Roll Out of Systematic Screening for Tuberculosis Using Portable Digital Chest X-rays and Computer Aided Detection Software

Keziah Gichanga, Dr. Samson Muga, Dennis Oira, Dr. Brenda Mungai, Dr. Lorraine Mugambi-Nyaboga, and Diana Munjuri.
Centre for Health Solutions - Kenya

HEALTH SYSTEMS STRENGTHENING ACCELERATOR

Context

In Kenya, the burden of TB and HIV is a significant concern. Based on a 2016 TB prevalence survey, it was found that there is a gap between the number of prevalent cases and the number of cases actually notified, with a ratio of 2.5:1. Further , about 48% of prevalent cases are missed each year. This alarming figure points to a crucial issue that needs to be addressed. One of the barriers identified in the survey was the lack of awareness about TB among the population, leading to suboptimal health-seeking behavior. Surprisingly, 67% of survey participants who displayed at least one TB-related symptom did not seek care because they did not perceive their symptoms as severe enough. This highlights the urgent need to improve TB awareness and education so that individuals can recognize the importance of seeking medical attention when experiencing symptoms.

Another concerning finding was that some prevalent TB cases showed no classical symptoms but were detected through abnormal chest X-ray results. This indicates that relying solely on symptom-based screening may miss a significant proportion of TB cases, causing delays in detection and treatment initiation. Therefore, it is crucial to implement a systematic screening approach that includes chest X-ray screening to ensure comprehensive and accurate diagnosis. The diagnostic process for TB also revealed significant gaps and delays. Many survey participants who actively sought care for TB symptoms were not diagnosed during their initial visit to a health facility. This points to leaks in the TB diagnostic cascade and inadequate diagnostic capacity in health facilities. These issues need to be addressed promptly to ensure timely and accurate diagnoses, which are crucial for early treatment initiation. To tackle these challenges, Kenya implemented the Introducing New Tools Project in collaboration with the Stop TB Partnership and the United States Agency for International Development (USAID). As part of this project, eight portable digital computer-aided detection (CAD) software-enabled chest X-ray machines were introduced in July 2022. These machines have been instrumental in systematic TB screening among adults and adolescents aged 15 and above, both in healthcare facilities and in the community. The screening strategy focuses on high-risk groups, including urban slum residents, immigrants and refugees, fishermen, people living with HIV (PLHIV), and individuals who have had close contact with TB patients. Facility-level screening targets patients seeking care, both inpatients and outpatients, while community screening occurs during outreaches and in refugee settings. The placement of these machines in health facilities was guided by the population at risk that the facilities serve. Additionally, the availability of molecular WHO-recommended rapid diagnostic tests, such as GeneXpert or Truenat, ensures comprehensive and accurate diagnosis. This initiative aims to improve TB detection rates, reduce the prevalence to notification gap, and ensure that individuals receive timely and appropriate treatment. By combining advanced technology with targeted screening strategies, Kenya is taking significant steps towards overcoming the challenges associated with TB in the country and ultimately improving public health outcomes.

USAID envisions strengthening the health system by promoting locally designed approaches that consider the unique conditions of each region, especially when reaching vulnerable populations. In line with this vision, the use of chest X-ray (CXR) has emerged as a sensitive tool for detecting pulmonary tuberculosis (TB) by identifying radiological findings that suggest the presence of TB. To enhance its effectiveness, computer-aided detection (CAD) software, recently recommended by the World Health Organization (WHO), has been incorporated, overcoming access and accuracy barriers in systematic TB screening using CXR. The introduction of CAD software has brought promising results, particularly in resource-limited settings where radiologists may be scarce. By relying on this software, which acts as an alternative to human interpretation for X-ray analysis, healthcare providers can detect TB cases with greater precision and efficiency. This technological advancement is a significant step forward in making CXR-based screening more accessible and reliable, even in areas where trained radiologists may be limited. Moreover, the use of CXR as a TB screening tool holds the potential to identify asymptomatic cases that might otherwise go unnoticed. Early detection of TB in individuals who do not display symptoms is crucial for preventing further disease transmission within the community. By employing CXR and CAD software, healthcare providers can proactively identify these cases, initiate timely treatment, and curtail the spread of TB.

