THE RAPID
SYPHILIS TEST
TOOLKIT

MANAGEMENT 4

Return to last page viewed

Management and Implementation of Rapid Syphilis Test Introduction: A Programme Manager's Guide

London School of Hygiene & Tropical Medicine · CIDRZ · CDC · ciSne · Fundação Alfredo da Matta · National Institute for Medical Research · Les Centres GHESKIO · SDI · Elizabeth Glaser Pediatric AIDS Foundation · SD Syphilis Screening Program · Universidad Peruana Cayetano Heredia · TDR For research on diseases of poverty UNICEF • UNDP • World Bank • WHO

Management and Implementation of Rapid Syphilis Testing Introduction: A Programme Manager's Guide

Return to last page viewed

Contents

Additional References

Laboratory-based evaluation of rapid syphilis diagnostics: Results from 8 SDI Sites
http://www.who.int/std_diagnostics/publications/manuals/syphilis_evaluation.pdf
Evaluating diagnostics: STIs
Evaluating Diagnostics: A guide for diagnostic evaluations
Evaluating Diagnostics: Evaluation of diagnostic tests for infectious diseases: general principles
Evaluating Diagnostics: Evaluation of rapid diagnostic tests: syphilis
Evaluating Diagnostics: Why do we need quality-assured diagnostic tests for sexually transmitted infections?

Hyperlinks

Please note that hyperlinks within this document are indicated by **text underlined** and **emboldening.**

Return to last page viewed

Abbreviations

ANC: Antenatal Care

ASSURED: Affordable, Sensitive, Specific, User- friendly, Robust and rapid, Equipment-free, Deliverable to those who need them

CSW: Commercial sex worker

EIA: Enzyme Immuno Assay

FTA-ABS: Fluorescent Treponemal Antibody Absorption Assay

IDU: Intravenous drug user

MCH: Maternal and Child Health

MOH: Ministry of Health

MSM: Men who have sex with men

NGO: Non-governmental organization

NPV: Negative Predictive Value

PMTCT: Prevention-of-Mother-to-Child-Transmission

PPV: Positive Predictive Value

QA: Quality Assurance

QC: Quality Control

RCH: Reproductive and child health

RPR: Rapid Plasma Reagin

RST: Rapid Syphilis Testing

STAT: Same-day-Testing-And-Treatment

TPHA: *Treponema pallidum* Haemagglutination Assay

TPPA: *Treponema pallidum* Particle Agglutination Assay

VDRL: Venereal Disease Research Laboratory

WHO: World Health Organization

Return to last page viewed

Executive Summary

There are many reasons to introduce rapid syphilis testing into clinical practice and within existing programmes in your country. These include increasing access to prenatal screening programmes to prevent congenital syphilis; controlling syphilis in high-risk populations; and performing an epidemiological survey to assess the syphilis burden in a population.

This guide is intended to assist programme managers in coordinating all aspects of the introduction and management of a rapid syphilis testing programme irrespective of the target population. This tool will guide a programme manager through each component of a rapid syphilis testing program, summarizing the key points of each and providing references to more in-depth documentation to be found in other chapters of this Toolkit.

Purpose of the document

This document should provide programme managers with the ability to:

- Document the key stages and critical components of the introduction of a rapid syphilis testing programme.
- Detail the processes to be undertaken when implementing rapid syphilis testing.
- Highlight the interaction between processes and the connectivity between all components of the programme.
- Provide a tool to assist in coordinating the implementation of a rapid syphilis testing programme.

Intended Target Audience

This document is intended to provide guidance to programme managers working for non-governmental organizations (NGOs), the Ministry of Health (MOH), or other bodies, programme managers responsible for introducing rapid syphilis testing, and/ or programme managers managing the programme post-implementation.

Return to last page viewed

How to use this document

This document is divided into 2 key sections. Section 1 details all activities involved in planning the introduction of a rapid syphilis test (RST) and Section 2 details the activities involved in implementing a rapid syphilis test programme. Together, this document should illustrate all of the major aspects of rapid syphilis test introduction that will be coordinated and managed by the Programme Manager.

The document is designed to be used in a chronological fashion, beginning with the Planning Stage for introduction of rapid syphilis tests through to monitoring and evaluating the effectiveness of a rapid syphilis testing programme.

Section 1 outlines the planning stages that a Programme Manager needs to consider before introducing a rapid syphilis test.

Section 2 outlines the activities necessary to roll out the rapid syphilis tests.

All related guidance tools that are included in the Rapid Syphilis Testing Introduction Toolkit are referenced throughout the document and the reader should refer to these Tools for additional information.

Primary health centre in Western Province, Zambia

Return to last page viewed

Overview of Rapid Syphilis Testing Program

The goals and objectives of rapid syphilis test introduction will have been determined in the earlier stages of planning (refer to **Planning 1 - Advocacy and Communications Strategy.**

As an example, the overarching goal of a rapid syphilis testing programme might be:

- The reduction of the prevalence of active syphilis infection, thereby leading to reductions in the transmission and incidence of disease
- The performance of a serological survey to determine the prevalence of syphilis in a defined geographic area and/ or among a defined population.

