Specimen Collection and Transportation System

What is the Specimen Collection and Transportation (SCT) system?

The SCT system is designed to ensure the seamless collection of sputum samples from symptomatic patients and delivery to accredited laboratories for microbiological testing for tuberculosis (TB). The system is staffed by a cadre of SCT agents and a coordinator who collect samples from pre-appointed collection centres, including Designated Microscopy Centres (DMCs) and medical colleges, and deliver them to labs for confirmatory tests including the Cartridge Based Nucleic Acid Amplification Test (CBNAAT), Line Probe Assay (LPA) and cultures.

The need for an SCT system

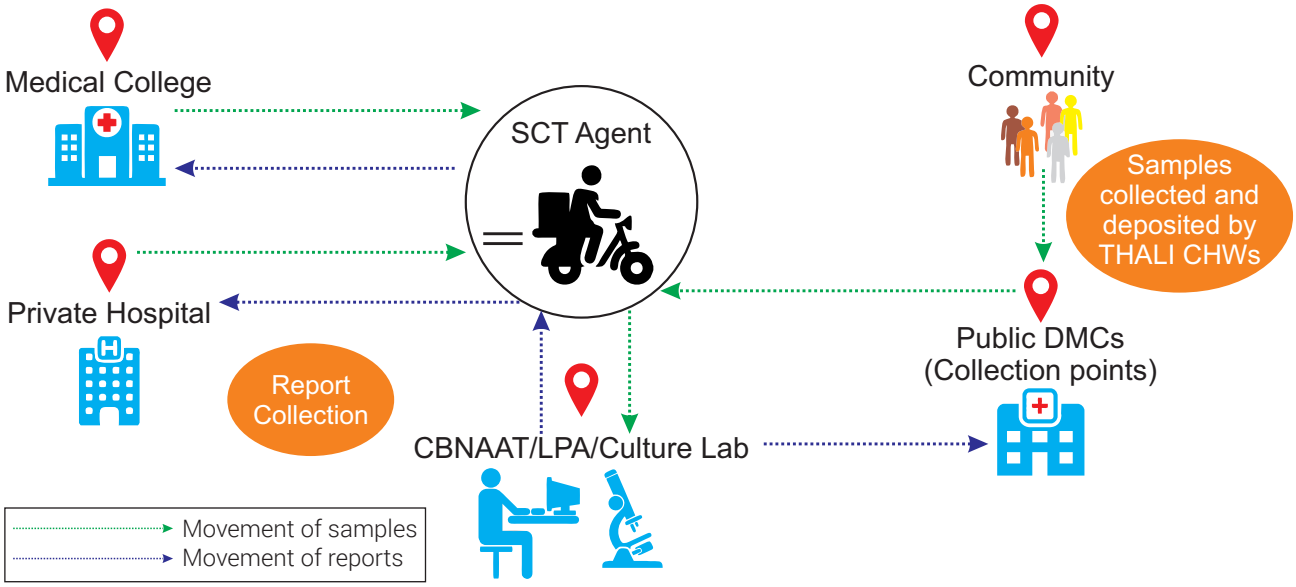
TB is a highly infectious disease caused by an airborne bacterium, and spreads through coughing, sneezing, and spitting. Each person with active TB has the potential to infect ten others in a year if left untreated. To reduce the risk of transmission, it is essential that the symptomatics be quickly diagnosed and initiated on treatment, so that they are rendered non-infectious within days. A delay in diagnosis prolongs the period during which a person can infect others, and also weakens the affected, whose symptoms only worsen over time.

When a doctor suspects TB, he refers the patient for testing. According to standards for TB care in India, microbiological confirmation is necessary for a TB diagnosis. In India, microbiological tests including sputum smear microscopy, CBNAAT, LPA and Culture tests are available free of cost in the public sector. In the private sector, large hospitals often have in-house testing, while smaller clinics outsource their testing to private laboratories. The onus, therefore, in most cases, is on the patient to go to a laboratory, get themselves tested, collect the results and return to the healthcare provider. This often leads to a delay in testing due to a variety of factors related to knowledge and access, including the cost of testing and

treatment, the distance from the patient's home to the lab and the timings during which the labs operate.

