THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Introduction of the LabXpert Connectivity Solution for TB Diagnostic Instrument Networks in Ethiopia

Background

Since 2016 the World Health Organization (WHO) and the Stop TB Partnership’s Global Laboratory Initiative (GLI) have urged countries to connect all molecular diagnostic instruments that produce digital data as part of the Framework of Indicators and Targets for Laboratory Strengthening under the End TB Strategy.¹

Over the past decade, Ethiopia has significantly expanded its network of TB diagnostic services to increase access to rapid molecular testing for TB and drug-resistant TB. As of March 2023, a total of 502 GeneXpert instruments were deployed across the country, with many in remote peripheral locations to ensure access to testing services which has also led to greater needs for programmatic supervision, instrument maintenance, transmission of test results and collection of performance data for timely reporting. Connectivity solutions make use of the digital data produced by diagnostic instruments to send, aggregate, and process data from multiple instruments using modems and other data transfer mechanisms.

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Additionally, connectivity solutions can be used to remotely monitor the performance of instruments in real-time and troubleshoot problems with utilization or maintenance, facilitate reagent forecasting and stock management, and allow for the rapid sending of test results to clinicians and to electronic patient registers and other information management systems.

As of early 2022, 286 GeneXperts in Ethiopia were connected to the GxAlert connectivity solution developed by SystemOne. However, only 159 of the instruments were reporting in real time due to outdated software at sites and shortcomings in the hardware required for data transfer. Furthermore, there were significant gaps in on-site and online technical support as well as in human resources capacity at testing sites and at the supervisory level to monitor and make optimal use of the data.

Project Description

Under the Stop TB Partnership/USAID introducing New Tools Project (iNTP), REACH Ethiopia has rolled out the LabXpert diagnostic connectivity solution in collaboration with MedX International (Uganda). Adoption of the LabXpert connectivity solution was selected by the Ethiopia National TB Program as a sustainable approach to connect the country’s GeneXpert instruments to:

- Rapidly transmit testing results to clinicians to enable timely enrollment of patients onto treatment
- Automatically transmit data to real-time dashboards for use at site, regional and national levels to monitor instrument functionality, maintenance status and inventory management
- Improve the programmatic data reporting system to strengthen overall lab programmatic management

Implementation Experience

LabXpert dashboards have been customized by MedX International according to the needs of the Ethiopia National TB Program, including results visualization, graphs, aggregated data, rifampicin resistance reporting, module functionality status, supply status over time, treatment indicators and maintenance status. During the pilot phase, national stakeholders decided to develop a remote desktop client (LabXpert relay) for installation on GeneXpert computers to upload all the information required from instruments, including data on all conducted tests, module serial numbers, module functionality log reports, ongoing tests, the last calibration date, and calibration reports.

Human resource capacity support was provided at national, regional and site levels to use the functionalities and resulting data from the LabXpert system and continuous site level support was given to promote increased facility level ownership of the connectivity solutions for sustainable implementation.

REACH Ethiopia procured the LabXpert software application code along with a customization and maintenance support package from MedX International. The project has built on recent investments made to strengthen in-country systems’ capacity in scaling up digital health information technology as per the national HSTP’s transformation agenda to ensure achievement of the goal of “Health for All”. The LabXpert connectivity project is being implemented in all 11 regions and two city administrations in Ethiopia. All data are hosted by the Ethiopian Public Health Institute (EPHI).

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Functionalities of the LabXpert System

1. **Improving Patient Linkage to Treatment**
   
   Since there is limited district (30%) and facility level (8%) coverage for on-site GeneXpert testing services in Ethiopia, most of the health facilities can access the rapid molecular TB testing services only through sample referral networks, which causes unnecessary delays in results delivery and subsequent treatment initiation. With the introduction of real-time connectivity through the LabXpert system, test results are now being timely transmitted to the designated clinical decision units using Short Message Service (SMS), which is expected to cut down the turnaround time for receiving test results. More than 720,000 SMSs have been sent to clinicians and patients, making 68% of test results available on the same day, compared to just 45% in the past.

