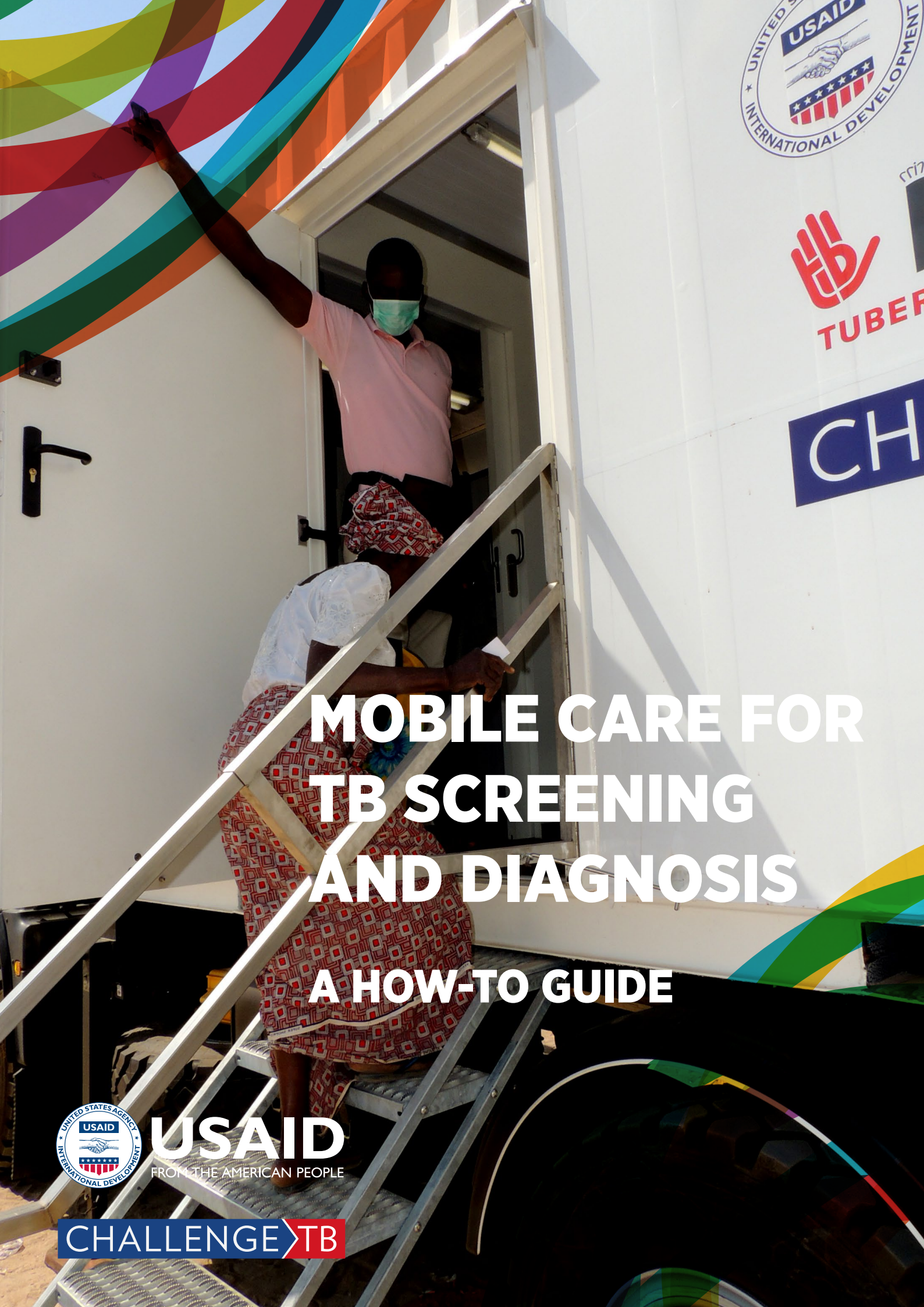


MOBILE CARE FOR TB SCREENING AND DIAGNOSIS

A HOW-TO GUIDE

USAID
FROM THE AMERICAN PEOPLE

CHALLENGE TB

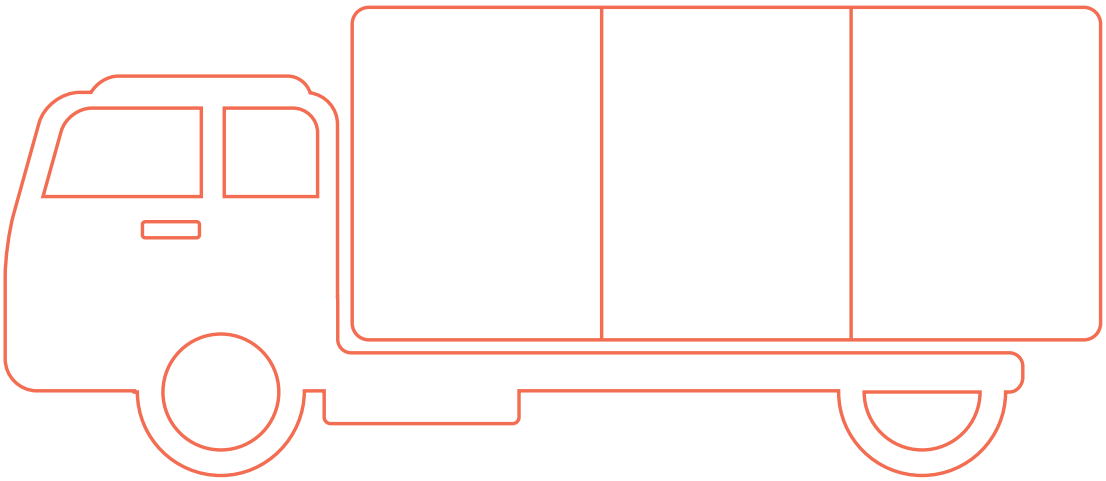
INTRODUCTION

Approximately 3.6 million people with active tuberculosis (TB) worldwide were 'missed' by health systems in 2017. Many people with TB face problems accessing quality-assured health services due to limited coverage, poverty, as well as a lack of general knowledge about the disease. In addition, National TB Programs (NTPs) often focus on passive case-finding as a result of constraints in human and financial resources.

One of the primary goals of the USAID-funded Challenge TB project is to increase TB case-finding and notifications by finding more of the missing patients. The World Health Organization (WHO) recommends systematic screening for high-risk and vulnerable populations, in particular, people living with HIV (PLHIV), close contacts of TB patients, prisoners, and miners. Other groups considered at high-risk are the elderly, people with diabetes mellitus, and healthcare workers.

Challenge TB provides technical assistance to NTPs to screen and diagnose TB among high-risk populations in the community by deploying mobile screening trucks. They not only help to find the missing patients but also reduce transmission in the community through early diagnosis and treatment, and create awareness about the disease along the way. Every truck is equipped with a digital X-ray, computer-aided detection for TB (CAD4TB), and a GeneXpert machine.

