Country in Focus: The Philippines

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Revolutionizing TB Screening and Testing: How Ultra-portable Digital X-ray with Artificial Intelligence-Powered Detection Software Together with On-site Rapid Molecular Testing are Reaching People Across the Philippines

Background

The Philippines faces one of the highest TB burden rates in the world, ranking 4th globally with an estimated 737,000 people becoming ill with TB each year.[1] According to estimates by the World Health Organization (WHO), 41% of these people with TB went without a diagnosis or were not accounted for in national data in 2022[1], resulting in a significant number of people not receiving proper treatment and care and increasing community transmission.

To find these missing people with TB, there is a critical need for innovative tools to screen and test for the disease, as advocated for in the Stop TB Partnership's Global Plan to End TB. Ultra-portable digital X-ray systems with computer-aided detection (CAD) software for TB utilizes deep learning artificial intelligence (AI) to detect abnormalities suggestive of TB on a chest X-ray, giving the potential to identify previously undiagnosed people with TB earlier and in areas with limited human resources. Another such tool is rapid molecular testing using real-time PCR technology at point-of-care, which can be used to provide bacteriological confirmation of TB and rifampicin resistance. The integration of ultra-portable digital X-ray systems with CAD software and rapid molecular testing has made TB screening and testing possible in remote areas of the Philippines that lack access to health facilities.

[1] WHO Global TB Report 2023 available from: https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2023

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Figure 1: *The 26 provinces and cities across the 5 regions of the Philippines in which the iNTP has been implemented*
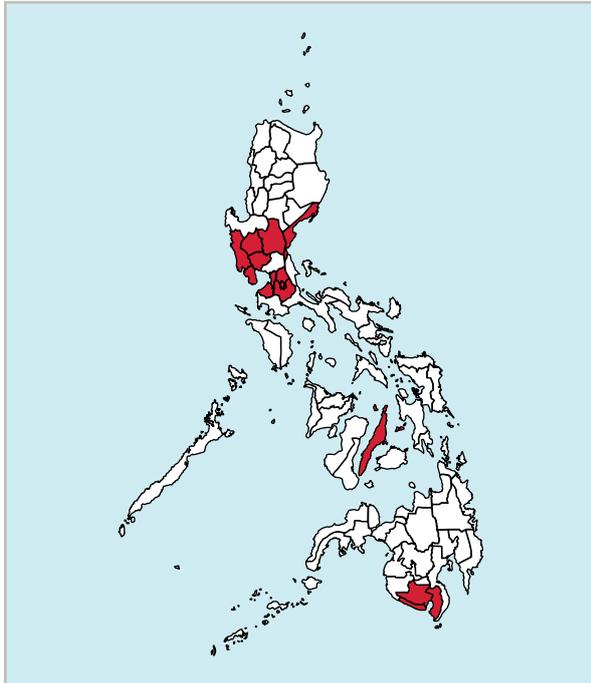
Under the *introducing New Tools Project* (iNTP), funded by the United States Agency for International Development (USAID), the Stop TB Partnership provided to the Philippines eight FDR Xair ultra-portable digital X-ray systems (Fujifilm, Japan) with CAD4TB software licenses (Delft Imaging, the Netherlands) together with 38 Truenat Duo workstations for rapid molecular testing using Truenat MTB Plus and Truenat MTB-RIF Dx tests (Molbio Diagnostics, India). These products were provided via Stop TB Partnership's Global Drug Facility (GDF).

The USAID's TB Innovations and Health Systems Strengthening (TB Innovations) Project implemented by Family Health International (FHI360), together with USAID's TB Platforms for Sustainable Detection, Care and Treatment (TB Platforms) Project implemented by University Research Co. LLC (URC), have been supporting the Department of Health (DOH) and the provincial and local health authorities in introducing these technologies for TB screening and testing across five (5) regions in the Philippines, encompassing 26 provinces and cities (Figure 1), with a focus on Geographically Isolated and Disadvantaged Areas (GIDAs). The objectives of the implementation were to (1) demonstrate feasibility and impact of converging these novel tools at point of care in the local setting, especially in GIDA and urban poor in selected provinces and cities through integrated active TB case finding and contact investigation; (2) facilitate local buy-in and build staff capacity based on training needs; (3) and identify best algorithms and approaches for implementing the package of tools.

