Original Article

Multicenter Implementation Evaluation of AI-Enabled Chest X-Ray Screening for Tuberculosis and Lung Nodules in Ethiopia

Amanuel Getachew[1], Eyob Woldeyohannes[1, 2], Amsalu Bekele[1, 2], Rahel Argaw Kebede[1, 2], Aschalew Worku[1, 2], Hanan Yusuf[1, 2], Amsalu Bitew[1, 2], Azmera Gissila[2], Hanna Damtew[2], Hawi Farris[2], Yonas Dendea[2], Wondwosen Ergete[2], Nathan Estifanos[3], Mekonnen Birhanu[4], Solomon Tessema[4], Selamawit Tilahun[1, 4], Million Mola[5], Eyob Kebede Etissa[1*]

Abstract

Introduction: Tuberculosis (TB) and lung cancer remain major public health burdens in low- and middle-income countries, including Ethiopia, where limited diagnostic and radiological capacity constrains early detection. Integrating artificial intelligence (AI) into chest X-ray (CXR) screening offers a scalable approach to enhance diagnostic accuracy, supporting timely patient management, and improving clinical outcomes. This study evaluated the prospective implementation of an AI decision-support tool (qXR) across three referral hospitals using the Consolidated Framework for Implementation Research (CFIR 2.0) and Proctor's implementation outcomes framework.

Methods: This prospective multicenter implementation study was conducted in three major referral hospitals in Addis Ababa, selected for their established TB and oncology services. Implementation determinants were mapped to CFIR 2.0 domains (Intervention Characteristics, Inner Setting, Outer Setting, Individuals, and Implementation Process). Implementation outcomes (Feasibility, Adoption/Concordance, Fidelity, Penetration, and Operational Challenges) were evaluated using descriptive statistics in SPSS version 25. Presumptive cases flagged by AI tool were reviewed by radiologists; concordant cases proceeded to bacteriological confirmation (GeneXpert) for TB or low-dose CT (LDCT) and Lung-RADS® evaluation for pulmonary nodules

Results: Out of the 23,916 collected chest radiographs, 21,692 were validly processed (Feasibility). The AI flagged 3,872 presumptive TB cases and 2,576 pulmonary nodules (392 high-risk, 2,184 low-risk). Radiologists reviewed 3,652 TB-flagged and 1,523 nodule-flagged cases, demonstrating low radiologist-AI concordance (Adoption): 12.1% (n=443) for TB and 11.3% (n=172) for nodules. Diagnostic cascade fidelity declined significantly during follow-up (Fidelity/Penetration): only 268 concordant TB cases underwent GeneXpert testing, yielding 24 confirmed TB cases, while 77 nodule cases underwent LDCT, yielding two confirmed primary lung cancers. Systemic determinants within the Inner and Outer Setting, including server downtime, X-ray equipment failure, GeneXpert cartridge shortages, and staff turnover, substantially curtailed downstream detection yield.

Conclusion: AI-enabled CXR is a practical screening tool, but sustainable impact requires human oversight, robust infrastructure, and strengthened health system support. Crucially, this necessitates seamless workflow integration, defined as the harmonization of the AI solution with existing digital radiography, DICOM protocols, Picture Archiving and Communication Systems (PACS), and routine radiologist reporting procedures. [*Ethiop. J. Health Dev.* 2026; 40(2)]

Keywords: Artificial Intelligence; Tuberculosis; Lung nodule; Qure.AI; Low- and middle-income countries

Introduction

Lung diseases, particularly tuberculosis (TB) and lung cancer, impose a substantial global health burden, with profound consequences for morbidity, mortality, and healthcare systems (1-3). In 2024, an estimated 10.7 million new tuberculosis cases were reported worldwide, disproportionately affecting low- and middle-income countries (LMICs), especially in the WHO regions of Africa, South-East Asia, and the Western Pacific (4). Missed detection and untreated cases are key factors driving continued transmission and hindering progress towards elimination goals (5). Regarding lung cancer, it is the most frequently diagnosed cancer, with 2.5 million new cases (12.4% of all cancers) and 1.8 million deaths worldwide (18.7% of all cancer-related fatalities) (6, 7), and remains the leading cause of cancer mortality (7, 8). If current trends persist, lung cancer is projected to cause 4.6 million new cases and 3.55 million deaths by 2050 (9).

Tuberculosis (TB) remains a major public health challenge in Ethiopia, while lung cancer is gaining recognition as a growing contributor to morbidity and mortality. However, timely diagnosis of both diseases is compromised by delayed presentation, a limited radiologist workforce, and increasing imaging demands. AI-assisted chest X-ray interpretation holds promise for prioritizing suspected TB and pulmonary nodules, potentially transforming diagnostic pathways within routine clinical care (1, 10, 11).

