# Monitoring and Evaluation Framework

# Specimen Referral Systems and Integrated Networks

# July 2018

# Table of Contents

## Overview of monitoring and evaluating specimen referral systems

This guide to monitoring and evaluating specimen referral systems should be used as a companion guide to the more comprehensive, GLI Guide to TB Specimen Referral Systems and Integrated Networks[1]. This document borrows heavily from the GLI guide, but also gives additional information on monitoring and evaluation (M&E) specifically, focusing on the objectives of specimen referrals as well as data systems and activities that should accompany the M&E framework.

In order to determine the success of a specimen referral system, the objectives must be clearly stated at the beginning in a measurable way. The main objectives of a specimen referral system are to:

- **Increase access** to diagnostic testing,
- **Improve the timeliness** of diagnostic test results (i.e., shorten turnaround times between specimen collection and return of results),
- **Ensure biosafety and biosecurity** of the specimen referral system;
- **Improve the quality** of diagnostic testing by improving the quality of the specimens, and
- **Increase cost efficiency** of the specimen referral system (which could include integration of multiple specimen or disease types, or with supplies, if integration is cost-effective), and in turn, diagnostic testing

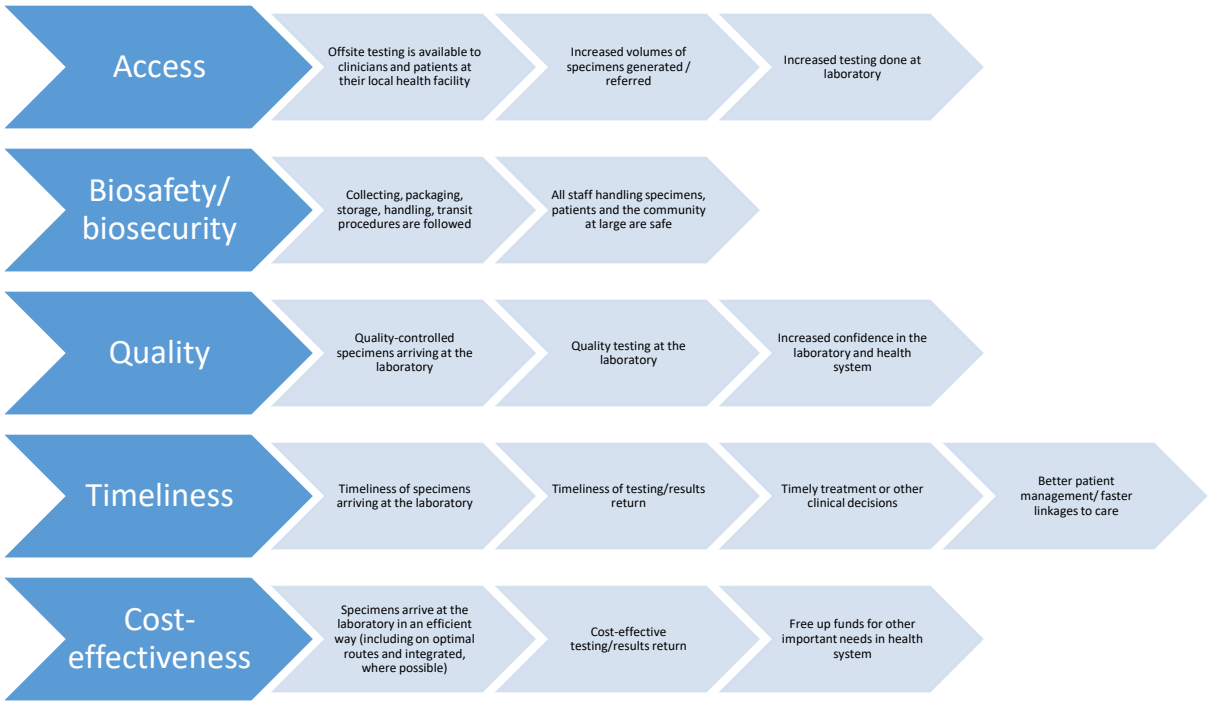
If these objectives are met, the specimen referral system will contribute to improved health outcomes through its function in strengthening the health system and specifically, the diagnostic network for TB.

### Theory of change

Specimen referral networks target a specific gap in services, namely lack of diagnosis at the point of care. With no network in place, patients and providers are limited in their ability to confirm diagnosis and start treatment, which leads to poor health outcomes. Where a quality-assured referral network is available with national coverage, patients and providers have improved access to specimen testing and are able to pursue appropriate treatment in a timely manner, which results in better health outcomes and ultimately, a decrease in disease burden. In reality, specimen referral networks may operate somewhere between these two extremes, and an M&E framework that allows for measurement of baseline indicators can be useful for setting up specific milestones as stakeholders plan and implement incremental steps aimed at reaching a high quality, safe, timely and cost-effective referral network at the highest level of coverage. Figure 1 describes how the referral network supports improved access, biosafety/biosecurity, quality, timeliness and cost-effectiveness for specimen handling.