This document serves as a guide to which steps and what preparations need to be undertaken to successfully organize both a truck and the team needed to staff it.



PLANNING

Procurement

The truck can be assembled or purchased ready-made. It should have a standard 20 ft shipping container divided into three compartments:

1. A lead-shielded X-ray compartment
2. Workstation
3. Laboratory

The following equipment needs to be procured:

1. Digital X-ray machine with CAD4TB (Computer-aided detection for TB)
2. Computer Workstations
3. GeneXpert MTB/RIF testing equipment
4. Biosafety cabinet
5. Air conditioners
6. Generator
7. Solar Panels
8. Regulator/Batteries/Inverter
9. Printers
10. Fridges
11. Router/Mobile Internet connection.

The following supplies and consumables also need to be procured:

1. Radiation protective equipment (e.g. lead aprons)
2. Strips for barcodes
3. Gloves/Masks/Protective Glasses
4. HIV testing kits
5. Sputum containers
6. GeneXpert Cartridges
7. Printer supplies (toner, paper)
8. Licenses (CAD4TB, internet)
9. Spare tires
10. Petrol for the generator
11. Diesel for the truck.

The truck has three sources of power:

1. **Generator:** This is the main source of power, it runs all the equipment including the air conditioners and the GeneXpert machine.
2. **Solar power:** The batteries are charged by the solar panels on the container roof and through an inverter can power all the equipment except the air conditioners. (The alternator also charges the batteries when the truck is in motion).
3. **National power grid:** The truck can also be connected to grid/mains electricity if available.