Early detection is essential to reduce the burden of tuberculosis (TB) and lung cancer. For TB, timely diagnosis using chest X-ray with bacteriological confirmation can help halt transmission, enable prompt

[1] Ethiopian Thoracic Society, Addis Ababa, Ethiopia
[2] College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia
[3] School of Public Health, Addis Ababa University, Addis Ababa, Ethiopia
[4] St. Paul Hospital Millennium Medical College, Addis Ababa, Ethiopia
[5] Kidus Petros Hospital, Addis Ababa, Ethiopia
***Corresponding Author Email: eyobke@gmail.com, Orcid: https://orcid.org/0000-0001-5880-3365**

treatment, and prevent long-term complications (1). For lung cancer, early-stage detection markedly improves survival compared with late-stage diagnosis, and screening programs using low-dose CT have demonstrated significant reductions in mortality among high-risk populations (8, 12).

Chest X-ray (CXR) remains one of the most widely accessible tools for large-scale screening in resource-limited settings. However, its diagnostic accuracy is constrained by inter-observer variability and a shortage of trained radiologists, often leading to missed or delayed diagnoses (13-15). Artificial intelligence (AI), particularly deep learning algorithms, has demonstrated significant potential to address these limitations. AI-enabled CXR systems exhibit high sensitivity and specificity for detecting tuberculosis and lung nodules, occasionally even surpassing the performance of expert radiologists (16, 17).

Extensive research has established the diagnostic potential of artificial intelligence (AI)-enabled chest X-ray (CXR) analysis for both tuberculosis (TB) and pulmonary nodules. For TB screening, AI algorithms consistently demonstrated sensitivity and specificity levels that meet or approach World Health Organization (WHO) benchmarks, supporting their potential utility as effective triage tools in high-burden environments (18-21). Similarly, in the context of pulmonary nodules, AI integration has been shown to enhance detection rates, decrease diagnostic errors, and facilitate earlier identification of potential malignancies (22-24). Collectively, this evidence provides a basis for examining the operational integration of these technologies into routine clinical workflows.

In LMICs, where advanced imaging modalities such as computed tomography (CT) are often inaccessible, AI-enabled CXR screening provides a scalable and cost-effective strategy for early detection of pulmonary diseases (2). This approach aligns with global health priorities by leveraging existing infrastructure, supporting diagnostic assessment, and expanding access to timely care (1, 2, 16).

The objective of this paper is to evaluate the implementation of an artificial intelligence (AI)-enabled chest X-ray screening system for tuberculosis (TB) and pulmonary nodules in three public referral hospitals in Addis Ababa, Ethiopia (25). We structured our evaluation using two complementary implementation science frameworks:

1. Consolidated Framework for Implementation Research (CFIR 2.0): To assess contextual determinants (barriers and facilitators) across five core domains: Intervention Characteristics, Outer Setting, Inner Setting, Individuals, and Implementation Process.

2. Proctor's Conceptual Framework for Implementation Outcomes: To operationalize success metrics, specifically evaluating Feasibility, Adoption/Concordance, Fidelity, Penetration, and Sustainability.

Methods and Material

Theoretical Frameworks

CFIR 2.0 Mapping

Contextual factors affecting software deployment, radiologist engagement, and patient diagnostic cascades were categorized into the five CFIR 2.0 domains:

Intervention Characteristics: Adaptability, evidence base, design quality, relative advantage, and software complexity of qXR.

Outer Setting: Critical external factors, including national health strategies, supply chain continuity for laboratory consumables, and external data governance policies.

Inner Setting: Structural characteristics, ICT infrastructure readiness, PACS/DICOM compatibility, and departmental communication workflows across participating tertiary centers.

Individuals: Roles, perceptions, staff turnover, and alignment among radiologists, radiographers, IT personnel, and clinical staff.

Implementation Process: Execution of multi-phase planning, pilot testing, local championing, and continuous quality-monitoring meetings.

Implementation Outcomes (26)

Feasibility: Proportion of total acquired CXR images successfully transmitted and analyzed by the AI cloud platform within routine workflows.

Adoption & Concordance: Degree of alignment between AI automated screening flags and senior radiologist interpretations.

Fidelity & Penetration: Rate of patient adherence and completion of protocol-mandated secondary diagnostic investigations (GeneXpert for TB; Low-Dose CT and biopsy for pulmonary nodules) among concordant cases.

Operational Challenges: Determinants causing service interruptions, delays, or dropouts across the diagnostic continuum.