[1] http://www.stoptb.org/wg/gli/assets/documents/GLI_Guide_specimens_web_ready.pdf

Figure 1:




## M&E framework

M&E frameworks frequently break these elements down further into measurable inputs, processes, outputs, outcomes and expected impact of a system level intervention to facilitate monitoring and evaluation over time, from baseline (no system in place yet) to endline (system fully implemented as designed). Figure 2 describes these elements in the context of a specimen referral network.

Figure 2:

**Inputs**

- Transport model
- Funding
- Providers trained on utilization of referral system

**Processes**

- Patients and providers utilize specimen referral on a routine basis
- Ongoing supervision and M&E for network strengthens network over time
- Quality assurance system provides useful data about performance

**Outputs**

- Increased number of specimens referred
- Patient specimens are referred in a timely, quality-controlled, efficient and cost-effective manner

**Outcomes***

- Increased number of referred specimens tested at the referral laboratory
- Increased number of facilities offering specialized diagnostics or referral services
- Increased access to diagnostic network
- Quality, timeliness, cost-effectiveness
- Provider confidence in diagnostic network improved
- Allow patients to access health services closer to their desired location without having to travel
- Cost savings to individual patients and no need to physically travel (takes burden off of patient)

**Impact***

- Higher patient utilization of overall health system
- Provider confidence to diagnose and treat disease
- Improved case detection and treatment outcomes, full drug susceptibility testing (DST)
- Reduced TB incidence and mortality

*Note: These indicators cannot all be fully attributable to the performance of the specimen referral network, but a robust referral network should contribute to these outcomes and impact

M&E for specimen referral systems then measures success against these objectives. The performance of the system should be examined at a high level as well as its operations at a more detailed level. At a high level, management of the specimen referral system should track key programmatic indicators such as case notification and treatment success, which ultimately affect disease burden and use data collected to inform decisions that will continuously improve the system. At an operational level, the national reference laboratory's quality assurance department and implementing/technical assistance partners should monitor input, process and output data on a routine basis to ensure that good quality specimens reach the testing sites in a safe and timely manner, quality results are returned rapidly, actions are properly documented in registers and forms, biosafety and biosecurity measures are followed properly, and packaging and transportation equipment meet applicable national and international standards. It is crucial that the M&E framework for any specimen referral system is considered early in the design phase in order to identify the data needed for monitoring the selected indicators and ensure that it is collected, analyzed and routinely used. It is also helpful if the specimen referral indicators are included in the disease-program's M&E framework, or the laboratory's, or both, such that the specimen referral network is measured as an input or supporting factor for the success of the program and/or laboratory.

## Indicators

As part of the M&E framework, indicators must be determined and standardized to measure success of the specimen referral system. There are many indicators that could be tracked; however, a suggested minimum list of performance indicators to be monitored is shown in Table 1. The indicators included are largely output and outcome indicators needed for routine monitoring and when they are analyzed, help identify where inputs/process investments are needed and the potential impact of the system on health outcomes. Additional process indicators such as the completeness of documentation (e.g., use and completeness of registers, logs, forms) or adherence to standard operating procedures (SOPs) and packaging standards are included and may be assessed during supervisory visits. A detailed description of the indicators, targets, and data sources is included in Annex A.

Table 1: Summary of key indicators for a specimen referral system

| Indicator | Type of indicator | Monitored by whom | Monitoring frequency |
|---|---|---|---|
| % of referring facilities that fill their specimen referral logbook (or equivalent) completely | Process | Verified by supportive supervisory visits | Quarterly |
| % of referring facilities that fill the specimen referral form (or equivalent) for each shipment made | Process | Referral Laboratory | Quarterly |
| Number of specimens (and shipments) referred for testing | Output | Referring facility | Monthly |
| Number of specimens transported | Output | By the transport service[2] as part of their service agreement | Monthly |
| Number of shipments transported | Output | By the transport service | Monthly |
| Proportion of specimens which were picked up by the transport service within the target turnaround time | Outcome | Referring facility | Monthly |
| Proportion of shipments that arrive at the referral laboratory within the specified transport time | Outcome | Receiving laboratory | Monthly |
| Proportion of test results that were picked up by the transport service or transmitted electronically within the specified turnaround time after generation of the test result | Outcome | Receiving laboratory | Monthly |
| Proportion of shipments that are delivered within the specified transport time | Outcome | By the transport service | Monthly |

[2] The courier service may be operated by the MoH or outsourced to another government entity, implementing/technical assistance partner, non-governmental organization, or private company.