The cost of equipment (including maintenance and running costs) should be adequately budgeted for. A lead time of about 9-12 months should be allowed for the procurement of all equipment.

Situational Assessment

Before implementation, the local health system surrounding the targeted population has to be prepared to cope with the anticipated increase in workload and provide quality-assured management and support of TB patients.

A socio-cultural analysis including the health-seeking behavior and religious and cultural practices of a particular group will help to design implementation approaches that are both feasible and acceptable to the community.

Identifying Risk-Groups

Risk-groups for TB have a TB prevalence significantly higher than the general population. For each risk-group, it is important to consider the population size, age and sex distribution, presumed prevalence of TB, and previous experiences of systematic screening.

Results should always be well documented and include the yield - the number needed to be screened (NNS) and the number needed to be tested (NNT) in order to diagnose one TB patient, and the investment costs.

The following practical issues need to be considered:

Review the existing evidence of under-diagnosis or -notification, and estimate the expected TB prevalence and NNS

For each risk-group, it is important to identify and estimate the population size that can and should be reached

Screening must be acceptable for the target population (free-of-charge and at a convenient time of the day)

Based on experience, a maximum of 200 people can be screened each day.

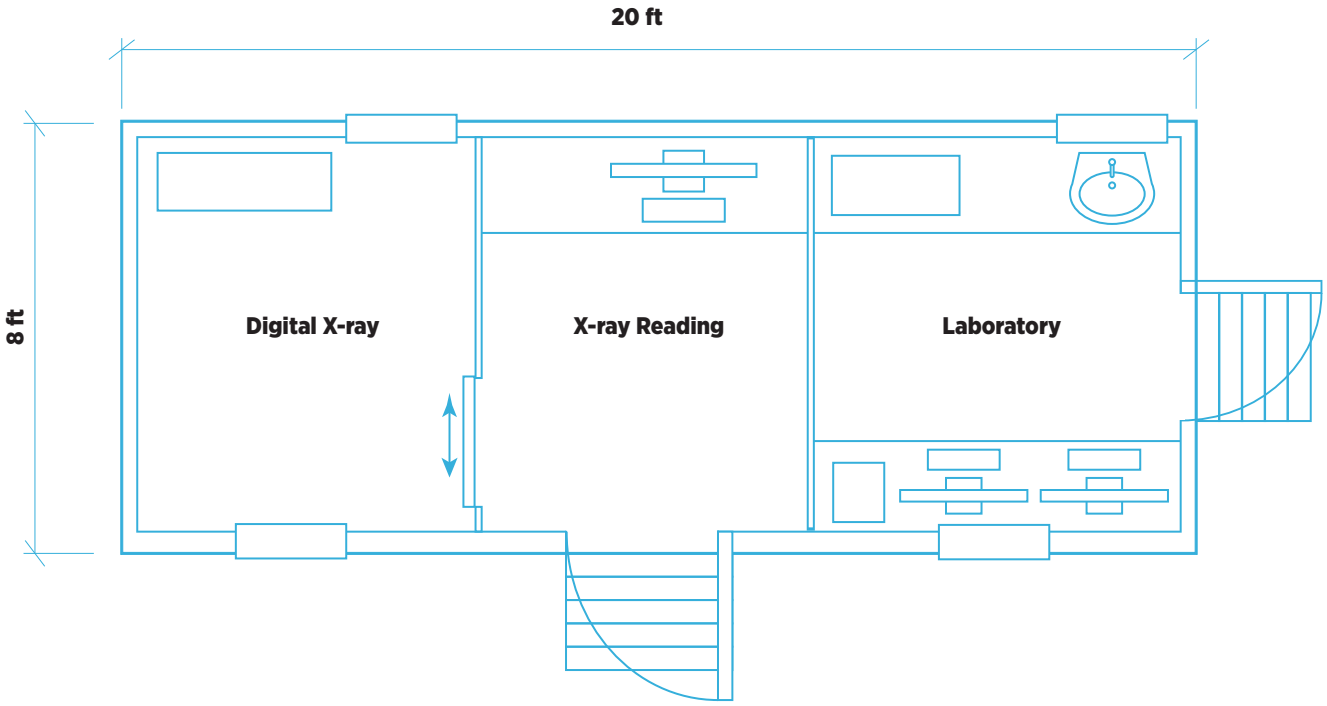
Technical Preparation

An implementation manual, that defines the approaches and the resources needed for the successful implementation of the intervention, must be developed.