Study Area and Context

Three hospitals in Addis Ababa were purposefully selected as national referral and training centers with sustained engagement in TB care and/or lung cancer management. Tikur Anbessa Specialized Hospital (TASH) is Ethiopia's largest tertiary referral and teaching hospital (>700 beds), with an ISO 15189–accredited laboratory, bronchoscopy services, and a recently launched nuclear medicine unit including SPECT/CT and a linear accelerator (27-30). St. Paul's Hospital Millennium Medical College (SPHMMC) is one of Ethiopia's largest public teaching hospitals (>700 beds), with an on-site microbiology/TB laboratory providing smear microscopy, GeneXpert, culture, and a comprehensive oncology center under development (31, 32). Kidus Petros Hospital is Ethiopia's national TB referral hospital (300 beds), the

country's first DR-TB treatment site, and remains a flagship drug-resistant TB initiating center (33-35).

Study Design and Population

A prospective, multicenter implementation study design was employed. The study population comprised all consecutive adult patients (≥18 years) presenting for routine chest radiography at participating imaging units during the implementation period.

Inclusion Criteria: Adults (≥18 years) undergoing CXR with AI-flagged abnormalities confirmed by radiologist review.

Exclusion Criteria: Known active TB or diagnosed lung cancer under current treatment, pregnancy, medical contraindications to CT imaging, or refusal of consent.

Implementation Process Phasing

Implementation was structured into four distinct, sequential CFIR-aligned phases:

1. Pre-Implementation & Infrastructure Assessment: A standardized baseline assessment of facility hardware, operating systems, network bandwidth (minimum requirement: ≥10 Mbps), and staff allocation was conducted. Institutional Memoranda of Understanding (MoUs) with the Ethiopian Thoracic Society (ETS) and legal Data Use Agreements (DUAs) with technology providers were executed (Annex 1).
2. System Deployment & Integration: qXR (Qure.ai, Class IIb EU MDR certified) was integrated into existing digital radiography pathways (FDR Smart X, GXR-68s, FCR Prima T2). Workflow setups varied by site: manual DICOM push at TASH, automated DICOM push at SPHMMC, and a dedicated local gateway server at Kidus Petros. The AI system functioned strictly as a triage decision-support tool.
3. Pilot Phase: Deployment testing was conducted using 50–100 CXRs per site to refine network throughput, DICOM metadata handling, and de-identification pipelines before clinical rollout.
4. Full Implementation & Quality Improvement: Multi-specialty clinical execution was supported by site-level implementation coordinators, weekly multidisciplinary discordance reviews, and standardized monitoring tools (QTrack and KoBoToolbox).

Operational definitions

- Presumptive tuberculosis refers to chest radiographs identified by qXR as containing radiographic abnormalities suggestive of pulmonary tuberculosis requiring radiologist review.
- High-risk pulmonary nodules refer to nodules classified by the qXR Lung Nodule Malignancy Score above the predefined threshold, indicating an increased probability of malignancy and requiring further evaluation with low-dose computed tomography (LDCT).
- Low-risk pulmonary nodules refer to nodules below the predefined malignancy threshold but still requiring radiologist review according to the implementation protocol.
- TB-only cases refer to examinations flagged for tuberculosis without concurrent pulmonary nodules.
- Nodule-only cases refer to examinations flagged for pulmonary nodules without suspected tuberculosis.

Patient Pathway

Patients entered the pathway through cough clinics, general outpatient departments (OPD), specialized OPDs (HIVand NCD), or inpatient wards. The AI software automatically identified radiographic findings suggestive of tuberculosis, including cavities, consolidation, fibrosis, and pleural effusion as well as pulmonary nodules. Nodules were further stratified into low- and high-risk categories using the Lung Nodule Malignancy Score.

Radiologists reviewed all AI-flagged cases, and only concordant cases proceeded to further investigation. TB cases underwent GeneXpert testing per national algorithm; those with negative GeneXpert but strong clinical suspicion could be treated empirically. Patients with radiologist-confirmed pulmonary nodules who fulfilled eligibility criteria were referred for LDCT according to the study protocol, classified using Lung-RADS® 2022, and either followed up at 3–12 months or referred for biopsy. In addition, chest radiographs acquired during the three months preceding implementation at TASH were retrospectively reviewed for pulmonary nodule detection.

