THE RAPID
SYPHILIS TEST
TOOLKIT

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IMPLEMENTATION 4

Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme

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Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme

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Monitoring and Evaluation Tool for a Rapid Syphilis Test Programme

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1. Purpose of the Document

This document will help a programme manager or supervisor to monitor and evaluate a rapid syphilis testing programme; to identify obstacles to rapid syphilis test implementation and find solutions; and to track the progress of country implementation plans against the expected milestones.

This document is applicable for use in:

- Performing a baseline assessment to determine the burden of syphilis.
- Developing and undertaking a routine monitoring programme.
- Designing and performing an external monitoring programme.
- Evaluating the impact of the introduction of rapid syphilis testing.

This Monitoring and Evaluation plan contains:

- A Framework for Monitoring and Evaluation planning.
- A Results framework.
- Definitions of key terms.
- Indicator and target setting.
- Data sources.
- Methods of data collection and reporting

Lukalanya health centre, Mongu, Zambia

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2. Introduction to Monitoring and Evaluation

What is monitoring?	What is evaluation?
Monitoring is the routine tracking of the key elements of a programme or project's performance. This is done through record keeping, regular reporting, surveillance* systems, health-facility observation and client surveys.[1] The purpose of monitoring is to measure changes during the intervention period.	The purpose of an evaluation is to determine the value of a specific programme. This is achieved using key indicators monitored over a specified period. These are measured in relation to a baseline assessment and the changes that take place during this defined period. An evaluation links observed outcomes to the programme objectives.

***Surveillance is the "routine tracking of disease using the same data collection method over time" in order to predict future trends and target prevention programmes.**
National AIDS programmes: a guide to monitoring and evaluation (2000)

Why is a Monitoring and Evaluation Plan important?

- It tracks the progress of programme implementation plans against the expected goals and milestones.
- It ensures continuous improvement and learning, through understanding the various factors that underpin increased coverage of quality-assured rapid syphilis testing.
- It identifies gaps or problems in real time and develops systems for improvement and corrective actions, such as guidelines, tools and technical assistance.
- It facilitates real-time, evidence-based decision-making.
- It ensures maintenance of high standards.
- It identifies opportunities and advocates for the strengthening of health systems.
- It provides an information base for future evaluations.

If there is an existing system in place for monitoring of other Sexual and Reproductive Health (SRH), Mother and Child Health (MCH) or Prevention of Mother To Child Transmission programmes, efforts should be made to integrate the specific performance indicators for syphilis rapid test introduction with those routinely collected and evaluated as part of the existing programme.

[1] Roll Back Malaria Draft Checklist for Developing a National Monitoring and Evaluation Plan for Malaria Control.

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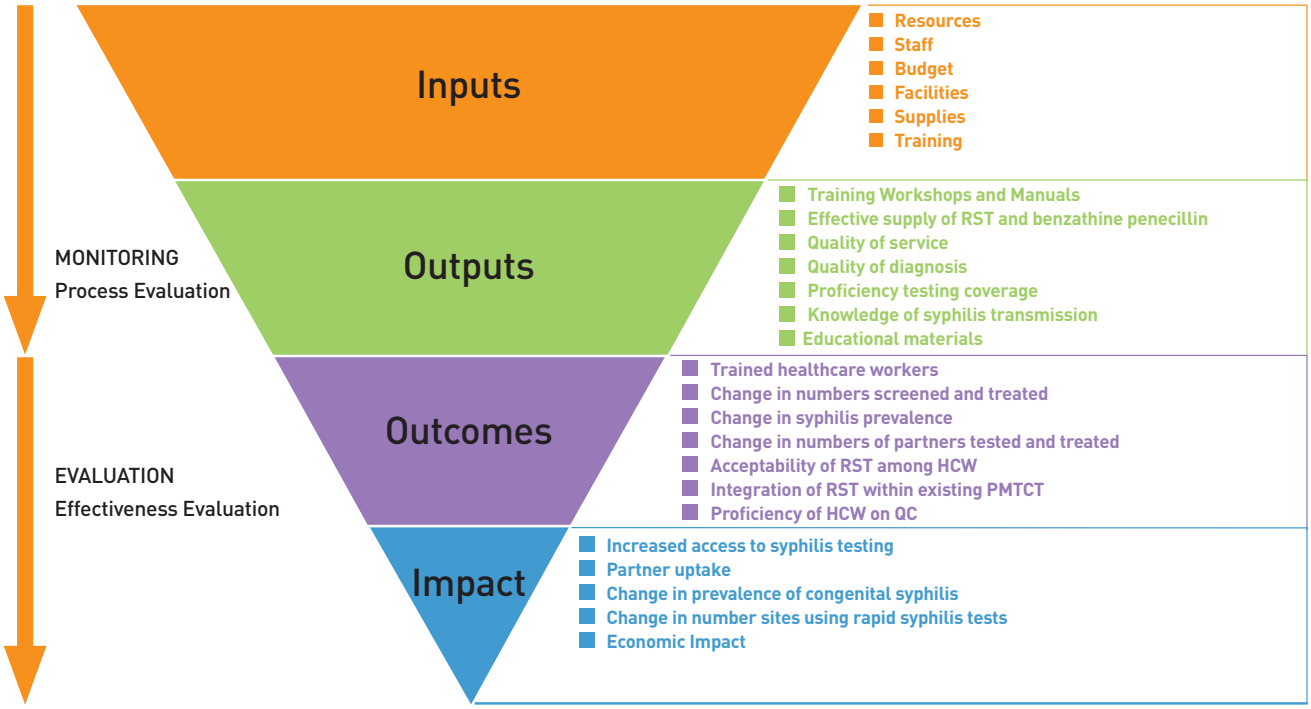
3. Developing a Monitoring and Evalutation Plan

The person responsible for monitoring should develop the Monitoring and Evaluation Plan for the programme. This plan should be prepared at the beginning of the programme. Tool 1 provides a checklist of the key criteria of a Monitoring and Evaluation Plan. Sections 4 to 13 of this document discuss the implementation of the plan in more detail.

Figure 1. Monitoring and evaluation results pyramid



Source: Modified from the National AIDS Council: Monitoring and Evaluation operations manual. UNAIDS, 2002.

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4. Identify a Clear Purpose for Monitoring and What Final Outputs are to be Achieved

The purpose of the programme should be clearly identified following the Situational Analysis in **Planning 1** (refer to **Management 1** for a sample Situational Analysis Tool). Your monitoring objectives should reflect the purpose of the programme. When designing a Monitoring and Evaluation Plan, you should address the following questions:

- What is the goal of the programme?
- What are the monitoring objectives
  - What will be achieved?
  - What are the anticipated outputs, outcomes and impact?
- What evidence is needed?
  - Set performance indicators **(see section 5 of this document).**
- How reliable is the data?
  - Perform a risk analysis of the quality and validity of the available data.

Antenatal care services in Callao-Ventanilla region of Peru

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5. Establish Performance Indicators

5.1 Setting Key Performance Indicators

An indicator is a quantitative or qualitative factor or variable that enables you to measure change over a specified period of time in order to assess the perfo rmance of an intervention.

You should select indicators based on the objectives, goals and activities of the programme, but you must also consider local prevalence levels, sexual behaviour and social behaviour.

You will need to develop a series of indicators for both internal and external routine monitoring. These can be evaluated during monitoring and evaluation activities. It is important to establish a set of key indicators, which will be used to demonstrate the attributable benefit of increased access to rapid diagnostic tests. They will be calculated based on routine information recorded by health care workers, and collected as part of the routine monitoring visits.

The list of indicators should be relevant, both to the programme and to national standards; they should be easy to interpret and feasible to collect; and they should enable tracking over time.[1] Indicators should demonstrate progress, relate to the programme objectives and be developed according to the SMART guidelines:

Objectives should ideally be **SMART**:

Specific	Objectives should be precise and well defined
Measurable	You should be able to measure whether you are meeting and have met the objectives or not
Achievable	Objectives should be achievable and attainable
Realistic	Objectives should be realistic given the resources you have and the context you are operating in
Timebound	Objectives should have a timeframe set within which they are to be delivered.

Indicator selection should be based on an initial risk assessment to assess the feasibility of data collection. They should include a mix of input, output, outcome and impact indicators, all linked to the programme goals and objectives (refer to **Tool 2** for examples of output, outcome and impact indicators, including how to measure them). Indicators should be standardized both within the programme and if possible with other programmes, such as Sexual and Reproductive Health, Prevention of Mother To Child Transmission or HIV programmes.

