



SPECIMEN TRANSPORTATION A HOW-TO GUIDE



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CHALLENGE TB

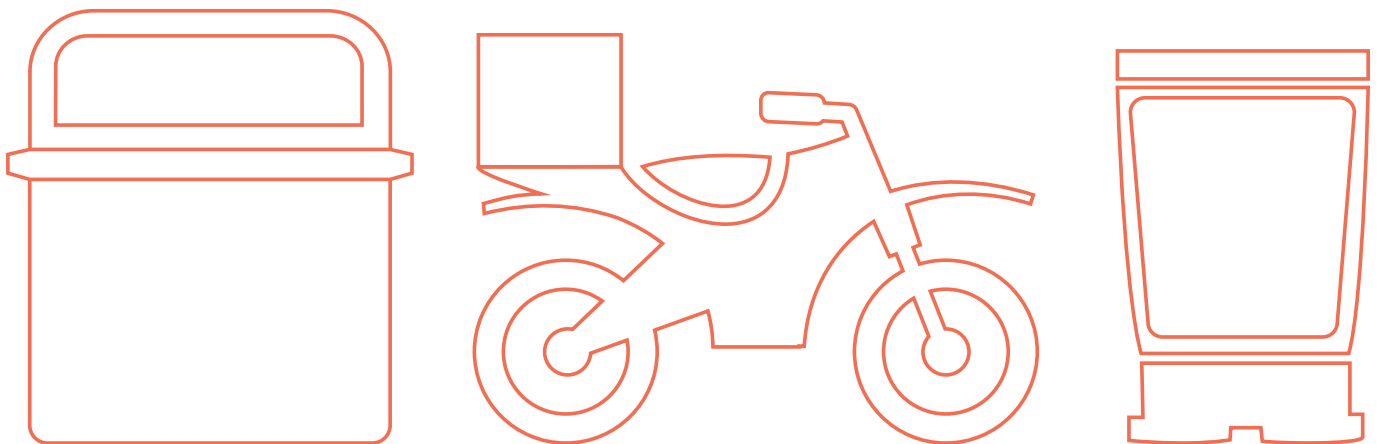
INTRODUCTION

The transportation of tuberculosis (TB) specimens in a reliable and efficient manner is essential for effective TB patient care, allowing for faster diagnosis, initiation of treatment, and patient follow-up. For decades, health facility staff and sometimes even patients themselves had to deliver TB specimens to the nearest laboratories. They were often faced with the complexity of transporting these valuable specimens in a safe and quality-assured manner and as a result, many TB patients failed to get a correct diagnosis and the much-needed treatment.

Since the introduction of the GeneXpert MTB/RIF test, TB programs and technical partners have started developing effective and efficient specimen transportation systems to maximize access to the rapid

and sensitive test for Mycobacterium Tuberculosis as well as drug-resistant TB. In 2018 the Global Lab Initiative (GLI) published the GLI Guide to TB Specimen Referral Systems and Integrated Networks which serves as a guide for TB programs, helping them to develop a comprehensive specimen transportation system.

The USAID-funded Challenge TB project continues to work on the strengthening of specimen transportation systems across the supported countries. At the country level, National TB Programs are increasingly working with Challenge TB to develop integrated specimen transportation systems in order to ensure universal access to diagnosis of TB.





RATIONALE

The detection of TB and testing for drug-resistance are fundamental parts of providing accurate diagnosis and TB treatment. The transportation of TB samples is an efficient method of increasing access to diagnostics in areas where testing is not currently available. This helps to prevent the need for patients to travel (with the associated costs) and leads to more equity in access to TB diagnosis and care. In addition, specimen transportation can often be more cost-effective than placing staff or procuring additional equipment to provide localized testing.

However, there are many difficulties in storing and transporting samples

between remote locations and reference laboratories. When it comes to setting up a specimen transportation system, one solution does not fit all, so for each aspect of the system design, the specific settings need to be taken into consideration.

This document shares the experiences of Challenge TB supported countries who have developed and implemented a specimen transportation system for TB. There is a generic overview of the different components of a specimen transportation system, and country-specific examples on setting up specific systems to support the diagnosis of pediatric and multidrug-resistant TB (MDR-TB), as well as setting up an integrated system.

IMPLEMENTATION

Management

The National TB Program is responsible for the coordination and supervision of specimen transportation in collaboration with other disease programs. Coordination is facilitated by the establishment of an integrated national specimen referral technical working group. The day-to-day management of the system is decentralized to the district level. The actual transportation of specimens can be outsourced to organizations with expertise in logistics, e.g., professional couriers/ transportation companies or the national postal system.

The transportation system must have a clear and regular schedule

There must be a consistent fuel supply

Couriers should be dedicated to specimen transport full-time in order to avoid competing priorities and disruption to services

Couriers are paid per kilometer or per sample/result transported and must, therefore, use logbooks to track mileage, specimens, and results

Health workers and laboratory staff must also use logbooks, enabling the movement of both samples and the results to be tracked

Laboratory Testing Capacity

When the specimen transportation system is being designed, the capacity of the health care system and laboratory network have to be evaluated by looking at:

- The expected number and type of samples to be collected
- The number of health facilities serving as collection points
- The number and level of laboratories receiving samples.

In most Challenge TB countries, the specimen transportation system is designed to provide universal access to rapid diagnosis of TB by linking health facilities to the existing GeneXpert network. There are exceptions in two countries where the transportation

systems have been set up with specific objectives in mind:

India: To increase the diagnosis of childhood TB.

Tajikistan: To provide early diagnosis and linkage to treatment for MDR-TB patients while expanding new drugs and regimens for MDR-TB.

Transport Options

Different transport options can be used depending on the local settings (e.g., the terrain, the distance between health facilities and laboratories, as well as available human and financial resources).

- Public transport can be used when the patient, family member, hospital attendant, or volunteer will transport the samples. Immediately upon receipt of the sample at the laboratory, the person transporting the sample must be reimbursed for transport costs at an agreed rate
- Motorcycles can be used to transport specimens from district health facilities to nearby GeneXpert services. The motorcyclists must be provided with cool boxes and triple-package containers
- Cold chain vehicles can be used to move samples for culture/DST. These

vehicles have different compartments: 1) room temperature; 2) 2-8 °C; 3) -20 °C. Different samples can be collected and transported, including samples for GeneXpert, first and second line LPA, and culture/DST.

The organization of the specimen transportation can be done by the Ministry of Health or can be outsourced to other organizations:

- Community-based organizations have strong links to the community and they have experience in identifying and referring presumptive TB patients (including contacts of TB index cases)
- Local logistics companies (private or the postal system) can also be hired to transport samples.

Logistics and Scheduling

Prior to the start of the specimen collection system, routing maps must be developed, which are used to map the most efficient route between health facilities and laboratories. The maps contain the Geographic Information System (GIS) coordinates of every facility and laboratory as well as the contact details of designated staff at service delivery points. Clusters of facilities are assigned to specific drivers, and a schedule is made which ensures all health facilities are visited at least once a week for the collection of specimens and the return of results.

For the referral and transport of TB samples (mostly sputum), the relevant equipment including sputum cups, transportation boxes,

and recording and reporting tools must be provided. The health facility staff must be trained in the collection, storage, and packaging of specimens. Fridges must be provided for the storage of collected specimens.

The name of each presumptive TB patient is recorded in a register kept by the health facility, and each sample is accompanied by a sputum request form. The driver signs the register to acknowledge the collection of the samples and signs the same register again when results are returned.

Specimen Packaging

The most important factors are the use of a triple packaging system to prevent damage and cross-contamination, storage (in a fridge for a maximum of one week), and transportation conditions.

The triple packaging method is used to pack specimens for transportation:

1. Primary packaging:

Wrapping the leakproof primary container in cotton wool or paper towel in sufficient quantities to absorb the entire contents in the event that the container leaks.

2. Secondary packaging:

The cotton wrapped primary container is

placed inside a secondary container e.g., a sealed ziplock bag or another container.

3. Tertiary packaging:

The secondary container and its contents are placed in a cool box or another appropriate container, in an upright position. The container should be shock resistant (hardcover) and it should protect the contents from physical damage during the trip. This container should be labeled according to (inter)national regulations for infectious materials.



Returning Results

In general, a well-organized specimen transportation system will reduce the average time between specimen collection and the delivery of the test results to the referral laboratory, the contamination rate, the specimen rejection rate, and the turnaround time from sample collection to the delivery of results. If it is working well, this reduces the time from the diagnosis of TB to enrollment on appropriate treatment.

In most countries, laboratory information systems include paper and electronic data capture tools. Patient information and logistics information on the collection and dispatch of specimens are collected by the health facilities and laboratories. GeneXpert results can also be sent through the GxAlert or DataToCare system which send the results as real-time information to respective clinicians.

Confidentiality

Patient confidentiality must be maintained by all staff involved (e.g., clinicians, nurses, transport personnel, lab personnel, and data clerks) throughout the entire process, from sample collection, until the dispatch of the results.

Important measures to maintain confidentiality include:

1. Only authorized personnel should have access to patient information
2. All persons should be trained in national standards and policies for maintaining confidentiality and held accountable for maintaining confidentiality

3. Procedures should be in place to secure patient information (e.g., information on test requisition forms and results reports) in the clinic and laboratory and during transport, such as returning results in sealed envelopes or sending them by encrypted digital means.

Patient confidentiality has to be strictly monitored during on-site supervisory visits by the program coordinators officials and project staff. During introductory meetings, this must be discussed extensively with all the parties involved.

Documentation

The logistics of a specimen referral system are based on Standard Operating Procedures (SOPs), guidelines, and recording/reporting tools.

The SOPs and guidelines include procedures related to specimen collection, packaging, sample transport, specimen tracking, biosafety, and the return of results. Other documents such as referral forms and registers, tracking slips, transportation manuals, logbooks, and data collection tools for monitoring and evaluation must be available.

Examples of these documents/tools can be found on the GLI website:

www.stoptb.org/wg/gli/

These generic tools can be adapted to the situation in-country.

When a specimen transportation system is implemented at the country level, indicators that measure referrals, results returns, test results, and the number of specimens transported must be collected.

Training

Planning meetings with all the staff involved must be conducted prior to the start of specimen transport.

All staff must be trained:

Community volunteers: On the symptoms of TB, (referral for) sputum collection, and completion of recording/reporting tools.

Clinicians and nurses at health facilities: On the symptoms of TB, sputum collection, labeling, storage and packaging procedures, biosafety measures, and how to complete recording/reporting tools.

Drivers: On safe driving, motorbike maintenance, biosafety measures, and how to complete recording/reporting tools. Drivers must also have a valid driving license and insurance.

Laboratory staff: On specific laboratory tests and how to complete recording/reporting tools.

Communication

Communication systems linked to the collection of specimens and the return of results need be set up properly and implemented according to documented procedures.

A communication system is needed that notifies on:

- Any delays in testing
- Any delays in the return of results due to commodity stockouts
- Rejected samples
- The breakdown of machines, power failures, etc. at laboratories
- Priority results (MDR-TB detected) or missing/rejected specimens

Monitoring and Evaluation

Regular mentoring, supervision and corrective action are provided by the central, regional, and district TB supervisors, project staff, and courier staff to ensure the SOPs are adhered to and the proper documentation is completed.

A monthly summary of all the specimen deliveries is made using the summary form for specimen delivery/result reporting and is discussed with stakeholders to identify any challenges and provide solutions.

Summary information on the utilization and performance of GeneXpert centers is sent to the National TB Program via a diagnostic connectivity system or by other means.

Periodic data quality assurance must also be carried out to ensure high-levels of data quality are maintained.

COUNTRY EXAMPLE - TAJIKISTAN

Early Diagnosis and Timely Enrollment of Drug-Resistant Patients

Since 2014, Tajikistan has been providing countrywide treatment for MDR-TB. New interventions in laboratory services under the National TB Program improved with the implementation of new TB detection methods including culture and drug susceptibility testing to both first and second line drugs, and molecular rapid TB testing using GeneXpert/MTB/RIF.

With the introduction of new drugs and shorter regimens an effective specimen collection, storage, and transportation system are crucial to ensuring the early diagnosis of TB patients and the identification of drug resistance. The selection of the optimal treatment regimen is also important for patient triage.

As a result of efforts made, with improved quality of specimen collection, storage, and transportation a total 3,063 TB cases were detected (24%) including 488 DR-TB cases (4%) among the 12,558 samples collected, delivered, and tested in sixteen Challenge TB sites in 2017 and the first six months of 2018.

The introduction of the specimen transportation system reduced the time from the detection of TB patients to enrollment on appropriate treatment. Preceding the launch, the turnaround time was around two months and this was reduced to between 2-14 days depending on the location and distance.



COUNTRY EXAMPLE - ZIMBABWE

Integration of Specimen Transportation Systems

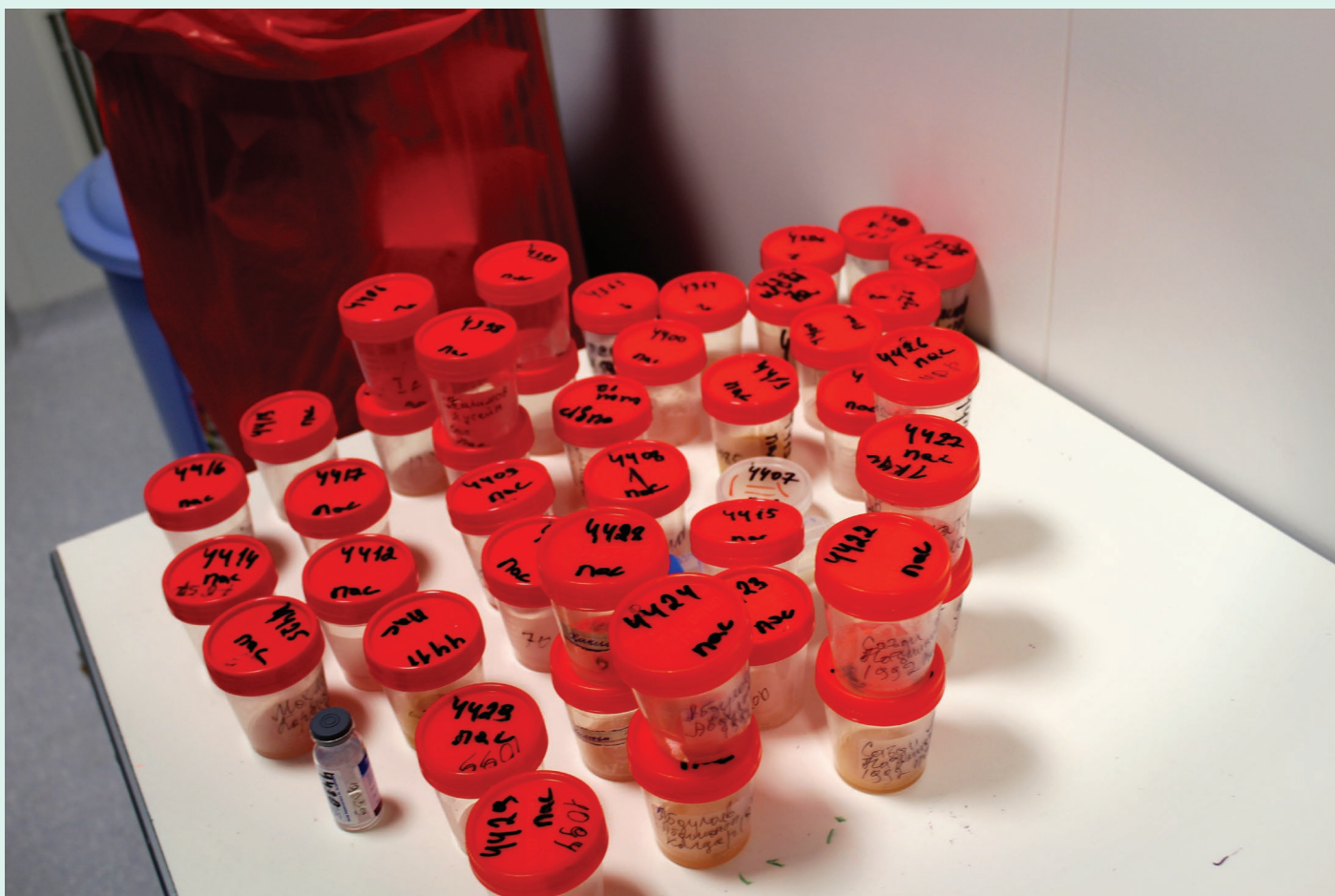
The TB/HIV co-epidemic in Zimbabwe means that people newly diagnosed with HIV are subsequently tested for TB using GeneXpert. The standard methods for detecting TB are often not sensitive enough (smear microscopy) or take too long (culture) to accurately detect TB in people living with HIV. The use of GeneXpert testing has allowed for the rapid and effective diagnosis of HIV-associated TB.

There is an increasing focus on working together with HIV programs in order to develop integrated transportation. Dedicated couriers transport sputum samples and other medical specimens from clinics to laboratories. The samples are arranged in the carrier box of the motorbike in such a way as to

prevent unnecessary movement during transportation. This is critical for viral load samples and full blood samples in order to avoid sedimentation. Viral load samples must be maintained at recommended temperatures and delivered to the laboratory within six hours of collection.

By developing integrated specimen transportation systems, both the TB and HIV programs combine testing for early diagnosis and anti-retroviral therapy (ART) treatment adherence. This also negates the need to develop of parallel systems. This dedicated specimen transportation system has led to a significant increase in the number of TB patients diagnosed among people living with HIV.





COUNTRY EXAMPLE - INDIA

Accelerating Access to TB diagnosis and Treatment for Pediatric Patients

It is estimated that around 1 million children become sick with TB every year, and a quarter of those infected die, making it one of the top ten causes of childhood mortality in the world. Diagnosing TB in children is difficult, not only do children have trouble producing sputum samples required for testing, but the sensitivity of smear microscopy remains low. TB in children can also be mistaken for other common childhood diseases such as pneumonia or other respiratory diseases.

WHO recommends that GeneXpert is used as the initial diagnostic test in all children thought to be infected with TB. In India, ten sites offer GeneXpert as an upfront test for pediatric patients. By facilitating an

efficient sample transportation system to these sites, the diagnosis of childhood TB has increased.

During the training of providers, special attention was paid to the collection of extra-pulmonary samples. The training focused on the collection of gastric aspirate and induced sputum. This made sure that for more than 90% of pediatric patients, the results reached the referring providers within 24 hours of the TB samples arriving at the laboratories.

DON'T FORGET TO

- Integrate transportation where possible
- Include the operational costs in the district health budget to sustain this system independent of donor funds
- Ensure that there are enough ice packs to cover specimen transportation more than once per week
- Provide a fridge (with freezer), and enough space to store samples until the courier arrives
- Make sure there is an adequate power supply at every facility
- Provide adequate storage facility at the laboratory to preserve the sputum samples that were not processed
- Ensure the shortest possible turnaround time from collection to test result and patient feedback.

RESOURCES

GLI Guide to TB Specimen Referral Systems and Integrated Networks

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

“Gearing Up” - The Story of Specimen Transport in Mozambique

<https://challengetb.exposure.co/gearing-up>

Specimen Transportation System: An Innovative Approach to Intensifying TB Diagnosis in Zimbabwe

<https://www.usaid.gov/what-we-do/global-health/tuberculosis/resources/results/innovative-approach-intensifying-tb>

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