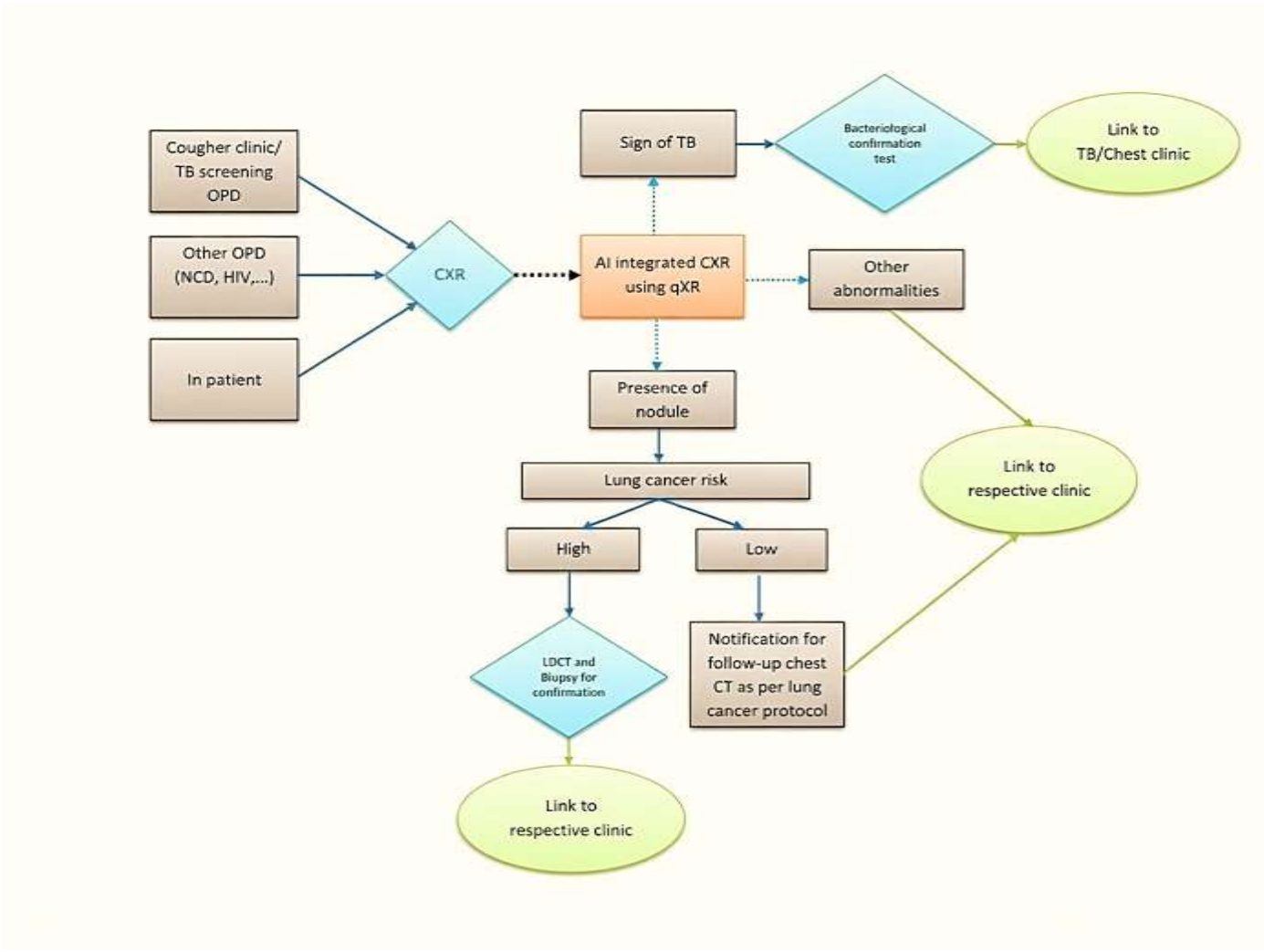

Figure 1: Patient pathway

Statistical Analysis

Quantitative implementation indicators, descriptive frequencies, percentages, and diagnostic yield metrics were calculated using SPSS version 25. Outcome metrics were mapped onto Proctor's taxonomy. Formal inferential hypothesis testing was not performed, as the study aimed to characterize implementation processes, feasibility metrics, and operational determinants.

Ethical consideration

The study protocol was approved by the Institutional Review Boards of Tikur Anbessa Specialized Hospital, St. Paul's Hospital Millennium Medical College, and Kidus Petros Hospital, with administrative clearance obtained from all participating facilities. Verbal informed consent was obtained from all patients or their legally authorized representatives. All patient data and radiological images were de-identified at the point of care using unique study codes before cloud transfer and analysis. Data were stored on secure, password-protected servers accessible only to authorized personnel. The study was conducted in accordance with the Declaration of Helsinki and national ethical guidelines.

