

## Moving Towards Expanded HIV Services for Children:

Readiness Assessment Checklist and Discussion Guide

IATT Toolkit, Expanding and Simplifying Treatment for Pregnant Women Living with HIV: Managing the Transition to Option B/B+ | www.emtct-iatt.org

#### 3.1 Background

In 2012, among 65 reporting countries, only 35 per cent of infants born to mothers living with HIV received an HIV test within the first two months of life and only one third of children living with HIV initiated treatment.<sup>1</sup> Compared to adults, paediatric ART coverage is quite low. The 2013 WHO *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection*, which recommends the initiation of lifelong ART for all pregnant and breastfeeding HIV-positive women (Option B+) provides an ideal opportunity to improve retention of the mother-infant pair within care, ensuring that all HIV-exposed infants receive a final definitive diagnosis and HIV-infected infants initiate ART. Given the significant gap between adult and paediatric coverage, this checklist outlines key programmatic considerations and priorities to ensure that children living with HIV are not left behind as efforts to eliminate MTCT of HIV are scaled up. This is particularly important, as improving HIV-free survival and providing universal treatment for children living with HIV are two of the primary targets in the Global Plan.

### 3.2 Purpose and Intended Use of the Tool

This document accompanies the HIV infant diagnosis and paediatric HIV treatment readiness checklist. It may be used to assess readiness by the health system to improve care and treatment for these children. This document is meant to explain in more detail in each of the following sections: political commitment and policy endorsement/roll-out strategy/ financial planning/service delivery model; human resource capacity; monitoring, evaluation and data use; site supervision and quality management; laboratory and clinical monitoring; antiretroviral regimen choice; supply chain management; identification and HIV testing for HIV-exposed infants; counselling on diagnosis, ART initiation and adherence; infant, child and adolescent diagnosis and treatment; retention in care and treatment; and family referrals and community involvement.

#### 3.3 Audience

The checklist is a tool that may be used by national and sub-national policymakers and programmatic leaders to review the steps needed to improve infant diagnosis and increase treatment coverage for HIV-infected infants and children.

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## 3.3 Systems Considerations

#### Political commitment and policy endorsement/roll-out strategy/ financial planning/service delivery considerations

This section of the checklist includes considerations that should take place at the central level regarding necessary policies and political endorsement to effectively rapidly scale up HIV testing, care and treatment services for children 0–19 years of age as well as financial, service delivery and human resource considerations for readiness. This checklist will be useful to government officials at the central, regional and district levels and highlights critical issues that need to be addressed to close the gap between adult and paediatric ART coverage.

It is recognized that successful programmes usually have one or more paediatric HIV 'champions' that continuously advocate for the goal of increased paediatric ART coverage and ensuring equal access to quality HIV services for children. This would be reflected in organizational structures if countries had full-time staff devoted to the paediatric HIV programme in their respective ministries who can lead active and goal-oriented activities of a nationally representative and diverse Paediatric Technical Working Group.

#### Human resource capacity

Because many areas where HIV-infection among children is prevalent have challenges in delivering paediatric medical care by paediatricians, an essential component for improving infant diagnosis and increasing paediatric HIV care and treatment coverage is assessing the national legislation and regulation regarding task sharing. Task sharing in this context includes nurse initiation and management of ART (NIMART) for children, pregnant women and adults. Addressing obstacles that limit or restrict expanded scopes of practice for appropriately trained professionals is critical. Absence of official sanctioning by the health ministry regarding task sharing (e.g., NIMART) results in a work environment without legal protections, thereby making the health workforce legally, professionally, ethically vulnerable for the services they provide.

Further assessing HRH capacity involves determining what kind of accurate workforce data is available to assist with program planning. Increasingly, countries are investing in human resources information systems (HRIS), which provide accurate, timely and comprehensive profiles of a country's workforce size, composition, and deployment patterns. When linked to broader health information – such as paediatric HIV disease burden, health services utilization and patient outcomes, HRIS can be a powerful tool for prioritizing health workforce deployment and resource allocation regarding workforce training in order to meet health system goals.



It is essential that core competencies for the regulated health workforce (e.g., nurses, doctors, clinical officers, laboratory technicians, etc.) are revised, updated and consistent with global HIV practices and standards, such as those defined in WHO's 2013 Consolidated ARV guidelines to diagnose, prevent and treat HIV. Planning for scale up of EID and paediatric ART involves outreach to relevant professional regulatory bodies in order to assess and ensure professional standards governing provider practices are consistent with paediatric HIV programme policies and protocols.

