STOP TB PARTNERSHIP | USAID *INTRODUCING NEW TOOLS PROJECT* (iNTP)

Results: Truenat

The iNTP introduced Truenat[1] to 9 high TB burden countries in Africa and Asia, with installations and testing starting in countries between Q4 2021 and Q3 2022. By implementing testing using 301 Truenat Duo systems (between 15-38 systems per country), the iNTP has been the largest multi-country roll-out of this innovative technology.
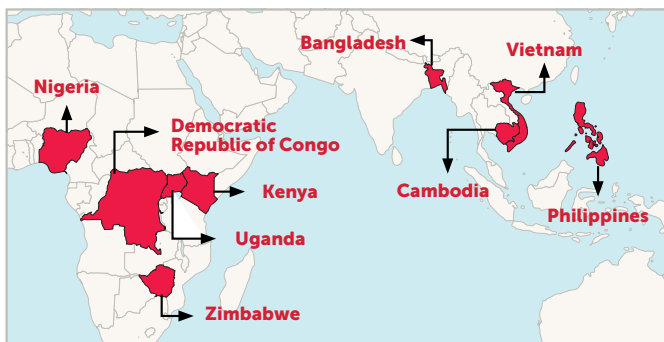
Truenat in the iNTP: At a Glance

Truenat implementation enabled the replacement of microscopy as a diagnostic test at project sites and demonstrated the feasibility of use of this new technology at peripheral health facilities and in active case finding scenarios. USAID in-country partners supported the National TB Programs in introduction of the Truenat technology. By Q3 2023, over 375,000 people were tested using Truenat and over 41,000 people with TB were identified, resulting in significant increases in access to rapid molecular testing compared to the period before implementation. By the end of year 1, over 80% of people newly diagnosed with TB were tested with a WHO-recommended test. Five of the project countries have already planned for scale-up of Truenat using Global Fund resources, including a total of 600 additional instrument systems.

[1] For background information on Truenat, visit: https://www.stoptb.org/sites/default/files/truenat_a_rapid_molecular_diagnostic_for_use_at_peripheral.pdf

Key Results

1. Introduction of Truenat resulted in **significant increases in access to rapid molecular testing,** compared to the period before implementation, when availability of such testing relied on referral of specimens or people to other sites, or was absent altogether: data from reporting countries showed that adoption of Truenat resulted in a median **percentage point increase of 57.1% (IQR: 9.2-87.2) in the proportion of people newly diagnosed with TB having access to a rapid molecular test** compared to the period one year before implementation.

2. Introduction of Truenat also resulted in increases in bacteriological confirmation. Data from reporting countries showed that adoption of Truenat resulted in a median percentage point increase of 11.1% (IQR: 0-32.6) in the proportion of people newly diagnosed with TB having bacteriological confirmation compared to the period one year before implementation.

3. Over 41,000 people with TB were detected using Truenat under the project as of Q3 2023.

4. 5 of 9 project countries (Bangladesh, Democratic Republic of the Congo, Kenya, Nigeria, Zimbabwe) already have plans for wider scale-up of Truenat using Global Fund resources. These countries are planning to more than double the sizes of their Truenat fleets, by procuring between 40 and 333 instrument systems, totalling 600 systems across the countries.

Figure 1: *Proportion of people newly diagnosed with TB having access to a rapid molecular test, before and during implementation of Truenat*
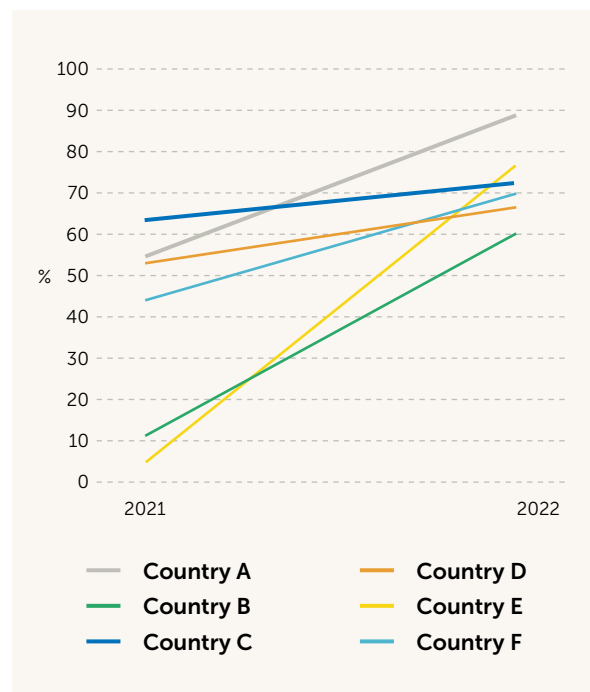
Main Learnings From Implementation