[1] UNFPA, Programme Manager's Planning Monitoring & Evaluation Toolkit :Tool Number 6: Programme Indicators, August 2004.

http://www.unfpa.org/monitoring/toolkit/tool6.pdf

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Table 1. Example of goals objectives, outcomes and impacts for rapid syphilis test introduction in ante-natal care

GOAL	OBJECTIVES	OUTCOME indicators, linked to the objectives which are specific, measurable, achievable, realistic and time bound	ACTIVITY, for which you will need inputs and which will result in outputs	OUTPUT indicators, which are specific, achievable, realistic and time bound	IMPACT indicators
To decrease incidence of congenital syphilis in Country [x] by [x] % over [x] period	**Objective 1:** To advocate for MOH to adopt policy to include RST in minimum package of MCH/ PMTCT/other services by [date]	Clinical guidelines include RST testing for [identify service level, e.g. primary health centre/ hospital/laboratory] by [estimated date]	Stakeholder identification, mapping and key messaging for advocating for RST	Number of meetings held/persons contacted Number of messages and support developed (eg TV spots, briefings with Parliamentarians, etc) Number of messages distributed (by type of format, eg. TV spots, leaflets)	- Increase in access to rapid syphilis tests for pregnant women - Increase in partner notification and uptake - Decrease in syphilis prevalence in pregnant women - Decrease in congenital syphilis prevalence
		[x] % change in budget allocations to include RST by [date]	Undertake an economic evaluation of RST introduction	Economic analysis undertaken in x facilities available by [date]	
	Objective 2: To train [x] % of HCW in [x] % of health units in performing the RST with high proficiency by [date]	[x] % healthcare workers trained on rapid syphilis testing in [x] % facilities by [date]	Develop the curriculum and a training plan	Training manual and training plan developed for both pre and in-service training of health workers by [date]	
			Conduct the training	Number of courses organized over [x] period	
		Number of healthcare workers scoring [→ x%] on DTS proficiency panel immediately after training workshop and/or within [x] period following training working	Performance evaluation	At least [x] number proficiency panel testing conducted in [x] % of facilities [x] times per yer/per project period	
	Objective 3: To implement same day testing [x] % of the time in [x] % of health centres	% of women attending ANC services who receive same day testing	Procurement, supply and distribution of rapid syphilis tests and/or benzathine penicillin	Rapid syphilis test kits and/or benzathine penicillin in stock in [x] % facilities within [x] period No stock-out of rapid syphilis test kits and/or benzathine penicillin in [x] % facilities during [period]	
			Quality Assurance and Quality Control program implemented on site	Quality Assurance and Quality Control system in place in x% health facilities by [date] Proficiency testing by healthcare workers meets [x] % target score	
			Monitoring and Supervision of health centres provided	M&E for rapid testing and treatment in place covering [x] % facilities of [defined frequency] during [period of time]	

Tool 2 provides more details on how the indicators can be measured and where the data can be collected.

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5.2 Setting Targets

You should set targets for each indicator to evaluate the success of the overall programme. Targets should be measurable over a specific time period and should be realistic and achievable. Targets can be percentage achievement targets, which are set against a standard, qualitative or qualitative targets, or time-bound targets.

Check for existing national or regional targets for routinely monitored performance indicators. If national or regional targets are not available, you can set targets according to:

- Political priorities or commitments
- Previous data from other surveillance or baseline surveys carried out by the Ministry of Health (MOH) or Non-Governmental Organizations (NGO), if available, or from published data.
- A pilot study performed within a defined period to establish targets (baseline survey)
- Comparison with other regions in the country who have previously introduced rapid syphilis testing.
- External comparison with neighbouring countries who have previously introduced rapid syphilis testing. Please note, it is important that the settings be comparable and that the use of these targets be adequately justified.

5.3 Data Collection, Sources of Information and Modes of Communication

Your choice of indicators and data collection tools will depend on the stage of the disease burden, the resources available and the capacity for reliable and accurate data collection. Refer to **Tool 3** for a sample data collection tool and **Tool 5** for a sample checklist for routine Monitoring & Evaluation. Data can be collected using:

- Questionnaire/Survey
- Population surveys
- Health facility assessments
- Surveillance studies
- Review of registers
- On-site observation
- Interviews
- Case studies

For a rapid syphilis test programme, data can be collected for the baseline assessment, routine monitoring and evaluation of the study using any of the following:

- Antenatal care or Prevention of Mother To Child Transmission Registers
- Mother and Child Health or Prevention of Mother To Child Transmission national programme records
- National surveys
- Facility Supply Records
- Personal Data Assistants (PDAs)
- District or national meetings.

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6. Qualification of Programme Monitors

Terms of Reference should be prepared for the Programme Monitor. Some of the key responsibilities of the Programme Monitor may include:

- Preparation of a Monitoring and Evaluation Plan in collaboration with the programme manager
- Selection and collection of key performance indicators
- Performance of a baseline survey
- Preparation of bi-annual or annual Monitoring and Evaluation reports
- Provision of support and technical assistance at health centres during the introduction of rapid syphilis testing
- Re-training of health care workers as necessary

Programme monitors should be trained. They will need to have sufficient scientific and/or clinical knowledge monitor the intervention or trial adequately. The monitor should keep training records for al trainers and health workers. **Implementation 3** is a detailed Training Plan for the operation of rapid syphilis testing.**Implementation 2** explains how to develop Quality Assurance (QA) and Quality Control (QC) systems for rapid syphilis testing. All programme monitors should be trained in all these areas.

Monitoring visits in indigenous community, Amazonas, Brazil

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7. Conducting a Baseline Survey

A baseline survey collects quantitative or qualitative data specific to the target population at the start of the project. A baseline survey is essential to evaluating the impact/success of the study upon completion. It should be conducted before the intervention phase of a programme. Unlike a situational analysis, a baseline survey collects information on specific data points in either a retrospective or prospective manner.

7.1 Objectives of a baseline survey

The objective of a baseline survey is to assess the pre-intervention state of syphilis screening services. The data from this survey will act as a baseline marker against which future progress can be measured. The data to be compared to the baseline markers will be collected through the monitoring process, using a predetermined set of indicators.

A baseline survey can be conducted retrospectively or prospectively.

- A retrospective survey will gather data that has already been collected at health facilities as part of routine care over the past months. In performing a prospective survey, output indicators will be collected through the use of tools designed by the programme.
- A prospective survey will collect data in the future months but will be completed before the intervention phase of the programme is implemented.

A retrospective baseline survey relies on the data which has been collected by health care workers or laboratory staff as part of routine data collection. You can find this in patient/ client registers, laboratory and testing registers, stock cards, stock requisition forms or in an electronic database. The data which can be collected for a retrospective survey will be limited by the routine record keeping of facility and laboratory staff and may not be as extensive as is required for the programme. If more detailed information is required, conduct a prospective survey using the specified data sources.

You can tailor a prospective baseline survey to meet the specific data needs of your programme. One useful tool might be an in-depth questionnaire to be completed for every patient who attends a clinic where syphilis testing services are to be introduced or the patient or laboratory register can be modified.

The duration over which data is collected will depend on the size of facilities and the number of patients who attend every week or month. A longer prospective survey will delay the introduction of rapid tests but will increase the sample size and power of any before-and-after comparisons that are made. An additional consideration when determining the duration of a survey is potential seasonality, which affects facility attendance. For example, if women are less likely to attend for antenatal care during the harvest season, the baseline survey should not be restricted to this period.

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Table 2. Advantages and limitations of retrospective and prospective baseline survey

	Retrospective	Prospective
Advantages	■ Can be performed quickly. ■ Requires no additional training of health care workers or laboratory staff. ■ Reduced cost and time. ■ Data covers a greater geographical spread. ■ Data can be collected over different points on time so a trend can be established.	■ Can collect in-depth, programme-specific outputs. ■ Quality of data will be of higher standard due to training of health care workers and monitoring by programme staff.
Disadvantages	■ Limited to information routinely collected by health care workers and laboratory staff: certain indicators may not have been collected. ■ Method of reporting events may vary across and within facilities. ■ May be missing data. ■ Data may not be reliable or accurate. ■ Information may be out of date. ■ Information may be biased. ■ Not applicable if conducting an outreach programme or targeting a previously un-tested population.	■ Requires a greater amount of time and cost ■ Requires health care workers to be trained in use of questionnaires or modified registers. ■ Health care workers may be subject to fatigue or lose a lot of time that should be dedicated to patient care if questionnaires are too lengthy.

> **A combination of retrospective** and prospective surveys might also be an option for programmes where there is limited time to perform an in-depth prospective but information beyond what would be available through a retrospective is needed.

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7.2 Sources of Data

Existing data that can be used for baseline data collection includes:

- Ministry of Health records
- Monthly district reports
- Published literature
- Focus groups with target population
- Patient registers can be used for data collection as part of a prospective baseline survey

Consider the following questions when you need to establish the reliability and relevance of existing data:

- What is the source of information?
- How long ago was it collected?
- What time period does it cover?
- How was it collected? What methods were used, and were they reliable?
- Is the data representative?

Refer to **Tool 3** for a sample data collection tool.

Monthly/annual reports to the Ministry of Health have two purposes. They are useful sources of information for baseline surveys, and they allow for time-bound analysis.

In the Callao region of Peru, a subregister of patient information was being used in addition to a patient register, and there was little uniformity in data capture between health centres. The CISNE research group have now proposed using just one register, and have suggested inserting an additional column for recording rapid syphilis test results and treatment here.

Methods of Data Collection

Interview: Interviews with health care workers are a valuable method of gathering qualitative data and may highlight problems previously overlooked. These could include, but are not limited to:

- Problems with staffing or staff turnover
- Problems with stock management or forecasting
- Problems with supply delivery
- Inexperience with quality systems
- Personal misconceptions about syphilis disease, testing or treatment.

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In Peru, focus group interviews were held with women attending antenatal care services. Their feedback highlighted the lack of knowledge within the Community of congenital syphilis, which helped the programme management team to understand how ignorance of syphilis poses a problem to pregnant women and their babies. The experience helped shape plans to create awareness of the disease and encourage uptake of syphilis screening.

The issues raised through interviews can be addressed or emphasized during training and ongoing programme monitoring. The identification of barriers and challenges will be of benefit not only to the implementation of rapid syphilis testing but also to the sustainability of syphilis screening programmes within the health care system.