| | | | |
|---|---|---|---|
| Proportion of shipments that were lost or damaged (disaggregated by route or district) | Outcome | By the transport service | Monthly |
| % of referral laboratories that fill their specimen reception logbook (or equivalent) completely | Process | Verified by supportive supervisory visits | Quarterly |
| Proportion of specimens that were rejected because of factors related to inadequate or improper transport, packaging, or documentation (disaggregated by referring site) | Outcome | Receiving laboratory | Monthly |
| Number of referred specimens tested at the referral laboratory | Outcome, but not fully attributable to the intervention | Receiving laboratory | Monthly |
| Proportion of referred specimens for which a result was returned | Outcome, but not fully attributable to the intervention | Referring facility | Monthly |
| Proportion of referred specimens for which a result was received within the target turnaround time | Outcome, but not fully attributable to the intervention | Referring facility | Monthly |
| Number of referral sites participating in the specimen referral system | Input | Regional or national level by TWG or MoH | Annually |
| % of regions that submit their routine data summary forms on time/in full | Process | Regional or national level by TWG or MoH | Annually |
| Unit costs such as cost per specimen or result transported per facility or per month | Outcome | Regional or national level by TWG or MoH | Annually |

Key indicators should be monitored routinely (e.g., monthly or quarterly) by the sites and transport service and reported to the district or regional quality officer. Other indicators may be more useful for monitoring trends, investigating specific issues or as quality checks during supervisory visits; thus, they may be collected on a less frequent or ad-hoc basis as needed for these specific purposes (more on frequency in the next section on "M&E Activities"). Additional indicators may also be developed by the laboratory technical working group (TWG) or quality officer to address specific aspects of the local situation.

Indicators calculated using aggregate data (e.g., total number of referred specimens tested) are useful to monitor overall performance, but to detect problems and initiate corrective actions, it may be necessary to disaggregate the data by referring facility, referral laboratory, individual courier, courier route, or district. For example, if specimens are referred to more than one laboratory (e.g., specimens sent to a local testing hub for testing and specimens sent to the national referral laboratory (NRL) for higher-level testing), the indicators should be monitored separately for each referral laboratory.

Several indicators measure performance against locally-determined target or specified times rather than against a standardized time because of variability in the factors that determine the time such as frequency of sample pick up, mode and distance of transportation, testing method, etc. The target or specified times should be established by the TWG. Methods to calculate turnaround times and targets are described in Annex B.

## M&E Activities

Monitoring and evaluation is critical at all phases of implementation – from a pilot project to a fully scaled intervention. For example, a detailed operational plan[3] for a pilot project must include a robust monitoring of key indicators throughout the project and evaluation at the end of the pilot in order to determine if it was a success and what needs to be improved during the scale-up phase. Once the pilot is over and the system has been adapted and scaled-up, routine monitoring and evaluation is needed as part of a continuous improvement cycle. At a minimum, the TWG or program management team in the MoH should conduct an annual review of summary indicators for each region and for the country which is then presented to a wide range of stakeholders. The annual review should touch on the following elements: Presentation and discussion of average values for each indicator, analysis of time trends to assess progress towards targets, description of strengths and weaknesses of the system, recommendations for improvement, etc. A continuous improvement approach will ensure the system's responsiveness, effectiveness, and efficiency. During all phases, these M&E activities also must be adequately staffed and financially resourced.

Data should be collected using the standardized registers, forms and logs on a daily basis by the referring facilities and the referral laboratories. This information should then be monitored and assessed during programmatic and/or laboratory supervisory visits at least on a quarterly basis. A review of a sample of the registers, forms, and logs should allow assessment of both process and performance indicators, including the proportion of shipments with correctly completed transport logs; proportion of specimens with correctly completed specimen referral and test requisition forms; and proportion of referred specimens with correctly completed entries in the specimen referral register, shipment registers, and specimen receipt registers. Supervisory visits are also an opportunity to assess the application of quality control practices and adherence to SOPs, biosafety and biosecurity measures, and packaging and transportation standards.

Countries may not have yet determined responsibilities and accountabilities for the M&E activities around specimen referrals and even if the activities have been assigned, there may not be adequate human or financial resources to cover the activities. One way to ensure data on specimen referrals is collected, analyzed and used for management is to integrate the specimen referral M&E activities and indicators into other programmatic activities and M&E frameworks. Once there are more examples from countries who are managing these processes well, they will need to be shared globally.

## Data Collection Tools

Standardized registers and forms must be provided and used throughout the system and required information properly and completely entered in all forms. Quality control should be practiced and documented during specimen collection, packaging and transport. For example, the quality of the specimens would need to be logged at the referring site and then verified by the testing laboratory, transport logs (which will also serve as chain of custody documentation) would need to accompany the shipments to show how many specimens and results are transported per facility, and specimen receipt logs should reflect receipt at the receiving site.

[3] An example of this plan can be found in the Specimen Referral Toolkit in an Excel file entitled: "Example Workplan - Specimen Referral System"

Key standardized documents to facilitate data collection for monitoring the specimen referral system are summarized in Table 2. These documents are available in the specimen referral toolkit[4] and should be customized to the local situation. All of these log books should be spot-checked during supervision visits to ensure completeness of data (a process indicator), which will then be used to generate summary data needed for calculating key indicators. The specimen referral toolkit also contains a summary form for submitting key indicators on a routine basis.

