriate communication approaches, of targeting education, and of integrating IEC with health and social services. http://www.searo.who.int/EN/Section10/Section18/Section356/Section424_1612.htm



Resource 35: Behavior Change Communication (BCC) for HIV/AIDS: A Strategic Framework, FHI (2002). FHI’s pragmatic BCC approach, based on sound practice and experience, focuses on building local, regional, and national capacity to develop integrated BCC that leads to positive action by stimulating society-wide discussions. This document outlines FHI’s BCC strategy for HIV. It has been developed for use by donors, partners, collaborators, and potential collaborators. <http://www.hivpolicy.org/Library/HPP000533.pdf>



Resource 36: Maternal and Newborn Care Practices Among the Urban Poor in Indore, India: Gaps, Reasons, and Program Options, Urban Health Resource Center and USAID (2008). This report, funded by USAID and presented by the Urban Health Resource Center, describes maternal-newborn care practices and care of infants aged 2 to 4

months in urban slum dwellings of Indore city, Madhya Pradesh (India). Strategies for supporting mothers and newborns include engaging in collective dialogue with mothers-in-law, elder ladies of the community, and TBAs. <http://www.uhrc.in/name-CmodsDownload-index-req-getit-lid-62.html>



Resource 37: Developing Materials on HIV/AIDS/STIs for Low-Literate Audiences, PATH and FHI (2009). This document can be used to develop BCC activities for the promotion of VCT for low-literate audiences. It provides modes and means of advocacy and marketing, materials production, and evaluation. It also includes training tools for counselors, a variety of advocacy methods and materials, a work plan and budget, as well as forms for pre-testing materials for focus group discussions.

<http://www.fhi.org/NR/rdonlyres/e2q7um2s2ffrtcjcesnjqhrgrt4bqawhrjqfreho2z23rc7lpxiuny3kekvsed4lg3sn5ocrpua3jn/lowlitguide2.pdf>



Resource 38: A Youth-Centered Counseling Model for HIV/STI Prevention and the Promotion of Sexual and Reproductive Health, Pan American Health Organization and WHO (2009). This document offers guidelines for achieving youth-centered counseling in the Americas, particularly Latin America and the Caribbean. The model draws on the following theoretical frameworks: client-centered counseling, the trans-theoretical model, goal-setting theory, motivational interviewing, and strengths perspective. The guide explains the essential components of each theory and how it is applied to sexual and reproductive health counseling.

<http://www.paho.org/english/ad/fch/ca/sa-youth.pdf>



Resource 39: Guidelines for Counseling Children who are Infected with HIV or Affected by HIV and AIDS, WHO (2009). This is a training guide for counselors who deal with CT for children living with HIV. There is a strong emphasis on dealing with the various psychosocial responses as well as disclosure issues. Advice on how to communicate effectively with children (at each age and stage of development), as well as what techniques can be used to draw out a child's feelings is incorporated into the guide.

<http://www.satregional.org/content/Publications/Skills%20Training%20E/CABA.pdf>

TREATMENT LITERACY AND ADHERENCE

Pediatric adherence guidelines must be developed that emphasize treatment literacy training targeted to caregivers of pediatric patients as well as the provision of medication administration tools and aids that will ensure the high levels of adherence. Pediatric adherence problems often occur when only a single caregiver is fully aware of and responsible for the child's medical needs. Thus, there must be a strong understanding of the nature of the family situation to ensure adequate support and understanding within the family about the importance of adherence to medication and clinical appointments.

ADHERENCE TO TESTING

After the initial blood test, families must return for test results as well as for subsequent testing depending on the results of the first test and decisions regarding infant feeding. If the first DBS PCR test is positive, a second test should be done for confirmation and results obtained. If the first DBS PCR test is negative, mothers and other caregivers living with HIV must be made aware of the need for follow-up testing for their infant in case of exposure during breastfeeding. A second test (either PCR or antibody) needs to be done after the child is weaned from breastfeeding according to the new recommendations. This must be made clear during pre- and post-test counseling and can actively be followed-up after cessation of breastfeeding through the use of CHWs and peer

counselors. In addition, testing needs of other children in the family should also be assessed during counseling. Note that some EID programs show very low return for result rates, and efforts to alleviate some of the burden on the caregivers, such as subsidized travel or a stipend to counterbalance missed work, might be worth consideration.