In the metropolitan city of Bengaluru, there are multiple labs which conduct CBNAAT testing, while LPAs and cultures are done at the National Tuberculosis Institute (NTI). The distances between the facilities which refer symptomatics and the labs result in further delays. In the public sector, where samples are transported from Designated Microscopy Centres (DMCs) to the labs by staff of the Revised National Tuberculosis Control Programme (RNTCP), it is a common practice to collect samples from patients only on certain days in a week, necessitating that patients provide the sample only on that day.
It is therefore essential that there be an SCT system in place to ensure that samples collected at the patients' convenience can be safely transported in a timely manner to the right lab for early diagnosis . The RNTCP's Guidelines for Partnership 2014 had sought public-private partnership for SCT. While the scheme had no takers in Bengaluru initially, in January 2018, KHPT began testing a model for SCT in BBMP and Bengaluru Urban to bridge the gap between sample collection and testing in a systematic manner. This was done under the Tuberculosis Health Action Learning Initiative (THALI), a four-year project which aims to strengthen TB patient care and support efforts, funded by the United States Agency for International Development (USAID).

In September 2018, the SCT system was transitioned to the Joint Effort for Elimination of Tuberculosis (JEET) project, funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Under JEET, the system provides sample collection and transportation services to private health facilities.



Causes for delays in diagnostic testing

- Patients going to smaller health facilities in the private sector have to take samples for testing, collect reports and return to the doctor for a prescription. This process can be delayed due to a variety of factors including the person's knowledge and perception of the importance of early testing, whether he/she can afford the tests and whether he/she has time to go for testing. Lack of support, old age and professional demands are also some common factors which delay testing and treatment initiation.

- In the public sector, there is no transportation system from DMCs (collection points) to the labs, and no designated staff to do this on a daily basis. Samples are sent to the labs on certain days of the week which may not be convenient for patients to come deposit a sputum sample.

The SCT system is important as it

- Relieves the patient of the burden of sample testing
- Reduces the time between collection of the sample and testing
- Removes the burden of sample transportation from DMC staff

Structure of the SCT System

KHPT operates an SCT system in 24 Tuberculosis Units (TUs) in BBMP and Bangalore Urban districts, employing 10 agents and one coordinator as of August 2018 .

There was earlier no agency in Bengaluru to carry out SCT. SCT was being done in other districts of Karnataka by commercial couriers who transported

samples from government facilities to labs. Initial consultations with commercial couriers were not successful as courier firms did not want to carry materials that were potential biohazards, the transport of which was not considered cost-effective because of the long distances to labs. Other deterring factors included the large number of labs that needed to be connected and the fact that samples would not necessarily be transported to the nearest one.

The need for the system was formalized after consultations with private sector doctors who found it difficult to convince their patients to get tested and were losing them to follow-up.

KHPT began operating the system in January 2018, working in consultation with the District TB Offices (DTOs). The DTOs provided KHPT with a list of high-burden DMCs, which could serve as collection points. There are 2-3 collection points per TU, and each collection point covers an average of 5-6 DMCs. The THALI Community Health Workers (CHWs) are responsible for bringing samples to the collection points at DMCs. Where applicable, the samples need to be tested with CBNAAT for diagnosis and drug sensitivity; such samples are sent to laboratories performing the CBNAAT test. CBNAAT testing is also done on samples from vulnerable groups, including children and the elderly. In case of positivity, further drug-sensitivity testing is done at the NTI through LPAs and Culture.

While eight SCT agents collect samples to be transported to CBNAAT, two agents have been deployed only to carry samples from the CBNAAT centres to the NTI. Each agent has his/her own route map which ranges from 25 - 60 kilometres .

A dynamic system

Route maps are regularly updated to adapt to changing guidelines for testing, the increasing number of samples collected, and the need to distribute them across testing centres to avoid overload at one centre.

The SCT agents also carry samples from private hospitals, who send samples for CBNAAT, LPA and culture tests, including samples from children and samples to be tested for extrapulmonary TB (including cerebrospinal fluid, gastric lavage etc.)

The test results are usually sent directly from the lab staff to the collection points at the DMCs. SCT agents collect the reports for private hospitals.

(From left, clockwise)- Sputum and fluid samples are packaged by the lab technician at the collection point; the SCT agent places the sample and paperwork in his bag; at the CBNAAT lab, the agent keeps the samples in the refrigerator prior to testing; the agent then collects the test results from the CBNAAT lab.