At minimum, a national training strategy for ART scale-up would include:

- · Prioritization of training resources to sites where scale-up activities are occurring;
- Assessment of provider training requirements so that in-service content appropriately targets need;
- Coordination of PEPFAR-implementing partners' training resources (including content, training venues, etc.) in order to avoid duplication of offerings and minimize gaps in coverage; and
- Evaluation of training experiences so as to ensure that the offerings are sufficient and adequately support sites providing scaled-up paediatric HIV services.

Significant investments have been made regarding in-service and pre-service training. In many instances, there has been little oversight or coordination regarding the nature of these investments. Review of these training curricula and ensuring consistency between in-service and pre-service offerings with the national HIV programme/policies is essential for maximizing and sustaining paediatric HIV scale-up efforts.

Ensuring that newly trained HIV providers remain engaged in paediatric HIV service delivery requires anticipatory planning to offset clinical practice challenges. As an example, as mid-level providers become increasingly engaged with initiating and managing paediatric HIV care, establishing appropriate referral systems and provider support networks offers a supportive environment for the newly trained mid-level clinician who may feel overwhelmed in assuming new responsibilities in patient care.

Most recently, a number countries have developed (or are developing) continuing professional development programmes (CPD), which are increasingly becoming a prerequisite for professional re-licensure. For example, Kenya's medical practitioners are required to renew their medical license annually and document specific CPD credits they have earned in a given year. Ensuring that CPD offerings contain updated information regarding paediatric HIV care is an effective strategy that enables practitioners to be apprised and updated in latest protocol recommendations.

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## **3.5 Implementation Considerations**

#### Monitoring, evaluation, data use and databases

To support infant diagnosis and paediatric HIV care and treatment services, the national HIV Monitoring and evaluation (M&E) framework tools should include information on children and routinely collect agreed upon indicators. The paediatric M&E priorities should include, for example: 1) strengthening routine paediatric programme monitoring; 2) ensuring high data quality; 3) supporting data use for evidence-based programme planning; 4) conducting programme evaluation and operational research; and 5) building M&E capacity.

The number of tools for routine monitoring should be kept as simple as possible. These tools can be either of an electronic or paper-based format, depending on the national resources. Some of these tools include:

- Mother and child pair longitudinal register: to collect information on infants' HIV exposure, DBS collection date, HIV test results and HIV final diagnosis, as well as information on linkages to clinical and non-clinical HIV services.
- Care and treatment register: to document cotrimoxazole prophylaxis administration, TB screening, ART initiation, ongoing ARVs provision and regimen, and information on linkages to other paediatric HIV clinical and non-clinical services
  - Child health card includes information on HIV exposure status, testing, and infection status and PMTCT ARV exposure, and similar card is provided to caregiver
  - Maternal health card includes information on HIV status and PMTCT ARV exposure
  - HIV-exposed and HIV-infected infant/child patient charts and registers link to maternal ART records and vice versa
  - A system for programme evaluation to detect early successes and challenges and to assess long-term paediatric outcomes allows for mid-course adjustments to better meet needs of children, their families, and the providers who serve them. The programme should aim to improve data quality, which can be accomplished through routine data quality assurance. At the end of the reporting period, collected information on key indicators should be aggregated, analysed, interpreted, summarized and widely distributed to stakeholders. The results should be used at each level from site (health facility, community) to national level to strengthen the national paediatric programme, including EID, assist in HIV commodities forecasting and planning strategies for scaling up national HIV paediatrics towards the Millennium Development Goals Monitoring, evaluation, data use and databases



#### Site supervision and quality management

Routine site supervision should be part of national management structures and should lead to actionable items for regular quality improvement (QI) and enable routine QI by sites. Malawi's routine site supervision system includes ministry, donor and implementing partner representatives and has been discussed widely for its completeness and value in reinforcing programme goals. Clinical mentoring could be provided within such a site supervision system, or could be performed outside it. Clinical mentoring is particularly valuable in early phases of decentralization or roll-out of new activities, to reinforce training and programme goals, and to provide support for decision-making by clinicians. Since infant diagnosis and paediatric HIV care and treatment may be perceived to require extra skills or knowledge, clinical mentoring may be particularly valuable in these early phases.

#### Laboratory and clinical monitoring

HIV-infected children require routine clinical and laboratory monitoring. At baseline, CD4 determinations are needed to determine treatment eligibility in clinically well children older than 5 years of age. Once on ART, children need to be monitored on a regular basis for two principal reasons: 1) to detect signs of drug toxicities related to ARV or other drugs that may be subclinical; and 2) to detect early treatment failures. In most paediatric HIV programmes, the use of second-line ART regimens is very limited and probably reflects the difficulties in identifying treatment failure by the use of clinical and immunologic parameters. Viral load is becoming, albeit slowly, increasingly available and should be used by clinicians to monitor children on ART. While data on how often and when to perform VL testing may not yet be available, algorithms for VL testing routinely after a period of time following treatment initiation or in the event of a clinical or immunological change can be considered.

