ULTRAPORTABLE DIGITAL X-RAY SYSTEM FOR TB SCREENING
Executive Summary

[Adapted from the report by DR. NUR FARHANA MOHAMAD]

Review Group Membership

MaHTAS Reviewer:
Dr Nur Farhana Mohamad
Dr Roza Sarimin
Dr Izzuna Mudla Mohamed Ghazali

External Reviewer:
Dr. Suzana Mohd Hashim
Dato' Dr. Mat Zuki bin Mat Jaeb
Dr. Norzaini Rose Mohd Zain
Datin Dr Zuhanis binti Abdul Hamid

For further information please contact:

Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya.

Tel: 603 8883 1248

Fax: 603 8883 1230

Available at the following website:
http://www.moh.gov.my

2023

Introduction

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.

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.

Organisational

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.

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].

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.