ADHERENCE TO TREATMENT

Once an infant or child is started on treatment, health care providers and caregivers of patients must be trained on the meaning and importance of adherence, as well as on dosing and swallowing of medications for infants. The provision of medication administration tools and aids should be required to assist counselors and caregivers. For example, clearly marked bottles, dosing syringes, and medication diaries can be used to counsel and help caretakers maintain high levels of adherence for their child. In the event that primary or secondary caregivers might be illiterate or innumerate, pictures, color-coded bottles, and pill charts should be employed. Pill charts are used to visually display pills/bottles (color and/or shape), names, and dosages for each medication and are used by health providers during counseling and have been found to be helpful in educating and aiding illiterate patients

As children mature, they should be age-appropriately counseled and educated about their disease, its treatment, and prevention of transmission. CHWs and counselors play a crucial role in helping children cope with their emotions. Because caregivers often refrain from telling children they are living with HIV well into adolescence, disclosure is often initiated by a HCW. Larger treatment programs for children should have disclosure programs to guide this process. Children will need to be educated about and may be involved in their own ART (Box 13). Health care providers and caretakers must decide what age-appropriate role the child will play in his/her treatment regimen. This role will depend on the child's understanding of the medications and his/her HIV status. The child may be able to appropriately dose medications, but should do so under adult supervision. Ongoing treatment literacy trainings should be conducted for children and teens to provide knowledge and skills to understand and manage their diseases appropriately. Topics should include beliefs toward HIV status, disclosure to others, treatment, care, opportunistic illnesses, nutrition, HBC, and the development of communication skills.

RETENTION IN CARE

Treatment literacy and adherence materials must also be tailored to address the importance of clinical follow-up. Because dosing of growing children is complex, regular follow-up of pediatric patients is imperative to maintaining effective treatment regimens. Possible side effects (SEs), triggers for seeking clinical follow-up, and where to go for clinical follow-up for SEs should also be addressed. Toxicities are also of concern and are more problematic for children in some cases, as children's bodies are still developing and children may be exposed to these drugs for much longer than adults. When initiation of treatment occurs at a very young age, caretakers must be made aware of signs and symptoms of adverse drug effects and understand the need to take the child in for clinical follow-up. As the child matures, he/she must be made aware of possible adverse effects with administration of these drugs.

Box 13. Implementation of a Comprehensive Program Including Psychosocial and Treatment Literacy Activities to Improve Adherence to HIV Care and Treatment for a Pediatric Population in Kenya

Background: A total of 1205 ART-naïve children living with HIV under 15 years of age in the Kibera settlement, Nairobi, were included in the program. A range of interventions were developed to promote ART adherence, including a child-friendly clinic environment, with toys, games, videos, and so on. Children were seen on a day dedicated to pediatric care. A pediatrician was available to attend to patients with complicated conditions, and group activities were provided for the children.

Intervention:

- Care of the entire family was provided at the same clinic.
- Group discussions regarding topics relevant to the parents or other adult caregivers were held on the days that children were seen at the clinic.
- Support also was enhanced by coordinating services with NGOs that could provide shelter or address other needs.
- Patients who missed appointments were contacted by phone or by a home or hospital visit.
- Special “fun days” were created in which staff, providers, caregivers, and children spent a day out together at child-friendly sites to strengthen the relationships between staff and patients/families.
- Numerous learning and counseling aids were developed.
- Individual therapy for adults, teenagers, and children and small groups for caregivers were also available.