#### Antiretroviral (ART) regimen choice

Paediatric antiretroviral drug preparations have increased in number, with further drug formulations expected to meet the unique dosing and acceptability needs of children. However, paediatric drug formulation availability is often negatively affected by small orders compared with adult drugs. Therefore, there is often a need for national HIV treatment programmes to rationalize drug formularies to ensure adequate supply and simplify treatment options. ART regimen choice must consider effectiveness, side-effect profile, availability, ease of administration, cost, and storage and distribution issues. Additionally, optimal regimen choices vary across age groups. Preferred ART regimens have been outlined in the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (please refer to <www.who.int/hiv/pub/guidelines/arv2013/download/en/> for more information).

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#### Supply chain management

Supply chain management is critical to ensure that necessary commodities are available at the point of care to identify HIV-exposed and infected infants, and translate into lifesaving paediatric HIV care and treatment interventions. This is increasingly important as services expand and ART regimens change with new guidelines. Personnel responsible for supply chain management are recommended to conduct the checklist items below, and also be familiar with paediatric HIV commodities, including testing supplies and reagents, and drug formulations in order to ensure a smoothly operating paediatric HIV care and treatment programme. HIV programme supervisors should be regularly updated on commodity forecasts, supply chain challenges, and strategies.

# Identification and testing of HIV-exposed infants and young children

Early diagnosis of HIV infection is essential for ensuring timely initiation of ART and reducing the high morbidity and mortality that occurs among HIV-infected children who do not receive treatment. In 2010, in response to emerging data showing dramatic survival benefits of early ART initiation among HIV-infected infants and children, WHO issued the revised 'Recommendations on the Diagnosis of HIV infection in Infants and Children' (<www.who.int/hiv/pub/paediatric/diagnosis/en/>). Key elements include:

- HIV virological testing to be used to diagnose HIV infection in infants and children below 18 months of age.
- All HIV-exposed infants to have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter.
- Infants with an initial positive virological test result to start ART without delay, and, at the same time, a second specimen to be collected to confirm the initial positive virological test result.
- Infants with signs and symptoms suggestive of HIV infection to undergo screening with HIV serological testing and, if positive, follow with virologic testing to confirm infection.
- HIV-exposed infants to undergo HIV serological testing at around 9 months of age (or at the time of the last immunization visit). Infants with reactive serological assays at 9 months should receive a virological test to identify HIV-infected infants who need ART.
- Children 18 months or older, with suspected HIV infection or HIV exposure, to have HIV serological testing performed according to the standard diagnostic HIV serological testing algorithm used in adults.

In 2012, among 65 reporting countries, only 35 per cent of infants born to mothers living with HIV received an HIV test within the first two months of life.<sup>2</sup> Initiation of lifelong ART to all

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pregnant and breastfeeding HIV-positive women (Option B+) provides an ideal opportunity to improve retention of the mother-infant pair within care, ensuring that all HIV-exposed infants receive a final definitive diagnosis and HIV-infected infants initiate ART.

HIV-exposed or infected children who aren't engaged in care during PMTCT have few opportunities for diagnosis and treatment; therefore testing and counselling in high-risk settings (provider-initiated testing and counselling [PITC] in in-patient facilities, malnutrition treatment clinics, tuberculosis clinics, children of adults on ART or TB treatment) remains one of the most common ways to identify HIV-infected children. Often these children are old enough (if older than 18 months) to undergo a rapid test, making quality assurance of and proficiency in use of rapid tests important. Using prevalence of positivity data from a variety of settings where children are universally tested, even for a short period, and diagnosed with HIV can prove very valuable in determining where additional testing would identify more children in need of treatment. Linkage to and retention in care has been a major challenge facing infant diagnosis and all PMTCT programmes, with numerous reports consistently demonstrating high rates of loss to follow-up along the PMTCT cascade. Therefore, assuring linkage from the testing settings to treatment settings is critical. This process can be facilitated if members of the same family are tested together and referred together.