The objectives of such a programme will vary depending on the target population. This might be pregnant women; men who have sex with men (MSM), intravenous drug users (IDUs); commercial sex workers (CSWs); or a mobile or transient workforce.

One objective of a potentially successful rapid syphilis testing programme should be the provision of same-day-testing-and-treatment (STAT). A test result turnaround time of between 20 and 30 minutes (depending on manufacturer's instructions) is one of the greatest benefits of rapid testing. It should be capitalized upon with the offer of immediate treatment services for all individuals identified as positive.

Same-day-testing-and-treatment is also applicable to programmes whose goal is to determine the prevalence and risk factors of syphilis in a region or in a population; it would be unethical to diagnose patients but not to offer appropriate treatment.

Same day testing and treatment in remote communities in the Amazonas state, Brazil

Return to last page viewed

1. Planning

1.1 Stakeholder Engagement

Interaction with stakeholders should be an ongoing, continuous process. Whether communication takes the form of written reports, informal conversations or annual meetings, stakeholders will be more interested and more invested in a programme if they are consistently reminded of its progress and its successes. Engaging with local stakeholders may become part of your routine activities and will likely be more in-depth, with discussions focusing on the daily challenges of programme implementation. Engagement with national and international stakeholders may take the form of dissemination of interim reports and interaction at large-scale conferences. Both instances should be briefly documented and should include the participants, topics and outcomes and programme timelines. See **Planning 1 - Advocacy and Communications Strategy** for more information on stakeholder engagement.

Refer to **Planning 1** **for guidance on engaging stakeholders** and **Planning 2** **for guidance on mobilizing and maintaining stakeholder interest.**

1.2 Financing the programme

You should prepare a budget estimating the cost of introducing a rapid syphilis test into current services. This should include all inputs required for the programme, including human resource requirements, operations and transportation requirements, and key supply requirements.

Implementation 1 - The Costing Guidelines for Syphilis Screening Strategies of this Toolkit provides a detailed set of guidelines on costing a rapid syphilis testing programme, including detailed questionnaires and calculations for estimating costs. These guidelines will allow you to:

- Estimate the total and average incremental cost of adding rapid syphilis testing to existing services
- Estimate the unit cost (e.g. cost per person treated) to understand the incremental cost of increasing access to treatment.
- Approximate the cost-effectiveness of the model

> **To ensure sustained delivery of syphilis sreening,** interventions must prove they are cost-effective relative to the alternative syphilis screening strategies and or competing health interventions at the local/national level.

Return to last page viewed

1.3 Choosing a Test

Evaluation of test methods:

Before any bulk procurement of rapid syphilis tests is made by your government or the donor agency that is funding the rapid syphilis test programme, a lab- or field-based evaluation of rapid syphilis test kits should be performed by the national reference laboratory or appropriate body, in accordance with national regulations. In order to assure availability of kits for testing, it will be necessary for each country to have checked the validity of and approved several rapid test kits for use in the country.

The Ministry of Health should establish a national policy regarding the appropriate tests to use and an approved algorithm for testing. Refer to Refer to **Laboratory based evaluation of Rapid Syphilis Tests (Manual of Operations)** for guidance on performing an evaluation of rapid syphilis tests.This methodology can be adopted for other diagnostic tests. Refer to Rapid Syphilis Testing Algorithms **Management 3** for guidance on developing testing and treatment algorithms for syphilis screening and treatment.

1.3.1 Types of tests

There is a range of diagnostic tests available to detect syphilis infection that depends on either direct visualization of T. pallidum or detection of specific and nonspecific antibody responses. **Table 1** summarises the operational characteristics of the various diagnostic tests currently available for the diagnosis of syphilis.

The requirement for additional equipment and refrigeration creates barriers to screening. Recognition of these constraints led to the evaluation of several rapid point-of-care (POC) tests based on the acronym ASSURED (Affordable, Sensitive, Specific, User- friendly, Robust and rapid, Equipment-free, Deliverable to those who need them).

The introduction of rapid tests enables health systems to expand screening programmes to include facilities without refrigeration while the rapid test results minimize losses to follow-up.

ASSURED criteria for point of care tests

Affordable
Sensitive
Specific
User- friendly
Robust and rapid
Equipment-free
Deliverable to those who need them

Reference: Peeling, R.W., Mabey, D., Herring, A. Hook, E.W. (2006). Why do we need quality-assured diagnostic tests for sexually transmitted infections? Nature Reviews Microbiology 4, 909-921