The implementation manual should contain the screening algorithm, standard operating procedures, and the job descriptions for the key personnel involved. It provides guidance on the role of advocacy, preparations for site visits, community mobilization, registration and recording, and actual screening (symptom questionnaire, sputum collection, digital X-ray, radiation safety), interpretation of X-ray (CAD4TB setting), GeneXpert testing and interpretation, and linkage to treatment.

Appropriate screening and diagnostic testing algorithms are necessary to ensure the intervention is successful. The principle behind this is to ensure a combination of screening and diagnostic tests that will enhance the chances of correctly diagnosing TB patients (true positive – with high sensitivity), while also ensuring that those without TB are correctly excluded (true negative – high specificity).

Floorplan



Maintenance

If the truck is purchased as a complete package, the following components are included in the general maintenance system: truck, container, generator, solar system, inverter, air conditioners, X-ray machine, biosafety cabinet, GeneXpert machine, fridges, computer, printer, internet router, and first aid box.

The components not covered by the warranty have to be scheduled for maintenance separately. Maintenance can be done by local contractors.

Regular checks:

- **Engine:** Routine check every 5,000 km. Oil change every 20,000 km
- **Generator:** Every 250 hours or 30 working days (whichever comes first)
- **X-ray machine:** Every 6 months
- **Xpert machines:** Annual calibration and change of faulty modules as they occur
- **Air conditioners, computers, printers, and fridge:** As required.

The truck also needs to be cleaned on a regular basis.

Warranty

The standard components of the truck are under warranty from the supplier: the truck itself, container, generator, air conditioners, X-ray machine, and biosafety cabinet. The warranty generally covers a period of two years, and general maintenance is scheduled to occur twice a year.

Any components purchased separately (e.g. GeneXpert machines) are not covered by the warranty.

Small repairs on the generator and air conditioners must be done locally as the technical staff responsible for solving problems under the warranty, are usually based outside the country.

Staffing

Staff can be hired permanently or recruited on an ad hoc basis based on the level of effort and the available resources.

The truck requires the following staff:

Active Case-Finding (ACF) Coordinator: coordinates the intervention from community mobilization up until the actual screening exercise. This includes establishing effective relationships with all parties involved, logistics management, monitoring the quality of the services provided, coordination of linking patients to treatment, data audits, submission of reports, and the monitoring and evaluation of results;

Radiographer: ensures all X-ray equipment is in good condition and in compliance with local laws and regulations. They prepare the X-ray workplace on a daily basis, take quality X-rays, keep records of X-rays (including repeat X-rays), check image quality and eligibility for reading, and keep records of dosimetry readings;

X-ray Technician: assists the radiographer in setting up the unit, enters patient information into the computer, prepares the patient for the radiological procedure, documents the completed radiological procedures, and updates the X-ray tally sheet and screening summary form;

Driver: responsible for the fueling, driving, and maintenance of the truck. They serve as a logistics officer, issue tally cards, notify security agents in case of imminent breach of security, and provide general support to the support staff as directed by the coordinator;

Laboratory Staff: performs GeneXpert tests, provides results, and ensures that waste is properly disposed of. They are also responsible for ensuring adherence to correct laboratory practice, recording results, and the maintenance of equipment. All results are registered and handed over to the District TB Supervisor who advises diagnosed TB patients appropriately;

District TB Supervisor: is a clinician and NTP staff member who serves as a link between the TB program and the screening team. They are part of the advocacy and mobilization team, and support the entire screening process, link and refer patients to a treatment facility, and trace diagnosed TB patients who do not show up for their results;

Community Mobilizer: prepares visits to the selected sites two weeks, communicates with district health departments and the state TB control program on issues regarding the field work, mobilizes the community, and carries out health education activities;

Data Clerk: records all presenting clients, issues barcodes, conducts symptomatic screening for all clients, assists in summarizing daily records of activities, records information of clients on presumptive TB registers, provides patient education to clients before GeneXpert testing, enrolls clients for follow-up diagnosis, provides test results to clients, and provides post-test education to clients;

Security Staff: ensures the safety and security of both the team and the equipment.