# Counselling on infant diagnosis, ART initiation and adherence/HIV testing and counselling of all child-at-risk settings

When HIV-infected children are identified early, during the PMTCT cascade, they may not appear ill, therefore careful counselling on the benefits and possible side effects of initiating ART is useful for caregivers and will affect adherence. Factors that influence caregiver decisions regarding whether children initiate and continue with treatment include transportation costs, food availability, time constraints, perception that the child is healthy, perceived stigma, religious beliefs, and male partner support. Therefore, these issues should be addressed during counselling, nutritional needs assessed for those affected by HIV, and appropriate referrals made. In addition, as treatment is initiated (regardless of CD4 count among children aged less than 5 years who may not have benefited from PMTCT programs), disclosure among family members may need to be addressed prior to disclosure to children. Family disclosure is a noted and strong factor in family adherence; adherence is critical to the individual's health (maintaining an adequately suppressed viral load), but also for public health, since poor adherence may lead to resistance, use of second- and third-line regimens, and added costs.

#### Sample collection transport and return of results





Timely delivery of test results – including DBS for early infant diagnosis, rapid test results for confirmation of diagnosis and viral load monitoring – is critical for initiation of treatment. Delays in the turnaround time of results are common in many settings and contribute to loss to follow-up, whereby HIV-positive infants are not enrolled in treatment until they are sick. Developing a national strategy for establishing an efficient transport system for the country is an important step in addressing this challenge. The communication channels between testing laboratories, which may only be at the central or regional level and facilities where DBS samples are collected, should be fully defined and functional. Procedures for following up on discordant results, rejected DBS samples and missing results should be outlined, and both medical and laboratory stafforiented on these procedures. Tofacilitate this, many countries have increased the use of SMS technology such as printers and/or cell phones to facilitate the more rapid return of results to health facilities and caregivers. Quality assurance of paediatric HIV testing is important and refresher trainings should be considered for sites that consistently submit poor-quality DBS samples.

Facility capacity to monitor the infant HIV testing cascade to identify where significant drop-offs occur can improve programme performance and result in the timely recuperation of children at risk of not returning for results, confirmatory diagnosis and treatment and children already lost to follow-up. Expanding access to ART where PMTCT services are provided will reinforce linkages between diagnosis and treatment, as children are more likely to disengage from care if MNCH services, testing and treatment are offered at different facilities.

# Infant, child and adolescent HIV diagnosis and treatment

Principles for increasing treatment coverage include: 1) active case-finding for infected infants, children and adolescents; 2) implementing the new WHO guidelines for treatment of HIV in children; 3) linkage and retention of infants, children and adolescents into clinical care and treatment; and 4) enhanced training of health-care providers to build capacity for paediatric HIV testing, care and treatment and to monitor impact of training through quality improvement, supervision and mentoring support.

Active case-finding includes testing at appropriate ages until a final infection status is determined for HIV-exposed infants, PITC in high-risk settings, such as in-patient wards, malnutrition treatment clinics, tuberculosis clinics, and among children of adults on ART. Testing targets are recommended, especially in districts where PITC is not systematically applied.

Implementation of the 2013 WHO Consolidated ARV Guidelines includes:

- Ensuring implementation of universal ART initiation for all HIV-infected children under 5 years, regardless of CD4 count or percentage;
- · Ensuring that treatment guidelines for older HIV-infected children and adolescents (age 5

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years and older) are aligned with adult treatment eligibility criteria;

- · Setting aggressive numeric age-disaggregated treatment targets;
- Ensuring that paediatric HIV services are decentralized along with adult HIV services and made available at the lowest-level possible with skilled health-care providers;

and

• Ensuring consistent supply of efficacious, easy-to-use regimens with optimal paediatric formulations.

Updated ART eligibility criteria expands paediatric HIV treatment eligibility, while simplifying programmatic implementation by no longer requiring CD4 testing for ART initiation in children under the age of 5. The revised guidelines also align CD4 count thresholds for treatment in children 5 years and older with those for adults.

Retention and linkage of infants, children and adolescents in lifelong care and treatment is enhanced with the following activities:

- Collecting and analysing data with age disaggregation whenever possible to improve programme planning and identification of gaps in programme services; and
- Ensuring quality-improvement activities that address the challenges of following mother-infant pairs and loss to follow-up of children and adolescents.

Enhanced training of health-care providers to build capacity for paediatric HIV testing, care and treatment and to monitor impact of training through quality improvement, supervision and mentoring support improves programme quality and outcomes for HIV-exposed and HIV-infected children. Supporting national programmes to strengthen policy and regulatory mechanisms to build human-resource capacity for paediatric HIV services through task sharing is critical to increasing treatment access to districts without multi-level health-care infrastructure.