Results and lessons learned: Of the 1205 children under care:

- Six hundred and fifty-seven (55 percent) initiated ART.
- Four hundred and fifty-two (69 percent) were still on ART in the following 11 months.
- Thirty-two (5 percent) had died.
- One hundred and six (16 percent) had transferred out.
- Sixty-seven (10 percent) were LTF.
- Seven children were switched to second-line therapy.
- The 12-month survival was 95.3 percent (95 percent confidence interval [CI]: 93.2–96.7) and the 24-month survival was 94.3 percent (95 percent CI: 91.9–96).
- Development and implementation of a child-centered approach to care and treatment of children and teenagers living with HIV is an important mechanism for improving adherence to ART and other aspects necessary for good clinical management of HIV disease.
- The program demonstrates the feasibility of implementing such a program in resource-constrained areas.

(Van Wingham et al. 2009)

TOOLS AND RESOURCES

The following tools and resources can be used to assist program implementers in adherence counseling and treatment literacy for mothers, caregivers, and children.



Tool 57: Adherence Counseling and Assessment of Patient's and Family's Neediness, BIPAI (2007). This questionnaire includes information on the family caregivers, treatment readiness, possible barriers to adherence and strategies to overcome these, and pharmacy literacy levels of caregivers.
http://baylorids.org/toolkit/tools/Tool_No_14.pdf



Tool 58: Community Health Workers, USAID (2009). These counseling cards are intended for health workers to use during sessions with prenatal and postpartum women living with HIV. Published in English and Swahili, the cards are tools that health workers can use to explain the risk of transmission of HIV from mother to child when no preventive actions are taken; infant feeding options for mothers living with HIV; the concept of acceptable, feasible, affordable, sustainable, and safe replacement feeding; and how to safely practice their chosen infant feeding method. <http://www.hciproject.org/taxonomy/term/433>



Tool 59: Adherence Education and Psychosocial Support Curriculum, BIPAI (2007). This 42-page curriculum is intended to assist health professionals in providing ongoing education and support to parents and caregivers of children living with HIV being treated with ARVs. The curriculum is designed to be used for a two-session adherence literacy course and ongoing clinic-based educational sessions. <http://baylorids.org/adherence/>



Resource 40: Implementation of a Comprehensive Program Including Psycho-Social and Treatment Literacy Activities to Improve Adherence to HIV Care and

Treatment for a Pediatric Population in Kenya, Van Winghein, J., B. Telfer, T. Reid, et al. (2008). The document describes the implementation of a variety of adherence interventions within a treatment program. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2613143/>



Resource 41: Adherence to Antiretroviral Therapy for Pediatric HIV Infection: A Qualitative Systematic Review with Recommendations for Research and Clinical Management, Simoni, J. M., A. Montgomery, E. Martin, et al. (2007). The document reviews over 50 documents and details methods for assessing adherence, and provides suggestions for best practices. <http://www.ncbi.nlm.nih.gov/pubmed/17533177>

INTEGRATIONS WITH EXISTING PLATFORMS

To get the most benefit out of EID, the entire MCH platform must be strengthened, integrated into pediatric HIV services, and supported by community-based care systems to ensure better case detection and follow-up of children exposed to HIV and their mothers. While integration must be encouraged at all levels of care, challenges may exist in ensuring infants and children exposed to HIV are both appropriately diagnosed and treated while also receiving basic primary and preventative care (i.e., vaccinations, nutritional support, etc.). The model of service delivery will differ depending on the setting and patient load. Programs may choose to integrate primary care into a pediatric center of excellence or may ensure that expansion of pediatric HIV/ART services is introduced and supported in the in the primary care clinic.

IDENTIFICATION OF INFANTS EXPOSED TO HIV

If possible, program implementers should conduct a system-wide assessment to determine where infants make contact with the health system after they are born. Linking infant follow-up for diagnosis, care, and treatment to PMTCT is a vital step in ensuring a continuum of care for infants exposed to HIV. Because treatment for children is often provided in a different clinic than where the mother received ANC or delivered, children exposed to HIV often go unrecognized when they present for early care. To facilitate prompt identification of infants exposed to HIV in the PMTCT setting, the mother's HIV status should be clearly indicated on her ANC card or chart, her handheld record if available, the child's health card (Box 14), or by other means. This should also include the PMTCT regimen received given the changes in treatment recommendations for infants living with HIV. In settings where coverage of PMTCT services is limited, vaccination programs hold great promise as an entry point for assessing infants, as well as mother, for HIV (see Box 11).