Three sites for sample collection

- Collection points at high-burden DMCs to which samples from other DMCs are funnelled by THALI CHWs and RNTCP staff
- Private hospitals, including paediatric samples and samples to test for extrapulmonary TB
- Homes of patients who cannot go to facilities because of various factors including old age, lack of mobility and severe illness.

Fluid and tissue samples await testing at the CBNAAT lab

Challenges to the SCT system

Packaging

- The high burden of patients in the DMC may lead to a delay in sputum sample collection and packaging, which can increasing waiting times for the agents.
- Improper packaging can result in leakage of the sample, which is a biohazard, and also ruin the documentation which is included in the packaging.

Documentation challenges

- If the forms are incomplete, if vital details including age, family history, mobile number and HIV status are missing, the sample will not be accepted by CBNAAT labs.

Logistical challenges

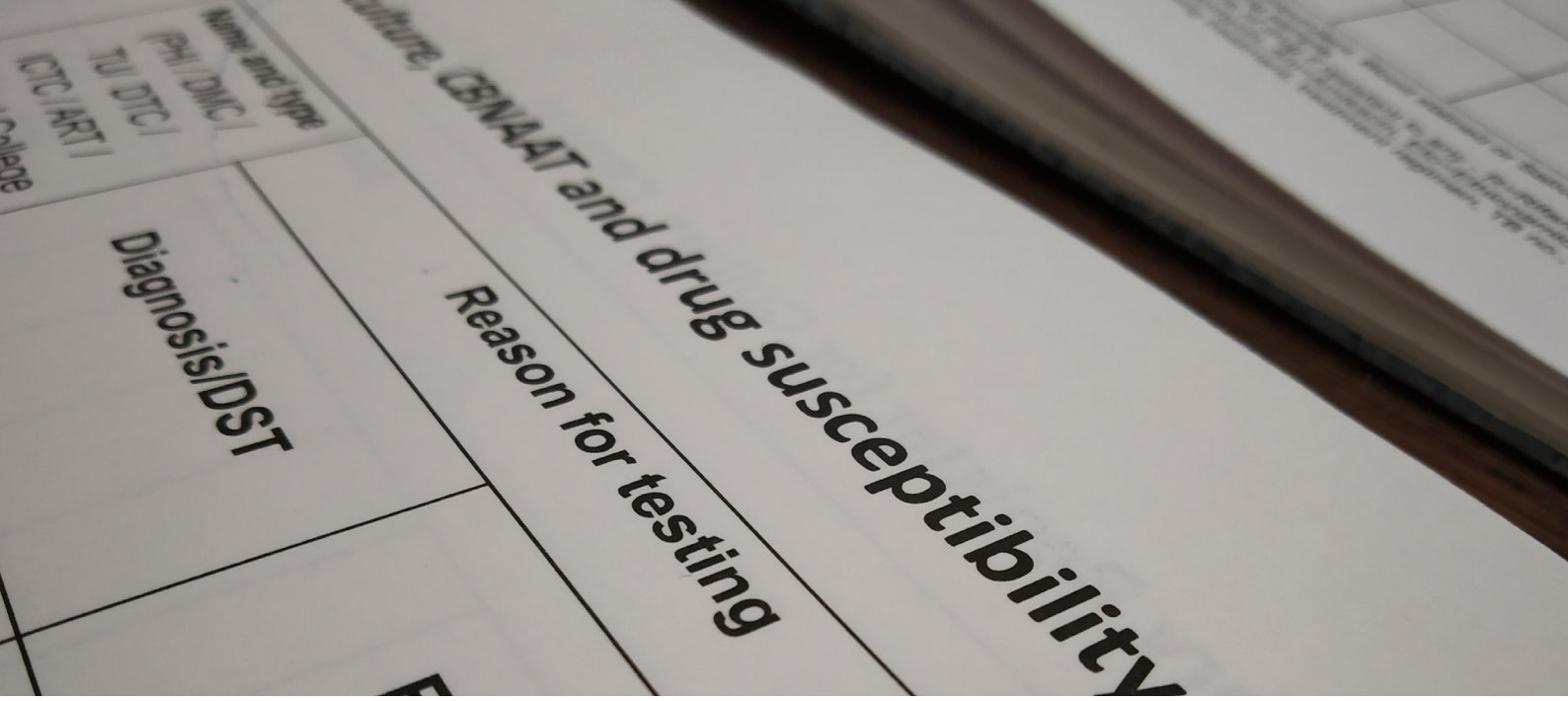
- Each agent deals with 8-10 samples per day, each of which is packaged in a sealed thermocol box. Agents find it difficult to carry these bulky packages across the city on two-wheeler transport.
- Poor roads and heavy traffic, especially in the rainy season affect the collection and delivery schedules of the SCT agents.