Table 2: Description of key data tools

| **Data collection tool** | **Description** | **Location** |
|---|---|---|
| Referring Facility Specimen Referral Log | Should record all specimens that are referred to an outside laboratory and date/time when the specimen was collected from the patient, when it was picked up, when the result came back and what the result was, when the result was delivered to the patient, and when the treatment was initiated, if necessary | Referring health facility |
| Copy of test requisition form | Test requisition forms usually come in carbon copy – the referring facility should keep one copy | Referring health facility<br>Referral laboratory |
| Individual specimen and results tracking log sheet | Should be signed by both sending and receiving parties, including drivers, along every change of hands to create a tracking system. This data could also be contained in a packing list (summary list of what is included in the shipment) or transport log (log to track kilometres, fuel, etc.). | Transport service |
| Referral Laboratory Specimen Reception Log | Should be filled by the laboratory reception when the specimen is received and should help the laboratory track the specimen through the testing and result issuance process; includes rejection reasons, if applicable, and issuance of results | Referral laboratory |
| **Data collection tool** | **Description** | **Data Source** |
| Specimen referral data summary collection form | Routine data collection form to summarize data over a period of time and submit to a higher level for review | All four data collection tools above |

Collection of data for monitoring turnaround times may be facilitated through the use of barcoded labels and a scanning system that records the date, time, and name of the individual in possession of the specimen at every step during the referral process (see case study for Lesotho in the GLI Guide to TB Specimen Referral Systems and Integrated Networks).

[4] The toolkit can be found on the Global Laboratory Initiative (GLI) website at http://www.stoptb.org/wg/gli/

## Annex A: Detail on Indicators

### Indicators to be monitored at the referring facility

| | |
|---|---|
| **Indicator 1.1a** | Number of specimens referred for testing |
| **Indicator 1.1b** | Number of shipments dispatched (optional) |
| **Indicator 1.2** | Proportion of referred specimens for which a result was returned |
| **Indicator 1.3** | Proportion of referred specimens for which a result was received within the specified target time |
| **Indicator 1.4** | Proportion of specimens which were picked up by the transport service within the target turnaround time |
| **Indicator 1.5** | Percentage of referring facilities that fill their specimen referral logbook (or equivalent) completely |
| **Indicator 1.6** | Percentage of referring facilities that fill the specimen referral form(s) (or equivalent) for each shipment made |

**Detailed description of indicators, targets, indicator calculations and remarks**

| **Indicator 1.1a: Number of specimens referred for testing** | |
|---|---|
| Purpose | Assess the utilization and uptake of referral services, identify gaps, and assist with planning |
| Target | Expected to increase initially |
| Numerator | Number of specimens referred |
| Denominator | Not Applicable |
| Frequency and location | Monitored monthly at each referring facility |
| Data Sources | Referring Facility Specimen Referral Log |
| Disaggregation | By referral laboratory |
| Remarks | Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established |

| **Indicator 1.1b: Number of shipments dispatched (optional)** | |
|---|---|
| Purpose | Optional indicator to measure if the transport service charges per shipment/per package |
| Target | Expected to increase initially |
| Numerator | Number of shipments dispatched |
| Denominator | Not Applicable |

| | |
|---|---|
| Frequency and location | Monitored monthly at each referring facility |
| Data Sources | Referring Facility Specimen Referral Log or packing list/transport logs[5] |
| Disaggregation | By referral laboratory |
| Remarks | Although the number is expected to increase over time, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established |

| **Indicator 1.2: Proportion of referred specimens for which a result was returned** | |
|---|---|
| Purpose | Assess the overall performance of the specimen referral and testing system |
| Target | >95% |
| Numerator | Number of referred specimens for which a result was returned |
| Denominator | Total number of specimens referred during the reporting period |
| Monitoring | Monitored monthly at each referring facility |
| Data sources | Referring Facility Specimen Referral Log |
| Disaggregation | By referral laboratory |
| Remarks | • 'Sample rejected' should be considered a valid returned result<br>• The indicator should be calculated for specimens for which the target turnaround time for the requested test has passed, for example with TB:<br>  • For microscopy and molecular tests and rejected samples, this indicator may be calculated using information from the prior month rather than the current month<br>  • Because of the long turnaround time for culture and DST, this indicator may be calculated using data for specimens that were referred 60 to 90 days earlier |

| **Indicator 1.3: Proportion of referred specimens for which a result was received within the specified target time** | |
|---|---|
| Purpose | Assess whether the referral system is meeting the target of improving the timeliness of diagnostic test results |
| Target | >95% |
| Numerator | Number of referred specimens for which a test result was received within the specified time |
| Denominator | Total number of specimens referred for which a result was returned |
| Monitoring | Monitored monthly at each referring facility |
| Data sources | Referring Facility Specimen Referral Log |
| Disaggregation | By referral laboratory |

[5] A packing list is a summary list of what is included in the shipment and a transport log is used to track kilometres, fuel, etc.