Several countries are starting to document the mother's HIV status on the child health card so that health workers can identify which children need additional HIV care and support. In these less traditional settings, identification of exposed infants can occur by review of the mother or infant health care where the mother's PMTCT status is documented on her and her child's health card or inquiring about the status of the mother. UNICEF is supporting countries to revise child health cards to include HIV-related information, making it easier to track exposed children and increasing the likelihood that they are referred for testing and early treatment if needed. Program implementers should contact their UNICEF country representative for assistance (www.unicef.org).

Adult care and treatment sites are also excellent opportunities to inquire about the HIV status and health of other family members, including children, and then facilitating HIV assessment of the family beyond the individual adult who is seeking treatment. Other opportunities to identify and refer infants and children with HIV include during hospitalization in pediatric inpatient wards, following deliveries by mothers who have attended PMTCT programs, and during visits by HBC

miss postpartum or MCH visits. ICAP representatives have recommended training a focal person at each site who would be responsible for following early identification of infants exposed to HIV, tracking them through diagnosis, and making certain that their results are delivered. These representatives would also ensure that the children are entered into care and treatment and that their families are counseled and linked to PLWH support groups. This linkage also needs to include ensuring that the mothers are also linked into care to ensure maternal health and to reflect new guidelines on the potential for maternal ART in PMTCT (WHO 2009).

Because the number of infants and children initiating treatment will likely increase dramatically on implementation of these services, treatment programs and protocols for addressing health concerns closely associated with HIV (e.g., diagnosis and care for TB in children) should also be strengthened and appropriately integrated into HIV and MCH services. Furthermore, to ensure maximum leveraging of resources while reaching as many mothers and children as possible, program implementers may consider the integration of opt-out antibody CT for all infants seen in MCH programs. Because testing remains expensive, using a rapid HIV antibody test to screen out negative results could reduce the number of samples that need to be collected and sent for PCR.

TOOLS AND RESOURCES



Tool 60: Pediatric HIV Toolkit, BASICS and USAID (2009). This comprehensive toolkit includes assessment tools in integrating pediatric HIV into child health programs, job aids and tools, and pediatric HIV orientation manuals for frontline workers. A guide for interviews for pediatric HIV case identification, referral, and care at the community level is also included. <http://www.basics.org/pediatric-hiv-toolkit.htm>



Resource 42: Improving Identification and Follow-Up of HIV-Exposed Children in Zimbabwe. This article reviews the introduction and use of child health cards in Zimbabwe, and includes lessons learned and recommendations for application in different settings. <http://ftguonline.org/ftgu-232/index.php/ftgu/article/view/2016/4028>



Resource 43: Child Health and Pediatric HIV/AIDS: A Brief Overview and Update, BASICS and USAID (2007). This technical background paper details information on providing nutritional care and support, regularly monitoring and promoting child growth, and ensuring good neonatal care for infants and children exposed to and living with HIV. http://www.basics.org/documents/pdf/Child_Health_and_Pediatric_HIV_and_AIDS.pdf

DATA MANAGEMENT

Once an infant exposed to HIV has been identified, another key challenge is keeping track of the child and matching any testing samples to the child. In Ethiopia and Tanzania, during the launch of the DBS program, regional NGOs and partners working at different levels developed an infant unique identifier system for identification, testing, and linkage of exposed infants them to treatment programs (Box 15).

On first identifying an infant exposed to HIV, each child should be given a unique infant diagnosis identifier (IDID) that is put onto the child's health card (tracking him or her through the various programs) and which is used to identify the child on all samples sent for testing (including repeat samples). This number is used to track the samples, and the system can include additional information relevant to the child or the program. Systems for documenting activities and recording infant diagnostic testing will need to be developed. Some systems may already be in place, while

others may need to be instituted at the site and the laboratory. It is key to ensure that any tracking system is fully integrated with previous efforts of the MOH and others in order to avoid parallel or duplicative reporting systems. Some of these systems are described below and examples of each can be found in Tool 62.