The screening tool recommended by the WHO, which combines chest X-ray and CAD software, offers high sensitivity and accuracy in detecting various diseases, including TB and lung cancer. Its implementation enables healthcare providers to identify potential health issues at an early stage, leading to better treatment outcomes and the potential to save lives. Additionally, the use of CAD software can result in significant cost savings by reducing the consumption of diagnostic consumables. With fewer tests required when utilizing this screening tool, there is less waste and reduced expenses for both patients and healthcare systems.

Activity Description

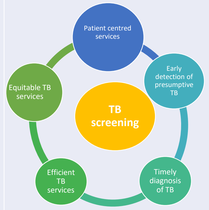
In Kenya, significant efforts have been made to address the issue of missing individuals with tuberculosis (TB) through the implementation of eight portable digital X-ray machines equipped with Computer Aided Detection for TB software version 7 (CAD4TBv7). This initiative is part of the Introducing New Tools Project, a collaborative effort between the Center for Health Solutions-Kenya (funded by USAID) and the Kenya National Tuberculosis, Leprosy, and Lung Disease Program (NTLD-Program).

The primary goal of this project is to conduct systematic TB screening among adults and adolescents aged 15 years and older in healthcare facilities and outreach settings, in accordance with the 2021 World Health Organization (WHO) guidance on systematic TB screening. To ensure effective implementation, a Chest X-ray (CXR) Subcommittee was formed under the leadership of the National TB program. This subcommittee consisted of professionals from diverse backgrounds, emphasizing inclusivity in decision-making processes. Prior to the implementation, the subcommittee addressed several key issues, such as identifying at-risk populations and determining suitable site locations. They also reviewed screening and triaging algorithms, conducted baseline site assessments, and ensured radiation safety by recommending the engagement of experts to assess the machines and procure necessary radiation protection accessories. The portable digital X-ray machines arrived in Kenya in May 2022, and healthcare workers assigned to implement the TB screening underwent comprehensive training on relevant procedures in June 2022. The county TB control teams, responsible for supervising the implementation, also participated in the training.

On July 15, 2022, six out of the eight selected facilities began the implementation of the TB screening program. The rollout of CAD4TBv7 enabled portable digital X-rays was carried out by the USAID TB ARC II project, considering all aspects of the WHO health system building blocks, including leadership and governance, service delivery, health system financing, the health workforce, and medical products and technologies. To ensure the successful execution of the project, human resources were prioritized. Seven radiographers were hired, and eight linkage assistants were engaged to minimize gaps along the TB care cascade. Facility-wide sensitization sessions were conducted across all eight sites, in collaboration with county and facility teams, to raise awareness, generate demand, and obtain buy-in from healthcare workers and county health teams. Technical assistance was provided by the National TB program, which offered onsite and remote mentorship and supervision.

In an effort to enhance county capacity, each of the eight radiographers provided on-the-job mentorship and training for two radiographers from the implementing county to ensure uninterrupted service provision. This comprehensive approach, supported by a collaborative effort and a focus on capacity building, aims to address the challenges surrounding TB detection and improve the overall health outcomes for individuals at risk of TB. Through these concerted efforts, Kenya is taking significant strides towards reducing the burden of TB by ensuring early detection and appropriate treatment, ultimately improving the well-being of its population.

Figure 1:Theory of change

Inputs	Interventions	Outputs	Outcomes	Impact
Ultra-portable CXR-CAD software Molecular diagnostics Technical support Partnerships		Proportion of people screened for TB using ultra-portable digital CXR Proportion of patients with suggestive of TB receiving molecular diagnostic testing Proportion diagnosed with TB- Bacteriologically confirmed and clinically diagnosed Proportion of people initiated and treated successfully for TB Proportion of TB recurrence or death	Increased case detection rate Reduction of TB mortality	Avert TB deaths Reduction of TB incidence

Activity Impact

Use of the CAD-enabled digital portable chest x-rays improved service delivery at the health facilities by adding onto the routine service delivery a high sensitivity screening tool coupled with the ability to perform image interpretation via the AI software. In deciding to place the CXR machines, targeting specific at-risk populations and ensuring the availability of an mWRD at the facility level further removed barriers to access to diagnosis and care by boosting the efficiency of the TB care cascade whilst also improving the diagnostic yield.