| | |
|---|---|
| Remarks | • Target time should be determined for each test required (e.g., Xpert MTB/RIF or culture) and the collection schedule used (e.g., on demand, daily, twice weekly, etc.)<br>• For this calculation, an entry that the specimen was rejected should be counted as a result and a target time for rejected sample notification determined<br>• This indicator should be interpreted in the overall context of the system's ability to return results. In networks where a high proportion of samples do not have a reported result, the value of this indicator could be satisfactory, but many samples are not included in the denominator.<br>• The indicator should be calculated for specimens for which the target turnaround time for the requested test has passed, for example with TB:<br>  • For microscopy and molecular tests and rejected samples, this indicator may be calculated using information from the prior month rather than the current month<br>  • Because of the long turnaround time for culture and DST, this indicator may be calculated using data for specimens that were referred 60 to 90 days earlier<br>• During a quarterly or semi-annual supervisory visit, the average turnaround time between collection of the specimen and receipt of the result by the referring site may be calculated as an additional performance indicator<br>• During a quarterly or semi-annual supervisory visit, the individual components of turnaround time (i.e. collection of specimen to pick up by a transporter, pick up to receipt at the referral laboratory, receipt to testing, testing to recording results, result release to pick up by a transporter, pick up to delivery, etc.) may be calculated as bottleneck analysis if overall turnaround time is not acceptable |

| **Indicator 1.4: Proportion of specimens which were picked up by the transport service within the target turnaround time** | |
|---|---|
| Purpose | Assess the performance of the system with respect to the timeliness of specimen pick-up |
| Target | >95% |
| Numerator | Number of referred specimens which were picked up by the transportation service within the specified time after specimen collection |
| Denominator | Number of specimens picked up by the transportation service |
| Monitoring | Monitored monthly at each referring facility |
| Data sources | Referring Facility Specimen Referral Log or transport logs |
| Disaggregation | By individual courier |
| Remarks | • Target should be determined for each collection schedule (e.g., on demand, daily, twice weekly). For example, <24 hr for daily pick-up or <7 days for weekly pick-up<br>• During a quarterly or semi-annual supervisory visit, the average time between collection of the specimen and pick-up by the transport service may be calculated as an additional performance indicator |

| **Indicator 1.5: Percentage of referring facilities that fill their specimen referral logbook (or equivalent) completely** | |
|---|---|
| Purpose | Assess data completeness |
| Target | >95% |
| Numerator | Number of referring facilities that fill their specimen referral logbook (or equivalent) completely |
| Denominator | Total number of referring facilities in the specimen referral network |
| Monitoring | Monitored and verified quarterly through supportive supervisory visits |
| Data sources | Referring Facility Specimen Referral Log |
| Disaggregation | NA |
| Remarks | This process indicator will help to monitor data completeness/quality/accuracy and should increase over time |

| **Indicator 1.6: Percentage of referring facilities that fill the specimen referral form(s) (or equivalent) for each shipment made** | |
|---|---|
| Purpose | Assess data completeness |
| Target | >95% |
| Numerator | Number of referring facilities that fill their specimen referral form (or equivalent) for each shipment made |
| Denominator | Total number of referring facilities in the specimen referral network |
| Monitoring | Monitored quarterly by the referral laboratory |
| Data sources | Individual Specimen and Results Tracking Log, Test Requisition forms |
| Disaggregation | NA |
| Remarks | This process indicator will help to monitor data completeness/quality/accuracy and should increase over time |

## Indicators to be monitored at the referral laboratory

| | |
|---|---|
| **Indicator 2.1** | Number of referred specimens tested at the referral laboratory |
| **Indicator 2.2** | Proportion of shipments that arrive at the referral laboratory within the specified transport time |
| **Indicator 2.3** | Proportion of test results that were picked up by the transport service or transmitted electronically within the specified turnaround time after generation of the test result |
| **Indicator 2.4** | Proportion of specimens that were rejected |
| **Indicator 2.5** | Percentage of referral laboratories that fill their specimen reception logbook (or equivalent) completely |

**Detailed description of indicators, targets, indicator calculations and remarks**

| **Indicator 2.1: Number of referred specimens tested at the referral laboratory** | |
|---|---|
| Purpose | Assess the utilization and uptake of referral services, identify gaps, and assist with planning |
| Target | Expected to increase initially and as new collection sites are added |
| Numerator | Number of referred specimens that were tested in the referral laboratory |
| Denominator | Not applicable |
| Monitoring | Monitored monthly at each referral laboratory |
| Data sources | Referral Laboratory Specimen Reception Log |
| Disaggregation | By referring facility |
| Remarks | Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in reliability of the new system is built |

| **Indicator 2.2: Proportion of shipments that arrive at the referral laboratory within the specified transport time** | |
|---|---|
| Purpose | Assess the performance of the system with respect to the timeliness of specimen transport |
| Target | >95% |
| Numerator | Number of shipments that arrived at the referral laboratory within the specified transport time |
| Denominator | Total number of shipments received during the reporting period |
| Monitoring | Monitored monthly at each referral laboratory |
| Data sources | Transport logs |
| Disaggregation | If applicable, by individual courier or route |
| Remarks | • Target transport time will depend on the mode of transportation and distance and should be specified in the transport service's service agreement. Target may vary by referring facility and individual courier<br>• During a quarterly or semi-annual supervisory visit, the average time between pick-up of a shipment to receipt by the receiving laboratory may be calculated as an additional performance indicator |

