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HIV Rapid Test Quality Assurance Checklist

4.1 Background

The past decade has seen a rapid global scale-up of HIV testing and counselling (HTC), the vast majority using HIV rapid tests (HIV RT). The relative simplicity of HIV RTs has expanded the accessibility of HIV testing in areas with limited laboratory facilities and no formal laboratory trained staff, thereby significantly increasing the number of persons who learn their HIV status. As the provision of antiretroviral therapy (ART) for all pregnant and breastfeeding women and for all children <5 years of age is scaled-up, there is an increased need to ensure the quality of HIV rapid testing and address common service delivery issues regarding HIV testing in maternal, newborn and child health (MNCH) clinics.

4.2 Purpose and Intended Use of the Tool

The purpose of this checklist is to facilitate the process of thinking through key HIV RT quality assurance (QA)[1] and programmatic issues needed to improve HIV rapid testing in MNCH settings. This document expands upon the Option B/B+ Readiness Assessment Checklist and offers more detailed recommendations on specific HIV testing activities.

4.3 Audience

This checklist will be useful for public health authorities, programme managers and laboratory technicians at the central, regional and district levels when planning for and establishing minimum standards and requirements for the quality assurance of HIV rapid testing in MNCH programmes.

4.4 Introduction

The World Health Organization *2013 Consolidated Guidelines on the Use of Antiretrovirals for the Treatment and Prevention of HIV Infection* recommended the provision of ART for all HIV-positive children <5 years of age and for pregnant and breastfeeding women living with HIV. Consequently, ART initiation is based solely on the result of the HIV RT for pregnant and breastfeeding women and for children 18 months – 5 years of age (children <18 months have PCR as their diagnostic HIV test). Misclassification (false positive or false negative) of HIV RTs can occur due to inherent limitations of the HIV RT, use of expired test kits, deviation from the national testing algorithm, (including a screening test, confirmatory test and tiebreaker), or any deviation from the HIV RT standard operating procedure. Responsible programming demands the implementation of QA systems to ensure the accuracy of HIV test results. In particular, it is important that HIV-negative women and children are not mistakenly initiated on lifelong ART, and that women and children living with HIV do not miss PMTCT and ART treatment opportunities due to misdiagnosis.

The following areas need to be addressed to assure the quality of HIV RTs: 1) a national policy for HIV RT QA; 2) standardized HIV RT training and national certification programme for testers;[2] 3) the regular use and review of a standardized HIV RT QA logbook;[3] 4) the implementation of a national HIV RT proficiency testing programme;[4, 5] and 5) the routine use of quality control (QC) samples. It is critical that all MNCH sites adopt these policy and QA activities to ensure the accuracy of HIV test results.

HIV Rapid Test Quality Assurance Checklist for MNCH Settings

Key: ▢ Before implementation ▢ Early in implementation ▢ During implementation

POLICY ENGAGEMENT	COMPLETED	IN PROCESS	NOT YET STARTED
National guidelines for laboratory quality assurance in HIV rapid testing (including proficiency testing and the use of a standardized HIV RT QA logbook)			
Costing and budget allocation for QA activities			
National technical working group (TWG) inclusive of stakeholders from MNCH, PMTCT, HIV treatment and laboratory to review HIV testing strategies and ensure the national HIV testing algorithm follows WHO guidance			
Implement mechanisms to address rapid test kit stock-outs, expired test kits and recalls			
Policy decision on the treatment of discordant couples			
Include RT QA monitoring in all site supervision visits			

TRAINING AND CERTIFICATION	COMPLETED	IN PROCESS	NOT YET STARTED
National policy requiring training, periodic re-training and certification of HIV testing personnel			
HIV testing training curricula incorporated into all pre-service and in-service ART and PMTCT trainings and including the use and analysis of standardized QA logbooks and proficiency testing			

USE OF STANDARDIZED LOG BOOK	COMPLETED	IN PROCESS	NOT YET STARTED
Standardized HIV logbook or register used to capture key HIV testing data (e.g., kit names, lot #, expiration dates, and result of each test in the algorithm)[a]			
HIV testing logbooks or registers harmonized *across* programmes and used at all sites (e.g., HTC, PMTCT, inpatient, etc.)			
Ensure that clinical site staff and site supervisors review standardized logbook data and perform corrective actions as needed			

PROFICIENCY TESTING AND QUALITY CONTROL	COMPLETED	IN PROCESS	NOT YET STARTED
Proficiency testing (PT) and quality control (QC) programme is in place to monitor the competency of all testing personnel and sites with dried tube specimens (DTS) or plasma			
PT programme data are used to provide timely feedback and corrective actions to the testing sites			

SERVICE DELIVERY	COMPLETED	IN PROCESS	NOT YET STARTED
Strategy for repeat testing during pregnancy/labour and delivery and during the breastfeeding period developed and implemented			
Strategy for HIV testing for older children of HIV-positive pregnant and breastfeeding women developed and implemented			
Partner testing and disclosure assistance services available for all pregnant and breastfeeding women			
Strategy to provide ART to HIV-positive male partners developed and implemented			
Implementing universal HIV screening at immunization clinics in high-burden settings			

[a] Revision of existing registers to include key HIV RT QA elements is an acceptable alternative.

Resources

1   Parekh, Bharat S., et al., 'Scaling Up HIV Rapid Testing in Developing Countries: Comprehensive approach for implementing quality assurance', *American Journal of Clinical Pathology*, vol. 134, no. 4, October 2010, pp. 573–584.

2   World Health Organization, 'Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a quality system approach', WHO, Geneva, 2005, available at <http://whqlibdoc.who.int/publications/2005/9241593563_eng.pdf?ua=1>.

3   World Health Organization, 'A Handbook for Assuring and Improving HIV Testing and Counselling Services: Field-test version', WHO, Geneva, 2010, available at <http://whqlibdoc.who.int/publications/2010/9789241500463_eng.pdf?ua=1>.

4   Parekh, Bharat S., et al., 'Dried Tube Specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings', Journal of Virological Methods, February 2010, vol. 163, no. 2, pp. 295–300.

5   Benzaken, Adele Schwartz, et al., 'External Quality Assurance with Dried Tube Specimens (DTS) for Point-of-Care Syphilis and HIV Tests: Experience in an indigenous populations screening programme in the Brazilian Amazon', Sexually Transmitted Infections, vol. 90, no. 1, February 2014, pp. 14–18.

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