Community Awareness

Preparatory Site Visits and Stakeholder Engagement

Prior to actual TB screening, a preparatory visit is conducted to selected sites by the ACF coordinator, community mobilizer and the district supervisor. The aim of the visit is to identify relevant stakeholders, sensitize and seek the cooperation of local authorities, assess the feasibility of conducting an effective screening, and ensure that all the necessary logistics for a successful TB screening are put in place. A consensus meeting is necessary to obtain the buy-in of all stakeholders by explaining the rationale for the screening exercise and how the community stands to benefit. Emphasis should be placed on voluntary participation. Specific meetings should be organized with the health workers in the area in order to ensure that TB patients are linked to care after screening and diagnosis. Following stakeholders' engagement activities all parties should be aware of their expected roles and responsibilities and the dates of the screening.

Community Mobilization

A few days before the screening and during the screening days, the community should be mobilized to participate using locally appropriate means such as:

- Town Criers/Announcers
- Handouts/Flyers/Leaflets
- Posters/Banners
- Community Drama
- Mass Text-Messages/SMS
- Social Media (e.g. Facebook)
- Radio/TV
- Word of Mouth

Screening/Diagnosis

The diagram below shows the screening and diagnostic pathway. Patients are enrolled into screening with an issued bar-coded card. The barcode number is a unique identifier for each client used throughout the screening process.

Clients are screened using a symptom questionnaire and a digital chest X-ray. For symptom screening, a client is considered to have a positive screening test, if they have a cough for two or more weeks (or a current cough in the case of PLHIV).

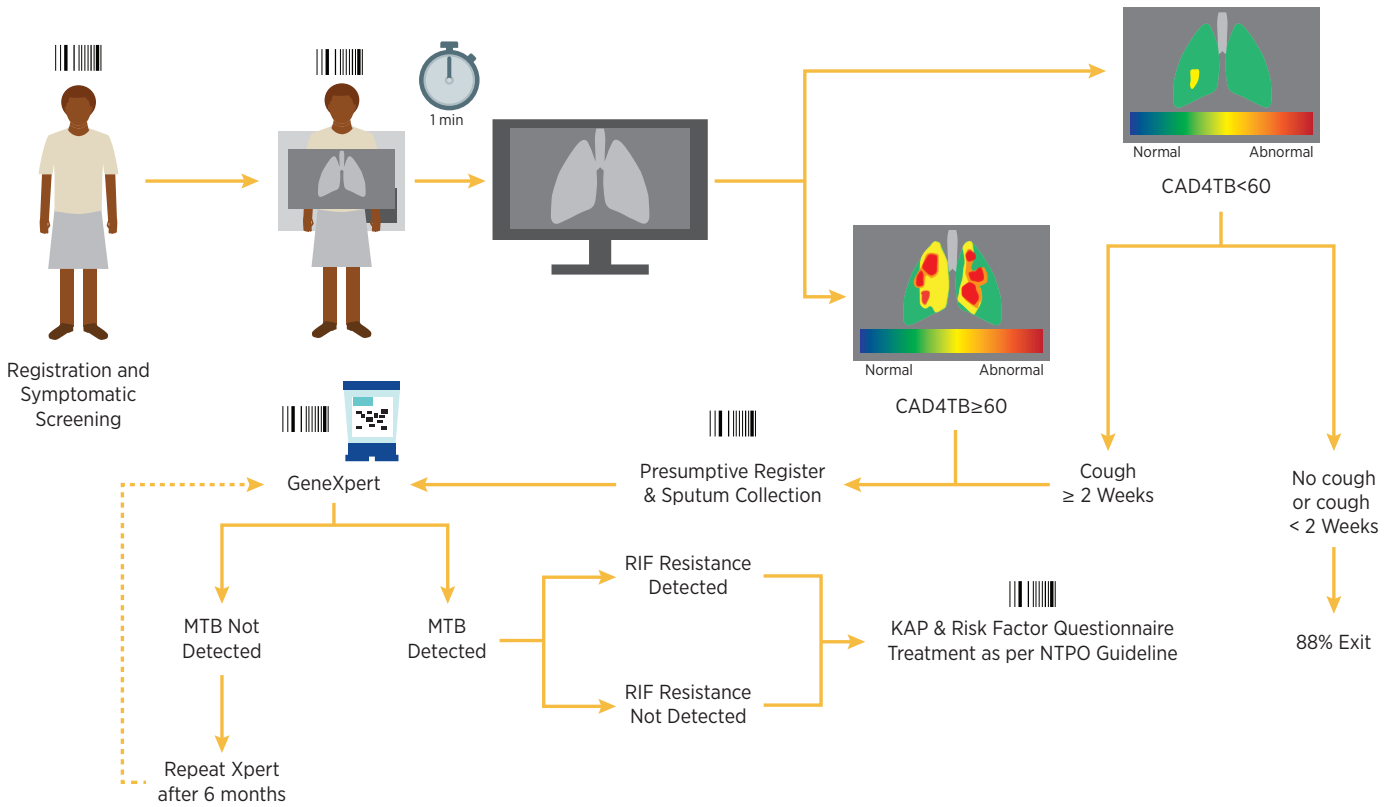
Chest X-ray screening entails interpreting chest radiographs using CAD4TB. The software assigns a score based on the likelihood that the client may have pulmonary TB (PTB). The threshold for the likelihood of PTB is selected beforehand. In most instances, persons with a CAD4TB score higher than 60 are considered to have a positive chest X-ray.