LIST OF INFANT DIAGNOSIS IDENTIFIERS

A list should be developed with the new IDID assigned to children at the site. A master list of numbers can be sent to the site with IDIDs to be assigned sequentially as testing is done or a list can be developed by assigning IDIDs based on the PMTCT number or other numbering system. The same IDID should be used each time a test is sent for a particular child. The list should include the IDID and basic information about the child: name, date of birth, gender, and other distinguishing information.

INFANT DIAGNOSIS REGISTER

In most settings, a new register will need to be developed to record infant diagnostic testing and accompanying information to be used for patient care as well as program monitoring. The register should include identifying information about the child (e.g., name, address, and date of birth) as well as data about testing (e.g., type of test, date, and result). It should also document whether a parent/caregiver has been informed of test results. In some settings, rather than establishing new registers, information on infant diagnostic testing may be incorporated into existing pediatric or PMTCT registers.

PATIENT MEDICAL RECORD

It is important to utilize a medical record system to record longitudinal information on the children receiving care. Clinical information that often changes over time (e.g., breastfeeding status, clinical findings, cotrimoxazole administration, adverse effects, and regimen changes) should be collected. In addition to a patient chart or forms, the handheld card for the mother and the child can also be modified to note that infant diagnostic testing was done and can include an IDID and test results if acceptable to the parent and community.

SPECIMEN LOG

An additional specimen log or checklist should be developed to record the IDID for all samples shipped to the laboratory. This form should accompany the samples to the laboratory, where it should be reviewed to assure that all samples are present and that results are sent to the clinic for each IDID on the log. If feasible, a duplicate copy should be kept on-site; this copy should be reviewed when results are returned from the laboratory in order to confirm that results were received for all samples that were sent. The results for each test should also be recorded in this log on receipt.

All systems for data collection and management should be designed to promote consistency and integration of all related services and departments, including PMTCT, VCT, care and treatment, and MCH clinics. HCWs should be adequately trained on the proper use of all forms and registers and the consistent use of established codes.

Box 15. Monitoring the Early HIV Infant Diagnosis Program in Tanzania

Background: The ICAP of Columbia University in collaboration with the MOH and Bugando Medical Centre are piloting an infant diagnosis program in the Lake region of Tanzania using DBSs for HIV DNA PCR testing. They aimed to establish an M&E system to track infants exposed to HIV for EID and referral to care and treatment clinics as appropriate.

Intervention:

- One hundred and four health workers at three sites were trained in identification of infants exposed to HIV, infants exposed to HIV testing algorithms, and drawing DBS samples.
- A paper-based M&E system was established including longitudinal infants exposed to HIV registers at each site, DBS laboratory request forms, specimen collection and results delivery logs, a laboratory register, two-way referral forms, and monthly summary forms to monitor the program at each site.
- A unique IDID was given at the time of registration of the exposed infant to identify and track infants exposed to HIV before they are referred to the care and treatment clinic.

Results and lessons learned:

- During a 12-week period, 245 infants exposed to HIV were identified.
- One hundred and seventy-eight (73 percent) were breastfeeding.
- Forty-five (18 percent) were less than 6 weeks of age; 88 (36 percent) were between 6 weeks and 6 months of age; 69 (28 percent) were 7 to 12 months of age; 23 (9 percent) were 13 to 18 months of age; and 8 (3 percent) were 19 to 24 months of age. One hundred and forty-two (58 percent) were referred from care and treatment clinics, 93 (38 percent) from PMTCT, and 7 (3 percent) from pediatric wards.
- All infants exposed to HIV who were older than six weeks of age were given cotrimoxazole and had DBS samples collected.
- Of the 186 (93 percent) infants exposed to HIV with DNA PCR results available, 24 (13 percent) tested positive, 161 (87 percent) tested negative, and 1 was indeterminate.
- Four deaths were reported among 24 DNA PCR positives, and none were reported in the PCR negative group. Parents of 13 (54 percent) infants exposed to HIV who tested positive and 81 (50 percent) of infants exposed to HIV who tested negative returned for follow-up.
- All 13 infants exposed to HIV who tested positive and received results were referred to care and treatment centers.
- Pilot stage data suggest that infants exposed to HIV can be successfully identified and tracked through the EID program using a paper-based monitoring system.