#### Retention in care and treatment

Health-care providers and systems play a critical role in retention. Patient or care giver satisfaction with health workers and health facilities can be aquality-improvement measure to increase retention. Providing training and redistributing the workload of providers will address lack of skills and reduce heavy workloads, which undermine relationships with patients. In addition, stigma and negative perceptions towards HIV-positive parents and children have reduced the numbers of mothers bringing their children in for diagnosis, care and treatment. Multiple sitelevel issues that influence retention of infected children in care and treatment programmes should also be addressed: clinic waiting times, understaffing, and in adequate clinical/laboratory services. Services that are bundled can address many of these issues, because cross-training can reduce workload and reduce stigma among health workers, and the 'one-stop shop' can reduce

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transportation costs and loss of time from work.

#### Family referrals/community involvement

The combination of various services needed to reduce paediatric HIV-infection morbidity and mortality may be provided by different partners through a continuum of service networks and through effective linkages between health facility, community and household. The overall goal of this linkage is to increase uptake of paediatric HIV testing, care and treatment services and improve long-term survival and retention of HIV-exposed/ infected children in care and treatment in order to thrive in adulthood.

At the family level: Family plays a fundamental role in the continuum of paediatric HIV care and treatment. Some of those roles include: connection to health facilities to access HIV testing, ARVs and other medications, adherence support, reporting side effects, ongoing engagement in health care for HIV-infected children and available services for children (e.g., visit to health facilities, services providing services for children affected by AIDS (OVC), nutrition, and immunization services).

At the community level: Community involvement will provide additional non-clinical services to families living with HIV-exposed/-infected or -affected children. Community organizations can support and guide families in need of HIV services for diagnosis, promote HIV de-stigmatization, and promote adherence to care and treatment to reduce lost to follow-up and family withdrawal from attending health facilities. Such organizations can also link families to additional services in the community (e.g., group and/or peer support services, social and economic assistance for children affected by AIDS, nutrition education, counselling services), and assist social workers to track families of children lost to follow-up or who self-withdraw from services. Community systems strengthening will ultimately increase the uptake of paediatric HIV services and significantly improve adherence and long-term retention.



#### Paediatric HIV Treatment Readiness Assessment Checklist: Moving Towards Expanded HIV Services for Children

The WHO 2013 Consolidated ARV guidelines recommend that all HIV-positive children younger than 5 years old should initiate ART, and that children aged 5–19 should initiate ART if they meet clinical criteria or have a CD4 cell count of  $\leq$ 500. Countries working to expand and strengthen their EID and paediatric HIV treatment programmes, including decentralization efforts or expansion of ART eligibility to any age, may find it useful to refer to this 'readiness assessment checklist', which addresses a range of issues, from national policy to facility readiness. The checklist and an accompanying discussion guide were developed by PEPFAR.

Key:	Before implementation Early	in implementation		During imp	lementation
SYSTEMS	SYSTEMS CONSIDERATIONS				
POLITICAL COMMITMENT AND POLICY ENDORSEMENT			COMPLETED	IN PROCESS	NOT YET STARTED
Commitme and sub-na ventions (d	nt to expand paediatric HIV services reflected in overall HIV/. tional) with inclusion of paediatric HIV advocacy messages a escribed below)	AIDS goals (national and package of inter-			
Full-time M collaboratic central, reg	inistry of Health staff responsible for paediatric HIV care and in with MNCH or Child Survival Units and HCT and Nutrition to ional and district levels	treatment (optimally in teams in the MoH) at			
Functional ers from Mi internationa health-care and adoles	baediatric HIV care and treatment technical working group (T NCH, laboratory services and other relevant areas within the I Il donors and non-governmental organizations (NGOs), repres worker (HCW) cadres, and organizations of people living with cents)	WG) includes stakehold- MoH, the private sector, sentative of various n HIV/AIDS (i.e., mothers			
National an count, and	d sub-national endorsement of ART for all children <5 years 5–19 years if CD4 ≤500, or other criteria based on national	irrespective of CD4 cell guidelines			
Updated N guidelines discussions	ational Paediatric HIV Care and Treatment Guidelines that real children <5 years and those 5–19 years if CD4+ $\leq$ 500) or son capacity and need to catch up to adult coverage	flect most recent WHO that reflect national			
Treatment of provincial a	coverage targets for children 0–14 years of age are included nd district plans	in national, regional,			
Updated pa plan to rapi through the services, in	aediatric HIV testing guidance and training materials accomp dly scale up the implementation of systematic PITC for child use of lay counsellors, nurses and other health-care provide patient and outpatient services, nutritional programmes and	anied by a strategic ren aged 0–14 years ers in postnatal care EPI			
National PN of mother-i HIV testing	ATCT guidelines address the importance of integrated and c nfant pair and includes latest WHO recommendations for infa	oordinated care ant and young child			
National tee • Collection • How to m • Further te • Screening or 12 mor • Routine H • Testing w	sting algorithm for HIV-exposed infants and young children a of DBS from 4–6 weeks of age for PCR testing anage an infant with positive PCR test indicating HIV infection sting of an infant with an initial negative PCR test to determin and testing of HIV-exposed infants initially identified at a lat ths of age IIV testing for final diagnosis >18 months and 6 weeks after ce ith presumptive treatment of clinically suspicious infants and	ddresses the following: on he final HIV status er age – e.g., at 6 ssation of breastfeeding d children			
National en children	dorsement of task sharing for collection of DBS and rapid te	sting of infants and			
National gu atric ART re	idelines and policy allow non-clinicians to initiate paediatric fills	ART and provide paedi-			
ROLL-OUT	STRATEGY		COMPLETED	<b>IN PROCESS</b>	NOT YET STARTED
Documente stakeholde	d national roll-out or scale-up strategy shared with impleme rs; regions develop strategies based on the national strategy	nting partners (IPs),			
Protocols f	or real-time evaluation of implementation to inform further so	ale-up complete			
FINANCIAL	PLANNING		COMPLETED	IN PROCESS	NOT YET STARTED
Costing of diagnosis f	routine testing of all children in high-risk settings, routine EID or all HIV exposed infants (HEI) <sup>a</sup> , and care and treatment stra	and reaching final attegy			
Costing of mens or ot	ART for all children <5 years, 5–15 years if CD4 $\leq$ 500, based her national plan	on selected drug regi-			
Conduct re	source gap analysis including recommendation on how to ac	ddress the existing gaps			
Increased p	programme funding needs reflected in budget				
Demonstra	tion of national and international financial commitment				