Return to last page viewed

Table 1. Serological tests for syphilis

Serology Tests	Target Antigen	Utility (confirm or screening)	Operational Characteristics
Non-treponemal			
Rapid Plasma Reagin (RPR)	Cardiolipin	Screening or marker of active infection	Cheap and simple agglutination test performed on a card and read by eye. Requires a simple rotator. Serum/ plasma sample. Need to screen 2 dilutions because of prozone effect. Experience necessary for reading.
Venereal Disease Research Laboratory (VDRL)	Cardiolipin	Screening or marker of active infection	Agglutination test. Requires a shaker and a microscope to read the test- a simple laboratory test. Serum/plasma sample. Need to screen 2 dilutions because of prozone effect. Experience necessary for reading.
Rapid non-treponemal	Immobilized cardiolipin	Screening or marker of active infection	Immunochromatographic strip or filter paper format. No equipment required. Serum or whole blood sample. Result in 30 mins. Basic training only needed for reading.
Treponemal			
Treponema Pallidum Haemagglutination Technique (TPHA) and Treponema Pallidum Particle Agglutination test (TPPA)	Lysed spirochaete bound to blood cells or microparticles	Screening or confirmation of syphilis in non-treponemal positives.	Agglutination test in microplate format. Requires equipment and refrigeration. Expensive. Technical expertise required. Reference laboratory test.
Enzyme immunoassays (EIA)	Recombinant treponemal antigen	Screening or confirmation	Antigen-antibody reaction with the treponemal antigen fixed onto the wells of 96-well microplates. Requires incubators, micropipettes, washer and reader. Objective readout and high throughput capacity.

Return to last page viewed

There are many commercial rapid syphilis tests available on the market. Given the high cost of field trials, a triage step to select a limited number of the most promising tests for field trials is necessary. This can be performed as a laboratory-based evaluation of test performance and reliability using archived serum specimens from diverse geographic locations. Alternatively, it can be done through field trials of test performance, utility in disease control and prevention, and acceptability to patients and care providers. This document is available here **http://www.who.int/std_diagnostics/publications/manuals/syphilis_evaluation.pdf**

The Laboratory-based evaluation of rapid syphilis tests (Manual of Operations) outlines the methodology and outcome of a laboratory-based evaluation of 6 commercially available rapid syphilis tests. The methodology outlined in this report can be adapted for country specific laboratory-based evaluation of rapid syphilis tests. **Management 3** provides guidance on how to integrate rapid syphilis testing into clinical practice. It presents algorithms for syphilis screening using rapid syphilis tests on their own, or in combination with other treponemal or non-treponemal laboratory tests such as rapid plasma reagin, *Treponema pallidum* Particle Agglutination assay or *Treponema pallidum* Haemagglutination assay.

1.3.2 Operational and Performance Characteristics

When performing an evaluation of rapid syphilis tests, you should assess the following operational and performance characteristics:

- **Sensitivity:** the proportion of persons with the disease/ condition (true positives) who are correctly identified as being positive by a diagnostic test.
- **Specificity:** the proportion of persons without the disease/ condition (true negatives) who are correctly identified as being negative by a diagnostic test.
- **Positive-Predictive Value (PPV):** the proportion of persons with a positive test result who have the disease/ condition.
- **Negative-Predictive Value (NPV):** the proportion of persons with a negative test result who do not have the disease/ condition.
- **Precision:** Measure of the test's reproducibility when repeated on the same sample
- **Accuracy:** The extent to which a value from a test reflects or agrees with the reference value of the analyte being tested

When selecting a rapid test, you should also consider the **ASSURED** criteria described in section **1.3.1** above.

Table 2 outlines the operational and performance characteristics of the different types of syphilis tests, highlighting the key features and benefits of rapid syphilis tests. **Table 3** summarises the performance of four rapid syphilis tests in a field evaluation conducted in 2006. This was done in a laboratory setting by trained laboratory technicians, and in health facilities by trained health care workers.

Table 2. Comparison of syphilis diagnostic tests

	For patients presenting with an ulcer or lesion			For screening					
				Non-treponemal tests		Treponemal tests			
Criteria	**Darkfield microscopy**	**Antigen detection (DFA-TP)**	**DNA detection (PCR)**	**RPR**	**VDRL**	**Rapid test**	**EIA**	**TPHA-TPPA**	**FTA-ABS**
Sensitivity	74-86%	73-100%	91%	86-100%	78-100%	84-98%	82-100%	85-100%	70-100%
Specificity	85-97%	89-100%	99%	93-98%	98%	94-98%	97-100%	98-100%	94-100%
Ease of use	Easy	Moderate	Complex	Easy	Easy	Easy	Moderate	Complex	Complex
Where used	Exam room, on-site lab1	Intermediate lab, referral lab	Referral lab	Exam room, on-site lab	Exam room, on-site lab	Exam room, on-site lab	Intermediate lab, referral lab	Referral lab	Referral lab
Equipment needed	Light microscope with darkfield condenser	Fluorescence microscope	Microfuge centrifuge, thermal cycler, incubator, microwell plate reader	Rotator	Light microscope	None	Incubator, microwell plate washer and reader	Incubator, microwell plate washer and reader	Fluorescence microscope
Training needed	Extensive	Moderate	Extensive	Minimal	Minimal	Minimal	Moderate	Extensive	Extensive
Average cost	US$ 1.40	US$ 3.00	US$14.00	US$ 0.50	US$ 0.50	US$ 0.55-3.00	US$ 3.00	US$ 3.00	US$ 3.00

Peeling R.W., Ye H. "Diagnostic tools for preventing and managing maternal and congenital syphilis: an overview", in *Bulletin of the World Health Organization* 2004;82: pp.439-46.

