

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Roll-out of the Integrated Connectivity Solution 'Tibulims' for TB Diagnostic Instruments in the Republic of Kenya



Background

Kenya is a high TB and HIV-associated TB burden country. In 2022, an estimated 128,000 people became ill with TB, of which an estimated 26,000 people died.¹ The country adopted GeneXpert in 2011, and the test has been scaled up to 239 instruments as of June 2023.

In 2014, Kenya introduced a connectivity solution for its network of GeneXpert instruments that combined the GxAlert software (SystemOne, USA) for fetching data with an indigenously developed software, GXlims, for analysis and visualization of data.

The roll-out of this connectivity solution resulted in significant benefits, including automated results transmission to clinicians via SMS (Short Message Service) and email, enhanced network monitoring through a national dashboard and improved inventory management of GeneXpert cartridges.

¹ World Health Organization, Global Tuberculosis Report 2023. Available from: <https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2023>

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Despite impressive results, there was a need for further adaptation of the connectivity solution to address ongoing challenges and respond to emerging opportunities. GXlims and GeneXpert utilization rates in 2020 were lower than national targets set by the National TB, Leprosy and Lung Disease Program (NTLD-P), (42% and 69%, compared to the set national targets of 80% and 100%, respectively) across all 47 counties. The country had also adopted the GeneXpert Ultra Assay and Truenat instruments for the diagnosis of TB and rifampicin resistance. These developments required an upgrade of the combined GxAlert and GXlims solution to maintain seamless connectivity and allow for the continuation of monitoring of utilization rates, case-based data transmission of TB results, and tracking of the consumption of test kits.

The NTLD-P in collaboration with the USAID supported Tuberculosis Accelerated Response and Care II (TB ARC II) activity implemented by Centre for Health Solutions - Kenya (CHS) conceived a new connectivity solution *Tibulims*, which serves as a local integrated connectivity solution for WHO-recommended molecular rapid diagnostics (mWRDs) and digital X-ray systems used by the Kenya NTLD-P. Tibulims is led and owned by the Ministry of Health. Under the USAID-funded *introducing New Tools Project* (iNTP), Stop TB Partnership provided support for the development and implementation of the Tibulims project. The iNTP also provided Truenat systems and Delft Light ultraportable digital X-ray systems with CAD4TB software for the computer-aided detection (CAD) of TB, both of which have been integrated into Tibulims.

Project Description

The use of Tibulims aims to maximize network uptime by enhancing reactive and preventive maintenance of both instrument and network issues. Additionally, the program's capacity is being strengthened to initiate and maintain application programming interface (API) connections with existing and future TB diagnostic instruments that produce electronic data. Given the gaps and opportunities identified in the current TB diagnostic instrument network, the integrated Tibulims connectivity solution minimizes the total cost of ownership and will further develop eHealth capacity within the NTLD-P. All the activities and planning for this project have been coordinated by the NTLD-P in collaboration with CHS.

The main objectives of the activities were as follows:

- Expand the connectivity of the current TB diagnostics instrument network and make provisions for easy integration of future diagnostic tools.
- Strengthen active TB diagnostic instrument network management for timely relay of results and utilization of network data for remote monitoring of instrument performance.
- Strengthen NTLD-P and county capacity for development, deployment and maintenance of connectivity solutions for TB diagnostics to ensure sustainability.



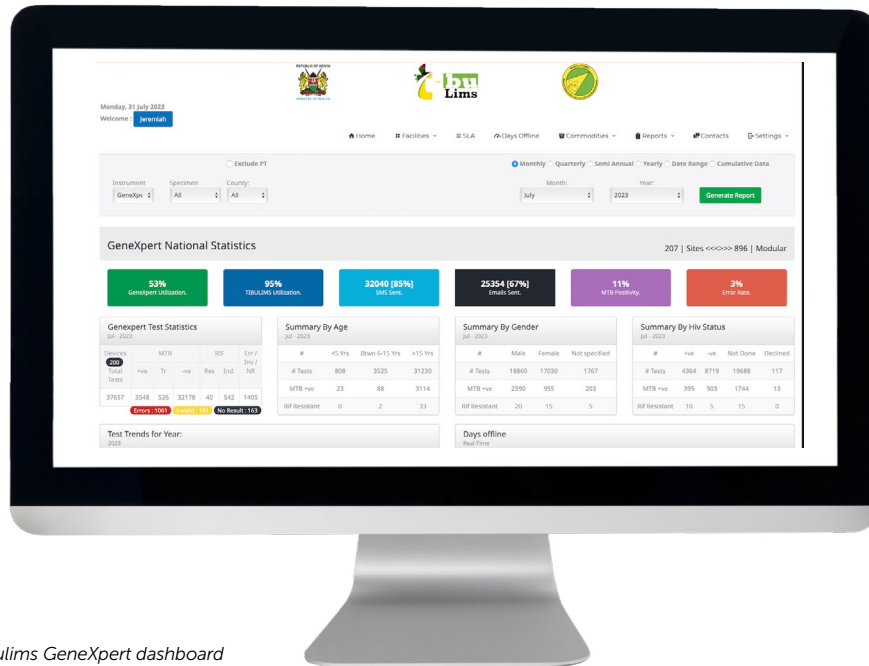
A radiographer is reviewing a chest X-ray based on the immediate interpretation of CAD4TB, Mutuati Sub-county Hospital, Meru county.