Surveys: Before surveys are conducted, you will need to create a summary data collection form in order to standardize the routine collection of data. Facility or programme staff may complete the data collection form on a bi-weekly or monthly basis, depending on workload and manpower. A data summary form will also be of benefit when collecting data as part of a retrospective survey to standardize the process and ensure no outputs are overlooked.

On-site observation: Information can be collected in real-time by an observer who uses a tool or checklist to capture the information of interest (refer to Tool 5 and Tool 6 for sample checklists)

Brazil

A baseline survey may not be feasible if patient registers are not up to date, or if there has been no prior screening for syphilis and HIV in the target population. Prior to the introduction of rapid tests for syphilis and HIV within the indigenous communities of the Amazonas region of Brazil, data on syphilis prevalence among pregnant women in the triple border area of Brazil, Peru and Colombia was used as a provisional estimate or baseline of syphilis prevalence levels among the indigenous population. This is because there was no prior syphilis or HIV screening performed within these communities to provide an estimate of baseline prevalence levels. It is important to adequately justify the use of data from a different target population to set a baseline, as it is difficult to evaluate the effectiveness of the programme without having data relative to the target population. In the case of the Amazonas indigenous study, the evidence for rapid syphilis test introduction within the indigenous communities was compelling enough for the Brazilian government to commit to the introduction of rapid syphilis and HIV screening for all indigenous communities in Brazil.

Health post in Parantins in the Amazonas region, Brazil

Rapid HIV and syphilis screening in the Lanomami Community, Amazonas, Brazil

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8. Routine Monitoring and Supervision

8.1 Routine/On-site monitoring

Frequency of monitoring

Once baseline data has been collected, routine monitoring should be performed daily or weekly during the pilot stage of the programme and thereafter at monthly or six-monthly intervals. Following roll-out of the rapid syphilis testing programme, evaluation should be performed on a yearly basis.

During the pilot stage of the programme, monitoring and supervision can be performed in a sample set of healthcare centres. Following nationwide roll-out of the rapid syphilis testing programme, all healthcare centres should receive monitoring and supervision visits at defined intervals to ensure correct programme implementation.

In Brazil, routine monitoring and supervision activities have been decentralized to Secretaria Especial de Saude Indigena (SESAI) coordination staff within each district. The implementation of a fixed schedule of internal monitoring visits has been challenging: this is due to the high cost and inadequate supply of airplanes to get to the communities, the high cost of gasoline, and the frequent low river levels that prevent access to communities by boat.

Because of the opportunistic nature of monitoring/supervision visits, it has been essential for technical coordinators and trainers to build staff capacity within the communities in the performance of the rapid tests and quality control using training workshops, and to maintain regular telephonic communication.

Try to integrate the monitoring programme for rapid syphilis testing with an existing Prevention of Mother to Child Transmission or antenatal care monitoring programme, so as to make optimal use of existing services.

In Uganda, monitoring and supervision visits for the rapid syphilis testing programme have been integrated with Prevention of Mother to Child Transmission programme supervision visits. Local Maternal and Child Health district monitors are responsible for both aspects. The programme coordinators use a checklist to indicate the specific activities to be monitored at the facility.

The list typically includes availability of stock and up to date protocols and records, review of records, direct observation of health care workers carrying out the rapid test and maintenance of equipment. Following the monitoring visit, reports of the visit are prepared and records stored of qualitative tracking of key activities, such as adherence to Standard Operating Procedures (SOPs) or direct observation of rapid testing.

Tools for Routine Monitoring

Monitoring Checklist: See **Tool 5** for a sample checklist.

Frequently Asked Questions (FAQs): This is a list of questions frequently asked by health care workers who routinely use the rapid syphilis tests, and a list of possible answers. It can be a working document used by the monitor to address queries, or it can be left on-site for use by the healthcare workers.
Refer to **Implementation 2** for a sample set of FAQ by healthcare workers

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Corrective Action Algorithm: When a monitor deems processes to be ineffective, s/he should develop a corrective action system to address the problem in real time and to reduce or eliminate the possibility of its recurrence in the long term. The corrective action algorithm is a decision tree of actions stemming from an ineffective process (for example an out-of-range test result on the Quality Control materials). It assists the monitor in troubleshooting and identifying the source of the problem and lists various corrective actions to re-solve the problem.

In Zambia, a corrective action algorithm was used to troubleshoot an out-of-specification result for the quality controls. The algorithm outlined the steps to be taken by the internal monitor to determine the cause of an out-of-specification result.

It helped narrow down the possibilities to ;

- the specimen used in quality control testing;
- the test (or test kit) used in quality control testing; or
- healthcare provider performance.

After determining the cause, the monitor was able to take the appropriate corrective action to resolve the problem. The corrective action algorithm used in Zambia is attached in **Implementation 2.**

8.2 External monitoring

External monitoring by an independent observer should be conducted routinely to ensure that programme goals and objectives and intermediate results are being achieved, and to assess the completeness and quality of data collection and analysis for the rapid syphilis testing programme.

External monitoring visits ensure that the programme is being carried out according to protocol. The external monitor or supervisor should assess the validity and accuracy of the data collected, examine the supply chain effectiveness and any quality assurance issues, and suggest corrective actions and recommendations to the sites as needed.

Refer to **Tool 6** for a sample indicator checklist for external monitoring.

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9. Monitoring Report

Following the monitoring visit, the monitor should report to the Project Coordinator and Programme Manager. The report should include:

- Date, site, name of monitor.
- Name of other personnel in attendance.
- Summary of documents the monitor has reviewed.
- Statement of findings.
- Statement of non-conformances and corrective actions carried out.
- Recommendations and conclusions.

Refer to **Tool 4** for a monitoring report template. This can be filed at headquarters (HQ) and/or a copy left on site as record.

The monitoring report, or a summarised version, should be delivered to the health centre concerned and to local management teams for review in a timely fashion. This will enable quick resolution of outstanding issues. The report should be part of an ongoing process of dissemination and also of your continuous engagement with stakeholders that are directly involved in the implementation of the programme at governmental and non-governmental level. It should be standardized to ensure consistency and to enable tracking of progress or ongoing problems

10. Data Analysis

Data from the routine monitoring and supervision and external monitoring activities should be analysed collectively over six-monthly or annual periods with reference to the overall programme objectives. Interim reports should be prepared by the programme monitor and/or programme manager.

Analysis can be performed when progress reports, quarterly reports on achievement of outputs, annual project reports and project delivery reports are required.

11. Evaluation of the Rapid Syphilis Testing Programme

> **Evaluation is the systematic and objective assessment** of an on-going or completed programme, its design, implementation and results. The aim is to determine the relevance and fulfilment of objectives, development efficiency, effectiveness, impact and sustainability.[2]

[2] OECD (2002), Glossary of Key Terms in Evaluation and Results Based Management
AVAILABLE AT: http://www.oecd.org/dataoecd/29/21/2754804.pdf

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11.1 Why should a programme be evaluated?

- To evaluate the effectiveness of programme.
- To track trends.
- To identify problem areas.
- To advocate for an allocation of resources.
- To identify programme and process improvements.
  - Did it work? Why not? How could it be done differently?
- To build knowledge for scale-up (nationwide)
  - What was learnt?
  - How can it be applied?

The outcomes of the rapid syphilis testing introduction programme in the indigenous population of the Amazonas region of Brazil have contributed to the Brazilian Ministry of Health's decision to introduce rapid HIV and syphilis tests into a newly formed national pre-natal and neonatal primary care network.

The investment of 9.4 billion reais ($5.8 billion) over four years aims to reach the estimated two million pregnant women who use the public health system within this time frame.

Following rapid syphilis test introduction in 7 developing countries in Asia, Africa and Latin America between 2008 and 2011, the governments concerned have announced plans to scale up rapid syphilis testing to make it available nationwide. This was achieved in part by the use of effective monitoring and evaluation systems

11.2 Frequency of Evaluation

The frequency of your evaluation activities will depend on your overall goals and objectives and your performance indicators. Targets should be time-bound. Evaluation should be performed as follows:

- Final programme evaluation should be performed at the end of the programme or intervention to evaluate the effectiveness of the intervention, the fulfilment of objectives, and the programme's impact and sustainability.
- Periodic midterm evaluations should also be performed to allow for process improvements. The frequency of mid-term evaluations will depend on the duration of the programme or intervention, and the depth of monitoring and analysis required.
- Real time evaluations should be performed at an early stage of the programme to trouble shoot any problems and to allow for process improvements.