This approach also addressed the issue of late diagnosis occasioned by sub-optimal screening strategies that were shown in the survey to be less sensitive in identification of presumptive TB cases. Additionally, each of the 8 devices had a dedicated radiographer and linkage assistant assigned to ensure consistency and continuity of service provision throughout implementation. In 7 out of the 8 sites, there were no resident radiographers prior to the roll out of the project and therefore implementation not only increased their diagnostic capacity but also added onto their skilled human resources.

Overall, the intervention was a success in addressing several key healthcare issues, such as reaching vulnerable populations, reducing missed cases, addressing inequality, and improving service delivery through the use of artificial intelligence and a sensitive screening tool. By using outreach and patient-centered care, vulnerable populations were reached, and missed cases were reduced. The intervention also addressed inequality by lowering screening costs and using technology to improve service delivery. The involvement of the counties ensured ownership and sustainability of the technology, making it a successful and impactful intervention. In conclusion, the intervention was a comprehensive and effective approach to addressing key healthcare issues.

Evidence

Preliminary data analysis asserts the value of the both technologies, Chest X-ray and Computer-Aided Detection software, in systematic screening for TB as evidenced by the about 30% positive yield on bacteriological testing. Additionally, across the 8 sites, there was a 38% increase in TB cases identified since implementation began compared to a similar period the previous year.

Figure 2: Data on the TB care cascade for those with CAD scores of 60 and above

Indicator	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Total
No. Screened with CXR	2642	2302	1626	2948	2366	3145	3275	2541	**20845**
No. With CAD Score >60	164	162	239	351	312	226	174	182	**1810**
Proportion with CAD Score >60	6.2%	7.0%	14.7%	11.9%	13.2%	7.2%	5.3%	7.2%	**8.7%**
No. Investigated	127	161	191	170	162	215	128	151	**1305**
Proportion investigated with bacteriological testing	77.4%	99.4%	79.9%	48.4%	51.9%	95.1%	73.6%	83.0%	**72.1%**
No. Bact Confirmed	46	56	48	30	48	53	34	68	**383**
Proportion bacteriologically confirmed out of those investigated	36.2%	34.8%	25.1%	17.6%	29.6%	24.7%	26.6%	45.0%	**29.3%**
No. Clinically diagnosed	43	49	65	54	131	65	56	38	**501**
Total TB cases	89	105	113	84	179	118	90	106	**884**
Proportion of TB notified cases that are bacteriologically confirmed	52%	53%	42%	36%	27%	45%	38%	64%	**43%**

Figure 3: Increase in site case finding

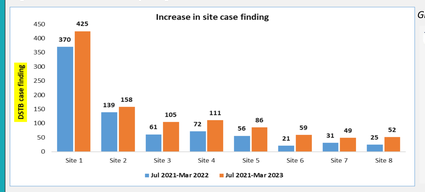


Figure 4: CAD4TB implementation process

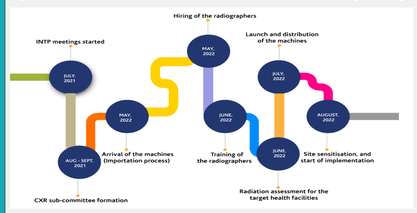


Figure 5: Kenya's Ministry of Health acknowledgement of CAD4TB and other new TB diagnostic tools rolled out in the Country to strengthen TB care

Global AIDS ambassador to a CAD4TB site

Figure 7: Targeted TB outreach using CAD4TB

Facilitators

The CXR subcommittee, led by USAID TB ARC II and NTLD, developed a policy for screening and triaging facilities in Kenya. Eight sites were chosen based on at-risk populations, including urban slums, high HIV/TB burden areas, fisher folk communities, and refugee populations. The facility selection required that the site selected have a molecular WHO-recommended diagnostic test for follow-on diagnostic testing. A threshold score of 60 was established, ensuring effective tuberculosis management and control.