| **Indicator 2.3: Proportion of test results that were picked up by the transportation service or transmitted electronically within the specified turnaround time after generation of the test result** | |
|---|---|
| Purpose | Assess the timeliness of reporting results |
| Target | >95% |

| | |
|---|---|
| Numerator | Number of test results that were generated for referred specimens that were picked up by the transportation service or electronically transmitted within the specified turnaround time after generation of the test result |
| Denominator | Number of test results that were generated for referred specimens and returned to the referring sites |
| Monitoring | Monitored monthly at each referral laboratory |
| Data sources | Referral Laboratory Specimen Reception Log and transport logs |
| Disaggregation | If applicable, by individual courier or route |
| Remarks | • Target turnaround may depend on mode of transportation and frequency of service. For electronic transmission, the target is <24 hours<br>• During a quarterly or semi-annual supervisory visit, the average time between generation of a test result and pick-up by the transportation service or electronic transmission may be calculated as an additional performance indicator<br>• The number of test results generated for referred specimens and returned to the referring sites may be monitored by as an additional output measure to assess the extent to which the system is improving access to diagnostic testing |

| **Indicator 2.4 Proportion of specimens that were rejected because of factors related to inadequate or improper transport, packaging, or documentation** | |
|---|---|
| Purpose | Assess the performance of the system with respect to transport, packaging, and documentation |
| Target | <5% |
| Numerator | Number of specimens that were rejected because of factors related to inadequate or improper transportation or packaging or documentation |
| Denominator | Number of specimens received |
| Monitoring | Monitored monthly at each referral laboratory |
| Data sources | Referral Laboratory Specimen Reception Log |
| Disaggregation | • By reasons for rejection, including:<br>  • Inadequate specimen volume or quality<br>  • Specimen leaked<br>  • Specimen contaminated or of insufficient quality<br>  • Specimen label is missing or illegible<br>  • Specimen not packaged according to SOP<br>  • Incomplete or illegible test requisition form<br>  • Transport time exceeded maximum allowed time<br>  • Cold chain not maintained (if applicable)<br>• If possible, by referring facility or individual courier |
| Remarks | During a quarterly or semi-annual supervisory visit, the number of specimens received by the referral laboratory could be compared to the number of specimens sent to the referral laboratory (i.e., sum of indicator 1.1 for all referring facilities) as an additional indicator to assess potential issues with the transportation process |

| Indicator 2.5: Percentage of referral laboratories that fill their specimen reception logbook (or equivalent) completely | |
|---|---|
| Purpose | Assess data completeness |
| Target | >95% |
| Numerator | Number of referral laboratories that fill their specimen reception logbook (or equivalent) completely |
| Denominator | Total number of referral laboratories in the specimen referral network |
| Monitoring | Monitored and verified quarterly through supportive supervisory visits |
| Data sources | Referral Laboratory Specimen Reception Log |
| Disaggregation | NA |
| Remarks | This process indicator will help to monitor data completeness/quality/accuracy and should increase over time |

## Indicators to be monitored by the transport service[6] as part of their service agreement

| | |
|---|---|
| **Indicator 3.1a** | Number of specimens transported |
| **Indicator 3.1b** | Number of shipments transported |
| **Indicator 3.2** | Proportion of shipments that were delivered within the specified transport time |
| **Indicator 3.2** | Proportion of shipments that were lost or damaged |

**Detailed description of indicators, targets, indicator calculations and remarks**

| Indicator 3.1a: Number of specimens transported | |
|---|---|
| Purpose | Assess the utilization and uptake of referral services, identify gaps, and assist with planning |
| Target | Expected to increase initially and as new collection sites are added |
| Numerator | Number of specimens transported |
| Denominator | Not applicable |
| Monitoring | Monitored monthly by the transport service |
| Data sources | Transport logs |
| Disaggregation | By referral laboratory |
| Remarks | • Monitoring the indicator should be included in the transport service's service agreement<br>• Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established |

[6] The courier service may be operated by the MoH or outsourced to another government entity, implementing/technical assistance partner, non-governmental organization, or private company.

| Indicator 3.1b: Number of shipments transported | |
|---|---|
| Purpose | Assess the utilization and uptake of referral services, identify gaps, and assist with planning |
| Target | Expected to increase initially and as new collection sites are added |
| Numerator | Number of shipments transported |
| Denominator | Not applicable |
| Monitoring | Monitored monthly by the transport service |
| Data sources | Transport logs |
| Disaggregation | By referral laboratory |
| Remarks | • Monitoring the indicator should be included in the transport service's service agreement<br>• Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established |

