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

Results: Ultra-portable X-ray and computer-aided detection (CAD)

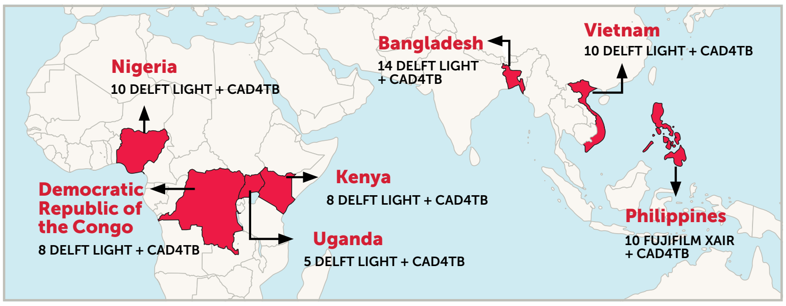

Photo source: IDDS

The *introducing New Tools Project* (iNTP) represented the largest multi-country roll-out of ultra-portable digital X-ray systems and computer-aided detection (CAD) software for tuberculosis (TB) screening programmes.

Ultra-portable digital X-ray systems are battery-operated, emit low radiation, and can be packed into backpacks or cases for transportation to field settings. CAD software leverages artificial intelligence (AI) to identify signs of TB in chest X-rays (CXR) and can be used alongside or as an alternative to human readers, as recommended by the World Health Organization (WHO) to screen or triage for TB.

Under the iNTP, **63 ultra-portable digital X-ray systems** (8 FDR Xair, Fujifilm; 55 Delft Light, Delft Imaging Systems) **with CAD** (CAD4TB, Delft Imaging) **were provided to 7 countries** to facilitate the detection of TB in high-risk populations and those that may face barriers to accessing services.

Total number of people reached for screening: 436,938
People diagnosed with TB: 13,967
People with lung abnormalities suggestive of TB detected by CAD and who received a confirmatory test: 42,097



X-ray/CAD in the iNTP: At a Glance

The roll-out of ultra-portable digital X-ray with CAD software enabled TB screening services to reach high-risk groups in underserved areas, with limited resources. The systems were utilized in both health facilities and in community settings. The United States Agency for International Development (USAID) in-country partners and national TB programmes (NTPs) implemented screening activities with this groundbreaking technology. Between Q4 2021 and Q3 2023, over 430,000 people were screened and almost 14,000 people with TB were detected. Most of the countries under the project have plans to scale up the use of digital X-ray with CAD using resources from the Global Fund and other partners.

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Key Results

1. *Screening Reach:* Overall, across countries, **over 430,000 people were screened** under the iNTP, demonstrating the potential of ultra-portable digital X-ray and CAD for TB screening in diverse settings. Screening numbers increased from just over 1,965 people in Q4 2021 to over 80,000 in Q2 and Q3 2023, as shown in figure 1, representing an increase of more than 4,166% in the number of people screened over the duration of the project.

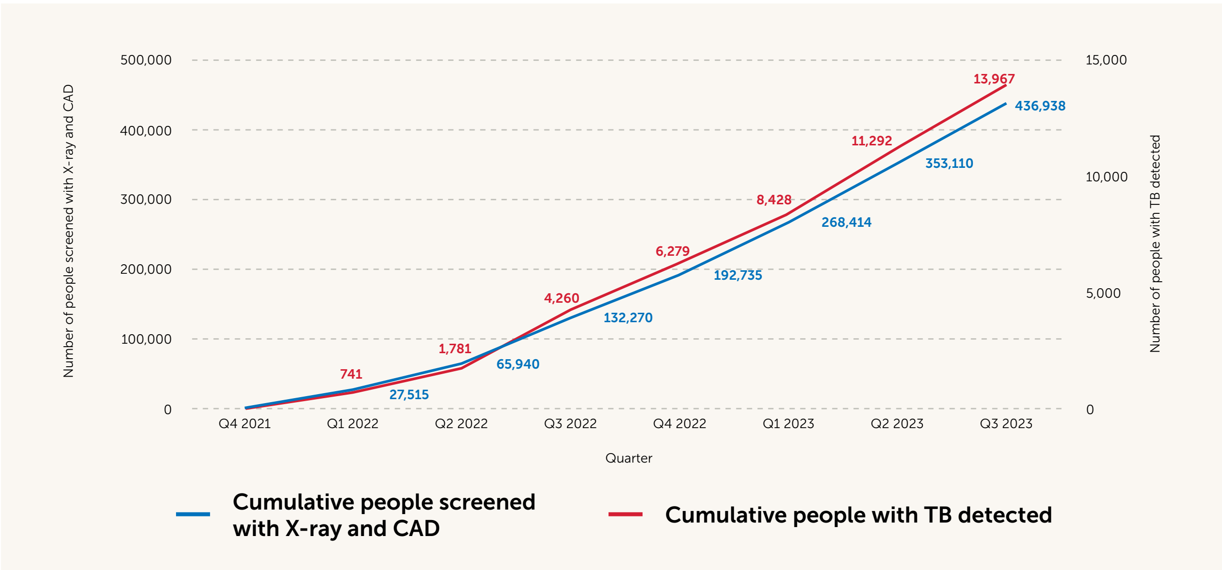
2. *People with TB Found:* Screening with these new tools identified **a total of 13,967 people with TB** across countries. The number of people detected with TB under the iNTP increased from 23 people in Q4 2021 to over 2,500 in Q3 2023, reflecting an over 100-fold increase.