Return to last page viewed

Return to last page viewed

Table 3. Performance characteristics of Select rapid syphilis tests

	Clinic: Whole Blood		Lab: Whole Blood		Lab: Serum	
Rapid Syphilis Test	**Sensitivity (%)**	**Specificity (%)**	**Sensitivity (%)**	**Specificity (%)**	**Sensitivity (%)**	**Specificity (%)**
Abbott Determine	59.6-88.5	97.9-99.4	77.1-100[a]	95.7-100[b]	88.5-100[c]	95.7-98.9
Omega Visitect	72.7-96.1	98.5-99.8	77.9-98.2	98.7-100[b]	84.2-96.1	98.1-99.1
Qualpro Syphicheck	64-84.3	97.8-99.7	70.8-97.6	98.6-99.7	67.4-99.7	98.4-99.6
Standard Bioline	85.7-100[d]	98.1-99.4	87.6-100[d]	96.1-99.4	90.2-100[d]	95.5-99.4

[a] n=40; [b] n=362; [c] n=83 and n=40; [d] n=30
Mabey D, Peeling RW, Ballard R, Benzaken AS, Galban E, Changalucha J, Everett D, Balira R, Fitzgerald D, Joseph P, Nerette S, Li J, Zheng H. "Prospective, multi-centre clinic-based evaluation of four rapid diagnostic tests for syphilis", in *Sexually Transmitted Infections 2006*;82:v13-v16.

1.3.3 National procurement of Rapid Syphilis Tests

National laws will decide which tests can be used in your country. It is important to understand what products have to date been registered/approved for use in your country. The quantification, qualification, product specification and pre-selection of suppliers are all important considerations when selecting a rapid syphilis test. It is important to achieve a fair and competitive price for products of assured quality whilst maintaining compliance with National Regulations.

Suppliers should be audited and/or monitored to ensure product quality, service reliability and good delivery time. Contact national regulatory agencies for guidance on national regulations.

Refer to **"The Use of Rapid Syphilis Tests"** for considerations in purchasing Rapid Syphilis Tests.

Return to last page viewed

The World Health Organization (WHO) Bulk Procurement Scheme

This service was created to facilitate access to high quality test kits and basic laboratory consumables and equipment at reduced costs. Through the scheme, rapid syphilis tests can be ordered by the following institutions:

- All regional offices of the World Health Organization
- All World Heath Organization country offices (orders are currently made through the regional offices)
- Non-governmental organizations which have official relationships with the World Health Organization
- Public health facilities (orders are made via World Health Organization country offices)

For a diagnostic test kit to become eligible to tender for World Health Organization procurement, it must pass the World Health Organization prequalification process and meet specific procurement criteria for test performance and manufacturing standards. Tenders from diagnostic manufacturers occur on an annual basis, by invitation only.

Further information on the World Health Organization Bulk Procurement Guidelines are available at:

WHO Contracting and Procurement Services (WHO/CPS)
Avenue Appia 20 1211 Geneva 27 Switzerland
Tel. +41-22-791 1801 Fax: +41-22-791 4196
Email: procurement@who.int
http://www.who.int/diagnostics_laboratory/procurement/en/

Return to last page viewed

2. Implementation

2.1 Understanding Local Circumstance: Conducting a baseline survey

When you were identifying the need for an rapid syphilis testing programme, you should have conducted a situational analysis to highlight the need for rapid syphilis testing within a chosen population (refer to guidance on performing a Situational Analysis in **Planning 1** and for a sample situational analysis checklist see **Management 1**). Building upon the information presented in the situational analysis, you should conduct a baseline survey to collect data specific to the target population and the facilities where the intervention will be introduced.

Your baseline survey should be conducted before you introduce the intervention phase of the programme and after a situational analysis. Refer to **Implementation 4 – Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme** for guidance on performing a baseline survey.

2.2 Ordering and Distribution

There are many components to be considered in order to create a supply chain system that functions and is capable of reaching multiple remote health facilities in a timely fashion. Stockouts interrupt health care services and impede a health care worker's ability to provide patients and clients with a high level of care. Effective supply chain management is therefore a valuable part of a functioning health care system. It is important also to refer to the national guidelines for supply and stock management. Each country, and sometimes each district, has its own schedule and policy for ordering, which may vary from monthly to quarterly to annually.

Refer to **Management 2** for further information on ordering and maintaining stock.

2.3 Training

Training is an essential part of a rapid syphilis testing introduction programme. It is key to developing the technical expertise and skills required for achieving a programme's objectives and realizing the stated goals. Managers should establish programme-level plans, policies, procedures, and quality assurance methods to ensure training is effectively and efficiently incorporated into project management functions. Furthermore, programme managers should develop specific plans to establish a quality assurance system for training and human resource development.