| Indicator 3.2: Proportion of shipments that were delivered within the specified transport time | |
|---|---|
| Purpose | Assess the performance of the system with respect to the timeliness of specimen transport and results return |
| Target | >95% |
| Numerator | Number of shipments that were delivered within the specified transport time |
| Denominator | Total number of shipments transported during the reporting period |
| Monitoring | Monitored monthly by the transport service |
| Data sources | Transport logs |
| Disaggregation | • By referral laboratory<br>• By transport of specimens and, if applicable, for transport of results<br>• If applicable, by route or individual courier |
| Remarks | • Monitoring the indicator should be included in the transport service's service agreement<br>• Target transport time will depend on the mode of transportation and distance and should be specified in the transport service's service agreement. Target may also vary by referring facility, referral laboratory, and transport route<br>• Average time between pick-up of a shipment to delivery to the receiving laboratory may be calculated as an additional performance indicator |

| Indicator 3.3: Proportion of shipments that were lost or damaged in transit | |
|---|---|
| Purpose | Assess the reliability of transport |
| Target | <5% |
| Numerator | Number of shipments that were lost or damaged in transit |
| Denominator | Total number of shipments |
| Monitoring | Monitored monthly by the transport service |
| Data sources | Transport logs |
| Disaggregation | • Shipments that were lost<br>• Shipments that were damaged<br>• If applicable, by route or individual courier |
| Remarks | • Monitoring the indicator should be included in the transport service's service agreement<br>• The district or regional quality officer may also compare the number of shipments received by the referral laboratory (indicator 2.2) with the number of shipments dispatched from the referring facilities (sum of indicator 1.1 for all referring facilities) as an additional quality check |

## Indicators to be monitored at the regional or national level by the TWG or MoH

| | |
|---|---|
| **Indicator 4.1** | Facility coverage of the specimen referral system |
| **Indicator 4.2** | Percentage of regions that submit their routine data summary forms on time/in full |
| **Indicator 4.3** | Cost per specimen or result transported |

**Detailed description of indicators, targets, indicator calculations and remarks**

| Indicator 4.1: Facility coverage of the specimen referral system | |
|---|---|
| Purpose | Assess the utilization and uptake of referral services, identify gaps, and assist with planning |
| Target | Initially expected to increase and eventually include all specimen collection sites in a catchment area |
| Numerator | Number of collection sites participating in the specimen referral system |
| Denominator | Number of sites eligible to participate in the specimen referral system |
| Monitoring | Monitored annually by the TWG or a management team in the MoH |
| Data source | Schedule and Routing Chart for Specimen Transportation or Survey or mapping of specimen collection sites |
| Disaggregation | By relevant region |
| Remarks | • The indicator may be monitored nationally or by the catchment area of a testing laboratory<br>• For planning and budgeting purposes, measurement of the proportion of eligible specimen collection sites that participate in the specimen referral system or the proportion of all specimen collection sites in the region or country that participate in the specimen referral system might be useful |

| Indicator 4.2: Percentage of regions that submit their routine data summary forms on time/in full | |
|---|---|
| Purpose | Assess data timeliness and completeness |
| Target | >95% |
| Numerator | Number of regions (districts, provinces, etc.) that submit their routine data summary forms on time/in full |
| Denominator | Total number of regions participating in the specimen referral network |
| Monitoring | Monitored annually by the regional or national level TWG or MoH |
| Data source | Referral Laboratory Specimen Reception Log |
| Disaggregation | • On time<br>• In full |
| Remarks | This process indicator will help to monitor data completeness/quality/accuracy/ timeliness and should increase over time |

| Indicator 4.3: Cost per specimen or result transported | |
|---|---|
| Purpose | Provide information for planning and budgeting and assess cost effectiveness |
| Target | May increase or decrease depending on the baseline system |
| Numerator | Total cost of specimen transport system |
| Denominator | Number of specimens and/or results transported |
| Monitoring | Monitored annually by the TWG or a management team in the MoH |
| Data source | Survey or cost analysis |
| Disaggregation | • By relevant region<br>• By different settings (e.g., a hard-to-reach peripheral setting or an urban setting) or different routes (e.g., peripheral facility to a nearby testing hub or a peripheral facility to the national laboratory) |
| Remarks | • Need to be consistent – so if include results in denominator during one period, must do so in another period<br>• Expect that the system will create efficiencies over time and the indicator will decrease, but this will not necessarily happen, depending on maturity and efficiency of system<br>• More on cost calculations in Annex B |