Implementation Experience

TB Innovations and TB Platforms Projects, in collaboration with the Department of Health, established strong relationships with community and national stakeholders to create an implementation roadmap and successfully integrate the use of Xair digital X-ray, CAD and Truenat technologies as screening and testing tools in accordance with national TB guidelines. A special Task Force was established to provide strategic and technical oversight, composed of representatives from DOH-Disease Prevention and Control Bureau (DPCB), DOH-Food and Drug Administration (FDA), National TB Reference Laboratory (NTRL), World Health Organization (WHO) Philippines, USAID and its implementing partners FHI360 and URC. A DOH Memorandum and special licenses from FDA were issued to authorize use of the novel tools; while Memoranda of Agreement (MOAs) between concerned Regional Centers for Health Development (CHDs) and local government units (LGUs) at the province and/or city levels were executed including application for local license to operate (LTO) for the ultra-portable X-rays. Demonstration (entire package of tools namely Fujifilm Xair with CAD4TB, Truenat and 3HR) and extension sites (Truenat and 3HR only) were selected based on technical

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criteria vetted and approved by the Task Force. Capacity building, mentoring activities and social preparation and mobilization were localized based on resources available and restrictions imposed during the ongoing COVID-19 pandemic in close coordination with local leaders and stakeholders. This also coincided with the introduction of electronic or paperless screening using the Care TB App linked to the country's Integrated TB Information System (ITIS).

Activities in the Philippines started in Q2 2022 and have been conducted largely in communities (basketball courts, school grounds, etc) as well as in barangay health stations, rural health units and other health facilities of varying sizes, leveraging the portability of the X-ray and Truenat systems to extend care to people who normally lack access to such testing. High-risk groups, such as indigenous populations, internally displaced persons and other hard-to-reach communities including in GIDAs, have been specifically targeted for screening.

To conduct community screening events, both TB Innovations and TB Platforms teams have often had to brave harsh conditions to reach individuals in remote areas, including crossing rivers and other bodies of water to reach remote islands, and challenging mountain paths. During screening campaigns, each individual receives a chest X-ray with CAD4TB and has sputum samples collected if assessed presumptive based on symptoms and/or CAD4TB reading. Any results indicating an abnormality score higher than the CAD4TB threshold of 60, which was later adjusted to 50, are referred for rapid molecular testing for bacteriological confirmation, using on-site Truenat systems. People with TB symptoms at such screening campaigns are also provided with molecular testing regardless of their CAD4TB score.

Project Impact

The iNTP has demonstrated the promising potential of Xair ultra-portable X-ray, CAD4TB and Truenat technologies in a high TB burden country. By focusing on hard-to-reach areas and high-risk populations, the project has successfully provided care to thousands of individuals who would have otherwise gone undetected. The linkage to local treatment centers has also ensured that the entire care cascade, from screening to diagnosis and treatment, has been made readily available to those in need. It also facilitated identifying contacts eligible for TB preventive treatment.

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41,000+
individuals screened using Xair and CAD4TB

7.5%
individuals with abnormal X-rays

1,000
individuals with TB and started on treatment

As of September 2023, the project had screened over 41,000 individuals using Xair and CAD4TB, with over 3,100 (7.5%) having an abnormal X-ray, and had consequently identified over 1,000 individuals with TB and started on treatment. Over 14,500 samples were tested on the 38 Truenat systems from April 2022 to September 2023, with 2,500 samples testing positive for TB. Furthermore, Truenat results have been made available either on-site during Active Case Finding (ACF) campaigns or within just 1-2 days after testing at all sites.

Community outreach efforts have consistently seen a good turnout of approximately 100-200 individuals daily. Furthermore, people in rural parts, especially GIDA areas, have been very appreciative of the outreach efforts as many have never had access to X-ray screening before. In certain GIDA sites, the screening and testing campaigns using these new tools have resulted in significant increases in TB case detection. For example, in Bantayan Islands, Cebu composed of 25 barangays and island communities accessible by 4-hour land trip and 1.5-hour ferry from Cebu City, the novel tools were instrumental in improving TB screening and testing since there were no X-ray and rapid TB testing facilities in the area, From 6 September to 15 October 2022, 21 out of 25 were reached for active case finding, integrated with childhood immunization campaigns, awareness and screening for diabetes, malnutrition and HIV among others. These efforts were able to identify 1,774 (9%) individuals with presumptive TB using Xair and CAD4TB in one month, 14 times higher compared to screening by symptoms in the entire previous year. With on-site Truenat, testing also increased 4x with 0-2 days turnaround time compared to 1-3 weeks turnaround in the previous year. The 1.5 month-long active case finding in Bantayan Islands identified 220 newly diagnosed people with TB, 37 (17%) were bacteriologically confirmed, and all were initiated treatment by the local health team.