Implementation of Truenat was found to be **feasible at lower level health facilities:** 256 of the 301 Truenat systems in the project were used at microscopy-level facilities. Rates of errors, invalids and other unsuccessful tests were relatively low, however there was wide variation across testing sites and countries particularly with the proportion of tests that were RIF indeterminate when bacterial load was low. Training requirements of end users were relatively low, though hands-on training is needed to gain competency and confidence in the manual steps including micropipetting. Compliance with conducting routine preventative maintenance is needed to keep error rates low.

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Comprehensive service and maintenance provided by Molbio in-country agents allowed for rapid on-site repairs and replacement of devices. Availability of in-country spare systems and parts facilitated the timely swapping of components as needed.

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The **in-built batteries of Truenat workstation devices allowed for uninterrupted testing** (up to 8 hours) in settings with power outages. Given the need to charge batteries, solar power systems were found to be effective especially in sites that experience multi-day power outages. Surge protectors and voltage stabilizers were found to be critical in settings that experience electricity fluctuations, to protect the devices from damage.

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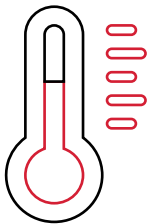
While the Truenat system is designed to be used at peripheral health facilities, one of the test components (Truenat chips) **requires storage under 30 degrees Celsius** to allow for the maximum shelf life. Sites in hot environments and without a cool room or refrigerator for storage of the chips may have experienced higher rates of errors especially towards the end of the products' shelf life.

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A pool of skilled personnel trained by the USAID Infectious Disease Detection and Surveillance (IDDS) project to be **superusers helped the national TB programmes** in most project countries with basic troubleshooting and provided remote and on-site supervision.

Use of Truenat in Community Settings

Two countries - the Philippines and Nigeria - used Truenat for active case finding in community settings, paired with ultra-portable X-ray systems equipped with software for the computer-assisted detection of TB, also provided under the iNTP. While the batteries, portability and ability to test at temperatures up to 40 degrees Celsius allowed for successful use in community settings, the number of specimens able to be run in a day was found to be insufficient given the large number of specimens collected during such events. Instead of using a single Duo workstation, active case finding events would be better equipped with a Quattro workstation or multiple workstations to allow for test results to be made available during the event.
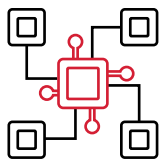
While the Truelab device has in-built **connectivity** capabilities, on-site configuration of devices and the need for software developments resulted in significant delays in set-up of connectivity in countries. Countries that have a connectivity system in place have been able to remotely monitor device performance and allow for test results to be sent rapidly to clinicians.

To enhance quality of testing, the IDDS project enrolled testing sites in most project countries in an **External Quality Assessment** (EQA) program consisting of 3 cycles of SmartSpot dried culture spots. All countries met the minimal performance benchmark of 80 percent.

For more country-specific learnings and results, see the Truenat implementation case studies on the iNTP Country Experiences webpage

🔍 https://www.stoptb.org/introducing-new-tools-project/country-experiences

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Stop TB Partnership

Resources Developed

Experience from the project has been used by the Stop TB Partnership to develop and refine a number of resources that can be used by any country interested in adopting or scaling-up Truenat:

Practical guidance on implementation of Truenat, developed in collaboration with USAID and GLI	**Click Here**
Training package including modules and facilitator and participant guides, developed in collaboration with USAID and the USAID IDDS project	**Click Here**
Case studies/webinars for experience sharing and to build awareness among countries outside of the project	**Click Here**
Recommended operational research questions	**Click Here**
A global framework of key performance indicators and targets for service and maintenance, with monthly performance of service providers reported by the manufacturer to countries and Stop TB Partnership's Global Drug Facility	**Click Here**
Online spreadsheet costing tool for scale-up of rapid molecular tests, including Truenat	**Click Here**

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