## Annex B: Methods to calculate turnaround times and costs

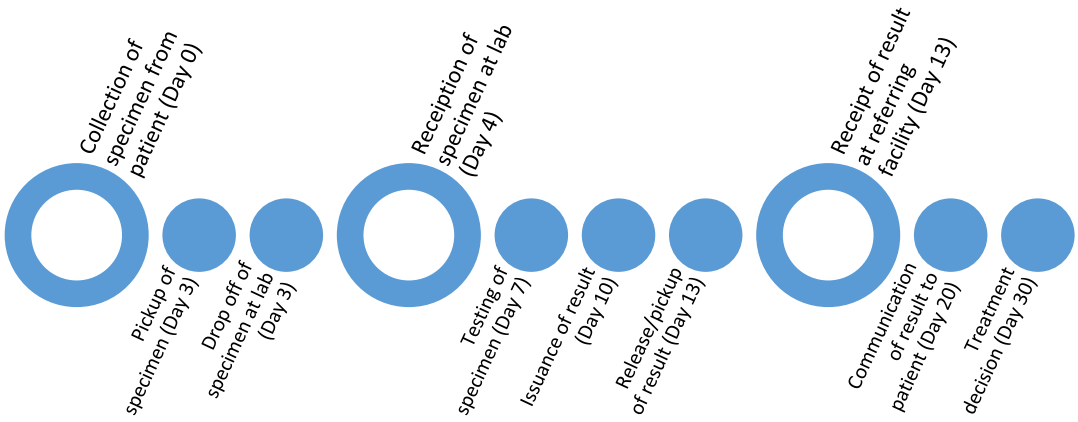
### Turnaround times

Turnaround time contains crucial information for measuring the success of a specimen referral system. Full turnaround time should include, but not be limited to, the following date/time data points:

- Collection of specimen from the patient
- Pickup of the specimen from the referring facility
- Drop-off of the specimen to the referral laboratory
- Reception of the specimen at the referral laboratory
- Testing of the specimen at the referral laboratory
- Issuance of a result at the referral laboratory
- Release/pickup of result from the referral laboratory
- Receipt of result at the referring facility
- Communication of result to the patient (if available)
- Treatment or management decision based on the results (if applicable/available)

The last two data points may or may not be available, but they will allow the specimen referral system to be linked to clinical management of the patient, which is the objective that the system aims to improve. An example of what the actual full turnaround time picture could look like is shown in Figure 3.

Figure 3: Example of full turnaround time actuals




It is important to understand and convey the target times between the actions listed above and the actual times, and both the overall turnaround time (collection of specimen from the patient to treatment or management decisions based on the results) as well as the individual pieces are incredibly important to understanding where the bottlenecks exist in the referral process. Although the indicators listed in detail in Annex A are focused more on percentage of specimens and/or results that are processed within a target time period, the absolute times are important. In the example in Figure 3, it is taking 13 days overall to

return a result and then an additional week to get the result back to the patient and make a treatment decision. We can see that the pickup and drop off of specimens/results is happening same-day (on day 3 and day 13, respectively), which tells us that the transport piece of the referral process is actually quite rapid, but there are other points in the turnaround where the process is held up. Comparing these actual times to targets, we could determine where to focus improvements. For example, if it is actually taking about six days from receipt of specimen in the laboratory to issuance of results, but the target is three days, there may be improvements that can be made in the laboratory to help recording specimens as they are dropped off or to speed up testing.

Targets should be determined by the laboratory or a laboratory TWG. Target time should be determined for each test required (e.g., Xpert MTB/RIF or culture) and each collection schedule (e.g., on demand, daily, twice weekly, etc.), for example, <24 hr for daily pick-up or <7 days for weekly pick-up.

## Costs

Calculating the cost of a specimen referral system is a complex analysis that is often over-simplified. There are many costs that go into a well-functioning system, some costs of which are "hidden" such as the time spent by individuals on oversight of the system. The following components should be included in the overall cost of the system:

- Both upfront capital and ongoing running costs for transport (either as an inclusive outsourced cost[7] or adding up individual cost components such as procurement of vehicles, payment of drivers, etc. if the system is being implemented by the MoH[8])
- Time for individuals who oversee the system within the MoH and at any implementing/technical assistance partner
- Carrying equipment (i.e. backpacks or boxes) and cold chain equipment (i.e. ice packs), including replacements (this may or may not be included in the transport service costs if outsourced)
- Initial and refresher training costs for couriers/transport service providers, referring facilities, referral laboratories
- Sensitization of referral laboratories and referring facilities before and after the system is implemented
- Communication costs between the referring facilities, referral laboratories and transport service
- Initial and ongoing printing/distribution costs for data collection materials
- Supportive supervision visits (which may not be dedicated to specimen referrals)

It is helpful if the costs are calculated using the same included components and if there is transparency on what is and is not included, at the very least. If the cost calculations are not consistent, i.e. from one country to another, it will be difficult to compare systems. Sub-analyses may be needed to assess costs in different settings (e.g., a hard-to-reach peripheral setting or an urban setting) or different routes (e.g., peripheral facility to a nearby testing hub or a peripheral facility to the national laboratory).

[7] For contracted specimen transport services, the cost is the total cost of the contract, which should be inclusive of all costs

[8] If the MoH operates its own referral network, there will be additional set-up costs such as procuring vehicles, specimen transport equipment and other gear as well as recruitment and training of drivers and other staff. There will also be ongoing running costs, such as fuel, replacement parts, refresher training, staffing, offices, insurance, programme management, oversight and M&E. If this is the case, a more in-depth cost analysis may be necessary and should be performed by an entity with financial expertise

Looking at the cost per specimen indicator (indicator 4.3 in Annex A), we would expect that the system will create efficiencies over time and the indicator will decrease, but this will not necessarily happen, depending on maturity and efficiency of system. For example, if the current system in place is ad-hoc and ineffective, putting in place a more robust system may increase costs initially.