Stakeholders, including experts, the National TB program, Christian Health Association of Kenya, Kenya Nuclear Regulatory Authority, county governments, consultant radiologists, and communities, collaborated to plan the implementation of the project. The CXR subcommittee, chaired by USAID TB ARC II and NTLD, led the planning, development, and policy development for screening and triaging algorithms, site selection, and baseline assessment of facilities.

The eight sites were chosen based on at-risk populations, including urban slums, high HIV/TB burden areas, fisher folk communities, and refugee populations. Facilities were required to have a molecular WHO-approved diagnostic test for bacteriological diagnosis after CXR screening. The committee of experts provided insights, the National TB program offered expertise, the Christian Health Association of Kenya provided radiation assessment services, and the Kenya Nuclear Regulatory Authority provided radiation safety and quality control measures. County governments played crucial roles in creating awareness and overseeing implementation both at facility and community level.

Challenges

- As with any complex implementation process, challenges arose along the way. During the course of implementation, there were unfortunate instances of commodity stock-outs in most of the implementing sites. This unfortunate situation led to a temporary shortage of the mWRD test, resulting in the use of microscopy as an alternative diagnostic tool. Microscopy, although widely available, is known for its lower sensitivity compared to the mWRD test. This unforeseen circumstance posed a challenge to achieving the desired level of diagnostic accuracy in the screening program.
- Another factor that emerged during implementation was the regulatory requirements regarding the tube current for general-purpose radiography machines. According to the Kenya regulatory authority, a minimum tube current of 50mA is mandated for such machines. However, the tube current for the CXR machines utilized in this program was 20mA, making them suitable only for special purposes, and specifically chest imaging. Therefore, despite the introduction of X-ray machines in the facilities, many of which did not have such equipment previously, the functionality of the machines was limited due to these regulatory constraints.
- Furthermore, during the radiation safety assessments conducted for the procured machines, it was discovered that there was significant scatter radiation. This finding highlighted the need for protective accessories to ensure the safety of both patients and healthcare workers. However, the initial implementation costs did not factor in the procurement of these additional accessories, leading to an increase in the capital investment required to ensure roll out the use of the digital, portable CXR machine whilst observing proper radiation safety measures.

Lessons Learned

- Implementation of the novel dual technology revealed the need for collaborative planning involving all stakeholders e.g. national and county programs, nuclear authority, radiologists, radiographers, partners.
- Ensuring the digital CXRs procured are in conformity with the in-country radiation safety standards is important before procurement.
- CAD CXR is capital intensive in terms of the costs related to engaging and retaining the human resources required for day-to-day implementation as well costs related to procurement of protective equipment such as mobile lead shields and lead gowns.
- In addition to screening for TB using CXR being an acceptable intervention, roll out of the CAD-CXR screening paired with a molecular diagnostic tool so far proves to be a high yield intervention based on preliminary results. The positive yield on bacteriological testing for those with high threshold scores is high (up to 30% positivity)
- The success of the pilot program in 8 sites across the country has highlighted the potential for even greater impact if scaled up. By reaching more vulnerable populations, access to healthcare services can be increased, leading to improved accuracy in diagnosis and treatment. The use of both CXR and lab diagnostics has proven to be effective in identifying and addressing health issues, providing patients with a more comprehensive approach to care. With continued investment and expansion, this program has the potential to revolutionize healthcare delivery and improve outcomes for patients nationwide.

USAID FROM THE AMERICAN PEOPLE
RESULTS FOR DEVELOPMENT
HEALTH STRATEGY AND DELIVERY FOUNDATION
ICF
BILL & MELINDA GATES foundation