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Implementation and Results

1. GeneXpert Systems

The existing GeneXpert Application Programming Interface (API) has been updated, and 219 GeneXpert instruments on 207 sites have been configured to facilitate reporting of Xpert MTB/RIF Ultra results. Instrument performance data sharing with visual dashboards at facility, subcounty, county and national levels is currently up and running.



An example of the Tibulims GeneXpert dashboard



The advantages of Tibulims are that it has really helped in registration of patients and reporting of the images done by the radiologist. Tibulims has also helped us in data collection. Patients' data and images have been easy to retrieve. Another advantage of Tibulims is that it has linked radiology with the laboratory's GeneXpert.

Wycliffe Onyango | Radiographer, Madiany Sub-County Hospital, Siaya County

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2. Ultra-portable Digital X-ray and Computer-aided Detection Systems

Following the successful development and testing of the CAD4TB Application Programming Interface (API), connectivity with this CAD software for digital X-ray results interpretation was rolled out in December 2022. The verification of data in CAD4TB boxes at each facility had to be completed prior to conducting system configuration to allow for the data to be uploaded from CAD boxes onto Tibulims. This was followed by verifying the uploaded data, assessing image quality and sensitizing health care workers on how to use the system. The data on the number of images taken across all 8 connected X-ray/CAD sites is now available on the Tibulims dashboard. It is also possible to generate reports for different periods for individual sites and aggregated reports for all sites. The data on the total number of images disaggregated by score categories, age groups and laboratory results as well as radiological reports is also available on the dashboard.

Technical support for the digital X-ray sites is being provided via phone, online (using TeamViewer and other desktop applications) and on-site visits.



Tibulims has made our work easier since previously we used to write on a piece of paper then send it to the X-ray room. Secondly, I can view X-rays from my phone, and this helps me in making decisions. I am also able to view reports from the radiographer and radiologist from my phone. Thirdly, it has reduced waiting time for the client. Overall, the system is good, and I fully endorse it. It is interactive and easy to use.

Dr. Danvas Nyakweba | Clinician, Madiany Sub- County Hospital, Siaya County

3. Truenat Instrument Systems

The Truenat API pilot testing was also successfully completed, and the Molbio technical team upgraded the system software, allowing the project team to roll out the API. All 38 Truenat devices are now configured to enable the upload of Truenat data onto Tibulims through the API gateway.

The testing data has been transferred to Tibulims servers, and the results can be accessed through the dashboards. Additionally, reports on instrument utilization, error rates and maintenance history can be viewed and downloaded from Tibulims. Furthermore, users can capture additional information when they run the tests, e.g., patient HIV status, patient type, etc. The clinicians and sub-county TB and leprosy coordinators can now receive SMS messages and emails regarding patients' test results. Truenat users can monitor their commodities, i.e., MTB Plus and MTB-RIF Dx chips. The relay of results via SMS messages and email has greatly strengthened the laboratory-clinical interface to ensure that patients can be called for initiation of treatment without having to wait for a physical copy of results.

The project team continues to provide technical assistance through visits to Truenat sites to troubleshoot and provide on-site support for uploading data onto Tibulims with the aim of promoting effective utilization of Tibulims.

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4. Interferon-Gamma Release Assays (IGRAs)

As part of integration, connectivity of Tibulims with IGRA machines was also explored. Unfortunately, the data push from these devices met a technological hitch as the devices did not have an end-to-end integration point. As a stop gap measure, an online reporting portal for summary aggregated data was developed to facilitate data visualization through the Tibulims system in the form of dashboards. The availability of aggregated data is useful because it provides reference to the total number of completed tests and commodity accountability.

The indicators that can be visualized include the following:

- I. Total IGRA devices connected
- II. Total tests conducted
- III. Results (Positive, Negative, No results, Indeterminate)

Lessons Learned

1

Meaningful and effective stakeholder engagement and collaboration in the conceptualization process is essential for the successful implementation of a connectivity solution.

2

Support and real-time response from the manufacturer of the TB diagnostic tools is crucial towards achieving and setting up a connectivity solution to help navigate the interoperability aspects.

3

Continuous training and refresher trainings of end-users and stakeholders, remote support, mapping of available and strengths of network coverage is key for the successful adoption and utilization of a connectivity solution.