2.3.1 Training Workshops

A training programme can be established through the creation of two levels of training workshops. The first, a Training of Trainers workshop, will equip trainers to train the health care facility staff who will be involved in the implementation of rapid syphilis testing. It should also provide internal monitors and supervisors with knowledge of the purpose, objectives and content of health care worker training. This will enable them to reinforce on-the-job application of skills developed through training by:

Return to last page viewed

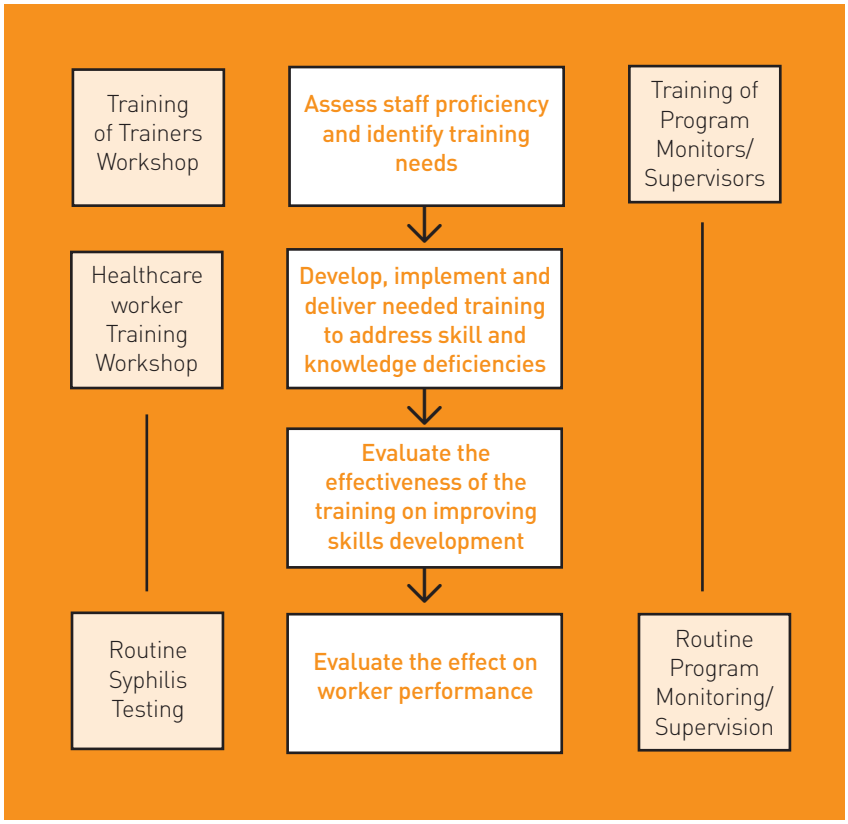
- Demonstrating skills
- Observing performance and assessing skill levels
- Offering constructive feedback
- Identifying and addressing barriers to effective performance of health care workers. These include motivation, communication and attitude.

The second level of training workshop is directed at the individuals who will be responsible for conducting rapid syphilis testing. It should be designed to equip staff with the practical knowledge and skills required to perform rapid tests as part of routine care.

2.3.2 Refresher Training Courses

Refresher training is an important aspect of programme implementation. The frequency and intensity of re-training will depend on staff experience. It can either be predetermined and included as part of the programme timeline, or be conducted in response to poor performance in quality assurance exercises. Generalized refresher training should be held every one to two years and should be integrated with refresher training workshops for other services offered alongside syphilis testing. For example, integrated refresher training for rapid syphilis testing and prevention- of-mother-to-childtransmission (PMTCT) programmes would decrease the time staff spend away from clinics and avoid interruptions in services due to staff absences.

Figure 1. Development of training plan



Return to last page viewed

2.3.3 Certification

All participants who successfully complete a training workshop should receive a certificate of participation (refer to **Implementation 3 – Training Package for Rapid Syphilis Testing** for a sample training certificate. The certificate should document:

- The name of the host organization
- The names of all contributing organizations or institutions including the Ministry of Health (if involved)
- The date of the training workshop
- The name of the participant
- The trainers' signatures

Certificates serve as evidence that an individual has attended a training workshop and should therefore be competent in the provision of rapid syphilis testing services. The content of the workshop should not be documented on the certificate but should be archived in a training folder that is stored in a central location and contains:

- A copy of the agenda
- List of participants
- List of presentations and worksheets
- List of evaluations conducted during the workshop.

Implementation 3 – Training Package for Rapid Syphilis Testing: Training of Trainers Workshop Preparation of this Toolkit contains a comprehensive set of guidelines on training healthcare workers and trainers and includes sample presentations for both sets of training workshops. You should make every effort to integrate training on new rapid diagnostic testing within national training programs, so as to minimize health care workers' time away from their clinics.

2.4 Test Introduction

Facilities should commence testing immediately upon completion of training workshops. Quality measures may be introduced in a phased-approach or alongside introduction of testing. This will depend on the ability of laboratory and programme staff to distribute quality materials, and on health care workers' experience with quality control measures. The intensity of training and supervision will gradually decline in frequency as health care workers become more accomplished, but it will need to be maintained in areas of high staff turnover.

