TECHNICAL HIGHLIGHT

Improving the Quality and Performance of TB Culture Laboratory Services Through Cold Chain Specimen Transportation System in Ethiopia

PROJECT CONTEXT

The health care system in Ethiopia relies upon a tiered network of health facility laboratories and reference laboratories, with an increasing degree of specialization at each tier. As part of this design, specialized tests have been decentralized at various laboratories throughout the country for tuberculosis (TB) diagnostic and patient follow up, including solid culture, liquid culture, line-probe assay (LPA), GeneXpert, electrolyte, hormone analysis and other organ function tests. To utilize this network effectively, it is essential to strengthen communication and data sharing systems at all tier levels. Robust supply chain systems must exist to ensure specimens requiring specialized testing are referred from one tier to the next. In the event of instrument breakdown or specimen backlogs, nearby reference laboratories must be able to perform referred specimens to ensure uninterrupted services provision.

While specimen referral services have been implemented at all tier levels with varying degrees of effectiveness, they have not been uniformly effective in all areas and specimen types because different temperature level requirements are needed to maintain quality. The Ethiopian Public Health Institute (EPHI) in collaboration with USAID's Help Ethiopia Address the Low Tuberculosis Performance (HEAL TB) project, implemented by Management Sciences for Health (MSH), designed a platform for van specimen transport system to be applied in the Oromia and Amhara regions. After the MSH/HEAL TB project ended on July 15, 2016, USAID's Challenge TB (CTB) project took over the initiative, also implemented by MSH and led by the KNCV Tuberculosis Foundation in Ethiopia.

At the beginning of the HEAL TB project in 2011, culture and drug susceptibility testing (DST) using solid media was available to the program in two regions to detect drug-resistant tuberculosis (DR-TB) and for monitoring treatment response, which made identifying drug-resistance patterns possible and allowed health care workers to provide more appropriate drug treatment for DR-TB patients. However, the limited number of culture

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laboratories, weak and uncoordinated specimen referral linkages, long distances between referring and testing sites, and weak means of transportation led to delays in specimen collection and delivery to testing sites and delays in delivering results, which hindered patient care and follow up activities in two regions. The introduction of new diagnostic technologies, particularly GeneXpert MTB/RIF service, was also challenging because of weak referral linkages, resulting in the inaccessibility of the service to support implementing programmatic management of drug-resistant tuberculosis (PMDT).

Thus, the HEAL TB project, Regional Health Bureau (RHB)/RL and EPHI identified TB specimen referral as a critical weakness that not only threatened the efficiency and accuracy of the laboratory service, but also influenced timely patient access to appropriate diagnostic services in routine programmatic practice. Thus, strengthening the TB specimen referral system in two regions was selected as a priority activity for collaboration between RHB/RL and the National Tuberculosis Program (NTP)/EPHI.

PROJECT IMPLEMENTATION

The courier system was primarily designed to address TB specimen transport from multi-drug-resistant TB (MDR-TB) Treatment Initiating Centers (TICs) to TB culture laboratories and sputum to GeneXpert sites. However, since there was a need for transporting other samples such as blood specimens for viral load testing, the vans also transported those on their way to and from the TICs. The frequency of the courier schedule was defined by larger volumes of specimens with a focus on inaccessible urban areas. An electronic specimen referral and results communication system was designed and implemented to facilitate prompt delivery of results. The new system was designed with the following principles in mind:

- Integration: Integrate the collection and transport of many samples in one trip
- Quality: Keep the quality of the specimens intact from collection to delivery to the labs
- Timeliness: Deliver the sample on time to the testing lab
- Saving resources: Cost-effective and efficient
- Regularity: Able to organize and remind the health facilities of regular test monitoring
- Customer satisfaction: Timely delivery of lab result and treatment initiation

Since August 2016, eight vans with built-in specimen transport systems were deployed in Amhara, Oromia and Addis Ababa regions. Of the eight vans, three were assigned to Amhara region to support specimen collection and delivery from nine TICs to two culture labs in the region. Similarly, three vans were assigned to Oromia region to support specimen collection and delivery from 18 TICs to three culture labs. The remaining two vans were stationed centrally both as back up and to support sample transport activities with the central reference lab and Addis Ababa region. After eight months (August 2016 - March 2017) of successful implementation of sputum transport in nine TICs and two TB culture reference laboratories and in consultation with the EPHI, the Amhara region increased transportation services to 79 health facilities. The weekly-integrated specimen transportation schedules specifically considered health facilities with heavy HIV and TB loads, and in accordance with the national integrated specimen guidelines, prioritized patients with indications for viral load measurement. If a health facility was a TIC, schedules for viral load specimen collection were synchronized with the monthly MDR-TB clinic days when sputum cultures were collected. EPHI also deployed the centrally stationed vans to collect specimen from Addis Ababa and surrounding Oromia region TICs and implemented integrated specimen referral in Addis Ababa region. In addition, EPHI used the vans to transport TB culture and viral load reagents that needed cold chain to maintain quality which can affect the quality of laboratory services.