(Nuwagaba-Biribonwoha et al. 2007)

TOOLS AND RESOURCES



Tool 61: Diagnosis of HIV Infection in Infants: A Comprehensive Implementation and Clinical Manual, ICAP and Columbia University Mailman School of Public Health (2007). This manual provides guidance and examples for laboratory and clinical data collections and management. <http://www.columbia-icap.org/resources/peds/files/Infantdx050307.pdf>



Tool 62: Three Interlinked Patient Monitoring Systems for HIV Care/ART, MCH/PMTCT (Including Malaria Prevention During Pregnancy) and TB/HIV: Standardized Minimum Data Set and Illustrative Tools, WHO, UNAIDS, UNICEF, and The Global Fund (2009). The three interlinked patient monitoring systems build and improve on the original 2006 patient monitoring tools by supporting integrated service provision, follow-up of mother-infant pair, and monitoring of key TB-related and pediatric variables. The MCH minimum dataset includes all routine core maternal and infant variables plus key HIV-related variables. The generic tools are illustrative, for country adaptation, and include individual medical cards, registers, and reports. http://www.who.int/hiv/pub/imai/pmg_form_booklet_090907.pdf



Resource 44: Electronic Medical Record Systems, Data Quality and Loss to Follow-up: Survey of Antiretroviral Therapy Programs in Resource-limited Settings. Forster, M., C. Bailey, M. W. Brinkhof, et al. (2008). This article “describes the electronic medical databases used in antiretroviral therapy (ART) programmes in lower-income countries and assess the measures such programmes employ to maintain and improve data quality and reduce the loss of patients to follow-up.” <http://www.ncbi.nlm.nih.gov/pubmed/19142294>



Resource 45: Patient Monitoring Guidelines for HIV Care and Antiretroviral Therapy (ART), WHO, UNAIDS, and USAID (2006). These guidelines provide an agreed list of essential minimum standard HIV care and ART patient monitoring data elements and their definitions to assist programs in keeping a longitudinal record summarizing each patient's history, providing continuity of HIV care. <http://www.who.int/entity/hiv/pub/ptmonguidelines.pdf>

PATIENT TRACKING AND RETENTION

Procedures to find pediatric patients who have missed appointments and bring them back to the clinic will need to be strengthened. Each clinic will need to develop their own protocols to track and review appointment compliance, to prioritize patients for follow-up, and to find and engage the families back in care. All caregivers should be educated in the need and importance of adherence and retention, as well as how to recognize severe SEs, comorbidities, and the possible development of resistance. Infants receiving care at these sites will benefit from the development of follow-up systems and a shift of emphasis from episodic to continuous care during early childhood (see Box 17).

For example, if a child was ill at a previous visit or had signs suspicious of HIV infection, he or she would be prioritized to return to the clinic. Similarly, if HIV DNA PCR results are positive for a child who has not returned to the clinic, efforts should be made to engage that family as quickly as possible. In some settings, CHWs, NGOs, and peer educators have been engaged to track families in local communities; in other settings, where mobile phones are widely available, staff members call or SMS primary caregivers who missed visits to reschedule their appointment date. Home visits are

often necessary, particularly in impoverished settings where cell phones are not available (see Box 5). Because both forms of outreach require accurate and up-to-date contact information from caregivers, changes in phone number and address should be requested and noted at each routine visit. An example of a paper-based tracking system can be found in Tool 64.