<sup>a</sup> According to WHO, infants and children born to mothers living with HIV until HIV infection in the infant or child is reliably excluded and the infant or child is no longer exposed through breastfeeding. For those <18 months of age, HIV infection is diagnosed by a positive virological test (HIV DNA or HIV RNA) six weeks after complete cessation of all breastfeeding. For a HIV-exposed children >18 months of age, HIV infection can be excluded by negative HIV antibody testing at least six weeks after complete cessation of all breastfeeding.

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SERVICE DELIVERY CONSIDERATIONS	COMPLETED	IN PROCESS	NOT YET STARTED
Minimum package of services to provide to HIV-exposed, HIV-infected children and adoles- cents is defined for each different level of the health-care system			
Systemcapacity (infrastructure, human resources, commodities) assessed and micro-planned for scal- ing up of paediatric HIV testing (including EID) and decentralizing paediatric ART to MNCH settings			
Timing and location of transition between MNCH and long-term treatment services determined (including consideration of lifelong ART provision within MNCH)			
Procedures for transfer of care during paediatric ART decentralization determined – i.e., categorization of patients requiring more specialized vs. routine care			
ProceduresfordeterminingHIVstatusofhospitalizedchildren,malnourishedchildren,childrenwithTB, and children of ART clients (family testing) and linkage to MNCH complete			
Procedures for treating partners and family members within MNCH			
Referral of stable ART clients at current ART facilities to new, decentralized ART sites			
HUMAN RESOURCE CAPACITY	COMPLETED	IN PROCESS	NOT YET STARTED
National endorsement of task sharing for paediatric HIV testing, ART initiation and mainte- nance on treatment			
<ul> <li>Assessment of human resource capacity (nurse, midwife, pharmacy, lab) to:</li> <li>Support ART scale-up among children</li> <li>Scale-up infant and young child HIV testing, as well as routine PITC to mothers during breastfeeding</li> </ul>			
Core competencies defined for each HCW in HIV management			
Implementation of training strategy for paediatric HIV provider-initiated testing and counsel- ling (PITC) and ART to support rapid scale-up of these services for children			
Updating of national in-service and pre-service curricula in PMTCT and ART for paediatric HIV testing, care and treatment, and disclosure			
Strategy for retention, in-service supervision, retraining and continuing professional develop- ment of health workers, especially for those providing paediatric HIV testing and ART			
ART REGIMEN CHOICE	COMPLETED	IN PROCESS	NOT YET STARTED
Optimization and rationalization of first-line regimen for infants, children and adolescents			
Plan for availability of lopinavir/ritonavir (Lop/r) for children <3 years old			
Plan for availability of efavirenz (EFV) for children >3 years old			
Simplification and harmonization of adult, adolescent and child (>3 years old) treatment regimens			
Plan for availability of a second-line regimen for all children that follows who guidance and best practices			
Establishment of pharmacovigilance system, where appropriate (see discussion guide)			
SUPPLY-CHAIN MANAGEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
Supply-chain gap assessment, including quantification, distribution and stock manage- ment, for testing supplies and ARV drugs at sites and reagents at laboratories (consider bulk procurement depending on demand, pooled procurement mechanisms) Systematic and consistent flow of data from the site and laboratory level to national level that informs accurate commodity forecasting			
<ul> <li>18-month forecast, quantification and supply plan developed</li> <li>Stock management of ART in MNCH settings (training, capacity, security)</li> <li>Sites and laboratories maintain appropriate buffer stock</li> <li>Knowledge of product specifications for EID, optimized sample collection materials (such as DBS bundles), product limitations (such as the short shelf life of EID reagents), appropriate delivery cycles</li> </ul>			
If modifying first-line regimen to lopinavir/ritonavir, plan for using ARVs which have already been procured <sup>b</sup>			
Revised supply-chain management system (consumption, forecasting and distribution) based on early evaluation			
IMPLEMENTATION CONSIDERATIONS			
M&E AND DATA USE	COMPLETED	IN PROCESS	NOT YET STARTED
Implementation of simplified medical records and registers for all mother-infant pairs, HIV- exposed infants and for HIV-infected children in pre-ART and/or ART, including updated tools to collect longitudinal data on paediatric HIV testing, paediatric pre-ART and paediatric ART			
Implementation of HIV-exposed maternal-infant card and child health card, both identifying the time of weaning from breastfeeding to identify ongoing exposure			