3. *Evidence for Scale-Up:* The project's success provides **compelling evidence supporting the scale-up** of digital X-rays with CAD across multiple countries. Significantly, 6 of 7 countries involved in the project are planning to scale up their deployment of this technology by procuring additional equipment through the Global Fund.

4. *Data Integration:* Successful **integration of screening data into connectivity dashboards used for laboratory instruments including GeneXpert and Truenat** streamlined the cascade of care and improved data accessibility in Kenya and Uganda.

5. *Community Screening:* The project demonstrated both **the feasibility and effectiveness** of using ultra-portable X-ray with CAD in **community settings.** Several countries capitalized on the portability of these machines, utilizing them for community-based screening initiatives. Notably, community-based screenings emerged as a highly successful approach, reaching the largest number of individuals. In several such campaigns, CXR and CAD were coupled with battery-powered Truenat instruments to enable same-day screening and diagnosis.

Figure 1: *Cumulative number of people screened with X-ray and CAD, and people with TB detected by the project*



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Implementation Challenges

Planning for implementation

- **Unforeseen costs:** CXR and CAD implementation was capital intensive. Besides initial equipment costs, some incidental expenses included:
  - Customs clearance (such as fees, VAT, warehouse rents)
  - Procuring additional equipment (such as radiation safety equipment)
  - Replacing equipment not covered by warranties (particularly batteries)
  - Equipment transportation (vehicle fuel and upkeep)
  - Additional human resources (including recruiting additional radiographers, radiologists, linkage assistants, data analysts and IT support, if needed).
- **Human resource constraints:** Lack of trained personnel and motivation among staff hindered implementation in some countries. High healthcare worker turnover at some sites challenged continuity of screening campaigns

Procurement and regulation

- **Documentation and approval processes:** Complex documentation and approval processes during regulatory clearance by local authorities, particularly for the ultra-portable CXR, caused delays both when initially importing products and when securing replacement parts.
- **Regulatory compliance:** Compliance with local and international regulations, such as those for radiation safety and for local approval of new technology, was important but challenging, resulting in delayed implementation. In particular, some countries required validation of the radiation safety of ultra-portable CXR before approving its deployment.

Implementation

- **Slow uptake:** In some settings, slow uptake of tools after arrival in the country hindered implementation and affected overall program performance.
- **Infrastructural requirements:** Identifying suitable sites for CXR and CAD equipment when setting up screening activities was challenging in some settings due to limited available space, especially for ensuring operation in line with radiation safety requirements and for optimal placement of detector and panel stands.
- **Compliance with diagnostic algorithm:** Challenges were faced in ensuring the correct referral of individuals for confirmatory testing. There were high levels of referrals of individuals who were CAD-negative and without symptoms for diagnostic testing and of clinical diagnosis among CAD-positive individuals who were negative on confirmatory tests. In some sites, clinical diagnoses made up more than 68% of all diagnoses, suggesting possible overdiagnosis. Further, complications were faced when handling the screening of children (<15 years), for whom CAD is not currently recommended by WHO.
- **Practical challenges of clinical evaluation when printing CXR images for follow-up:** Countries without health information systems such as PACS needed to print CXR and CAD results for clinical evaluation but lacked access to printers during outreach campaigns.

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Equipment operation and technical challenges

- **Connectivity issues:** Connectivity issues between CXR and CAD system components were a common problem across sites, affecting the use of the equipment and requiring troubleshooting in the field.
- **Quality of X-ray images varied:** The quality of CXR images taken by operators using the ultra-portable equipment was not always optimal; adequate training to ensure correct equipment handling is essential.
- **Equipment portability:** CXR/CAD systems were reported to be too heavy for frequent transportation, especially the Delft Light, meaning some settings deployed them only for facility-based use. Although motorized transport was necessary to reach communities, ultra-portable systems still facilitated greater access than van-based systems.
- **Equipment malfunctions and maintenance:** Equipment malfunctions, particularly with X-ray generators and solar panels (such as the battery and connection cord), impeded implementation and stalled screening campaigns. Delays were further exacerbated by long turnaround times for shipment of replacement parts, while some key components, such as equipment batteries, were only covered by a limited warranty.

Considerations for scale-up

- **X-ray image storage:** Challenges were faced in managing the local storage of all CXR images and CAD outputs due to large CXR file sizes.
- **Project scale-up:** Long-term project planning may be affected by a lack of global and national guidance on how to scale-up the technologies at a local and global level, particularly with regards to integration with the national TB program and engagement of additional implementing partners in the scale-up of project activities.