Return to last page viewed

2.5 Quality Assurance and Quality Control

Accuracy and reliability of diagnostic/laboratory testing will be critical to the success of a diagnostic test introduction programme. In order to ensure this reliability and reduce errors to a minimum, a quality system that addresses all aspects of testing, including point-of-case tests, is essential. Even in sites which conduct only rapid syphilis testing, it is still essential to set up all the elements of a quality system.

Quality assurance is an integrated management function that deals with setting policy and running an administrative control system to ensure the usability of the product; in this case, the rapid syphilis test. It ensures that a process or device is of the quality needed and expected by the operator. Quality control is a system of routine standard technical activities undertaken to measure and control the quality of testing against a defined set of criteria or standards. It ensures correct operation of the rapid diagnostic tests and correct diagnosis.

As rapid syphilis testing is rolled out and/or expanded into large numbers of testing sites, it will be very important to implement a quality management system as detailed in this Toolkit to assure the quality and reliability of test results.

Implementation 2 – Quality Management System Guidelines for Rapid Syphilis Testing of this Toolkit provides guidance on establishing a Quality Assurance system for Rapid Syphilis Testing.

2.6 Monitoring and Evaluation

Routine monitoring and scheduled evaluations are critical components of any rapid syphilis testing programme. **Implementation 4 – Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme** of this Toolkit is used to define the key indicators and approach to data collection. Your Monitoring and Evaluation Plan should:

- Track the progress of country implementation plans against the expected milestones.
- Ensure continuous improvement and learning through an understanding of the various factors that underlie increased coverage of quality-assured rapid syphilis testing.
- Facilitate real-time, evidence-based decision-making.
- Identify obstacles to the implementation of rapid syphilis testing and find solutions.

Return to last page viewed

2.7 Dissemination

Planning 1 and 2 of this Toolkit provide guidance on developing advocacy and communication tools and activities to disseminate the progress and results of the rapid syphilis test programme. Communication of progress and results to the relevant stakeholders is an essential part of the uptake of rapid syphilis testing by donors, health officials and the public.

An effective dissemination and communication plan should:

- Sensitize and educate the community about the disease, testing for it and what treatment is *available*.
- Promote safe sex practice.
- Counsel to reduce prevalence.
- Promote partner engagement through a more integrated approach, e.g. using partner invitation slips and thereby fostering awareness.
- Target health care workers as well as patients.
- Utilize integrated HIV and syphilis services.
- Promote engagement of key stakeholders (integrated HIV partners, non-governmental organizations, Ministry of Health, laboratory partners).

As the pilot data is analyzed, you will need to organize stakeholder meetings to disseminate the results. These should occur on multiple levels. You must present results to health care workers, laboratory personnel, and district staff involved directly in the implementation of the project. You must also meet with organizations and governmental officials working at a national level to effect policy change. You should maintain regular contact with all stakeholders to inform them of the progress and success of the project to date, and the expected date of dissemination and conclusion of the project. Finally, you will need to arrange a final meeting to disseminate the project's findings,

Dissemination activities during RST launch, Lima, Peru

Return to last page viewed

3. Planning for Scaling Up

It is essential to maintain the momentum of the programme through exit from the pilot into the scaling up phase, so that skills gained during the initial stages can be sustained. The pilot study should have been introduced through existing health system structures. In this way, you will have built a strong foundation for scale up and expansion of the programme. The components of the pilot system – training, quality assurance, supply chain management, testing and treatment – can be expanded to a larger scale based on your initial experiences. Your ability to scale up will depend on the support and commitment of stakeholders: their engagement is critical before and during programme implementation.

These are some of the matters that you should consider for scale up:

- Who will be responsible for performing and/ or managing a particular activity?
- How will the transfer process occur?
- Are there performance standards to be maintained?
- How will it be funded?
- Who will be responsible for maintaining the Quality System?
- How will the programme be monitored?
- What will be the role of the community in managing or monitoring the programme?
- Can the programme be integrated into an existing programme, such as a Maternal and Child Health (MCH) or Prevention of Mother to Child Transmission programme?
- Can training be integrated with existing national level training programmes?

> **The transfer of activities and knowledge** should be done formally, so that all stakeholders concerned are aware of the commitments and responsibilities necessary to the continuation of the programme at national level.

Return to last page viewed

The planning of an exit strategy is not a single event but a series of steps. The following table outlines the essential elements of a rapid diagnostic test introduction programme. You will need to consider these in order to transfer from pilot stage to nationwide roll-out. You should also factor in the risks of transfer and potential solutions to overcome them.