<sup>b</sup> For more information, please refer to the Updated Paediatric ARV Formulary List at http://www.emtct-iatt.org/wp-content/uploads/2014/04/IATT-Sept-2013-Updated-Paediatric-ART-Formulary-Report3.pdf

M&E AND DATA USE	COMPLETED	IN PROCESS	NOT YET STARTED
MCH register allows for documentation of key paediatric HIV testing and treatment indicators – e.g., infants receiving an HIV test initiation and already on ART for children			
ART register allows for documentation of key paediatric HIV care indicators – i.e., cotrimoxazole prophylaxis, TB screening and INH prophylaxis			
Tools/registers in MNCH and ART clinics allow for cohort monitoring of maternal ART retention, HIV-exposed infant retention, and outcomes in care			
Children initiated on ART in MNCH settings are included in site and national-level ART M&E systems			
$\label{eq:system} A system/protocolincludes paedia tric ART initiation in MNCH in district and national ARTM \& E systems and the system of t$			
System to track and measure linkages/transition between MNCH, exposure period and long-term HIV care and treatment for HIV-exposed and HIV-infected infants and children (linkages tracked, with unique identifier)			
Standardized appointment registers are used to strengthen identification of defaulting mother- infant pairs			
Programme evaluation designed to detect early successes and challenges, and to assess long-term infant and child outcomes			
Routine data quality assurance conducted Harmonization of MNCH and ART data-review processes			
<ul> <li>National standardized laboratory requisition form for PCR testing of DBS, which includes:</li> <li>Maternal and infant ARV exposure and infant feeding status included in forms</li> <li>Patient identifier to allow linkage, at the laboratory and at the site, of multiple samples from same infant</li> </ul>			
DATABASES	COMPLETED	IN PROCESS	NOT YET STARTE
Laboratory-based PCR testing data in each PCR laboratory, including clinical and demographic data from the laboratory requisition form, are stored in electronic database for ease of analysis			
Laboratories evaluate their PCR testing data at regular intervals for programme monitoring and planning purposes			
Databases from multiple national PCR testing laboratories can be merged to create a national database on PCR testing that is used to produce regular reports on national EID programme, as well as for national programme monitoring and planning purposes			
National infant HIV testing coverage can be calculated from site-based HIV-exposed infant registers or testing logbooks and laboratory-based electronic data	_		
Systems in place to link infants and mothers across multiple databases at site, laboratory, sub- national and national level			
SITE SUPERVISION AND QUALITY MANAGEMENT	COMPLETED	IN PROCESS	NOT YET STARTE
Routine site supervision and clinical mentoring for quality of care Continuous quality improvement process for paediatric PITC and ART in MNCH programme			
LABORATORY AND CLINICAL MONITORING	COMPLETED	IN PROCESS	NOT YET STARTE
Current geographical distribution of laboratories meets current and projected programme needs, with maximum efficiency of testing, and avoids redundancy of human resources or machine canceles.			
Capacity to provide early infant diagnosis using DBS (with reliable sample transport and result distribution) or point-of-care test in MNCH and ART clinics			
Capacity to monitor for common ART-related toxicities			
Availability of baseline CD4 (point of care, or reliable sample transport with result distribution)			
Innovative solutions to scale-up of infant HIV testing, including point of care early infant diag- nosis (EID) technologies (as these become available and are pre-qualified by WHO)			
Capacity to monitor response to treatment using viral load			
Evaluation of laboratory human resources, PCR testing capacity and platforms for concurrent scale-up of VL monitoring and infant HIV testing			
Capacity to screen for or diagnose common paediatric opportunistic infections (e.g., malaria, tuberculosis, cryptococcus, etc.)			
LABORATORY QUALITY ASSURANCE MEASUREMENTS FOR PCR TESTING OF DBS	COMPLETED	IN PROCESS	NOT YET STARTE
Routine monitoring of DBS sample quality			
Routine running of quality controls while conducting PCR testing			
Implementation of policy for re-testing the following sample PCR results in the laboratory as part of internal laboratory measurements: positive PCR, equivocal PCR, negative PCR			