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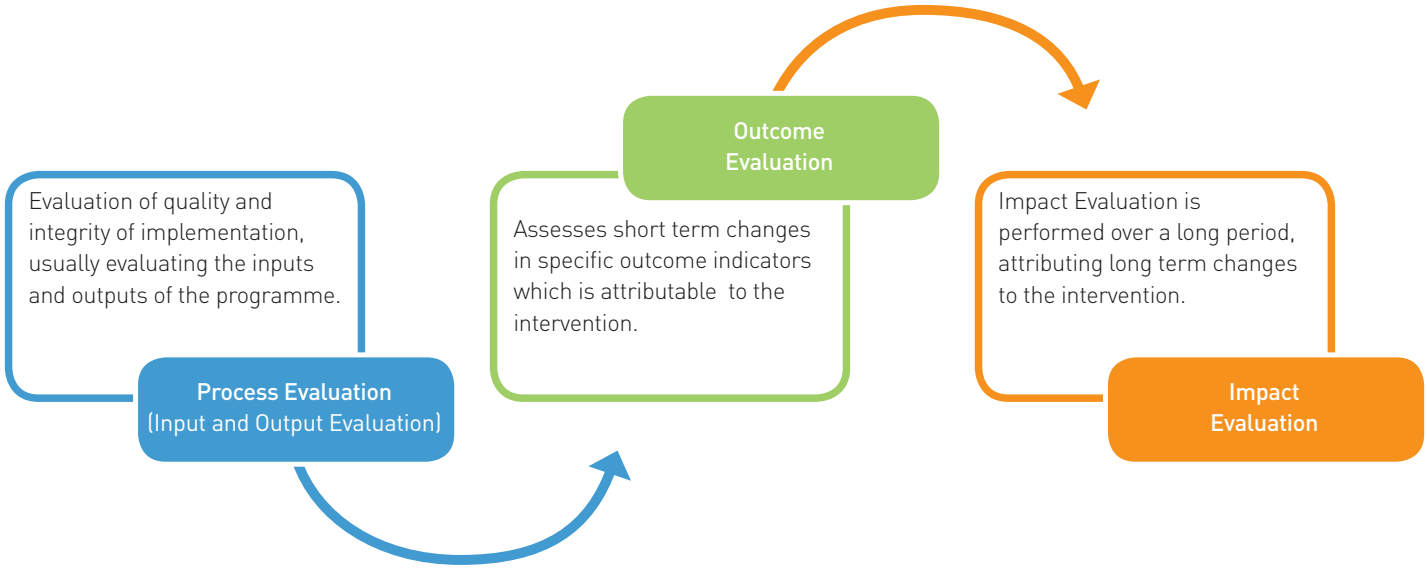
11.3 The Evaluation Process

Figure 2. The three types of evaluation: Process, Outcome and Impact evaluation



Process evaluation, or input and output evaluation, evaluates the inputs, outputs quality and integrity of your programme or intervention. It aims to determine how programme or intervention processes can be improved by identifying problems and recommending solutions for process improvement. For example, one of your programme objectives might be to train a fixed percentage of health care workers to perform rapid syphilis testing. Your process evaluation will assess if a training manual and training plan has been developed for both pre and in-service training of healthcare workers by a specified date.

Outcome evaluation measures the short-term effects of the intervention. For example, if your programme objective is to train a fixed percentage of health care workers to perform rapid syphilis testing, your outcome evaluation will compare the number of staff providing rapid syphilis testing who have received training with the total number of staff who perform rapid syphilis testing. If an inadequate number of health care workers have been trained, or if there is high staff turnover resulting in a drain of trained staff, efforts can be made for new training workshops or re-fresher training to be undertaken.

Impact evaluation assesses whether the programme or intervention is achieving the intended impact. It aims to evaluate how the target population is being affected by the intervention. For example, to measure the impact of increased access to syphilis screening among pregnant women, the impact evaluation may compare the number of pregnant women being screened for syphilis before and after the test intervention period.

Refer to **Tool 2** for further examples of output, outcome and impact indicators for a rapid syphilis test intervention programme.

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You should consider the following points when performing an evaluation:

- What are the overall programme goals and objectives?
- What evaluation indicators do you need to focus on?
- What method of evaluation will you use and how will you analyse the data?
- Who are the audience and major stakeholders to whom data should be disseminated?
- How will you communicate your evaluation results to your chosen audience?

11.4 Data presentation and dissemination

Submit evaluation data and reports to regional and global levels for review, using existing mechanisms and reporting systems. You must ensure that they are also disseminated to the key stakeholders and champions identified in **Planning 1 – Advocacy & Communications Strategy** of this Toolkit. Refer to **Planning 2 – Advocacy & Communications Activities** for further guidance on disseminating to key stakeholders.

Frequent analysis and dissemination of data allows for:

- Continuous assessment
- Planning of future work
- Identifying opportunities to build on strengths
- Identifying weaknesses and developing strategies for process improvement
- Identifying training needs

You will need to consider these points:

- What and where is the capacity to respond to the information?
- Is the decision making structure clear? (Refer to situational analysis in **Planning 1 – Advocacy & Communications Strategy**)
- What information do funding agencies need?

Appendix 1. Sample Monitoring and Evaluation Plan for a quality assured rapid syphilis test introduction programme provides a sample Monitoring and Evaluation plan designed for MOH and NGO programme managers to evaluate a rapid syphilis testing programme that can be used by countries to adapt to their specific programmatic settings.

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12. References

- **Implementation 3 -Training Package for Rapid Syphilis Test Introduction**
- **Planning 1 Advocacy and Communications Strategy**
- **Planning 2 Advocacy and Communications Activities**
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Tool 1. Framework for monitoring and evaluation plan

Use this table as a checklist for developing your monitoring and evaluation plan

Activity	Complete	Further information required
MONITORING		
Are Goals and Objectives defined?		Refer to Planning 1 of this Toolkit
Are indicators selected?		Refer to page 5
Are targets set?		Refer to page 7
Has a data collection method been identified?		Refer to page 7
Has a qualified individual been identified to perform monitoring?		Refer to page 7
(For pilot studies) Has a region/sample of health centres been identified for monitoring?		Refer to page 13
Baseline survey performed?		Refer to page 9
Frequency of monitoring determined?		Refer to page 13
Monitoring checklist developed?		Refer to page 13 and Tool 5
Troubleshooting guide/Corrective Action algorithm developed?		Implementation 2
Monitoring Report complete?	On-going	Refer to page 15 and Tool 4
Data Collection & Analysis?	On-going	Refer to page 15
Data Disseminated?	On-going	Refer to page 18
EVALUATION		
Process (Input and Output) Evaluation		Refer to page 17
Outcome Evaluation		Refer to page 17
Impact Evaluation		Refer to page 17

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Tool 2. Monitoring and Evaluation Reporting Matrix

Indicator Title	Operational Definition	Measurement Tool
Output Indicators		
Effective supply of Rapid Syphilis Tests	**Numerator**: Number of clinics experiencing stock out of syphilis test during [x] time period **Denominator**: Total number of clinics implementing Rapid Syphilis Testing during [x] time period	Health Facility Stock card
Effective supply of Benzathine Penicillin	**Numerator**: Number of clinics experiencing stock out of benzathine penicillin during [x] time period **Denominator**: Total number of clinics implementing Rapid Syphilis Tests during [x] time period	Health Facility Stock card
Proficiency Testing coverage	**Numerator**: [x] number proficiency panel testing conducted in [x] number of facilities [x] times per year/per project period within [x] time period **Denominator**: Total number of facilities providing rapid syphilis testing within [x] time period	Proficiency Test Record/Report
Outcome Indicators		
Proportion of healthcare workers trained on the use of RST	**Numerator**: Number of healthcare workers that have received training on RST and are performing RST testing in [x] number of facilities during [x] time period **Denominator**: Total number of staff providing RST testing in [x] number of facilities during [x] time period	Training Records
Proportion of first antenatal visit attendees who are screened	**Numerator:** Number of first visit antenatal care attendees in [x] facilities who are screened for syphilis within [x] time period **Denominator:** Total number of first antenatal care attendees in [x] facilities within [x] time period	MOH reports/ MCH/PMTCT programme records/patient registers
Proportion of pregnant women screened who tested positive	**Numerator:** Number of pregnant women with a positive syphilis serology in [x] facilities within [x] time period **Denominator:** Total number of pregnant women with positive syphilis serology in [x] facilities within [x] time period	MOH reports/ patient registers
Proportion of infected pregnant women who are treated on the same day	**Numerator:** Number of seropositive syphilis pregnant women receiving at least one dose of benzathine penicillin on same day of testing in [x] facilities within [x] time period **Denominator:** Total number of pregnant women with positive syphilis serology in [x] facilities within [x] time period	MOH reports/ MCH/PMTCT programme records/patient registers
Proportion of infants born to syphilis positive women who are treated	**Numerator:** Number of infants born to syphilis seropositive women who are treated with at least one dose of penicillin in [x] facilities within [x] time period **Denominator:** Total number of live births to syphilis seropositive women in [x] facilities within [x] time period	MOH reports/ MCH/PMTCT programme records/patient registers

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Indicator Title	Operational Definition	Measurement Tool
Outcome Indicators		
Proportion of pregnant women attending ANC whose male partner was tested	**Numerator:** Number of infected pregnant women whose partners attend for treatment (at least one dose of benzathine penicillin) in [x] facilities within [x] time period **Denominator:** Total number of syphilis seropositive women in [x] facilities within [x] time period	MOH reports/ patient registers
Impact Indicators		
Increase in access to tests	**Numerator**: Number of clients being screened for syphilis in [x] facilities within [x] time period **Denominator:** Number of clients being screened for syphilis at baseline in [x] facilities within [x] time period	MOH reports/ patient registers/ Baseline data collected
Syphilis prevalence among target populations (ANC, STI patients, FSW, MSM)	**Numerator:** Number of syphilis positive cases in target population in [x] facilities within [x] time period **Denominator:** Total number screened for syphilis in target population in [x] facilities within [x] time period	MOH reports/ patient registers
Congenital syphilis rate	**Numerator:** Total number of congenital syphilis cases per national case definition in [x] facilities within [x] time period **Denominator:** Estimated number of live births in [x] facilities within [x] time period	MOH reports/ MCH/PMTCT programme records/patient registers

Refer to WHO, 2011. A Tool for Surveillance, Monitoring and Evaluation of Congenital Syphilis Elimination Efforts within Existing Systems, for a further list of indicators.