In Oromia region, the three vans focused on transporting sputum specimens for TB cultures from 18

TICs to four culture laboratories including to the Ethiopian National Tuberculosis Reference Laboratory (NTRL). To take full advantage of the van specimen transportation system, Oromia region also planned to integrate specimen transportation in 114 heavy HIV and TB load health facilities starting in July 2017.

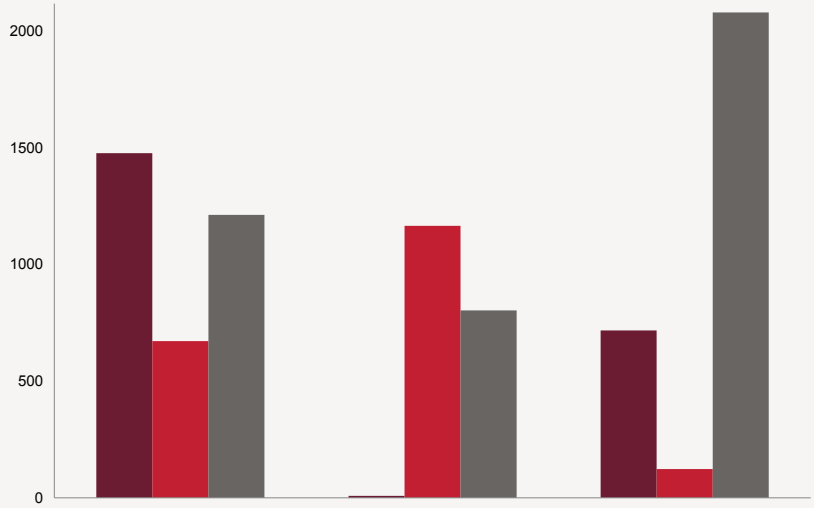
As an integral part of van specimen transportation system, CTB is currently supporting the implementation of an online eSpecimen[1] system in Amhara, Oromia and Addis Ababa regions to track sample pick-up and delivery, and communicate results, so lab results can arrive instantly. The eSpecimen RS implementation is currently active at EPHI, Jimma University Mycobacteriology Research Center, Adama Regional Lab, Harari RL and Addis Ababa RL. Software training was given to 236 personnel (221 laboratory professionals, nine TB focal persons and six data clerks).

Limited internet connectivity during the widespread social unrest in the country between July and September 2017, was the greatest challenge that hampered the implementation of the electronic sample referral and results delivery system.

RESULTS AND ACHIEVEMENTS

- A total of 28 TIC and 71 GeneXpert testing health facilities were supported through the new sample transport system.
- A total of 8,256 specimens were transported from health facilities to testing laboratories using the cold chain vehicles. Of the specimens transported, 3,360 were collected for TB culture testing, 1,976 for GeneXpert testing, and 2,920 for viral load testing (Figure 1).
- The average days between specimen collections at the health facility to specimen delivery at the testing laboratory showed improvement over time was reduced from more than a week to one day in the last two months. (Figure 2)
- The average sample rejection rate using cold-chain vans was 0.3%, which is far lower than the baseline average rejection rate of 3.4% at Adama Regional Laboratory.

FIGURE 1. Summary results of the cold-chain vehicle supported sample transport system, August 2016-June 2017



	# of specimen transport for TB culture test	# of specimen transport for GeneXpert test	# of specimen transport for viral load and other tests
Oromia	1477	8	717
Addis Ababa	671	1165	123
Amhara	1212	803	2080

[1] eSpecimen is an electronic sample referral and results delivery systems. When a sample is ready for transportation to the lab, the referring health worker sends an SMS with the code and quantity of the sample. This notification goes to the courier driver and the lab. At the same time, the message is displayed at the e-specimen website (www.especimeneth.msh.org). When results are ready both the treating health worker and the patient are notified through SMS. In addition, the result is uploaded to the website from where health workers can print the information.

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Authors

This publication was written by Degu Jerene Dare with contributions from Dereje Habte Woldehanna, Gudeta Tibesso and Bihil Sherefedin.

For more information, please contact lessons@msh.org.

FIGURE 2. Comparison of the traditional postal system and cold chain vehicle in terms of quality and timeliness of sputum sample referral

Characteristics	Traditional postal courier system	Cold chain vehicle
Average days between specimen collection and delivery to testing site	≥ 7 days	1 day
Initiation of specimen processing by the laboratory	5 days	2 days

Percentage of specimens rejected
Decrease from 3.4% to 0.3%

WAY FORWARD

By supporting routine specimen transportation through cold chain vehicles in Oromia and Amhara regions, Challenge TB has demonstrated improvements in the timeliness and quality of sputum specimens for TB culture. More specifically, the newly designed system:

- Contributed to the reduction of the average sputum transportation and delivery time from about one week to one day.
- Enhanced specimen integrity during transportation.
- Led to better communication between TB culture laboratories and van couriers enabling culture labs to process specimen in timely manner.
- Significantly reduced the number of specimen rejected due to poor specimen transportation.

Van sputum transport is very critical to access limited TB culture laboratories by a large number of health facilities located in a country with difficult terrains. Moving forward, proper cost-effectiveness analysis should be conducted before considering a nation-wide scale up.

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