Services provided under a family-centered continuum of care have shown to retain children in care and treatment. Family care case managers can be trained to assess, support, and coordinate retention for children and families/caregivers including linkage with community-based services (Box 16). The following tools and resources are intended to assist program planners in designing appropriate strategies to track and retain patients in the continuum of care.

Box 16. Keeping our Children Alive and Kicking: Improving Adherence and Retention in Pediatric HIV Care and Treatment Programs: The Vietnam Experience, FHI

Background: Developing appropriate care and treatment services for children infected with HIV in a low-prevalence setting is challenging. Many argue that given the relative rarity of pediatric HIV infection and the complexity of pediatric care and treatment, care should be provided in specialized pediatric referral centers. However children infected with HIV and their caregivers need comprehensive psychosocial support and focused adherence support to improve health outcomes and keep them in care. It is difficult to provide appropriate, community-level support when children and caregivers attend clinics far from home. Furthermore, it is plausible that adherence is optimized and LTF minimized when services are provided close to home

Intervention:

- FHI, supported by USAID and the U.S. President's Emergency Plan for AIDS Relief, worked with the MOH, provincial AIDS authorities, and district hospitals to establish pediatric HIV care and treatment sites in six district-level hospitals in Vietnam using a family-centered care approach.
- Extensive psychosocial and adherence support, including regular assessment and support for adherence in the home, is provided to children by a multidisciplinary team, including home-based teams, PLWH support groups, adherence counselors, and the family-centered care case manager.
- All are trained to provide age- and developmentally appropriate psychosocial and adherence support to children and families.
- A case manager provides ongoing holistic assessment of children and identifies those who need additional support such as food support, school enrollment, playgroups, and social welfare services.

Results and lessons learned:

- A total of 102 children are now registered across five family-centered care sites, and 60 are on ART.
- Of the 60 children on ART, 30 have been enrolled in the program for just over three years, and to date there has been no LTF of any of the children enrolled in care and support or on ART.

- Caregivers and health workers report excellent clinical and immunological outcomes, including high adherence and school enrollment rates as well as improved nutrition.
- PMTCT is now provided in all family-centered care sites, allowing for the smooth transfer of PMTCT infants into care and treatment services.
- Providing pediatric care and treatment services close to home in family-centered care sites with good community linkage facilitates good adherence and high rates of retention in care.
- Vietnam is now in a position to scale-up district-level pediatric care into existing adult sites using the family-centered care approach.
- There has been scale-up of DBS and DNA PCR to ensure that Vietnam is able to implement early treatment of infants living with HIV.

(Burdon et al. 2009)

TOOLS AND RESOURCES



Tool 63: Sample Patient Tracking Form, BIPAI (2008). This chart allows HCWs to track a patient through unique identifiers such as referral sources.
http://baylorids.org/toolkit/tools/Tool_No_18.pdf



Tool 64: Diagnosis of HIV Infection in Infants: A Comprehensive Implementation and Clinical Manual, ICAP and Columbia University Mailman School of Public Health (2007). This manual provides guidance and examples for follow-up systems, including appointment systems, monitoring appointment attendance, and follow-up of missed appointments. <http://www.columbia-icap.org/resources/peds/files/Infantdx050307.pdf>



Resource 46: Keeping our Children Alive and Kicking: Improving Adherence and Retention in Pediatric HIV Care and Treatment Programs: The Vietnam Experience, Burdon, R., P. N. Vu, P. T. Phan, et al. (2009). This presentation details adherence and retention programs in Vietnam, including efforts to date and suggested next steps. http://www.hivimplementers.com/pdfs/Session%2043/43_1260_Burdon.pdf

CONCLUSION

This toolkit was designed to provide technical guidance on the planning and implementation of the WHO recommendations through suggested activities, tools, and resources. Many more tools and resources exist for the activities described within this document, and each program manager, designer, and implementer of pediatric HIV services may have preferred options that were not included here. Our hope is that this toolkit will provide a framework to use when considering implementing the WHO pediatric treatment guidelines, as well as provide some helpful tools and resources to make the process as effective and efficient as it can be.

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