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Tool 3. Sample baseline survey & routine monitoring checklist for integrated syphilis and HIV package in PMTCT

A. Facility Information. In the past one month:	
A1. How many pregnant women attended the antenatal care clinic (total)?	
A2. How many pregnant women attended antenatal care for the first time before 16 weeks gestation?	
A3. How many pregnant women attended antenatal care for the first time after 16 weeks gestation?	
A4. Number of days health facility experienced stock outs:	
HIV Test Kits	
Rapid Plasma Reagin test kits (reagents and test cards)	
Syringes (for rapid plasma reagin)	
Penicillin	
Rapid syphilis test kits	

B. Syphilis Screening Programme. In the past one month, using the rapid syphilis test kit:	
B1. How many pregnant women were tested for syphilis?	
B2. How many pregnant women tested positive for syphilis?	
B3. How many syphilis-positive women were treated with at least one dose of benzathine penicillin?	
B4. How many syphilis-positive women were treated with the first dose of benzathine penicillin on the SAME day as their test?	
B5. How many syphilis-positive women received their first dose of treatment before 16 weeks gestation?	

C. HIV Testing and Counselling. In the past one month:	
C1. How many pregnant women were known HIV positive before this pregnancy?	
C2. How many pregnant women were tested for HIV?	
C3. How many pregnant women received their HIV test results?	
C4. How many pregnant women tested HIV positive?	
C5. How many HIV positive pregnant women received a maternal dose of anti-retroviral (ARV) prophylaxis?	
C6. How many HIV positive pregnant women were referred to care and treament?	

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D. Partner Uptake of PMTCT Package of Services. In the past one month:	
D1. How many partners were tested for syphilis using the rapid test kit?	
D2. How many partners tested positive for syphilis using the rapid test kit?	
D3. How many partners were treated with at least one dose of benzathine penicillin?	
Among partners who tested positive for syphilis with the rapid test	
Among partners who were treated presumptively (not tested with rapid test, but exposed to a syphilis-positive partner)	
D4. How many partners were tested for HIV?	
D5. How many partners received their HIV test results?	
D6. How many partners tested HIV positive?	
D7. How many HIV-positive partners were referred to care and treatment?	

E. Labour and Delivery. In the past one month:	
E1. How many deliveries were performed?	
E2. How many babies were born from syphilis-positive mothers at this health facility?	
E3. How many syphilis exposed babies were treated with benzathine penicillin?	
At labour and delivery	
At postnatal visit	
E4. How many babies were born to HIV-positive mothers at this health facility?	
E5. How many HIV-exposed infants received an infant dose of anti-retroviral prophylaxis?	

F. HIV & Syphilis Co-Infection. In the past one month:	
F1. How many pregnant women were co-infected with HIV and syphilis?	
F2. How many partners were co-infected with HIV and syphilis?	

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Tool 4. Monitoring Report Template

Study Details	
Study Title	
Site Name	
Site type	Central Laboratory ☐ Clinic ☐
Name of site director/manager	
Participants in field visit	
Prepared by	
Annex (list of persons met)	
Date of last monitoring visit at this site	

Results
Observations, Recommendation and Action Plans
Detail any deviations from the study protocol, non-conformances and corrective actions performed on site
Conclusions
Signatures (Monitor and Reviewer)

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Tool 5. Sample checklist for routine monitoring & evaluation

Internal Monitoring Control

Site Monitoring Checklist
District: Facility name:Date:

1. Quality Assurance and Performance			
Activity	**Scores**	**Corrective Action (where necessary)**	**Comments**
I. Staff performing the test: a. Nurses b. Lay counsellors a. Others, specify.	a.		
	b.		
	c.		
I. Preparing patient for syphilis testing			
I. a. Testing space b. Biosafety rules conformance	a.		
	b.		
I. Preparation of cassettes and test tubes			
I. Disinfecting testing space/disinfectant used			
I. Drawing blood (procedure)			
I. Dropping blood on sample well			
I. Timing and reading of results			
I. Disclosing of syphilis test result (procedure)			
I. Counselling patient on treatment			
I. Counselling patient on partner notification (incl. issuing out partner invite)			

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2. Quality Control and Rapid Syphilis Test Kits storage			
Activity	**Scores**	**Corrective Action (where necessary)**	**Comments**
I. Reviewed: a. Registers b. Stock cards c. Inventory forms d. Stock storage e. Temp. Log in storage space f. Data summary forms (accuracy)			
	a.		
	b.		
	c.		
	d.		
	e.		
	f.		
XIII. Quality Control a. Quality Control performed b. Appropriate results c. Inappropriate results d. If yes to c. any corrective action taken e. Outcome f. Any preventive measure put in place			
	a.		
	b.		
	c.		
	d.		
	e.		
	f.		

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2. Quality Control and Rapid Syphilis Test Kits storage			
Activity	**Scores**	**Corrective Action (where necessary)**	**Comments**
3.0 Medical Supplies			
XIV. Availability of medical supplies			
a. Test kits	a.		
b. Gloves	b.		
c. Syringes	c.		
d. Needles	d.		
e. Sharp bins	e.		
f. Biohazard bags	f.		
g. Disinfectants	g.		
h. Benzathine Penicillin	h.		
i. Adrenaline	i.		
j. Capillary tubes	j.		
k. Vacutainers	k.		
l. Pens	l.		
Total scores from applicable items:			
Marking key: 1 = Poor 2 = Medium 3 = Good 0 = Not in place X = Not applicable Note: Marked out of maximum possible scores from applicable sections!			

Completed by: **Sign.:** **Date:**

Internal Monitor/Coordinator

Reviewed by: **Sign.:** **Date:**

Co-Investigator

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Tool 6. External monitoring checklist

Key to symbols used in check boxes:

1 = Poor 2 = Medium 3 = Good ✗ = No ○ = Not applicable

Activity		Result	Observation/Comments
1. Facility			
1.1	What is the condition of the building/ work area?	☐	Lighting Ventilation Temperature Noise Benches Storage space Office space
1.2	Is there adequate laboratory space/ workbench for testing? Is the area large enough? Is the area clean?	☐	
1.3	Does the laboratory conform to any national standards/accreditation body?	☐	
1.4	What types of communications are available?	☐	Post, telephone, fax, mobile phone, computer (with e-mail, printer, internet), photocopier
1.5	Is the facility maintained in a clean and sanitary condition?	☐	
1.6	Is there separate examination room/ consultation room?	☐	
1.7	Is there adequate electricity and running water?	☐	What % of day is there electricity/ running water?
1.8	Are gloves available and used routinely?	☐	
1.9	Are hand-washing supplies and facilities available in a convenient area?	☐	
1.10	Do the facility staff have access to reliable form of transportation (vehicle, motorcycle, bicycle)	☐	
	TOTAL SCORE	/	

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Activity		Result	Observation/Comments
2. Personnel & Training			
2 .1	Indicate details of staff involved in the care of study population (syphilis)	☐	Number of: ■ Physicians ■ Nurses ■ Laboratory technician ■ Other
2.2	Provision of adequate training – training manual and records of training workshops? (Operation of Bioline, Quality Assurance, biosafety, stock management) How much formal/informal training is done on-site? At national/international level?	☐	Training of trainer/district trainers Training staff on patient management Training of internal monitor Training on all supply chain aspects – stock management/ordering lab consumables/ drugs
2.3	What is the staff turnover?	☐	Frequent/infrequent
2.4	Are personnel aware of their contribution to achieving quality objectives?	☐	
2.5	Quality performance of health care workers: their ability to provide patients with high quality of care	☐	■ Approaching the patient ■ Providing patient with information about syphilis and syphilis testing ■ Performing the rapid test ■ Disclosing the results of the rapid test ■ Counselling the patient ontreatment ■ Counselling the patient on partner notification ■ Literacy, organizational skills and decision making skills
2.6	Do staff demonstrate professionalism? Is patient confidentiality maintained?	☐	
2.7	Is the number of staff adequate for the site workload?	☐	How many tests does each staff member perform per month
2.8	Acceptance of rapid syphilis testing by health care workers	☐	How is the testing & associated Quality Control perceived by health care workers? Ease of use/Facility level interviews
	TOTAL SCORE	/	

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Activity		Result	Observation/Comments
3. Biosafety			
3 .1	Has the site documented and implemented procedures to identify and manage biohazard and risks?	☐	Standard Operating Procedures for Biosafety (refer section 5.7)
3.2	Is Personal Protective Equipment (PPE) available and used? Are lab coats and laboratory linens routinely washed?	☐	Lab coats/gowns, gloves, mask, footwear
3.3	Is biohazard waste disposed of safely?	☐	Does disposal comply with local standards?
	TOTAL SCORE	/	
4. Equipment			
4.1	Is refrigerator clean and organized?	☐	
4.2	Are refrigerator/freezer temperatures monitored and recorded, if present?	☐	
	TOTAL SCORE	/	
5. Quality Management System: Documentation control			
5.1	Does facility have a storage and archiving system for SOPs and records? Hardcopy or electronic copy? Are all procedures stored in a laboratory procedure manual that is easy to access?	☐	Hardcopy or electronic copy?
5.2	Are Standard Operating Procedures, forms and templates present and visible in the clinic, including: Operation of SD Bioline? Quality Assurance/Quality Control testing? Blood draw/finger prick? Training? Supply chain management? Biosafety? Ministry of Health Standard Operating Procedure for anaphylactic shock?	☐	Standard Operating Procedures document that procedures are pre-specified