14,500
individuals tested wtih Truenat

2,500+
samples tested positive for TB

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Lessons Learned
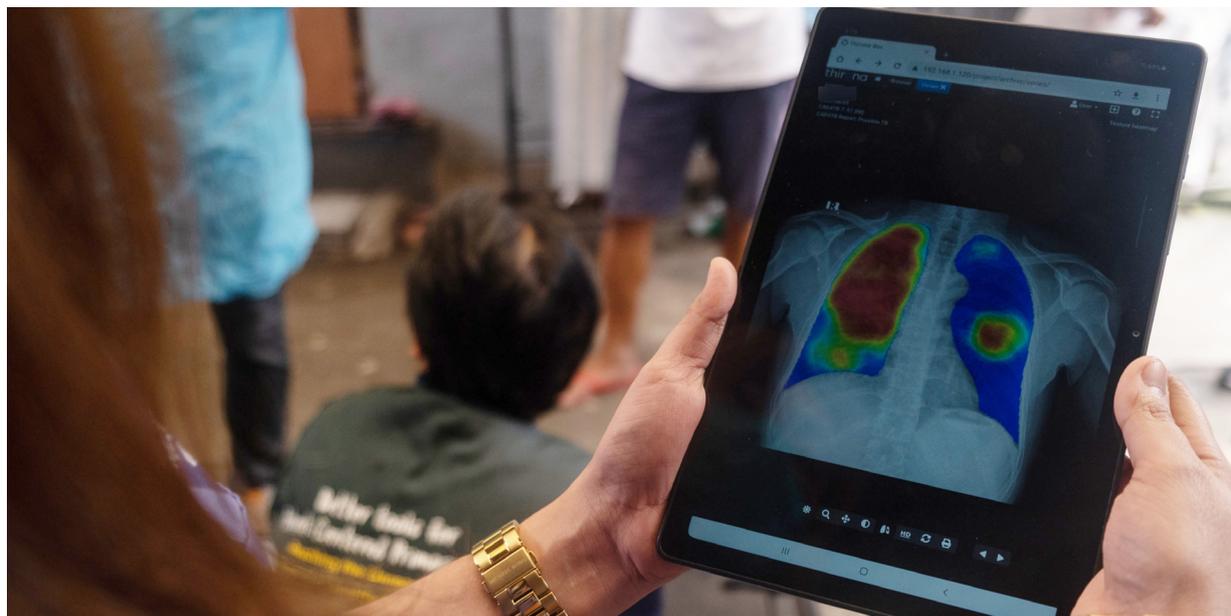
As this was the first systematic large-scale introduction of these technologies in the Philippines, it is important to note that the early stages of implementation were not without challenges. These included delays in receiving regulatory approval and licenses to operate the ultraportable X-ray devices, customs clearance, equipment issues, and software connectivity problems. Although these delays caused setbacks in initial implementation, it was helpful to have Fujifilm's local presence in the country assisting with quicker turnaround times. The Molbio local agent, now Getz Healthcare, is also able to provide replacement and repair of Truenat equipment and parts as needed, with two spare systems on standby as needed.

Setting up the Xair, CAD4TB and Truenat systems during ACF activities have been found to be relatively easy. The minimal biosafety and infrastructure requirements of Truenat, coupled with the fact that the battery is able to last a full day of operation when local power is not available, has made it attractive for use in active case-finding activities. Staff have reported that testing is simple, although ACF activities have occasionally identified a large number of people with symptoms or with TB abnormalities from the chest X-ray, requiring more than one Truenat system to prevent a backlog of specimens for testing.

It was observed during training that the level of sample manipulation required to run Truenat tests could result in errors, particularly during the first few months of implementation. Therefore, the FHI360 project team set up a Truenat support group to closely monitor and provide technical support to end-users. Recurrent errors were reported to the Molbio local agent, which provided remote assistance or on-site visits for additional troubleshooting.

This approach helped reduce the error rate during DNA extraction from 6.6% in Q2 to 0.7% in Q3 2022. While the error, invalid, or indeterminate rate on the MTB-RIF Dx test increased in Q3 2022, additional site support visits are planned to the facilities where these errors were reported.

Because many of the end-users had limited exposure to molecular testing, the FHI360 project team adapted the training package developed by Stop TB, USAID's Infectious Disease Detection and Surveillance (IDDS) Project and the Global Laboratory Initiative (GLI), to include additional modules on biosafety and good clinical laboratory practice to ensure that basic laboratory skills were reinforced; these modules have now been adopted into the Stop TB/ USAID IDDS/GLI training package. Standardized training guides and job aids for staff training and mentoring reduces error rates and increases compliance with procedures and recording and reporting. There is a need to consider country reporting requirements, connectivity, infrastructure needs, and capacity within the existing health management information system to facilitate easy data capture and reporting. Having local ambassadors/ early adopters of the tools to advocate to their peers improves local stakeholder buy-in for continuity and sustainability.

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Looking Forward

Starting from January 2023, the TB Innovations Project team has successfully handed over the activities to the Department of Health, and the TB Platforms Project team continues to use ultra-portable X-ray, CAD and Truenat with continuing evidence of positive results in reaching and detecting people with TB. To scale up these activities further, the country teams are working closely with all partners to ensure that results are documented in Health Technology Assessments of these new tools, to fulfil the requirements for potentially using domestic funds to expand use of these technologies in the country.

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

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