Those who test positive on either or both of the screening tests are classified as presumptive TB patients and evaluated further by doing a GeneXpert test on the spot. All clients are also offered an HIV test unless they have a recent documented negative test result or are on anti-retroviral treatment.

A health-seeking behavior and risk factor questionnaire are administered to TB patients with a bacteriologically positive GeneXpert test. If the patient has a CAD4TB score above 60 and is not confirmed by GeneXpert testing, they are referred to a medical officer for further diagnosis.

Note: All infectious and non-infectious waste must be separated into different bins with different labels, so that it can be disposed of properly.

Screening and Diagnostic Pathway



Treatment

All diagnosed TB patients must be registered and initiated on appropriate treatment. The district TB supervisor is part of the team at the screening points and they link the patients to the nearest health facility where they are managed under routine program conditions.

All other patients who need medical evaluation are referred to the nearest health facility using a specific referral form filled in by the truck coordinator. This includes patients with general TB symptoms, and/or a positive X-ray, but a negative GeneXpert test.

Monitoring and Evaluation

A reporting framework that obtains information on the cascade of screening and diagnosis is used to obtain data for each individual and is disaggregated by age and sex.

The key indicators include:

1. The number of persons enrolled for screening by age and sex
2. The number of enrollees screened by age and sex
3. The number of clients presumed to have TB (symptom screen and X-ray) by age and sex
4. The number of presumptive clients tested with GeneXpert by age and sex
5. The number of rifampicin-sensitive (RS) - TB patients by age and sex
6. The number of rifampicin-resistant (RR) - TB patients by age and sex
7. The number of RS-TB patients on treatment by age and sex
8. The number of RR-TB patients on treatment by age and sex.

Data entry is done both on paper and electronically (Excel/EPI INFO). Different forms and registers are used for data collection: a community mobilization logbook, high-risk population register, patient enrollment form, X-ray logbook, laboratory register, and patient referral forms. A column can be added to both the general laboratory and treatment register for noting whether the patient on treatment has been diagnosed through screening.

Based on the information from the key indicators, additional investigations should be done if the data shows a low number of persons enrolled in screening, a low proportion of presumptive TB patients, and a higher than expected NNS.

COUNTRY EXAMPLE - MALAWI

Using a Global Fund grant, the National TB Program procured seven trucks equipped with GeneXpert and X-ray machines, which are being used to conduct systematic screening and diagnosis in the community.

Challenge TB provides technical assistance on the mapping of sites, the actual screening, X-ray calibration, community mobilization, TB infection control and prevention, recording and reporting, and the linkage of patients to treatment and care.

The NTP expects that by screening high-risk communities, 8.6% of people screened will be identified as presumptive cases whilst the yield of TB disease is estimated at 1%. Challenge TB continues to provide the necessary expertise to ensure that the expected results are realized.

Between April and June 2018, 8,072 people were screened, 3,495 people with presumptive TB were identified and 75 were ultimately diagnosed with TB (73 with DS-TB and 2 with DR-TB), representing 0.93% of persons screened. The NNS was 108.

COUNTRY EXAMPLE - NIGERIA

In Nigeria, the trucks are called “WoW” trucks, an abbreviation of Wellness on Wheels. The trucks were procured and are funded by USAID’s Challenge TB project and commissioned at the end of 2017. The communities targeted for screening were selected based on high TB notification rates in areas with poor universal access to diagnostic services. Target populations and areas include prisons (without routine entry/exit screening services), HIV treatment centers in secondary and tertiary institutions, and hard-to-reach areas with limited access to health care and GeneXpert testing.

Challenge TB supports the cost of deploying and staffing the two trucks. The driver, ACF coordinator and radiographer are on permanent contracts, and the other five are on renewable contracts. Targeted outreach activities are organized with support from community-based organizations.

The implementation of the WoW campaign for TB active case-finding commenced within urban/rural communities with limited access to health care and GeneXpert testing in Kano and Lagos State, covering six local government areas across the two states.

Between November 2017 and August 2018, 42,455 people were screened, 5,178 people with presumptive TB were identified and 4,253 were tested with GeneXpert, resulting in 507 patients diagnosed with TB (485 with DS-TB and 22 with DR-TB), representing 1.2% of persons screened. The 1.2% represents a TB prevalence of 1,200 per 100,000 population.

The rate is two times the prevalence in the general population as reported in the 2012 National TB Prevalence Survey, indicating significant yields from this intervention, with an acceptable NNS and NNT of 84 and 8 respectively.

COUNTRY EXAMPLE - ZIMBABWE

In 2017, Zimbabwe started ACF among high-risk communities using mobile teams using equipment in trucks. The screening is done by applying a symptom questionnaire, digital X-ray and GeneXpert MTB/RIF testing. Districts were selected based on risk mapping exercises focusing on low notification rates and poor treatment outcomes.

The interventions are supported by the International Union against TB and Lung Disease (The Union) and implemented through a local partner the Family AIDS Caring Trust (FACT). Funding support is provided by the Global Fund and Challenge TB. FACT works with the facility, district, and provincial teams to conduct screening and link diagnosed patients to treatment in selected priority districts.

In Zimbabwe screening for diabetes mellitus has been added to TB screening, given that the disease is frequently diagnosed in patients with TB. Every person who is screened is also checked for the signs and symptoms of diabetes, and if these are present, then a laboratory test is done on the spot. If the result shows an elevated Random Blood Sugar (RBS) > 11.1 mmol/L the person is linked to care.

Between February 2017 and June 2018, 54,311 people were screened, 17,414 people with presumptive TB were identified, and 985 patients were ultimately diagnosed with TB (975 with DS-TB and 10 with DR-TB), representing 1.81% of those screened.

IMPORTANT FACTORS

- A maximum of 200 people can be screened each day
- The staff can be away from home for long periods of time
- For security reasons, the working hours of the truck are between 9 am and 6 pm
- The CAD4TB threshold can be subject to change for efficiency reasons. This is decided by the screening team, led by the ACF Coordinator.

RESOURCES

USAID-Funded "Wellness on Wheels" Trucks Provides Mobile 'One Stop Shop' for Tuberculosis Diagnosis and Treatment
https://medium.com/@USinNigeria/usaid-funded-wellness-on-wheels-trucks-provides-mobile-one-stop-shop-for-tuberculosis-diagnosis-9a1057621d50

Delft Imaging OneStopTB Clinic
https://www.delft.care/onestoptb/

Handbook for District Hospitals in Resource Constrained Settings on Quality Assurance of Chest Radiography
http://www.challengetb.org/publications/tools/ua/XRayQAHandbook.pdf

Handbook for District Hospitals in Resource Constrained Settings on Quality Improvement of Chest Radiography
http://www.challengetb.org/publications/tools/ua/XRayQIHandbook.pdf

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