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Activity		Result	Observation/Comments
5 .3	Do procedures include: ■ Date of creation/modification? ■ Version number? ■ Page number? ■ Name of originator and validator?	☐	
5.4	Are procedures and record forms standardized with the rest of country facilities?	☐	Following review of all country facilities If yes, how are they controlled?
	TOTAL SCORE	/	
6. Quality Management System: Data collection			
6.1	Are clinical records/patient register kept centrally in the health facility?	☐	
6.2	Are patients assigned a unique numerical identifier? If yes, is the number specific for the health facility, the region, or the country?	☐	
6.3	Are clinical records computerized? If so, what software package is used?	☐	
6.4	Is there traceability/identification of Quality Control records to patient registers?	☐	Expand
6.5	Are all documents/registers/ worksheets initialled and dated by personnel performing the test, and patient identification (ID) included?	☐	
6.6	Is hand writing legible?	☐	
6.7	Is data being routinely collected? Are data collection forms and questionnaires collected regularly and double entered?	☐	
6.8	What is total local population? Total adult population (15 – 49 yrs)? Total young adult population (15 – 24 yrs)?	☐	
6.9	What is the number of local health facilities in the country? What is the total number of districts/ regions in the country? What is the total number of health provinces in the country?	☐	Public, private, tertiary hospitals, secondary referral hospitals, district general hospitals, primary health care clinics, health posts, counselling and testing centres

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Activity		Result	Observation/Comments
6.10	What is the geographical coverage of testing?	☐	
6.11	Is written informed consent from patient required?	☐	
6.12	Is syphilis rapid testing integrated with HIV rapid testing?	☐	
6.13	Are partners tested and treated? Are patients counselled in the event that the partner does not attend for testing and treatment?	☐	
6.14	Are there clinical algorithms for **testing** and **treatment** visible in the clinics?	☐	
6.15	How are weak positives managed? Is this detailed in the Standard Operating Procedures or in an algorithm for re-test?	☐	
6.16	Is there immediate treatment when test positive?	☐	
6.17	Is Same Day Testing and Treatment recorded?	☐	
	TOTAL SCORE	/	
7. Quality Management System: Process & Quality Control			
7.1	Do the personnel carrying out process control have adequate training for the tasks and have adequate knowledge of the quality management system?	☐	Supporting evidence from training records and evidence of the quality control process to assess personnel. Training procedures signed off by supervisor/trainer (refer to section 2.2)
7.2	How often are internal quality controls carried out? What is the source of quality control material used?	☐	
7.3	How often are external quality controls carried out? What is the source of quality control material used?	☐	Standard Operating Procedures document that procedures are pre-specified
7.4	Do quality forms include appropriate/ related information for testing?	☐	
7.5	Are quality control records up to date and reviewed?	☐	

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Activity		Result	Observation/Comments
7.6	Are Quality Control records/ documents stored/archived? For how long?	☐	
7.7	Are results interpreted and recorded according to SOP?	☐	Compare completed quality record with Standard Operating Procedures.
7.8	Is qualification of personnel carried out using Dried Tube Specimen/ proficiency panel?	☐	Observe staff perform rapid test using proficiency panel (record results for each individual). All steps should follow Standard Operating Procedures.
7.9	Is the Dried Tube Specimen identification number recorded on the quality/proficiency panel testing form?	☐	
7.10	Are Quality Control forms initialled and dated by personnel performing test?	☐	
7.11	Are Corrective and Preventive actions detailed on the Quality Control form?	☐	
7.12	Are the forms signed off by an internal monitor following corrective action?	☐	
7.13	Is syphilis status reported only when internal and external controls are within specification?	☐	Review registers/log books/record forms
7.14	Is there incoming Inspection of rapid syphilis kits? ■ visual inspection (appropriate labelling, signs of damage, or contamination) ■ testing kit using proficiency panel at central laboratory for each new lot and shipment for verification – including acceptance criteria ■ Is a sample of each kit lot retained at the central laboratory?	☐	Quality Records
7.15	Is each lot within each shipment of material or components assigned a distinctive code so material or component can be traced through manufacturing and distribution?	☐	Date of last check. Records
7.16	Are rejected components, material, and containers quarantined and clearly marked to prevent their use?	☐	
	TOTAL SCORE	/	

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Activity		Result	Observation/Comments
8. Supply Chain			
8 .1	Is there a documented process /inventory control to provide and maintain stock and for ensuring purchase orders and follow up?	☐	Standard Operating Procedures for Biosafety (refer section 5.7) Stock Card and Daily Stock Inventory Card. Ensure that forecasting, inventory management, distribution, management information systems are adequately addressed. Is there effective control for planning for, placing orders for, and verifying purchased products?
8.2	What is the distribution plan for rapid tests?	☐	i.e. delivery to a central warehouse/ distribution unit for storage and shipped to facilities according to demand
8.3	To how many facilities are products being distributed from central stores? What % of the country is being covered for distribution?	☐	Central stores
8.4	How are supplies distributed?	☐	Car/van/motorbike/bicycle
8.5	Are there any significant challenges in distributing products to health facilities?	☐	Central stores, Lack of roads, very long distances
8.6	Is the site ever unable to perform testing because there are no kits/ supplies on hand? If yes, how frequently does this occur? If unable to test, how is information supplied to clients?	☐	Log book/ stock cards
8.7	What is the average distribution schedule to the health facilities? How is the requirement for product quantity determined?	☐	Monthly, quarterly? By average consumption?
8.8	Is there sufficient capacity to ensure products are distributed in timely and safe manner?	☐	Covered trucks, cars, sealed boxes, renting/ purchasing additional vehicles, outsourcing
8.9	Is minimum stock on-hand?	☐	At facilities and distribution centre (if applicable) Look at re-order levels
8.10	Is there trending of stock/stock-outs to improve forecasting?	☐	Check stock control cards

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Activity		Result	Observation/Comments
8.11	Is there always a stock of penicillin available?	☐	
8.12	Is there any re-using of supplies?	☐	Tips, gloves, slides, Petri dishes, Pasteur pipettes
8.13	Are all supplies stored properly?	☐	In accordance with the manufacturer's directions (kits, stored off the floor?)
	TOTAL SCORE	/	
11. Process Improvement			
11.1	Have any projects been undertaken for process improvement?	☐	Related to internal monitoring activities
12. Other Research Activities			
12.1	Are other studies ongoing or planned in the clinic? If yes, do they involve the same study population? If yes, will the enrolment period be the same?	☐	

M&E Plan for Project 47697
Accessible Quality-Assured Tests for Sexually Transmitted Infections

I. Introduction

The purpose of this M&E plan is to define the focus and scope of data collection for monitoring and evaluating the performance of the Accessible Quality-Assured Tests for Sexually Transmitted Infections (STI). It reflects the goals and objectives of the grant with a specific focus on activities two and three. The M&E plan contains a results framework, key M&E questions, definitions of key terms, indicators, data sources/methods, and data collection and reporting by type of site and an annex for documenting stakeholder engagement by each site.

As stated in grant proposal, the overall **goal** of the Accessible Quality-Assured Diagnostic Test for Sexually Transmitted Infections (Project 47697) is to decrease the burden of STIs and their sequelae through increasing access to quality-assured diagnostic tests in developing country settings. This grant is implemented by the Sexually Transmitted Diseases Diagnostics Initiative (SDI), housed in the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (WHO/TDR). The project is designed to produce a global framework and tools for the introduction and sustainable adoption of quality-assured rapid STI tests.

The overall goal will be reached through addressing the following two objectives 1) increase access to rapid STI diagnostic tests in developing countries; and 2) ensure the quality of STI rapid diagnostics and diagnostic testing in developing countries. Project activities, however, consist of a series of demonstration projects in seven countries whose purpose is to **assess the feasibility and benefit of introducing a rapid test for syphilis into health facilities that provide antenatal, PMTCT, and health services for populations at high-risk of contracting sexually transmitted diseases**. Benefits, in this case, are defined as increased access to testing and treatment (effectiveness of rapid test introduction) and cost effectiveness. Evidence produced from these demonstration sites will be channeled to key country – level policy makers and program managers through various stakeholder engagement activities. The project objectives as stated in the proposal therefore represent a vision for the use of this evidence should countries adopt the rapid test and scale up its use country-wide. Although the demonstration sites will measure changes in access and quality as part of assessing the feasibility and benefit of rapid testing, the success of these demonstration sites should not be determined in reference to these higher-level, population- and facility-based outcomes.

II. **Focus of M&E Plan**

The M&E plan outlined below will focus on Activities 2 and 3.