Figure 2. The Scaling Up Process

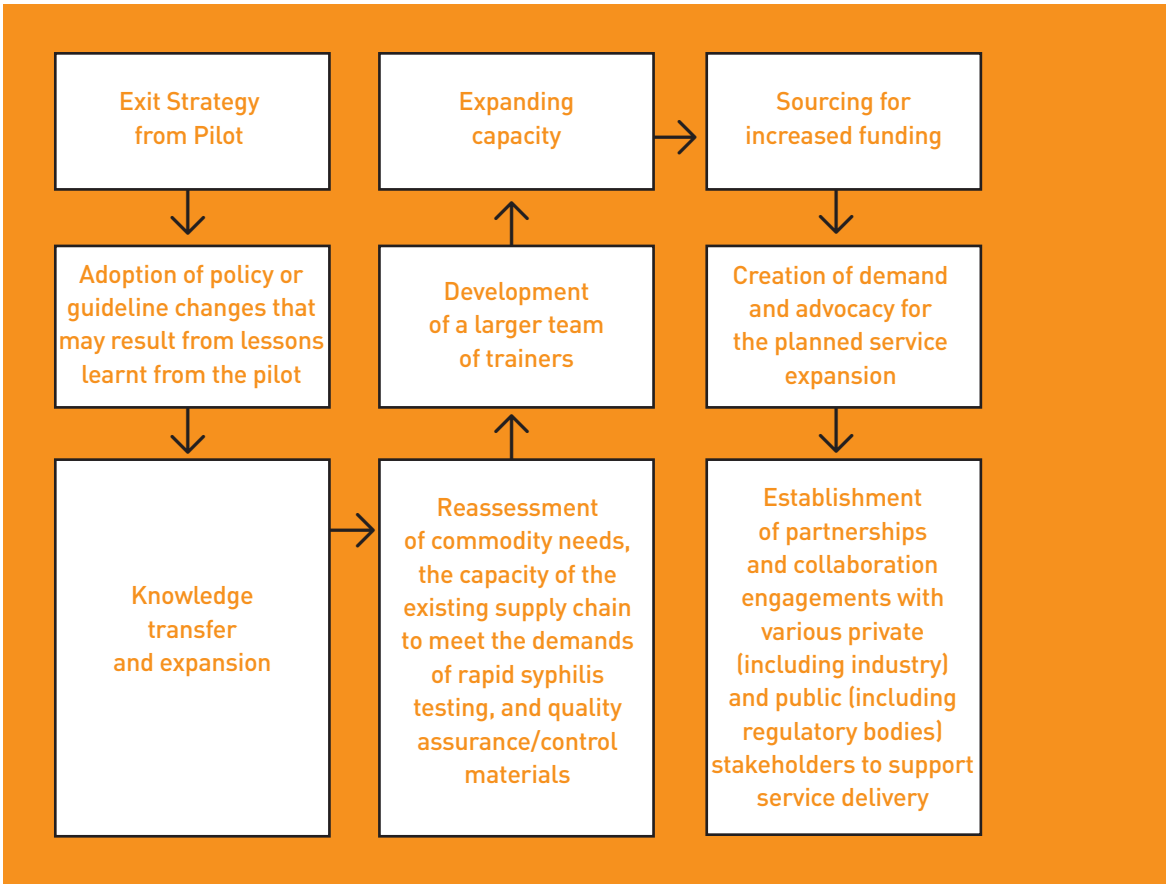


Table 4. Planning for scale-up – consider the following programme activities

Activity	Risks associated with transfer from pilot to national roll-out	Recommended solutions and Actions for Phase Out	Tools from pilot stage that can be used during scale-up	Responsibility after Pilot Stage
Quality System	✓ Feasibility, frequency & financing of a quality control system for RST within the MOH. ✓ Introduction of an over ambitious quality system that cannot be sustained. ✓ Loss of skills of HCW and laboratory technicians with respect to manufacture and testing of quality samples during transfer. ✓ Inability of laboratory to obtain high titre specimens for Dried Tube Specimen manufacture. ✓ Inability of district to maintain supervision of quality system and failure to implement corrective actions where necessary.	✓ Engage with central laboratories to develop a sustainable quality system and integrated HIV/syphilis panel. ✓ Engage in discussions with relevant stakeholders to determine what aspects of quality system (DTS Proficiency Panel testing and/or kit QC testing and/or confirmatory re-testing and/or incoming inspection of new lots) could be sustained. ✓ Discuss frequency of QC and determine what is feasible given cost restrictions and goals of quality system. ✓ Prepare technical guide-lines for implementing internal and external quality control for rapid testing at the central laboratory and at the health centre. ✓ Train MOH supervisors on quality control aspects to ensure technical proficiency. ✓ Draw up budget for costs of implementing a routine quality program.	✓ EQA/DTS manufacture and testing guidelines and record forms. ✓ Internal QC manufacture and testing guidelines and record forms. ✓ Incoming Inspection testing guidelines and record forms.	Local partnerships. MOH, MOH laboratories, laboratories already collaborating with MOH in quality assurance, district laboratories and district medical office, district supervisors.