Photo source: IDDS

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Learnings From Implementation

Planning for implementation

- **Multi-stakeholder collaboration:** Mapping and engaging the necessary stakeholders, including donors, civil society organizations and community leaders; local, regional, and national governments; manufacturers; and regulatory authorities from the outset is important to ensure rapid uptake and sustainability.
- **Stakeholder engagement:** Partners that can support community-based screening need to be engaged and sensitized from the outset to facilitate timely mobilization and resource availability, to ensure the rapid uptake and deployment of the tools.
- **Resource development:** From the earliest stages, developing standard operating procedures, methods of distribution, checklists for site selection and readiness (considering infrastructural requirements), capacity building plans, and a roadmap for scale-up is important to guide implementation.
- **National guidelines:** Aligning the CAD screening algorithm with existing national TB guidelines improves acceptability. Consider screening for additional diseases alongside TB for a more integrated approach.
- **Program monitoring:** Ongoing monitoring of program outcomes throughout the care cascade in line with agreed targets is important for identifying areas for improvement.
- **Mentorship and training for end-users:** In-person training, sensitization, mentorship, and refresher training are essential to optimize equipment utilization and ensure compliance with the screening algorithm by equipment operators and clinicians. Multiple users per site should be trained to ensure continuity especially when there is frequent staff turnover. Training government biomedical and IT staff to provide technical support can enable troubleshooting during field operations.
- **Workforce motivation:** Where workforce motivation may be an issue, consider incentives such as covering travel expenses when attending remote screening campaigns or offering training opportunities to help maintain motivation and retain staff.

Procurement and regulation

- **Customs and approval processes:** Plan for customs clearance, lengthy approval processes, and compliance with regulatory requirements from the outset to avoid delaying implementation. It is further important to sensitize and coordinate with the relevant regulatory authorities since regulation pertaining to the radiation safety of ultra-portable CXR is often outdated or in its infancy, given the innovative nature of the technology.

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Implementation

- **Supplementary equipment for recharging:** At sites where electricity supply is limited, recharging equipment at the health facility using a combination of electrical and solar energy and the provided power banks or solar panels in field operations is important. Voltage stabilizers may be necessary to protect CXR equipment against electrical fluctuations.
- **Radiation safety:** An assessment of the radiation safety of ultra-portable CXR conducted by Stop TB Partnership in collaboration with Médecins Sans Frontières (MSF) identified that all systems were able to be safely operated in line with international standards when following safety procedures such as wearing a lead apron and triggering exposures from a safe distance using a switch. [1]
- **Portable molecular diagnostics:** Combining CAD with portable molecular diagnostic tools such as Truenat (utilized in Nigeria and the Philippines) and TB-LAMP (deployed in Nigeria) reduces time to diagnosis and treatment as well as loss to follow up, especially in remote community-based screening campaigns. Given its higher throughput, TB-LAMP was found to be better suited to cope with the high number of individuals identified through CAD/CXR screening referred for confirmatory testing.
- **Internet connectivity:** At sites where internet access is not reliable, data SIM cards may be procured to send data at a relatively low monthly cost (approx. USD 7 at the Uganda project sites), or offline deployment of CAD should be considered.

Equipment operation and technical challenges

- **In-country manufacturer local agents and spare parts:** The availability of technical support and spare parts within the country is essential to ensure equipment faults can be repaired or replaced without long turnaround times. To ensure a common understanding of what will be provided by a manufacturer's local agent, it is critical to have a service level agreement that clearly outlines the service and maintenance coverage along with key performance indicators and targets.
- **Technical support:** Effective communication between local agents, manufacturers, and users needs to be established using channels that are suitable for end users in peripheral settings and available within the working hours of the screening program.

Considerations for scale-up

- **Cloud storage:** Procuring unlimited cloud storage should be considered due to the large imaging file sizes involved.
- **Data systems:** Strong, integrated data systems improve the accessibility of screening data for follow-up and diagnosis, quality assurance of CAD readings, and monitoring and evaluation of screening programs.
- **Preparing for project scale-up:** It is important to plan for sustainability and scale-up from the initial stages of the project, especially by ensuring engagement of all stakeholders including the national TB program, implementing partners, and donors.

[1] Paulis LE, Schnerr RS, Halton J, Qin ZZ, Chua A (2025). Assessment of scattered and leakage radiation from ultra-portable X-ray systems in chest imaging: An independent study. PLOS Glob Public Health 5(1): e0003986. https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0003986

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Resources Developed

The Stop TB Partnership has utilized the experience of the project and lessons learned to develop and refine a number of resources that can be used by any country interested in adopting or scaling up X-ray and CAD:

Practical guidance on the implementation of X-ray and CAD, developed in collaboration with USAID and Global Affairs Canada, and available in English, French, Spanish and Russian.	Click Here
Training package including modules and facilitator and participant guides developed in collaboration with USAID and the USAID Infectious Disease Detection and Surveillance (IDDS) project.	Click Here
Case studies for sharing experiences from the project and to raise awareness among countries outside of the project.	Click Here
Focus Group on AI-Based Imaging in TB (FG-AITB) is a webinar series which has enabled experiences to be shared by the iNTP and other countries and projects implementing these innovative digital tools.	Click Here

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