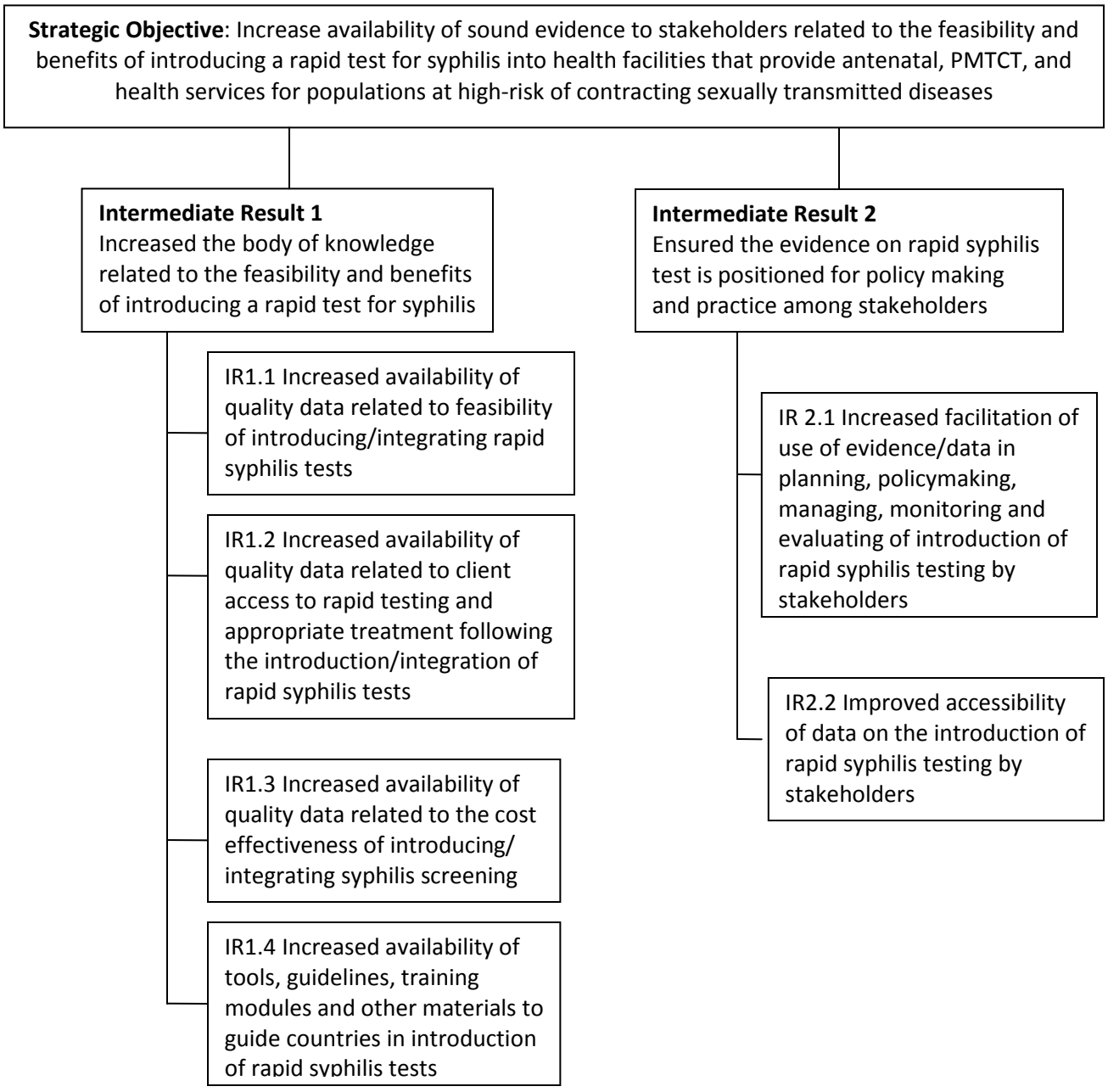
Activity 2	Demonstrate the attributable benefit of increased access to antenatal syphilis screening through integration with: -Prenatal services -Prevention of Mother To Child Transmission (PMTCT) Programmes for HIV
Activity 3	Demonstrate the attributable benefit of increased access to STI diagnostics in high risk populations

The specific and strategic objective of these activities is to: *Increase availability of sound evidence to stakeholders related to the feasibility and benefits of introducing a rapid test for syphilis into health facilities that provide antenatal, PMTCT, and health services for populations at high-risk of contracting sexually transmitted diseases.* There are two main intermediate results or outcomes of the project that represent critical steps toward achieving the strategic objective. In order to achieve the strategic objective, the project must have:

1. Increased the body of knowledge by assessing the feasibility, effectiveness, and cost effectiveness of introducing a rapid test for syphilis; and
2. Ensured that the evidence on rapid syphilis test is positioned among stakeholders for policy making and practice.

The relationship between the strategic objective, intermediate results and sub-results is presented in the following framework.

Results Framework
Accessible Quality-Assured Tests for Sexually Transmitted Infections



III. Program Activities (Activities 2 & 3)

Demonstration projects

The LSHTM team will conduct demonstration projects to gather evidence of the feasibility of rapid test introduction and cost-effectiveness. These demonstration projects will validate the attributable benefit of increased access to rapid quality-assured STI tests in two populations for which access to diagnostics are urgent priorities, syphilis screening for pregnant women and STI screening for high risk populations.

The demonstration projects on increased access to syphilis screening in prenatal populations are also designed to provide evidence on the feasibility and cost-effectiveness of integrating syphilis screening into existing prenatal and Prevention of Mother to Child Transmission Programmes for HIV. Countries have voiced difficulties in coping with multiple vertical donor programmes, often with conflicting agendas and draining already scarce human resources. Integration of services not only makes economic sense but can avoid tragedies of babies avoiding HIV and dying of syphilis.

The demonstration projects will be implemented at sites in seven countries, four of which have been SDI evaluation sites since 2001. These sites have considerable expertise and experience with conducting clinical trials in accordance with Good Clinical Practice and Good Laboratory Practice. The first year will be spent on project development consultations, site preparations and obtaining institutional board and human subjects' ethics committee approval. The demonstration projects will be initiated in the second year. The recruitment is expected to be completed by the first quarter of the third year. Data analyses, consultations to review the results and the implications of the findings, and dissemination of project outcomes to stakeholder for consideration in scaling-up will be completed within the third year.

Positioning the evidence: stakeholder engagement

In addition to managing the demonstration projects that will produce evidence for policy making and programming, the project aims to ensure that the evidence produced reaches decision makers at country level and is strategically positioned so as to inform key stakeholders and decision making processes. The stakeholders' buy-in from the inception of the project is absolutely crucial for ensuring the translation of evidence into policy.

For the first year of the project, each site identifies and engages key stakeholders to determine what information is needed in the country and how best to position and develop the project. These meetings are held periodically through the 3 years of the grant, either in conjunction with other meetings or as stand-alone meetings to update all the stakeholders on progress and lessons learnt. The key stakeholders are:

Ministries of Health: All country site PIs will engage programme directors and policy makers for Maternal and Child health, reproductive health, STI/HIV control, PMTCT and VCT programmes for HIV to obtain endorsement for our project and to co-develop the project to leverage ongoing efforts in similar areas and to avoid duplication. Issues such as what the needs are and where rapid tests would make an impact in saving babies, selection of the project sites, how the testing

is to be introduced, what evidence they would like to see to change policy are issues that are negotiated between the project and ministries of health.

Country Regulatory Authorities and Ministries of Finance: The project will consult these stakeholders on regulatory approval processes for new tests and for work on modeling cost-effectiveness.

Non-governmental organizations and other donor agencies: The project will consult with NGOs in the field of maternal and child health and related activities and develop synergies with related activities for prenatal screening.

Scientific and research communities: The stakeholders' meetings include experts in the field from academic institutions and research institutes to solicit their input into advocacy and study design. The projects aims and activities are presented at national and international scientific conferences.

General public/at risk populations: Since most people who are infected with syphilis have no symptoms and yet consequences of infection are serious, it is important to educate the public and especially at risk populations and encourage them to come in for testing or agree to testing in outreach settings. This link to the targeted users of this test is largely done through media campaigns and press releases. For example, in China and Brazil, the projects have been featured repeatedly in the print media and on television. Interviews are planned with the project director and others on the team with local media.

Positioning the evidence: dissemination of results

In addition, the projects have created their own branding for easy recognition. They have pamphlets, web sites and cards, and small items, such as small package of tissues in China, printed with their project logo to distribute during their campaigns.

The project will have a Sharepoint for sharing of documents and updates. PIs will meet annually to report on updates and facilitate communication between projects, exchange of ideas and sharing experiences and lessons learnt.

Under Activity 1 the project will hold meetings/workshops in three regions of the world where the burden of syphilis is highest, i.e. Africa, Asia, and South and Central America. At each of these regional meetings, the project will inform 12- 15 high burden countries not funded through the project about the project objectives, tools that will be developed for their use and other resources.

Throughout the duration of the grant, and at the conclusion of the demonstration projects, all the results will be disseminated through all of the above channels in addition to being written up in open access peer-reviewed publications. There will be consultations with policy makers in each country to present the evidence. The models produced will demonstrate the potential impact and cost-effectiveness of the approach and be used to facilitate policy discussions and implementation strategies.

IV. M&E Questions to be answered

The M&E plan will address the following questions:

1. Is the project producing the evidence necessary to answer the following questions?

    - Is introducing/integrating a Same-Day Testing and Treatment (STAT) strategy for syphilis into existing or routine antenatal, PMTCT, STI/HIV clinics **feasible**?
        a. Acceptability to HCWs,
        b. Supply chain performance,
        c. Quality of the test,
        d. Quality of care

    - Is introducing/integrating rapid syphilis testing into ANC, PMTCT, STI/HIV clinics **effective** in reaching clients?
        a. Access to testing
        b. Access to treatment

- Is introducing/integrating the rapid syphilis testing into existing ANC, PMTCT, STI/HIV clinics **cost-effective**?
    - Cost per case of congenital syphilis
    - Cost per case of averted

2. Is the project positioning the evidence for policy making and practice among stakeholders?

- Is the project facilitating the use of evidence in planning, policy making, managing, monitoring and evaluating the introduction/integration of rapid testing?
- Is the project improving access to data on the introduction/integration of the rapid test?