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LABORATORY QUALITY ASSURANCE MEASUREMENTS FOR PCR TESTING OF DBS	COMPLETED	IN PROCESS	NOT YET STARTED
Participation in an in-country or an international external quality assurance (EQA) programme			
Implementation of SOPs for equipment maintenance and calibration			
Adherence to biosafety policies			
PCR results are reviewed and signed by supervisor/laboratory director before being reported			
IDENTIFICATION AND SCREENING FOR HIV-EXPOSED INFANTS AND YOUNG CHILDREN	COMPLETED	IN PROCESS	NOT YET STARTED
Infants and young children are routinely screened for HIV exposure and HIV infection at: • Immunization clinic (EPI) • Under 5 clinic • At risk child consultation • MNCH clinics • OPD • TB clinics • Malnutrition clinics • HIV/ART clinic • In-patient wards			
Integration of infant and young child HIV testing into all MNCH services			
Implementation of routine provider-initiated HIV testing and counselling (PITC) of mothers post-partum			
COUNSELLING ON INFANT TESTING, ART INITIATION AND ADHERENCE	COMPLETED	IN PROCESS	NOT YET STARTED
Enhanced counselling at ANC regarding importance of repeat HIV testing of infants and young children until six weeks after cessation of breastfeeding Specialized messaging and support services for caregivers of infants and children initiating			
ART			
Developmental approach to child-focused HIV counselling incorporated in ART counselling			
services (testing, disclosure and adherence support) Alternative protocols developed for children whose caregivers decline HIV testing or treat- ment initiation			
Protocols developed for disclosure, and incorporated into routine-care algorithm			
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RETENTION IN CARE AND TREATMENT	COMPLETED	IN PROCESS	NOT YET STARTED
Strategies to improve retention of HIV-exposed and HIV-infected infants include community outreach, peer support groups, escorted referrals, family clinics, integrated services and coordinated appointments with mother and infant			
Retention of HIV-exposed infants through end of breastfeeding, including ascertainment of final diagnosis			
System to ensure that all HIV-infected children are enrolled in ongoing HIV care and, if eligible, treatment			
Strategy and implementation plan for nutritional assessment, counselling, and support			
Models of service delivery that consider harmonized/bundled follow-up and co-appointments for infected mothers and their children (post-partum, immunization, TB screening, well-child clinic and nutrition services, etc.)			
Facility and community-based services to track defaulting mother-infant pairs throughout breastfeeding period, children receiving treatment and to support adherence			
FAMILY REFERRALS	COMPLETED	IN PROCESS	NOT YET STARTED
Linkage between all services providing infant and young child HIV testing and paediatric ART services using systems such as triplicate referral forms, patient escorts, use of unique patient ID numbers recorded at referring and receiving service, appointment registers, designated staff to follow up on all HIV-infected infants and children			
Strategy, implementation and evaluation plan to provide HIV infected women, their children and families with economic and social protection services			
Refer infected women and all of their children to social services and community-based support			
COMMUNITY INVOLVEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
Families living with HIV are engaged in the planning, implementation and monitoring at national, sub-national and community levels			
National communication strategy for 2013 WHO Consolidated ARV Guidelines includes infant and young child HIV testing messages			
Community-based activities and services support HIV treatment scale-up and retention for children			



#### Resources

1 World Health Organization, *Global Update on HIV Treatment 2013: Results, impact and opportunities,* WHO, Geneva, 2013.

2 Joint United Nations Programme on HIV/AIDS, *A Progress Report on the Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive*, UNAIDS, Geneva, 2012.