2. **Improving Data-Driven Decision Making**

   It is now possible for GeneXpert instruments to transmit real-time laboratory programmatic data using the LabXpert system enabling regional and national health information systems to inform data-driven decision making. Moreover, with the LabXpert portal, it is also possible to generate aggregated TB laboratory performance reports on a monthly, quarterly, and annual basis. This data is provided by the designated reporting units (health facilities/districts/zones/regions/national level) for the programmatic management of lab services.

3. **Monitoring GeneXpert Instrument Functionality and Maintenance Services**

   In-country capacity has been established to monitor TB laboratory systems’ performance using LabXpert, including instrument functionality, maintenance status and timing of calibration, and inventory management. It is also possible to monitor the functionality of modules and to identify module failure rates and reasons for failures such as disabled modules or those with hardware problems.
4. **Inventory Management**

The LabXpert system allows for monitoring of TB laboratory inventory of GeneXpert cartridges and sputum cups, as well as other supplies, to ensure proper stock management.

![Stock Levels](image)

5. **Facilitating Service Requests**

LabXpert enables laboratories to extract reports on module, computer and software failures directly from the GeneXpert instruments. Laboratories can then report on such cases and LabXpert sends automatic emails with necessary installation qualification and system log reports to the manufacturer. This reduces the time required to replace modules and conduct other maintenance work.

![Facilitating Service Requests](image)

6. **Monitoring Utilization of Instruments**

By enabling calculation of instrument utilization on a module and facility level, LabXpert empowers TB laboratory managers to effectively plan their workload, manage the specimen referral system and identify needs for additional instruments or relocation if necessary.

![Monitoring Utilization of Instruments](image)
7. Geographical Mapping

It is now possible through the LabXpert system to visualize test performance using regional geo-locations. This geo-mapping capability provides invaluable insights into testing levels and caseloads of a specific location, allowing for better planning and allocation of resources.

Lessons Learned

1. GeneXpert instruments connected through fixed wired broadband internet cables demonstrated more stable internet connectivity than those connected through a mobile 4G modem. As a result, it is recommended to connect all instruments using a fixed wired broadband.

2. The real-time transmission of data from all connected instruments is possible only when all instruments have an active connection. To ensure uninterrupted connectivity and for troubleshooting, a hotline support help desk has been established by the project.

3. The local server that stores the TB laboratory information must be reliable and should have good connectivity with ample server space, and preferably a back-up server.

4. An uninterrupted power supply is key for the optimal functioning of GeneXpert instruments and to fixed wired broadband modems. If the power supply is not stable, procurement of power-backup systems should be considered.

5. In the intermediate and long term, for continuing optimal functionality and sustainability of the system as a real-time TB LMIS, the project will continue its advocacy and build the institutional capacity of the host government at the federal, regional and service delivery levels to influence the strengthening of the national TB laboratory diagnostic network system.
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Conclusion

The introduction of LabXpert has strengthened the country’s TB diagnostic network by providing a sustainable approach to establishing and maintaining connectivity, resulting in decreased time to TB treatment initiation through real-time transmission of GeneXpert diagnostic testing results directly to clinicians. Availability of real-time data on testing levels across facilities has improved overall laboratory programmatic management and planning. With the ability to remotely monitor instrument performance status, maintenance needs and stock inventory management, the Ethiopia National TB Program can optimize access to rapid molecular TB diagnostic services to detect TB and screening for possible drug-resistant strains for early treatment initiation and to reduce transmission in the community.

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Disclaimer: The findings in this publication are those of the authors and do not necessarily represent the views of the U.S. Agency for International Development or the U.S. Government.

For more information on the introducing New Tools Project, visit:

https://www.stoptb.org/accelerate-tb-innovations/introducing-new-tools-project