V. Definition of terms

<u>Feasibility of test introduction</u>: the sustained ability of health facilities to integrate rapid syphilis testing into routine antenatal care [PMTCT, STI/HIV clinics]. Includes the following elements:

1) acceptability by HCW
2) supply chain effectiveness (forecasting and avoiding stock-outs);
3) performance of rapid test (Quality Control); and
4) Quality Assurance and Quality of Care: quality of testing and treatment process (the quality of syphilis testing provided and ability to detect and treat positive cases)

- Quality Control: Ability of the test to distinguish between samples that are known to be either syphilis-positive or syphilis-negative
- Quality Assurance: Ability of the health care worker to correctly perform rapid tests according to the manufacturer's guidelines
- Quality Performance: Ability of HCW to provide patients with a high standard of care and will address the following:

- Approaching the patient
- Providing the patient with information about syphilis and syphilis testing
- Performing the rapid test
- Disclosing the results of the syphilis test
- Counseling the patient on treatment
- Counseling the patient on partner notification

Effectiveness of introduction/integration of testing in terms of client access to testing and treatment:

- the proportion of patients presenting who are screened for syphilis
- The proportion of positives who are treated for syphilis on the same day or referred

Cost-effectiveness: cost per case of congenital syphilis or syphilis averted; cost per woman treated

VI. Monitoring and Evaluation

The project will be monitored internally by the SDI staff using monthly teleconferences with the WHO regional staff and principal investigators to ensure that milestones are reached. In addition, each country project will develop its own monitoring and evaluation plan to enable SDI staff and external monitors to track progress against objectives and outcomes and report to stakeholders. Data collection throughout the project will serve the dual purpose of program management (including ensuring continuous quality improvement and tracking milestones) as well and assessing overall performance against objectives and expected results. In some cases data will be used for real-time decision making and problem solving and in other cases data will be used to track performance and report on results. In some instances, data sources may serve both purposes. Please see the country specific M&E plan for details on the data to be collected at each demonstration site.

To ensure that results and intermediate results are being met, the SDI team at the LSHTM and the PIs in country will conduct internal and external monitoring visits. During these visits, the team will assess the completeness, quality, and timeliness of data collection and analysis. During the internal monitoring visits, investigators from the within the country will review the clinic logbooks on site where patient information and testing results are recorded. The QC logbooks will also be reviewed and checked for any non-conformances, in which event the corrective actions, such as re-training of staff, will be undertaken at that time.
The external monitoring visits are carried out by external independent reviewers and the final output is an external monitoring report detailing how the monitoring is carried out and the outcomes of the visit. The external monitoring visit ensures that the project is being carried out according to the project protocol (especially if informed consent is needed), it assesses the validity and accuracy of the data collected, examines the supply chain and any QA issues, and suggests corrective actions and recommendations to the sites as needed.

Stakeholder engagement will be tracked in each country using a tracking checklist (see annex 1) that will be updated on a regular basis by the PI. The production and dissemination of results and technical materials, which includes advocacy (policy and programme guidance for countries), web based interactive mathematical model, algorithms (technical guidance on developing

testing and treatment algorithms) , policy platform (strategies for test introduction), supply chain and stock management guidelines, cost-effectiveness analysis, training manual for use of tests, quality assurance/quality control package, will be monitored and reported by the LSHTM team.

The indicators for the M&E Plan reflect a combination of process and outcome indicators that demonstrate progress in project activities to support the intermediate results and the overall strategic objective of the project (i.e. demonstration sites). The data sources supporting these indicators require both quantitative and qualitative data.

VII. Indicators & Data Sources

Result 1: Increased body of knowledge related to the feasibility and benefits of introducing/integrating the rapid test in target populations (ANC, PMTCT, high risk groups)

Results	Indicators	Data Sources
IR 1.1 Increased availability of quality data related to the feasibility of introducing/integrating rapid syphilis tests	Number of demonstration sites collecting and reporting data on the sustainable ability of health facilities to introduce/integrate rapid syphilis testing into routine antenatal care, PMTCT, STI/HIV clinics	- Results from demonstration sites - Teleconferences with PIs
	Validation of integrated service models to increase access to diagnostics (through leveraging resources and infrastructure already available for HIV and prenatal care)	- Results from demonstration sites
IR 1.2 Increased availability of quality data related to client access to syphilis testing and treatment following the introduction/ integration of rapid syphilis tests	Number of demonstration sites collecting and reporting data on changes in access to testing	- Results from demonstration sites - Teleconferences with PIs
IR1.3 Increased availability of quality data related to the cost effectiveness of	Number of demonstration sites collecting and reporting data on the: cost per case of congenital syphilis or syphilis averted and	- Results from demonstration sites based on: - Facility level interviews, observations and

introducing/integrating rapid syphilis test	cost per woman treated	reviews of the routinely collected register data and accounts using checklist to support cost data collection for RPR testing in health facilities. - Teleconferences with PIs
IR1.4 Increased availability of tools, guidelines, training modules and other materials to guide countries in introduction of rapid syphilis tests	Number of demonstration sites using or adapting SDI framework, tools, guidelines, training modules and other materials to guide them in the introduction of rapid syphilis tests	- Results from demonstration sites - Teleconferences with PIs
	Development and validation of a Quality Control/Quality Assurance system for diagnostics in remote settings	- Guidelines - Presentations at conferences/meetings
	Number of tools, guidelines, training modules and other materials developed	- Published or reported examples of tools, guidelines, training modules and other materials developed

Result 2: Ensure the evidence on rapid syphilis test is positioned for policy making and practice

Results	Indicators	Data Sources
IR 2.1 Increased facilitation of use of evidence/data in planning, policymaking, managing, monitoring and evaluating of	Instances in which information produced through the demonstration sites is used in: ▪ Policy development ▪ Planning and/or resource allocation ▪ Program design and improvement ▪ Program management, including facilities management and patient	- Citations and/or references of results from the demonstration sites in policy, planning and other program documents, - Key informants who report considering findings from the demonstration sites in reaching their decision.

introduction of rapid syphilis testing by stakeholders	care and management ▪ Advocacy	
	Instances where the demonstration sites resulted in scaling up of rapid syphilis testing in target population	- Documentation from country/program of scale-up (i.e. scale-up strategies and implementation plans, budgets, etc)
	Instances of activities that include active engagement of stakeholders in multiple phases of the demonstration study process.	- Participant lists and agendas from stakeholder meetings - Tracking sheet/ Stakeholder engagement updates to record instances of stakeholder engagement (ref Annex 1) -
IR 2.2 Improved accessibility (dissemination) of data related to the introduction of rapid syphilis testing by stakeholders	Instances where key actionable findings, experiences and/or lessons learned from the demonstration sites are available to decision makers and/or stakeholders	- Reports and publications, and accompanying presentations, posters, etc. that present actionable research findings, experiences, and/or lessons learned, and communicates that information to stakeholders/decision-makers who can use those findings to make program or policy decisions.
	Number of SDI/host country print, electronic, and video publications	- Publication lists including media campaigns, press releases, pamphlets, websites, etc.
	Number of articles published in peer-reviewed journals	- Citations and/or references

VIII. Demonstration sites reporting by type of site

Activities 2 and 3 are being carried out in a variety of settings and populations so that the results from this study can be generalized to as many countries as possible. The project sites were chosen based on their expertise and experience evaluating rapid syphilis tests. They are located in countries where the government has shown a strong interest in scaling up the use of rapid syphilis tests if the study shows promising results. There was also the opportunity to determine the feasibility of integrating syphilis screening into existing prenatal services or global health initiatives such as those sponsored by the Global Fund or PEPFAR.

The monitoring and reporting of certain results related to the introduction or integration of rapid syphilis testing will vary by country and demonstration site depending on the type of service and target population. Table 1 maps the demonstration sites by type of service and local population. The qualitative outputs such as feasibility and quantitative aspects, such as

effectiveness/access and cost-effectiveness will have standardized measurements among all sites allowing for a fully integrated and unbiased study to be made among all sites.

Table 1. Study settings for Rapid Syphilis Test Introduction

Study Setting		**Brazil**	**China**	**Haiti**	**Peru**	**Tanzania**	**Uganda/Zambia**
Income ranking		Upper middle	Middle	Low	Lower middle	Low	Low
Prenatal:	-no PMTCT		X		X	X	
	-with PMTCT			X		X	X
High Risk populations			X			X (some)	
Remote communities		X		X			
Health system-wide introduction				X		X	

NB. High-risk populations will targeted in Tanzania through the introduction of rapid tests to the district VCT clinic. The presence of a large mining and transient population in Tanzania has resulted in a large number of sex workers; however, no specific intervention will target these individuals outside of VCT.

Annex 1: Stakeholder engagement updates:

Name and location of site:

Date:

Stakeholder	Action	Outcome to date
International agencies (WHO/PAHO/World Bank)		
Government (Ministry of Health, Finance, Education), Regulatory authorities		
Regional & Local Government		
Political parties/Social Movements, funders		
Private sector (companies)		
Nongovernmental (Religious groups and leaders, NGOs,)		
Health professional associations/unions		
Media (newspaper articles, broadcast coverage, public debate, posters, brochures) Universities Journals		
Indigenous groups, High risk groups, Women's groups, Patients at ANC, Community leaders, Labor unions		
Any other stakeholders (please detail)		