Systemic delays

- Inter-district SCT is not possible as samples from BBMP can only go to labs within the BBMP and samples from Bengaluru Urban can only go to Bengaluru Urban for reporting purposes. As a result of this geographical demarcation, SCT agents have to travel much further distances instead of going to a nearby lab which may be in the neighbouring district,
- Delays in collection inevitably lead to delays in depositing the samples. CBNAAT labs are open until 3:30 p.m. and are often unable to accept samples for storage after that time. If a CBNAAT lab does not have storage space, or if lab personnel are not available, agents must go to another CBNAAT lab to drop off the sample Since CBNAAT labs can usually test only 12-16 samples on a single machine on one day, they often have a backlog which delays testing even if samples are delivered on the same day as collection.
- The feedback system from labs to providers and collection centres is not robust. While reports are shared directly from the labs to the providers and collection centres, it is only the positive reports that are shared immediately. The negative reports are shared later, during which time both the provider and symptomatic person do not know if the person is positive or not.

Value addition

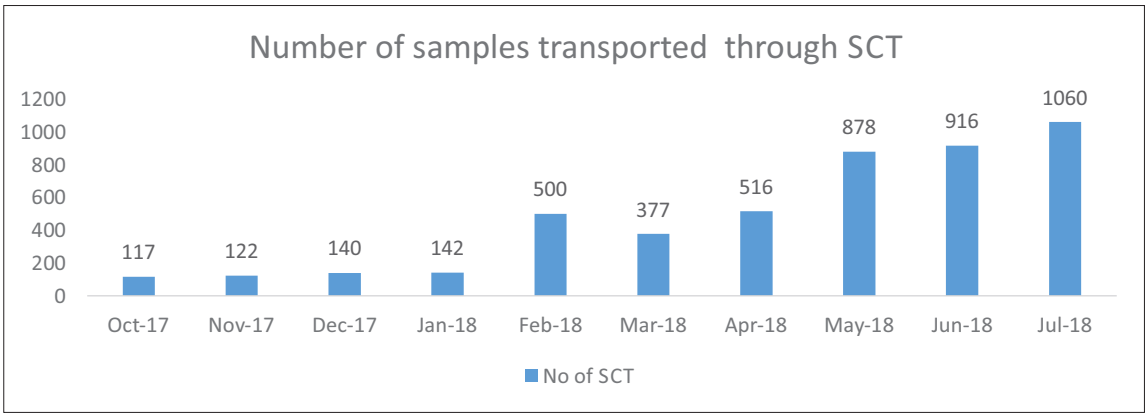
- The SCT system is essential to reduce the time lag between sample collection and lab testing, resulting in early diagnoses and improved notification. A positive diagnosis, which is confirmed to be drug-sensitive or drug-resistant TB (DRTB), can be quickly communicated to the provider, allowing the patient to be initiated on treatment immediately.
- The SCT system strengthens the existing lab testing infrastructure with a robust reporting system.
- SCT has helped providers manage DRTB patients through optimum treatment, get interim treatment outcomes and recognize early if the treatment is not working. Patients with DRTB do not respond to the core drugs of the treatment regimen. DRTB is more difficult to treat and patients must be regularly tested using culture tests during follow-up to ensure that their medication is working.
- The SCT system has the potential to evolve to meet the needs of collection points both in the government and in the private sector. It evolved from a system taking samples only from private providers to the CBNAAT lab to including DMCs as collection points and then expanding to include testing after CBNAAT as well (LPA, culture). The SCT system can be scaled up as well, adding more routes as the number of referring and testing facilities increase.