Return to last page viewed

Activity	Risks associated with transfer from pilot to national roll-out	Recommended solutions and Actions for Phase Out	Tools from pilot stage that can be used during scale-up	Responsibility after Pilot Stage
Training system	✓ Loss of skills of HCW and laboratory technicians with respect to testing, reporting and manufacture of quality control specimens.	✓ Issue training certificates to all trained healthcare workers. ✓ Offer re-training to HCW that scored lower than the required score for EQA DTS panel before phase-out ✓ Ensure district supervisor and laboratory staff are adequately trained on all aspects of quality and internal monitoring ✓ Involve district/MOH at early stage of phase out ✓ Ensure capacity building on site among HCW ✓ Develop a cascade of trainers so the capacity to train is at all levels, including local level ✓ National stakeholder meeting will provide opportunities for training all levels ✓ Ensure district supervisors and laboratory staff are adequately trained on all aspects of the quality system.	✓ Trainer of trainers guide ✓ Job descriptions (Internal Monitor/ Supervisor, Laboratory personnel for DTS manufacture, Data Manager, Programme Manager, HCW) ✓ Guidelines, FAQ, troubleshooting guide ✓ Certification of trained staff ✓ Proficiency Checklist when there is high turnover of staff	MOH/Reference laboratory

Return to last page viewed

Activity	Risks associated with transfer from pilot to national roll-out	Recommended solutions and Actions for Phase Out	Tools from pilot stage that can be used during scale-up	Responsibility after Pilot Stage
Internal monit-oring/ Super-vision	✓ HCW may lose motivation if regular supervision is not maintained ✓ Quality Control may not be done if not reviewed on a regular basis ✓ Problems can escalate if there is no regular supervision	✓ Phase out frequency of internal monitoring visits to shift responsibility to district/MOH level and build capacity among HCW at the health centres. ✓ Coordinate visits with district supervisor to work together and to provide training for district supervisor ✓ Ensure district supervisors are aware of roles and responsibilities prior to exit through hosting of adequate training and accompanied site visits ✓ Draw up budget of costs of implementing a routine supervision/monitoring program ✓ Involve district/MOH at early stage of phase out. ✓ The pilot study team should do a follow up visit after exit using an Exit strategy checklist	✓ Monitoring SOP & checklist, including recommended frequency of monitoring ✓ Monitoring Report template ✓ Country M&E plan with defined indicators for monitoring ✓ Corrective action/ troubleshooting guide for internal monitor in event of unacceptable test results and other non-conformances	District/MCH/RCH coordinator District health office. District supervisors.

Return to last page viewed

Activity	Risks associated with transfer from pilot to national roll-out	Recommended solutions and Actions for Phase Out	Tools from pilot stage that can be used during scale-up	Responsibility after Pilot Stage
Supply Chain	✓ Delay in introduction of tests because of difficulties in procurement. ✓ Stock outs causing interruptions to testing	✓ Pilot an order through local distributor and determine what assistance they can provide. ✓ Ensure staff at health centre are aware of the importance of tracking supplies and ordering. ✓ Share experiences with MOH, DHO as part of final dissemination. ✓ Use HIV rapid test or other diagnostic procurement as an example of how process can work and potential problems that will need to be avoided. ✓ Ensure district supervisors are familiar with supply chain problems and are capable of addressing local problems. ✓ Introduce MOH/DHO to WHO Bulk Procurement Scheme.	✓ Local distributor contact details ✓ WHO Bulk Procurement Scheme Guide ✓ Documents/Stock cards for tracking supply	MOH/district health office and district stores/ Central stores

Return to last page viewed

Activity	Risks associated with transfer from pilot to national roll-out	Recommended solutions and Actions for Phase Out	Tools from pilot stage that can be used during scale-up	Responsibility after Pilot Stage
Dissem-ination	✓ No policy change ✓ Facilities will revert to testing using reference method.	✓ Engage all relevant stakeholders in meetings for dissemination. ✓ Ensure all interested parties have access to project results, costing information, final report (including DHO, MOH, other NGOs working in overlapping fields etc.) ✓ Schedule meetings with stakeholders at all levels from MOH/ national to facility level. ✓ Challenges and issues during RST introduction can be obtained from the internal monitors checklists and the weekly/monthly monitors meeting minutes	✓ Develop a communication strategy ✓ Communicate challenges and lessons learned ✓ Guidelines/FAQ/ Troubleshooting guide ✓ Website for accessing study documentation	Programme Manager and pilot study team

Return to last page viewed

Return to last page viewed

4. References

- Planning 1 – Advocacy & Communications Strategy
- Planning 2 – Advocacy & Communications Activities
- Management 1 – Model for Integration of Rapid Syphilis Tests within Maternal and Child Health and/or Prevention of Mother to Child Transmission Programmes at Primary Healthcare Settings
- Management 2 – Supply and Stock Management for Healthcare Workers and Health Care Facility Staff
- Management 3 – Developing Syphilis Testing and Treatment Algorithms Using Rapid Tests
- Implementation 1 – The Costing Guidelines for Syphilis Screening Strategies
- Implementation 2 – Quality Management System Guide for Rapid Syphilis Testing
- Implementation 3 –Training Package for Rapid Syphilis Testing
- Implementation 4 – Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme