TECHNOLOGY REVIEW (MINI-HTA)

ULTRA-PORTABLE DIGITAL X-RAY SYSTEM FOR TB SCREENING

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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EXECUTIVE SUMMARY

Background

Tuberculosis (TB) remains a public health challenge worldwide. TB has caused an estimated 1.3 million deaths in 2022. The current state of the TB situation in Malaysia is complicated by a number of factors, including the prevalence of HIV infections, cases of antibiotic resistance, immigration from high-TB-burden countries, the presence of non-communicable diseases, and patterns of international travel.

It is noted that many people with TB who tested positive for culture showed no symptoms at all. Hence, it is important to screen high-risk asymptomatic groups. A chest X-ray and a molecular fast diagnostic test using a World Health Organization (WHO)-recommended diagnostic test are two of the suggested TB screening modalities as suggested by the WHO TB screening guidelines. However, CXR can be costly and logistically challenging, particularly if screening is done outside the health facilities. Technologies such as portable X-ray systems can improve access to tuberculosis screening outside of health centres. These systems are intended for usage primarily when planned diagnostic and/or screening procedures are far from medical or healthcare facilities. The latest technology; ultraportable X-ray or known as handheld X-ray is smaller and lighter than portable X-ray; which can be carried out by a single person and be set up in minutes.

Recently, this device has obtained approval from the Medical Radiation Regulatory Division. Hence, this review was requested by the TB and Leprosy Control Sector, Disease Control Division, Ministry of Health Malaysia, to assess the evidence on the effectiveness, safety, and economic implication of the ultra-portable X-ray system as they are planning to use this technology to screen high-risk groups who are unable to undergo a chest x-ray at nearby health facilities.

Objective/ aim

The objective of this technology review was to assess the effectiveness, safety, and economic implications of ultra-portable digital X-ray for TB screening.

Methods

A systematic search was conducted on the following databases without any restriction on publication language and publication status. The Ovid interface: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to Dec 1st, 2023. Searches were also run in PubMed and INAHTA databases. Google was used to search for additional web-based materials and information. Additional articles were identified by reviewing the references of retrieved articles. The last search was conducted on 1st December 2023.

Results and conclusions

Search results

A total of **134** records were identified through the Ovid interface, Pubmed and other sources. After screening, 12 articles were assessed for eligibility and 122 records were excluded. After reading, appraising, and applying the inclusion and exclusion criteria to the 12 full-text articles,

five were included while the other seven were excluded since the studies had irrelevant populations and few were narrative reviews. All full-text articles finally selected for this review were four cross-sectional studies and one qualitative study.

Efficacy/ effectiveness

There was limited retrievable evidence showing that an ultraportable digital x-ray system with AI-enhanced interpretations demonstrated variable sensitivity ranging from 89.4% to 95.3% and variable specificity ranging from 29.8% to 62.8%. The combination of chest X-ray (CXR) and symptoms reported higher sensitivity (97.7%) in detecting TB in remote settings. Limited retrievable evidence suggested that while the ultra-portable system met operational standards, it exhibited slightly lower image quality than conventional systems, yet yielded comparable TB detection rates. Limited retrievable evidence suggested high agreement between ultra-portable digital x-ray device and conventional methods.

Safety

There was very limited retrievable evidence showing that radiation levels from the ultra-portable X-ray system for participants and health workers remained below international safety limits. Despite this, additional precautions were taken by the National Lung Hospital in Vietnam, such as technicians being positioned away from sites and protective gear being worn. Notably, limited evidence on the safety of such ultraportable X-ray systems was available in medical databases. However, certain products had received CE/USFDA certification, while others were in the certification process. The Philippines' FDA approved the use of these machines in TB screening, and in Malaysia, [redacted] was classified as a Class C Medical Device by the MDA.

Economic implication

There was no retrievable evidence on the cost or cost-effectiveness of an ultraportable X-ray system for TB. Instrument costs vary significantly based on factors such as make, regulatory clearance, availability, and procurement terms. FDA or CE-approved models typically range from [redacted].

Organisational Issues

Healthcare providers’ perspective

Limited evidence on the experiences of healthcare providers from six pilot sites, including countries like Nigeria, Vietnam, and Zambia, using ultraportable digital x-ray systems with DXR-CAD software for TB screening highlighted its potential to decentralize TB screening, emphasizing its portability and integration capabilities. However, challenges such as battery limitations, image quality concerns, and data integration complexities were also identified.

Guidelines

In 2021, the WHO and International Atomic Energy Agency (IAEA) set technical specifications for ultra-portable X-ray systems, emphasizing their use in remote areas when transferring patients to hospital radiology departments is unfeasible. The Stop TB partnership, backed by USAID and Global Affairs Canada, introduced guidelines for TB screening using CAD technology and ultra-portable X-ray systems. These guidelines address the challenges of system weight, battery reliance, radiation safety, and emphasize the need for proper training and compliance with safety standards.

Conclusion

Based on the review, limited retrievable evidence suggests that ultraportable X-ray systems, coupled with AI and computer-aided detection, have the potential to enhance TB screening in remote settings. Its performance is moderate in sensitivity ranging from 89.4% to 95.3%, and specificity ranging from 29.8% to 62.8%, better compared to symptom screening alone. Limited retrievable evidence also indicates that these systems appeared safe with exposure and leakage doses below the recommended limits for TB screening. However, economic implications remain unclear, and organizational challenges include integration complexities, limited capacity in implementing computer-aided detection, lack of radiation safety guidance, and the dual need for data protection and sharing, demanding comprehensive support, despite being perceived as valuable for TB screening decentralisation in a programmatic setting.

TABLE OF CONTENTS

ABBREVIATION

AI	Artificial intelligence
ACF	Active case finding
CAD	Computer-aided Detection
CAD4TB	Computer-aided detection for tuberculosis
CASP	Critical Appraisal Skills Programme
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
CXR	Chest x-ray
cm	centimeter
DLB	Delft-Light Backpack
DOT	directly observed treatment
DXR-CAD	x-ray systems integrated with computer-aided detection
GB	gigabites
GHz	gigahertz
HCW(s)	Healthcare workers
kg	kilogramme
kV	kilovolts
kW	kilowatts
IAEA	International Atomic Energy Agency
IQR	Interquartile range
MaHTAS	Malaysian Health Technology Assessment Section
mAs	Milliampere-seconds
MD	Mean difference
mGy/h	Milligray per hour
mm	millimeter
MOH	Ministry of Health
Mpixel	megapixel
mSv	millisieverts
NLH	National Lung Hospital
NNS	Number needed to screen
NNT	Number needed to test
NTEP	National Tuberculosis Elimination Program
OR	Odds ratio
PACS	Picture Archiving and Communication System
PC	Personal computer
RAM	Random-access memory
RoB	Cochrane Risk of Bias Tool
ROBIS	National Collaborating Centre for Methods and Tools
SID	Source-image distance
SSD	Solid-state drive
USAID	United States Agency for International Development
TB	Tuberculosis
US FDA	United States Food and Drug Administration
WHO	World Health Organization
WMD	Weighted mean differences
µm	micrometer

1.0 BACKGROUND

Tuberculosis remains a significant global health issue, with a high burden of disease and mortality. In 2022, TB has caused an estimated 1.3 million deaths.[1] Approximately 7.5 million people worldwide have been newly diagnosed with TB in 2022; the highest number since the World Health Organization (WHO) began monitoring TB globally in 1995. Based on geographic distribution, 46% of those who developed TB were located in Southeast Asia.[1] In Malaysia, the estimated total TB incidence was 113 (95% CI 92 to 130) per 100,000 population in 2022.[2]

As part of the established Sustainable Development Goals, the World Health Assembly adopted the WHO's post-2015 End TB Strategy in 2014 to end the worldwide TB epidemic. The WHO End TB Strategy aims for an 80% reduction in incidence and a 90% reduction in death by 2030, compared with 2015 levels.[3] The first pillar of the End TB Strategy seeks to achieve universal access to integrated patient-centred TB care and prevention, prioritising vulnerable and difficult-to-reach populations. This includes early diagnosis, appropriate treatment for all patients with TB including shorter oral treatment regimes, and systematic screening of contacts and high-risk groups.[3] Starting in 2015, Malaysia has implemented high-risk group screening in accordance with the WHO End TB Strategy.[4] Numerous factors contributed to the ongoing complexity of the TB situation in Malaysia, such as the increased prevalence of HIV infections, cases of antibiotic resistance, the influx of immigrants from countries with high TB burdens, the existence of non-communicable diseases, and patterns of international travel.[5] Ministry of Health (MOH) Malaysia has been emphasising TB screening for individuals who are at a high risk of contracting the disease for a number of years now. Those with a high risk of developing TB include close contacts with TB cases, immunocompromised patients, substance abusers, prisoners, and residents of elderly nursing homes.[4]

Assessing a person's symptoms of TB disease is usually the first step in deciding whether to do a diagnostic work-up for the disease. However, many individuals with culture-positive TB did not exhibit any symptoms or may feel that the symptoms they experienced were too mild to be reported, resulting in the possibility of missed diagnosis. A local study conducted among prisoners found that close to half of those with microbiologically confirmed TB did not show any symptoms.[6] This shows that symptom-based screening is not enough and would results in clinical deterioration and transmission to others. To enhance the detection of TB and identify those who should receive preventive therapy, WHO has updated the TB screening guidelines in 2021.[7] Apart from symptom screening, some of the recommended screening modalities include, molecular rapid diagnostic test using diagnostic test recommended by WHO and chest x-ray.[7] Chest X-ray (CXR) is a reliable screening tool, however, it can be costly and logistically challenging to use, particularly when screening is done outside of the health facilities; i.e. screening high-risk individuals in prisons, correctional facilities and detention centres. In Malaysia, CXR has been the main screening tool for detecting TB among the asymptomatic high-risk population.[4] Technologies such as portable X-ray systems can improve access to tuberculosis screening outside of health centres. These systems are intended for usage primarily in situations where planned diagnostic and/or screening procedures are far from medical or healthcare facilities. Portable X-ray or mobile X-ray is essentially an X-ray machine that can be moved and smaller than a fixed X-ray. The use of portable X-ray together with

compatible AI (Artificial Intelligence)-powered Computer-Aided Detection (CAD) software solutions could significantly increase the diagnostic capacities of the system, efficacy and efficiency, and its appropriateness to use.[8] The latest technology; ultraportable X-ray or labelled as handheld X-ray is smaller and lighter than portable X-ray; which can be carried out by a single person and be set up in minutes.

Recently, this device has obtained approval from the Medical Radiation Regulatory Division. Hence, this review was requested by the TB and Leprosy Control Sector, Disease Control Division, Ministry of Health Malaysia, to assess the evidence on the effectiveness, safety, and economic implication of the ultra-portable X-ray system as they are planning to use this technology to screen high-risk groups who are unable to undergo a chest x-ray at nearby health facilities as one of its outreach activities.

2.0 OBJECTIVE / AIM

The objective of this technology review was to assess the effectiveness, safety, and economic implication of ultra-portable digital x-ray system for TB screening.

3.0 TECHNICAL FEATURE

An ultra-portable X-ray system consists of a few basic parts; an X-ray generator, generator stand, X-ray detector, detector stand, a console (workstation) with imaging processing software, an external charging system and a carrying system which can be bags or case. There are a few ultra-portable X-ray systems available in the market.

In 2021, The WHO and the International Atomic Energy Agency (IAEA) collaborated and has published a document on the Technical Specifications for a Portable Digital Radiography System. This collaboration was prompted by the significant and growing demand from member States, non-governmental organisations and donor organisations for the use of portable digital X-ray devices in various clinical diagnostic applications. This document outlines the minimal specifications for digital ultra-portable X-ray systems. The technical characteristics and minimum requirement of a portable X-ray generator include:[8]

- the voltage ranges from 50 kV to not less than 90 kV (better with minimum range at least: from 50 kV up to 110 kV, preferably digitally displayed
- current-time ranges from 0.5 to 2.5 mAs (better with minimum range at least: from 0.3 to 100 mAs), preferably digitally displayed

For X-ray tube and collimator:

- Stationary or rotating (better) anode with focal spot size less than 1.3mm
- Heat storage capacity of the anode at least 10,000 HU (preferably higher) and/or Nominal Radiographic anode input power (IEC 60613, ed 3) at least: 0.45 kW (=90 kV x 2.5 mAs / 0.5 s), preferably 22 kW (=110 kV x 100 mAs/0.5s)
- Preferably, high anode temperature alarm and automatic blockage/alarm for high tube temperature

- Multileaf collimator with patient centering light. Total filtration with collimator not lower than 2.5 mm @70kV (or calculated on the product voltage available) Al equivalent (10)

The X-ray generator exposure features:

- Time range must include the range from 0.04 to at least 0.5 s (better with minimum range at least: from 0.01 to 4.0 s)
- Automatic Exposure Control facility
- Exposure release switch, preferably detachable, cordless remote control
- Maximum exposure switch operating distance to be specified as well as the optimal source-image distance (SID)
- Exposure capacity when fully charged (battery autonomy time) greater than 100 exposures.

As for the X-ray generator stand/frame, the frame must be lightweight and vertical movements range must include the range from 50 to 150 cm from ground. The stand/frame shall be capable to set the best Generator's position for all the clinical applications/uses/interventions requested and available.

The WHO document also stated that the technical characteristics and minimum requirement of a portable X-ray detector as follow:[8]

- Active detector area not less than 35 x 43 cm
- Time to display image after exposure no longer than 10 sec
- Pixel pitch not greater than approximately 150 µm
- Spatial resolution not less than 3 lp/mm (better: at least 3.5 lp/mm)
- Dynamic range of A/D converter at least 14 bit (preferably 16 bit) or at least 10 pixels resolution
- Exposure capacity when fully charged (battery autonomy time) at least 100 chest X-ray @ 90KV (or calculated on the product voltage available)
- Detector connectivity to workstation capabilities (wireless feature/option preferably included)

As for the X-ray detector stand/frame, the frame must be lightweight and vertical movements range must include the range from 50 to 150 cm from ground.

The 2021 WHO document also mentioned about the minimum requirements of workstation /console accompanying the portable X-ray system. The minimum requirements were as follow:

- One Led or LCD colour display, at least 13”, at least 2 Mpixel (system integrated or external)
- Two or more Microprocessors, each of at least 1.7 GHz
- RAM at least 6 GB
- Hard drive not less than 500 GB SSD
- Ability for high-resolution (at least 1440 x 1440) images to be retrieved, reproduced and stored without loss of quality
- Capacity to store and to transfer data to other workstations/PC-consoles/networks
- Display languages should include at least English (National language/s of the user/s will be an asset)
- Additional generator-integrated console/monitor/viewer are an advantage/Wireless feature shall be included.

The minimum requirements for the included software in the portable X-ray system was also discussed in the WHO document.[8] Dedicated software for calibration and image management, with at least all the following functions to be included, and DICOM 3.0 compatible (image storage and transfer):

- Patient registration/data
- Exposure parameter regulation; exposure parameter registration/recording
- Image processing (clip, zoom, magnifier, invert, rotate, flip, annotations, measurements, digital collimation, etc.), image view, detail enhancement and noise suppression, tissue equalization
- Alphanumeric annotation of images required
- Chest X-ray programme by default with patient thickness range including at least the range from 14 to 40 cm
- Last image hold facility required, displayed on clear screen
- Storage capacity of at least 2000 images, with capacity for removable media storage
- Interoperability with local and/or national Picture Archiving and Communication System (PACS) where available
- Preferably: interoperability with other Software
- Demonstrated integration with AI-powered Computer-Aided Detection (CAD) solutions
- To be supplied with original necessary licenses (CAD, PACS, etc.) in final beneficiary name.
- If Computer Aided diagnostics/AI is included in the equipment offered, it has to be approved by WHO, or a stringent regulatory agency for “software as medical device” and compliance must be demonstrated. The manufacturers shall state the intended purpose of the CAD (diseases/ conditions covered, screening, diagnostics and standards approved).

4.0 METHODS

A systematic review was conducted. Search strategy was developed by the two authors and an *Information Specialist*.

4.1 SEARCHING

The following electronic databases were searched through the Ovid interface:

- MEDLINE® All < 1946 to 1st December 2023>
- EBM Reviews - Health Technology Assessment 4th Quarter 2016
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to December 2023
- EBM Reviews - Cochrane Central Registered of Controlled Trials November 2023
- EBM Reviews - Database of Abstracts of Review of Effects 1st Quarter 2016
- EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016

Other databases: PubMed, US FDA, INAHTA

General databases such as Google Scholar was used to search for additional web-based materials and information. Additional articles retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. **Appendix 1** showed the detailed search strategies. The last search was conducted on 1st December 2023.

4.2 SELECTION

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria. Relevant articles were then critically appraised depending on the type of the study design. Studies were graded according to *US/ Canadian Preventive Services Task Force* (**Appendix 2**). All data were extracted and summarised in evidence table as in **Appendix 3**.

The inclusion and exclusion criteria were:

Inclusion criteria:

a.	**Population**	People at risk of tuberculosis
b.	**Intervention**	Ultra-portable digital x-ray system
c.	**Comparator**	Xpert testing (molecular rapid diagnostic test) Standard x-ray system
d.	**Outcomes**	Effectiveness/Accuracy: Yield, case detection rate, sensitivity, specificity, number needed to screen (NNS), number needed to test (NNT) Safety: Adverse events, complications, radiation dose, leakage dose Organisational issues: Acceptability, barriers, facilitators, trainings, infrastructure issues, guidelines Economic implications: cost, cost-analysis, cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, cost-minimisation, budget impact analysis
e.	**Study design**	HTA reports, systematic review with/out meta-analysis, randomised controlled trial (RCT), cohort, diagnostic, case-control, economic evaluation studies

f.	Full text articles published in English

Exclusion criteria:

a.	**Study design**	Case report, case series, animal study, laboratory study, narrative review
b.	Non-English full text articles	

5.0 RESULTS

Search results

An overview of the search is illustrated in Figure 4. A total of 132 records were identified through the Ovid interface and PubMed while two were identified from references of retrieved articles. No duplicate references were found; 134 potentially relevant titles were screened using the inclusion and exclusion criteria. Of these, 12 relevant abstracts were retrieved in full text. After reading, appraising, and applying the inclusion and exclusion criteria to the 12 full-text articles, 5 were included while the other seven were excluded since the studies had irrelevant populations and few were narrative reviews. All full-text articles finally selected for this review were four cross-sectional studies and one qualitative study.

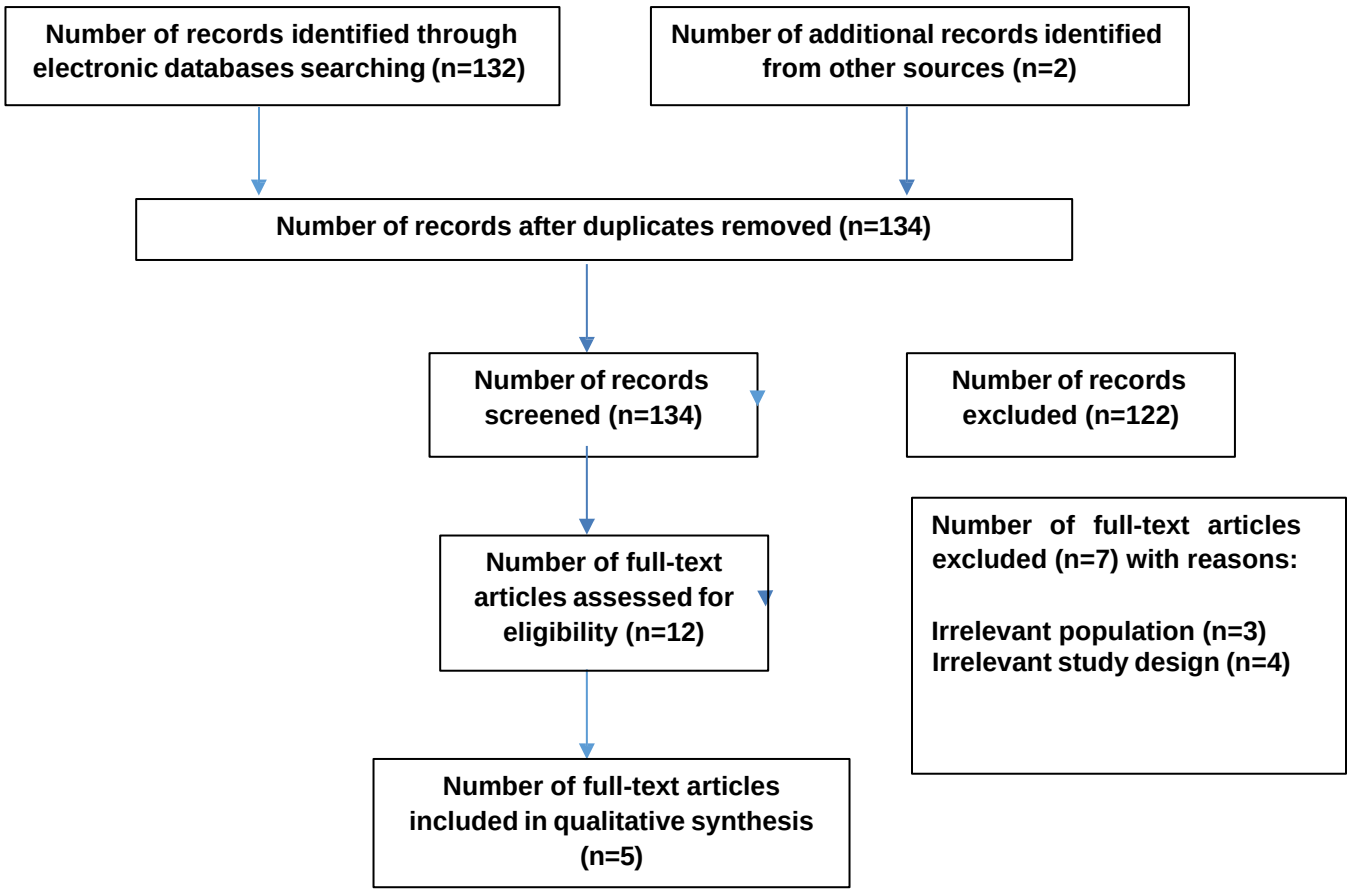

Figure 4: Flow chart of retrieval of articles used in the results

Characteristics of included studies

There were four cross-sectional studies, which reported on the effectiveness of ultraportable digital x-ray systems for TB screening. There was one qualitative study that reported on the acceptability, lessons learned, and perceived limitations of the technology from the health provider's perspective**.** The included studies were conducted mainly in Nigeria, Vietnam, and India. Most studies included ultraportable digital x-ray systems MinXray, Fujifilm FDR Xair, Delft Ultra, Delft Light, and MINE2. The studies were published between the year of 2021 to 2023. Table 2 displays the characteristics of the included studies in this review.

Table 2: Characteristics of the included studies

Study	Study design	Number of patients	Intervention	Comparison	Outcomes
1.John S et al. (2023) -Nigeria	Cross-sectional study	5,298 individuals ≥15 years, 51% females 49% males	Screening using ultraportable CXR and AI	-Screening using cough ≥2weeks -Screening using any cough -Screening using any symptom - Screening using ultraportable CXR and AI threshold 0.5 -Combined screening CXR and AI threshold ≥0.5 with symptom cough ≥2 weeks	**Effectiveness** - Yield of different algorithm in TB detection and utilization of tests
2. Vo L N Q et al. (2021) -Vietnam	Cross-sectional study	In vitro evaluation in radiological dept: 14 radiologists and 28 Xray-technicians In vivo deployment at 2 districts of Vietnam 4394 persons screened by CXR (82.0% by reference system and 18.0% by ultraportable system)	Ultraportable X-ray system -FDR Xair XD2000 system (Fujifilm)	National Lung Hospital (NLH) standard CXR	**Effectiveness** In vitro evaluation: -key product specifications and operating parameters in comparison to manual In vivo deployment: -Mean abnormality scores of images taken **-**Yield of ultraportable x-ray system and standard x-ray in TB detection **Safety** **-** exposure and leakage doses

Study	Study design	Number of patients	Intervention	Comparison	Outcomes
3. Odume B et al. (2023) -Nigeria	Cross-sectional study	8230 participants during community screening	Ultraportable digital xray Delft-Light Backpack (DLB)		**Effectiveness:** -TB prevalence
4. Kamal R et al. (2023) -India	Cross-sectional study	100 participants suspected TB	Ultraportable digital Xray Mine 2	Health facility based digital Xray service	**Effectiveness:** - Agreement between image qualities
5. Qin ZZ et al. (2023) - Cambodia, Nigeria, Pakistan, Uganda, Vietnam, and Zambia	Qualitative study	26 interviewees with varying roles: supervisory, clinicians, radiographers, and radiologists.	Ultra-portable digital x-ray systems integrated with CAD software Four ultra-portable DXR systems (Fujifilm FDR Xair, Delft Ultra, Delft Light, MINE2) and three CAD software products (Lunit INSIGHT CXR, qXR, CAD4TB) were used		**Organisational** **-** acceptability, lessons learned and perceived limitations of the technology from the health provider perspective

5.1 EFFICACY/ EFFECTIVENESS

The results for effectiveness are summarised in Table 3.

John S et al. (2023) has conducted a cross-sectional study involving screening camps in Gombe and Adamawa states of Northeast Nigeria to assess the performance of ultraportable X-ray devices coupled with AI in detecting TB in remote settings. The camps involved the screening of 5,298 individuals, with 51% being females and 49% males. A mobile team consisting of a registration officer, data entry staff, a radiographer and a coordination officer attended each community camp. The screening included symptom assessment (cough, fever, night sweats, and weight loss) and CXR using a MinXray Impact system interpreted by AI (qXR V3). The AI interpreted all CXR images immediately onsite. Sputum samples were collected from individuals with abnormality scores of 0.3 or higher or those reporting TB symptoms, and the samples were tested using Xpert MTB/RIF. The performance of screening with different combinations of CXR read by AI and symptoms were evaluated.[11, level III]

The results showed that 2,685 (51%) females and 2,613 (49%) males were screened. The median age of males was 39 (IQR: 26–53) and for females, it was 36 (IQR: 26–48). The study reported different yields based on the screening approach. Using the traditional criterion of prolonged cough (two weeks or more), 20% (1,056) of individuals were identified as having presumptive TB. The yield increased to 36% (1,889) when any duration of cough was considered, and further to 58% (3,084) when any of the four symptoms were used. A total of 14.5% (770) of participants had abnormality scores of 0.3 or higher on CXR, and 8.4% (447) had a score of 0.5 or higher, indicating radiological abnormalities. Sputum samples were collected from individuals with abnormality scores of 0.3 or higher or those reporting TB symptoms. Xpert testing detected TB in 8% of those tested, resulting in a prevalence rate of 1,604 per 100,000 screened. All identified TB cases were linked to treatment. The results from the study showed different screening approaches demonstrated varying sensitivity and specificity. Screening using a cough of two weeks or more had a sensitivity of 40% and specificity of 61.5%, using 394 tests, while using any cough to screen increased sensitivity to 62.4%, using 639 tests. If any symptom was used to screen, then the sensitivity rose to 90.6% (77 of the 85 people with TB would be identified) but 906 tests would be needed. Using CXR alone with a threshold score of 0.30 produced a sensitivity of 95.3% but a lower specificity of 29.8% requiring 738 Xpert cartridges. Using a higher cut-off of 0.5 only used 424 tests to identify 89.4% of people with TB with a specificity of 62.8%. Combining CXR with a threshold score of 0.5 and a cough of two weeks or more identified almost all TB cases on Xpert, and used 682 cartridges.[11, level III]

Another cross-sectional study was conducted by Vo L N Q et al. (2021) to evaluate the safety, image quality, and yield of using an ultra-portable X-ray system for active case finding (ACF) in comparison with facility- and community-based radiographic reference systems in TB prevention and care in Vietnam. The objectives involved an 'in vitro' evaluation of emission levels and operating parameters, comparing the ultra-portable system with a conventional radiographic reference system. Additionally, an 'in vivo' deployment in two remote areas of Vietnam assessed image quality, abnormality rate, and tuberculosis case detection yields. The ultra-portable system, comprising a battery-powered X-ray generator and a flat-panel detector, was evaluated for safety and image quality through visual grading analysis and quantitative

analysis using AI software. The study involved participant recruitment from the National Lung Hospital and community-based screening campaigns in Phuoc Son and Tan Hiep, Vietnam with data collected through a combination of radiologic inspection, visual grading analysis, and quantitative analysis using AI software during both 'in vitro' and 'in vivo' phases. Operational and radiological performance characteristics were reported and image quality was compared between the ultra-portable and two reference systems. Image quality was rated by three radiologists and by AI software. The results showed that the ultra-portable system operated within advertised specifications and radiologic tolerances, except for X-ray capture capacity, which was 58% lower than the reported maximum of 100 exposures per charge. The mean image quality rating from radiologists for the ultra-portable system was significantly lower than the reference (3.71 vs. 3.99, $p< 0.001$). However, there were no significant differences in TB abnormality scores using the AI software between the reference (0.37, 95% CI: [0.32, 0.41]) and the ultraportable X-ray system (0.37, 95% CI: [0.32, 0.42]), with a p-value of 0.571. Additionally, there was no significant distinction in the proportion of CXR images graded as having parenchymal abnormalities suggestive of TB by the on-site radiologist between the reference (5.1%) and ultraportable X-ray system (6.8%), with a p-value of 0.056. Moreover, rates of sputum collection and testing (85.1% vs. 84.1%), diagnosis of all forms of TB (12.3% vs. 11.3%), and linkage to care (95.2% vs. 100.0%) showed similar and comparable outcomes between the reference and ultra-portable X-ray systems. The yield of TB patients linked to care from the combined ACF campaigns was 555 per 100,000 for the reference system, resulting in a number needed to screen (NNS) of 180, compared to a yield of 759 per 100,000 and an NNS of 132 for the ultraportable X-ray system.[12], level III

Odume B et al. (2022) has conducted a cross-sectional study in Nigeria to assess the usefulness of of portable digital X-ray, the Delft-Light Backpack (DLB) for TB ACF in hard-to-reach Niger Delta communities using the WHO 3B TB screening/diagnosis algorithm. All consenting eligible individuals in the targeted communities were screened for TB, regardless of the presence of respiratory/constitutional TB symptoms. Contacts of confirmed TB cases were also screened. Exclusions comprised confirmed TB cases on treatment or follow-up, children under four years, and asymptomatic pregnant women. The screening process utilized the WHO 3B screening/diagnostic algorithm, with health outreaches conducted by a predefined schedule developed based on a list of hard-to-reach communities. A mobile Digital Light-Based team, including a radiographer, data clerk, directly observed treatment (DOT) officer, and community mobilizer, conducted community outreaches. The DLB X-ray, utilizing CAD4TB v6 software for image analysis, was employed for screening. Participants with a CAD4TB score ≥60 were encouraged to produce on-the-spot sputum. Sputum specimens and electronic CXRs of those unable to produce sputum were sent for further evaluation by independent radiologists. Confirmed TB cases were promptly notified and treated. The primary outcome was the prevalence of TB cases among participants in the TB screening outreaches. Secondary measures included the proportion of TB cases among presumptive TB cases identified after DLB X-ray, the NNS to diagnose one person with active TB, and the number needed to test (NNT) to identify a TB case.[13, level III]

The results showed that during the project, a total of 8,230 clients were screened for TB, with 47.2% males and 52.8% females. Akwa Ibom and Cross-River states contributed 32.9% and 67.1% of participants, respectively. The modal age group for all participants was 35 to 44 years, while for those with presumptive TB and confirmed TB cases, it was ⩾65 years. A total of 1,140 persons were identified with presumptive TB, and 98 TB cases were confirmed, resulting in a prevalence rate of 1.2% among all participants and 8.6% among those with presumptive TB.

Males (12.0%) with confirmed TB among presumptive cases were significantly higher than females (5.6%). Akwa Ibom State had 40 diagnosed TB cases, while Cross River State had 58. Of all TB cases, 96.9% were placed on treatment, and a small percentage were lost to follow-up, predominantly males. The study found an NNS of 84 and NNT of 12 to diagnose one person with active TB in hard-to-reach areas using DLB X-ray, with significantly higher numbers for females.[13, level III]

Another cross-sectional study was conducted by Kamal R et al. (2022) in India to evaluate the agreement and quality of CXR images obtained from the ultra-portable digital X-ray compared to the routinely used digital X-ray machine. The comparison was made between images captured by a newly developed handheld X-ray machine, Mine 2© (Lipomic India Pvt. Ltd.), and a digital X-ray machine routinely used under the National Tuberculosis Elimination Program (NTEP). The Mine 2 device, weighing 1.8 kg, consists of an X-ray generator, a digital detector, and a laptop with inbuilt router for image transfer. It is portable, battery-operated, and designed for use in hard-to-reach areas. The study included 100 participants who met the NTEP criteria for suspected pulmonary TB, with exclusion criteria such as pregnancy, severe illness, and spinal deformities affecting the ability to stand erect. Participants underwent CXR twice, once with the NTEP digital X-ray machine and once with the Mine 2 handheld X-ray machine. The images, lacking personal identifiers, were independently analysed by two radiologists based on 15 parameters related to CXR image quality. These parameters included aspects such as respiration state, rotation, costophrenic angles, airway and mediastinum size, bones, cardiac shadow, diaphragm position and shape, effusion, lung fields, and hilum. Each parameter was binarily graded, and an overall quality score (on a scale of 1 to 10) was assigned to each image. The primary outcome measured intra-rater agreement and Cohen's kappa values for each of the 15 parameters between the two machines, individually for each radiologist. Additionally, unweighted mean and median percentage agreement and kappa values were calculated across all 15 parameters. The results showed that the intra-observer (radiologist) agreements regarding the status of the 15 CXR parameters ranged between 74 per cent and 100 per cent, with an unweighted mean of 87.2 per cent (95% confidence interval: 71.5-100). The median Cohen's kappa values for intra-observer agreement were 0.62 and 0.67 for radiologists 1 and 2, respectively. In addition, on comparison of the overall median score of quality of the image, the handheld machine images had a higher score for image quality.[14, level III]

Table 3: Summary of results for effectiveness

Study	Study design	Number of patients	Intervention	Comparison	Outcomes
1.John S et al. (2023)	Cross-sectional study	5,298 individuals ≥15 years, 51% females 49% males	-Screening using ultraportable CXR and AI threshold 0.3	-Screening using cough ≥2weeks -Screening using any cough -Screening using any symptom - Screening using ultraportable CXR and AI threshold 0.5 -Combined screening CXR and AI threshold ≥0.5 with symptom cough ≥2 weeks	Prevalence TB 8% by Xpert testing Yield of different algorithm in TB detection and utilization of tests: 1. Screening using cough ≥2weeks: Sensitivity – 40% Specificity – 61.5% using 394 tests. 2. Screening using any cough: Sensitivity – 62.4% using 639 tests 3. Screening using any symptom: Sensitivity – 90.6% using 906 tests 4. Screening using ultraportable CXR and AI threshold 0.3 Sensitivity – 95.3% Specificity – 29.8% using 738 tests 5. Screening using ultraportable CXR and AI threshold 0.5 Sensitivity – 89.4% Specificity – 62.8% using 424 tests 6. Combined screening CXR and AI threshold ≥0.5 with symptom cough ≥2 weeks Sensitivity – 97.7% Specificity – 36.0% using 682 tests

Study	Study design	Number of patients	Intervention	Comparison	Outcomes
2. Vo L N Q et al. (2021)	Cross-sectional study	In vitro evaluation in radiological dept: 14 radiologists and 28 Xray-technicians In vivo deployment at 2 districts of Vietnam 4394 persons screened by CXR (82.0% by reference system and 18.0% by ultraportable system)	Ultraportable X-ray system -FDR Xair XD2000 system (Fujifilm)	National Lung Hospital (NLH) standard CXR	In vitro evaluation: Key product specifications and operating parameters in comparison to manual – on most metrics, performed in line with values in manual except Xray capture 58% lower than reported max 100 exposures per charge -mean image quality rating from radiologists: lower than reference (3.71 vs 3.99, p<0.001) In vivo deployment: -No significant difference in mean abnormality scores of images taken by reference and ultraportable xray. -No significant difference in CXR suggestive of TB, rates of sputum collection, testing, diagnosis of TB and linkage to care between two groups -Yield of TB: Ultraportable Xray-759/100,000, NNS 132 (0.76%) Reference system-555/100,000, NNS 180 (0.56%)
3. Odume B et al. (2023)	Cross-sectional study	8230 participants during community screening	Ultraportable digital xray Delft-Light Backpack (DLB)	Health facility based digital Xray service	TB prevalence among all participants: 1.2% TB among presumptive TB: 8.6% Number needed to screen: 84

Study	Study design	Number of patients	Intervention	Comparison	Outcomes
4. Kamal R et al. (2023)	Cross-sectional study	100 participants suspected TB	Ultraportable digital Xray Mine 2		Agreement between image qualities -Intra-observer (radiologist) agreements regarding the status of the 15 CXR parameters ranged between 74% and 100%, with an unweighted mean of 87.2% (95% CI: 71.5-100). -Median Cohen's kappa values for intra-observer agreement were 0.62 and 0.67 for radiologists 1 and 2, respectively

5.2 SAFETY

Vo L N Q et al. (2021) mentioned in their cross-sectional study in Vietnam that for participants in the study, the reported exposure and leakage doses of the ultra-portable X-ray system were well below the average annual radiation dose from the environment (3 mSv) and the annual accepted dose of ionizing radiation for general public (1 mSv). Regarding the health workers and especially the radiographers, the leakage doses were similarly below international guidelines on the stochastic limits for the occupational exposure of <20 mSv/year over five years. However, despite granting community authorization for the ultra-portable X-ray system, the the radiology department of the National Lung Hospital (NLH) took additional measures by assigning two radiography technicians to assist the attending radiologist. To address any lingering concerns, the system was strategically placed away from the congregated areas at the screening sites, and the technicians wore protective lead vests.[12, level III]

There was no other retrievable evidence on the safety of ultraportable x-ray system from the medical databases. Few ultraportable digital x-ray system products have CE/USFDA certification including Delft Light and Fuji Xair, while some products were in the process of obtaining such certification. In the Philippines, the Food and Drug Administration (FDA) Philippines has approved the use of ultraportable X-ray machines in TB screening programs. In Malaysia, Fuji Xair has been registered with MDA as Class C Medical Device.

5.3 ECONOMIC IMPLICATION

There was no retrievable evidence on the cost or cost-effectiveness of an ultraportable X-ray system for TB. Instrument costs vary significantly based on factors such as make, regulatory clearance, availability, and procurement terms. FDA or CE-approved models typically range from [redacted]

5.4 ORGANISATIONAL ISSUES

5.4.1 Healthcare providers' perspective

Qin Z Z et al. (2023) conducted a qualitative study involving project staff and healthcare workers at six pilot sites including in Pakistan, Vietnam, Zambia, Ghana, Nigeria, and Cambodia, to assess early implementers' experiences and lessons learned when using ultraportable digital x-ray systems integrated with computer-aided detection (DXR-CAD) software for TB screening. In Nigeria and Vietnam, DXR-CAD supported community-based active TB case finding in hard-to-reach areas, while four other projects mainly focused on facility-based screening. In Zambia and Cambodia, DXR-CAD was utilised in remote clinics, in Pakistan in tertiary hospitals, and in Ghana for systematic screening in prisons. Cambodia and Pakistan also employed these tools for community-based ACF in rural and mining areas. The six projects utilized four ultra-portable DXR systems (Fujifilm FDR Xair, Delft Ultra, Delft Light, MINE2) and three CAD software products (Lunit INSIGHT CXR, qXR, CAD4TB) in various combinations. Semi-structured interviews were conducted with project staff and healthcare workers at the six pilot sites. Transcripts were coded and analysed using a framework approach. The themes that emerged were subsequently organised and presented using the Consolidated Framework for Implementation Research (CFIR). The objective was to involve at least two healthcare workers (HCWs) per site, encompassing roles such as radiographers, radiography technicians, radiologists, and other clinicians engaged in routine care. This goal was met at all sites except Nigeria, where no HCWs were present. Interviews with HCWs covered aspects such as their experience of use, regulations, and logistics (e.g., procurement, installation). To gain insight into programmatic considerations and implications, interviews were conducted with at least one program manager per site, considering the limited number of eligible participants.[15, level III]

The results showed that the study identified barriers and facilitators to the implementation of DXR-CAD for TB screening from the perspective of early implementers. The technology was overall perceived as a tool to decentralize TB screening and triage in programmatic settings ranging from facility-based triage to hard-to-reach areas. Early adopters highlighted key facilitators like portability, streamlined product integration, comprehensive training and support, and the potential for CAD integration into health information systems and diverse data storage solutions. Conversely, implementation challenges include compromises associated with enhanced portability, such as battery life, reliance on internet connectivity, maneuverability, and image quality for larger patients. Additionally, complexities arise in integrating DXR with CAD systems, limited capacity for CAD implementation, absence of international radiation safety guidelines, the dual necessity of patient data protection and sharing, and the demand for comprehensive service and maintenance support.[15, level III]

5.4.2 Guidelines

The WHO and the IAEA jointly established the Technical Specifications for A Portable Digital Radiography System in 2021, outlining minimum requirements for digital ultra-portable X-ray systems.[8] These specifications guide decision-making on selection, regulation, incorporation, allocation, and utilization of such systems, emphasizing their use in remote locations or for economically convenient outreach interventions. The document specifies that portable X-ray systems are not intended for patients who can be transported to hospital radiology departments. According to IAEA Safety Standards Series No. SSG-46 (10), these units should only be used when transferring patients to a fixed unit is impractical or medically unacceptable. The decision to purchase such equipment should consider local epidemiology, overall health needs, and health system characteristics, rather than focusing solely on a specific disease.

The Stop TB partnership organised by the United Nations and supported by the United States Agency for International Development (USAID) and Global Affairs Canada together with expertise from a broad spectrum of country, regional, and global partners in the shared mission to revolutionize the TB space and end TB by 2030, developed a practical guide for screening and triage for TB using CAD technology and ultra-portable X-ray systems. The document outlined:[16]

Implementation Considerations for Ultra-Portable X-ray Systems:

- Ultra-portable X-ray systems, marketed for their portability, may be too heavy for a single person (29.4 kg to 33.2 kg), limiting their practicality.
- In off-grid settings, reliance on battery power restricts throughput, making these systems suitable for lower screening volumes (up to 50-200 X-ray scans per day).
- X-ray systems' field image collection relies on battery capacity; supplementary power sources, like extra detector batteries, can extend operating time.
- Radiation safety is maintained, with CXR delivering a low dose below average environmental exposure. Both Fujifilm FDR Xair and Delft Light emit less radiation than stationary machines.
- The stretchable hand switch enables remote operation, reducing radiation risk. Adherence to international safety standards and local regulations is crucial.
- The console laptop is solely for receiving CXR images; unauthorized software installation or hardware connection may lead to system failure. Emphasis is placed on compliance with imaging guidelines and protection policies, using the minimum necessary radiation for quality images. Workstations include tools for image optimization.

Operational Considerations for CAD and Ultra-Portable X-ray Systems:

- A situation assessment should be conducted to evaluate existing public health interventions, literature, and policy, as well as health system integration and ICT infrastructure.
- A market analysis for ultra-portable X-ray systems and CAD software should be performed, and selected systems, software, and ancillary items should be procured locally.
- Regulatory compliance for importation and CAD software use should be ensured, obtaining necessary approvals for indoor and outdoor use, and radiation safety measures should be designed.

- X-ray technicians, community healthcare workers, and support staff should be hired, ensuring adequate staffing for system transport.
- Training materials for clinicians and healthcare workers should be developed, and staff should be trained on system use, radiation safety, and maintenance.

5.5 LIMITATIONS

There were limitations in this review and these should be considered when interpreting the results. Although there was no restriction in language during the search, only the full-text articles in English published in peer-reviewed journals were included in the report, which may have excluded some relevant articles and further limited our study numbers. Most studies included in this review were cross-sectional studies. The evaluation of ultra-portable X-ray systems is contingent on specific technologies and findings may not be extendable universally to other devices. Findings may have limited generalizability as they are specific to certain geographic locations (Nigeria, Vietnam, India) and may not represent broader populations or diverse healthcare settings.

6.0 CONCLUSION

Based on the review, limited retrievable evidence suggests that ultraportable X-ray systems, coupled with AI and computer-aided detection, have the potential to enhance TB screening in remote settings. Its performance is moderate in sensitivity ranging from 89.4% to 95.3%, and specificity ranging from 29.8% to 62.8%, better compared to symptom screening alone. Limited retrievable evidence also indicates that these systems appeared safe with exposure and leakage doses below the recommended limits for TB screening. However, economic implications remain unclear, and organizational challenges include integration complexities, limited capacity in implementing computer-aided detection, lack of radiation safety guidance, and the dual need for data protection and sharing, demanding comprehensive support, despite being perceived as valuable for TB screening decentralisation in a programmatic setting.

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APPENDIX 1: LITERATURE SEARCH STRATEGY

1 TUBERCULOSIS, PULMONARY/ (3679)
2 (tuberculosis adj1 pulmonary).tw. (2491)
3 TB.tw. (18877)
4 ultra portable digital x-ray.tw. (1)
5 Ultra portable DXR system*.tw. (0)
6 (Digital chest adj2 radiography).tw. (23)
7 (mobile chest adj2 radiography).tw. (7)
8 (Portable adj1 x-ray).tw. (136)
9 RADIOGRAPHY, THORACIC/ (2661)
10 (radiograph* adj1 thoracic).tw. (248)
11 (portable adj1 radiography).tw. (12)
12 SENSITIVITY.mp. and SPECIFICITY/ [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word] (31613)
13 Diagnostic accuracy.tw. (16389)
14 Screening.tw. (151323)
15 sensitivity.tw. (189293)
16 1 or 2 or 3 (20702)
17 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (3014)
18 16 and 17 (132)

Other Databases		
PubMed		Same MeSH and keywords as per MEDLINE search
INAHTA		
US FDA		

APPENDIX 2: HIERARCHY OF EVIDENCE FOR EFFECTIVENESS

DESIGNATION OF LEVELS OF EVIDENCE

I	Evidence obtained from at least one properly designed randomized controlled trial.
II-I	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III	Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

APPENDIX 3: EVIDENCE TABLE

Evidence Table : Effectiveness/ safety/ organisational/ economic implication
Question : What is the effectiveness, safety, and cost-effectiveness of ultraportable CXR for TB?

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
1. John, S, Abdulkarim, S, Rahman, M et al. (2023). Results from TB screening using ultraportable x-ray and artificial intelligence in remote populations in northeast Nigeria. 10.21203/rs.3.rs-2714909/v1.	Cross-sectional study **Aim:** To evaluate the performance of CXR and AI as part of TB screening in remote rural populations of northeast Nigeria. **Methods:** -Screening camps were organized in Gombe and Adamawa states of Northeast Nigeria using a team consisting of a registration officer, data entry staff, a radiographer, and a coordination officer. -TB symptoms (cough, fever, night sweats, and weight loss) were screened for, and CXR was administered to all consenting individuals ≥ 15 years. -The MinXray Impact system, interpreted by AI (qXR V3), a fully integrated wireless setup that can be operated without electricity and weighs approximately 30kg, was utilized.	III	5,298 individuals during 66 camps; 2,685 (51%) were females, and 2,613 (49%) were males -all individuals older than 15 who were not currently receiving TB treatment was eligible to participate in TB screening. -All consenting participants were screened for TB symptoms verbally (cough and duration, fever, night sweats and weight loss) and offered a CXR.	Ultraportable CXR with AI	Different combination of symptoms And CXR -Screening using cough ≥2weeks -Screening using any cough -Screening using any symptom -Screening using ultraportable CXR and AI threshold 0.5 -Combined screening CXR and AI threshold ≥0.5 with symptom cough ≥2 weeks		Results: Prevalence TB 8% by Xpert testing Yield of different algorithm in TB detection and utilization of tests: 1. Screening using cough ≥2weeks: Sensitivity – 40% Specificity – 61.5% using 394 tests. 2. Screening using any cough: Sensitivity – 62.4% using 639 tests 3. Screening using any symptom: Sensitivity – 90.6% using 906 tests 4. Screening using ultraportable CXR and AI threshold 0.3 Sensitivity – 95.3% Specificity – 29.8% using 738 tests 5. Screening using ultraportable CXR and AI threshold 0.5 Sensitivity – 89.4% Specificity – 62.8% using 424 tests	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
							6. Combined screening CXR and AI threshold ≥0.5 with symptom cough ≥2 weeks Sensitivity – 97.7% Specificity – 36.0% using 682 tests **Authors conclusion:** Ultra-portable CXR can be used to provide better TB screening in hard-to-reach areas. Symptom screening may miss large proportions of people with bacteriologically confirmed TB. Employing AI to read CXR can improve triaging when human readers are unavailable and can save expensive diagnostic testing costs.	

Evidence Table : Effectiveness/ safety/ organisational/ economic implication
Question : What is the effectiveness, safety, and cost-effectiveness of ultraportable CXR for TB?

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
2. Vo LNQ, Codlin A, Ngo TD et al. Early Evaluation of an Ultra-Portable X-ray System for Tuberculosis Active Case Finding. Trop Med Infect Dis. 2021;6(3):163.	Cross-sectional study **Aim:** To evaluate safety, image quality and yield of using an ultra-portable X-ray system for active case finding (ACF) in comparison with facility- and community-based radiographic reference systems in tuberculosis (TB) prevention and care in Vietnam. **Methods:** **- First objective:** Conduct an 'in vitro' evaluation of the emission levels and standard operating parameters for posteroanterior (PA) chest radiography of an ultraportable, battery-powered X-ray system (Fujifilm Xair), and compare its image quality with conventional, stationary radiographic reference system **- Second objective:** Perform an 'in vivo' deployment of the ultra-portable X-ray system in community-based TB ACF campaigns and compare image quality, abnormality rate and TB case detection yields of the ultra-portable,	III	4394 persons were screened by CXR, of whom 82.0% (3604/4394) were screened by the reference system and 18.0% (790/4394) by the ultra-portable system.	Ultraportable CXR	Semi-portable Xray generator		**Results:** -Ultra-portable system **operated within advertised specifications and radiologic tolerances**, except on X-ray capture capacity, which was 58% lower than the reported maximum of 100 exposures per charge. -**Mean image quality rating** from radiologists for the ultra-portable system was significantly lower than the reference (3.71 vs. 3.99, $p < 0.001$). -**No significant differences in TB abnormality scores** using the AI software ($p = 0.571$), nor in any of the steps along the TB care cascade during ACF campaign. -**Proportion of CXR images graded as having parenchymal abnormalities suggestive of TB** by the on-site radiologist was not significantly different between the radiography systems (5.1% for the reference vs. 6.8% for the ultraportable, $p = 0.056$). -**Rates of sputum collection and testing** (85.1% vs. 84.1%), diagnosis of all forms of TB (12.3% vs. 11.3%) and linkage to care (95.2% vs. 100.0%) were comparable between the reference and ultra-portable X-ray systems.	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	battery-powered X-ray system compared with a community-based radiographic reference system, consisting of a semi-portable X-ray generator that required a continuous power connection -'in vitro' evaluation was conducted in the radiology department of the National Lung Hospital (NLH) in Hanoi, Viet Nam -'in vivo' deployment occurred in two remote areas of Viet Nam: a mountainous district (Phuoc Son) and an island (Tan Hiep) of Quang Nam province - X-ray generator was the Fujifilm Digital Radiography (FDR) Xair XD2000 system (Xair; Fujifilm Corporation, Japan). -Data collected through a combination of radiologic inspection, visual grading analysis, and quantitative analysis using AI software during both 'in vitro' and 'in vivo' phases. -Operational and radiological performance characteristics were reported and image quality was compared between the ultra-portable and two reference systems. Image quality was rated by three radiologists and by AI.						-**Yield of TB patients** linked to care from the combined ACF campaigns was 555 per 100,000 for reference system for NNS of 180 compared to a yield of 759 per 100,000 and a NNS of 132 for the ultra-portable X-ray system. The post hoc analysis in the subgroup of persons screened by the ultra-portable device at their homes (260/790 = 32.9%) showed a yield of two persons with TB linked to care for a yield of 769/100,000 and an NNS of 130. **Safety:** -For participants: Reported exposure and leakage doses were well below the average annual radiation dose from the environment (3 mSv) and the annual accepted dose of ionizing radiation for general public (1 mSv). -For health workers and especially the radiographers: Leakage doses were similarly below international guidelines on the stochastic limits for the occupational exposure of <20 mSv/year over five years. **Authors conclusion:** Despite some shortcomings, ultra-portable X-ray systems have significant potential to improve case detection and equitable access to high-quality TB care.	

Evidence Table : Effectiveness/ safety/ organisational/ economic implication
Question : What is the effectiveness, safety, and cost-effectiveness of ultraportable CXR for TB?

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
3. Kamal R, Singh M, Roy S, et al. A comparison of the quality of images of chest X-ray between handheld portable digital X-ray & routinely used digital X-ray machine. Indian J Med Res. 2023;157(2&3):204-210.	Cross-sectional study **Aim:** To compare the image quality of CXR taken by a newly developed handheld X-ray machine with routinely used reference digital X-ray machine **Methods:** **-**100 participants with suspected pulmonary TB were recruited from the outpatient departments of a medical college and a community health centre in Agra. -Each participant underwent CXR twice, once with each machine. -Both sets of de-identified images were independently read by two radiologists, who were blinded to the type of X-ray machine used. -Primary outcome: agreement between image qualities produced by these two machines. -No comparison of characteristics or diagnosis of pathological findings was made in this study.	III	100 participants with suspected pulmonary TB	Handheld Xray machine	Routinely used digital xray machine		**Results:** -Intra-observer (radiologist) agreements regarding the status of the 15 CXR parameters ranged between 74 per cent and 100 per cent, with an unweighted mean of 87.2 per cent (95% CI: 71.5-100). -Median Cohen's kappa values for intra-observer agreement were 0.62 and 0.67 for radiologists 1 and 2, respectively. -Compared to overall median score of quality of the image, the handheld machine images had a higher score for image quality. **Authors conclusion:** Handheld X-ray machine is easy to use and can potentially be carried to any area, produces X-ray images with quality that is comparable to digital X-ray machines routinely used in health facilities.	

Evidence Table : Effectiveness/ safety/ organisational/ economic implication
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Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
4. Odume B, Chukwu E, Fawole T, et al. Portable digital X-ray for TB pre-diagnosis screening in rural communities in Nigeria. Public Health Action. 2022;12(2):85-89.	Cross-sectional study **Aim:** To assess the usefulness of portable digital X-ray, the Delft-Light Backpack (DLB) for TB active case-finding (ACF) in hard-to-reach Niger Delta communities using the WHO 3B TB screening/diagnosis algorithm. **Methods:** -Focused on participant data in the community-based TB ACF pilot project conducted in hard-to-reach communities in the Niger Delta region of the South-South Region of Nigeria from December 2020 to May 2021. -Encompassed all hard-to-reach communities in Akwa Ibom and Cross River States, -These areas, characterized by poor geographical and healthcare access, were purposely selected from TB LON Region 2 of Nigeria, a region with seven states in Southern Nigeria.	III	-All consenting eligible clients in the hard-to-reach communities, screened irrespective of the presence or absence of respiratory/constitutional TB symptoms, along with consenting contacts of TB cases. -Exclusion criteria involved confirmed TB cases on treatment or follow-up, children under 4 years, and asymptomatic pregnant women. - A total of 8,230 clients (males: 47.2%, females: 52.8%) were screened for TB during the entire project: Akwa Ibom and Cross-River states contributed respectively 2,707 (32.9%) and 5,523 (67.1%) participants.	Portable digital Xray			**Results:** -8,230 participants (males: 47.2%, females: 52.8%) underwent TB screening and 1,140 (13.9%) presumptive TB cases were identified. -TB prevalence among all participants and among those with presumptive TB were respectively 1.2% and 8.6%. -number needed to screen was 84. -Among people with presumptive TB, the proportion of males and females with confirmed TB was respectively 12.0% and 5.6% ($P < 0.001$). **Authors conclusion:** TB screening using DLB X-ray during community-based ACF in hard-to-reach Niger Delta communities of Nigeria showed a high TB prevalence among participants. Nationwide deployment of the instrument in hard-to-reach areas is recommended.	

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4. Odume B, Chukwu E, Fawole T, et al. Portable digital X-ray for TB pre-diagnosis screening in rural communities in Nigeria. Public Health Action. 2022;12(2):85-89.	-The study population included all consenting eligible clients in the hard-to-reach communities, screened irrespective of the presence or absence of respiratory/constitutional TB symptoms, along with consenting contacts of TB cases. -Exclusion criteria involved confirmed TB cases on treatment or follow-up, children under 4 years, and asymptomatic pregnant women. -WHO 3B screening/diagnostic algorithm was applied, utilizing a mobile DLB team for each community outreach. -The primary outcome measure was the prevalence of TB cases among participants, with secondary measures including the proportion of TB cases among presumptive TB identified after DLB X-ray, the NNS to diagnose one person with active TB, and the NNT to identify a TB case.							

EvidenceTable : Effectiveness/ safety/ organisational/ economic implication
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Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
5. Qin ZZ, Barrett R, Del Mar Castro M, et al. Early user experience and lessons learned using ultra-portable digital X-ray with computer-aided detection (DXR-CAD) products: A qualitative study from the perspective of healthcare providers. PLoS One. 2023;18(2):e0277843**.**	Qualitative Study **Aim:** To uncover the acceptability, lessons learned and perceived limitations of ultraportable digital xray from the health provider perspective, to guide programmatic implementation. **Methods:** -Semi-structured interviews were conducted with project staff and healthcare workers at six pilot sites. -Transcripts were coded and analyzed using a framework approach. -Themes emerged were subsequently organized and presented using the Consolidated Framework for Implementation Research (CFIR).		26 interviewees with varying roles: supervisory, clinicians, radiographers, and radiologists.	Ultraportable digital x-ray systems			**Results:** -Participants recognized the portability as the main advantage -Limitations include: it involves several compromises on throughput, internet dependence, manoeuvrability, and stability, as well as suitability for patients with larger bodysizes. Complexity increases with interoperability between hardware and software, and between different electronic health information systems. Limited capacity to implement these technologies, especially due to the need for threshold selection, and lack of guidance on radiation protection suitable for ultraportable digital xray machines. -Respondents stressed the importance of having protected means of sharing patient medical data, as well as comprehensive support and warranty plans. **Authors' conclusion:** Study findings suggest that ultraportable digital xray system with CAD was overall well received to decentralise radiological assessment for TB, however, the improved portability involved programmatic compromises. The main barriers to uptake included insufficient capacity and lack of guidance on radiation protection suitable for UP DXR.	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
							guidance on radiation protection suitable for UP DXR.	

TECHNOLOGY REVIEW (MNI-HTA)

ULTRA-PORTABLE DIGITAL X-RAY SYSTEM FOR TB SCREENING

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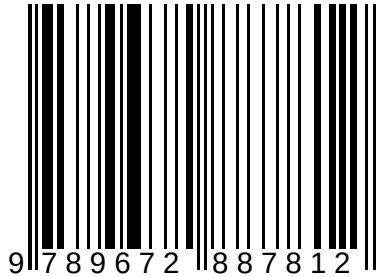

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