Data

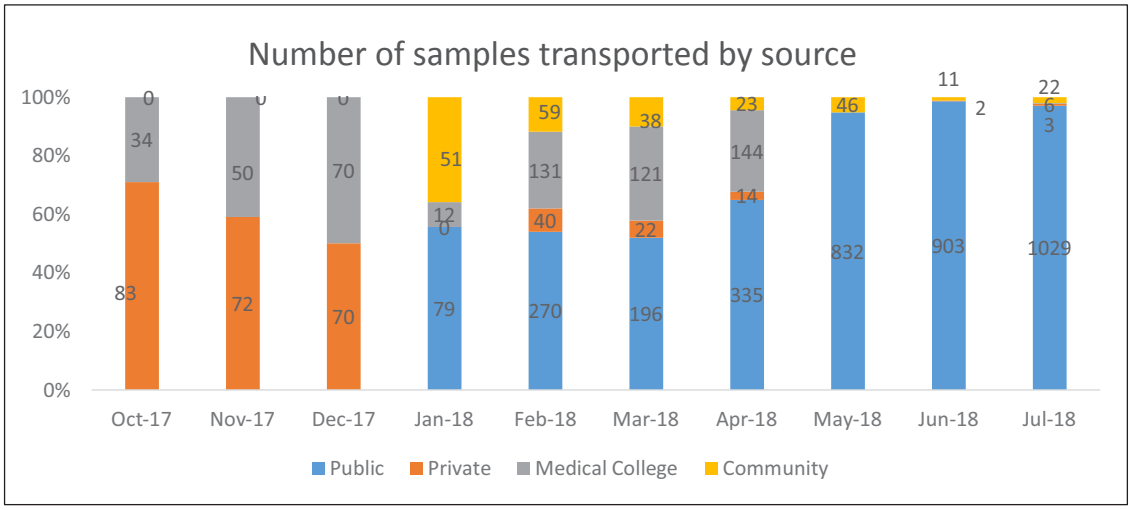
Number of samples transported till July 2018

Having a systematic SCT from January 2018 increased the number of samples transported gradually in comparison with an ad hoc mechanism that existed under the THALI project before January 2018.



**A total of 4768 samples were transported in the period October 2017- July 2018, of which 1154 patients were diagnosed with TB. 1139 of those cases were pulmonary TB cases, and 15 were extrapulmonary TB cases. 1133 cases were drug-sensitive, and the remaining 21 were drug-resistant TB cases.*

Number of samples transported by source



Voices

"Earlier, we were facing so many problems. We did not have separate staff to carry samples to DMC, but we had to manage. There was often a delay in getting results. A delay in results means it is difficult to start treatment on time. We find this system very useful as no sample goes missing, and we get results much faster. Quick results mean it is easy to begin treatment. We need this process to continue."

Somashekar S H, Senior Treatment Supervisor, Bengaluru Urban district

"Last year, we were sending samples through courier services. We would call them, but they wouldn't come for two-three days. They didn't know how to handle the samples and they would leak during transport. We had to start treatment with just sputum testing. Now, we have sample collection everyday. We are getting results much more quickly."

Anita, Lab Technician, Nelamaheswari DMC, Bengaluru Urban district

"We face different challenges everyday, from long waiting times at collection points, lack of storage space in the testing facilities to fixed operating times of the testing centres. However, we work on maintaining a good rapport with the RNTCP and lab staff in order to tackle these challenges. We have largely received good feedback from them, and most of them have a good opinion of our agents."

Mallesh, former SCT coordinator, KHPT

Conclusion

The National Strategic Plan for TB Control in India (2017-2025), emphasizes the need for a decentralized sputum collection and transportation system from public health institutes and DMCs, which can reduce the turnaround time of samples and enable early diagnosis of TB. It also sets out the need for engaging with NGOs and the private sector to ensure the success of such a system. Institutionalizing SCT within the RNTCP to serve both public and private health facilities is an important step towards filling a gap in the system which results in testing and treatment delays. The SCT system aims to streamline TB testing and benefit facilities and labs, but the ultimate beneficiaries are the individuals and the communities. SCT is one important element of the approach to patient-centred care, which eases patients onto the road to recovery and supports their treatment and follow-up with a health care provider of their choice.

While it may be scaled up, replicated and adapted to the requirements of different geographies and care settings, it is essential that a comprehensive package of guidelines, including safety protocols for transport and packaging be integrated into the system, along with capacity building of the associated staff.

KHPT
IT/BT Park, 5th Floor, #1-4, Rajajinagar Industrial Area, Behind KSSIDC Administrative Office, Rajajinagar, Bengaluru - 560 044.
T: +91 80 4040 0200 **W:** www.khpt.org **E:** khptblr@khpt.org

Disclaimer:This document is made possible by the generous support of the American people through the United States Agency for International Development (USAID).The contents are the responsibility of KHPT and do not necessarily reflect the views of USAID or the United States Government.