4

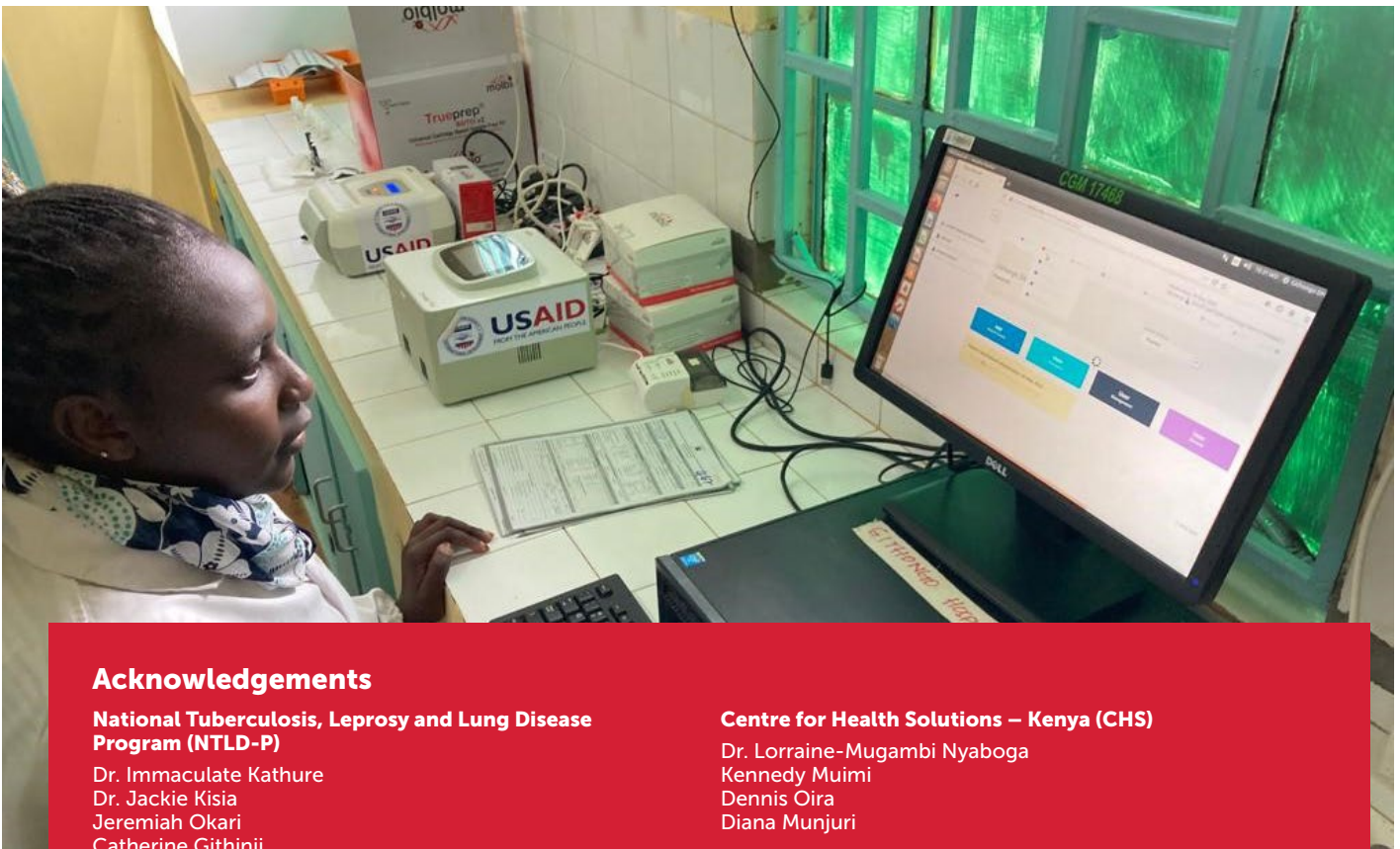
In the dynamic landscape of TB diagnostics, particularly in molecular diagnosis, the development of new TB tools should prioritize flexibility and improved instrumentation to enable seamless integration with connectivity solutions.

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Conclusion

The introduction of the integrated connectivity solution Tibulims has improved and strengthened Kenya's TB diagnostic network. Tibulims is a home-grown integrated solution that ensures the country's ownership as it is led and owned by the Ministry of Health of Kenya. The project has achieved real-time reporting for all connected GeneXpert, Truenat and CAD4TB devices. The project has managed to expand the connectivity of the current TB diagnostic instrument network, enabled the timely transmission of results, and strengthened the country's capacity through utilizing data to meet continuous training and technical support needs.

By taking the decision to build their own system, the country has demonstrated the importance of national ownership for ensuring sustainability of the intervention.



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

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