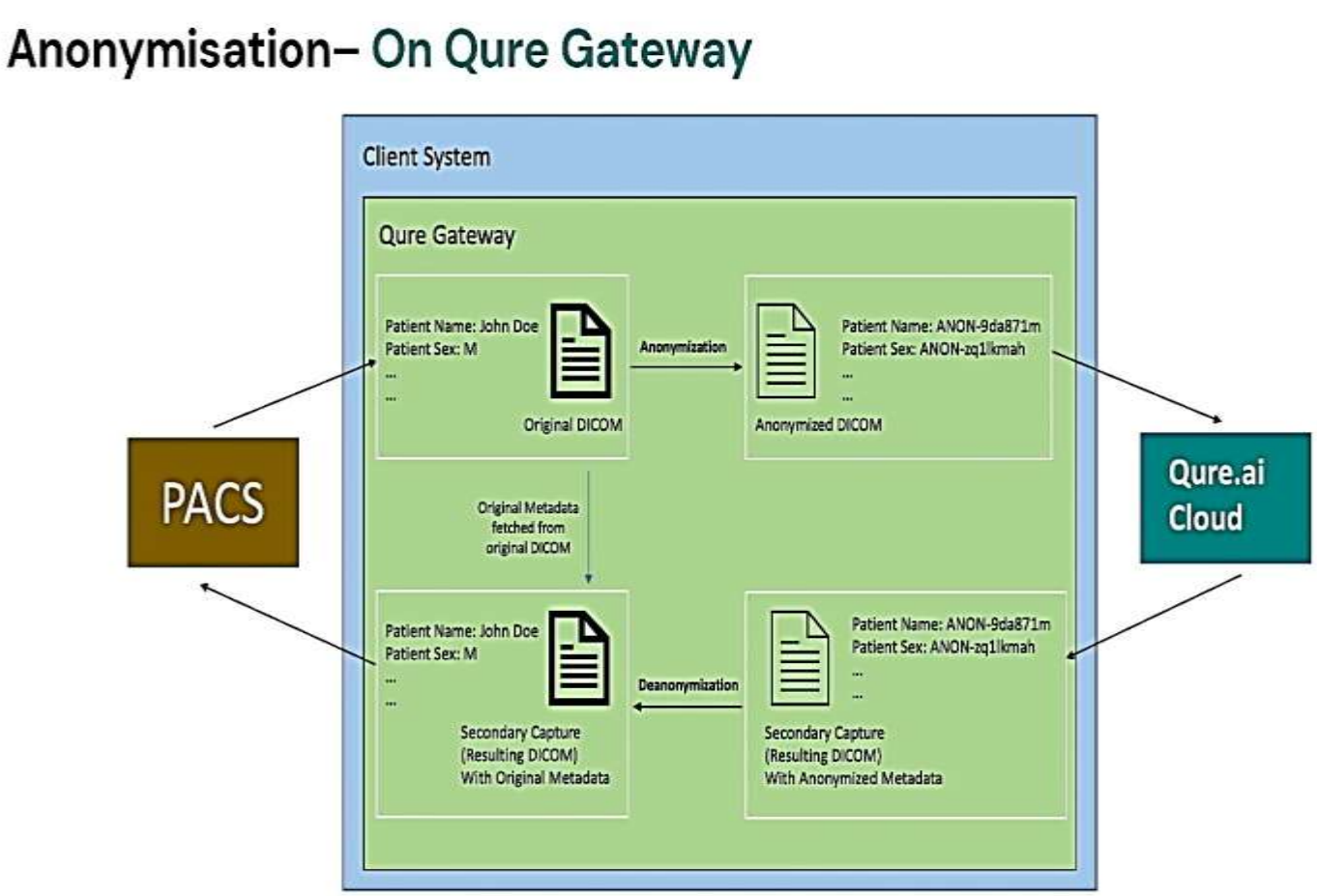

Figure 2: Data anonymization

Results

Implementation Outcome 1: Feasibility and Technical Performance

During the evaluation period, 23,916 DICOM chest radiographs were generated across the three hospital sites. Of these, 2,224 (9.3%) were excluded due to corrupted DICOM header metadata, incorrect modality tags, sub-optimal projection angles, or severe image-resolution artifacts. A total of 21,692 valid CXRs were successfully uploaded to and analyzed by the qXR AI platform (Technical Feasibility Rate: 90.7%). Routine processing speed averaged <1 minute per image during periods of stable network connectivity. The AI system identified 15,244 (70.3%) scans as negative for targeted abnormalities; these patients proceeded directly through routine standard-of-care pathways. (Fig 3)

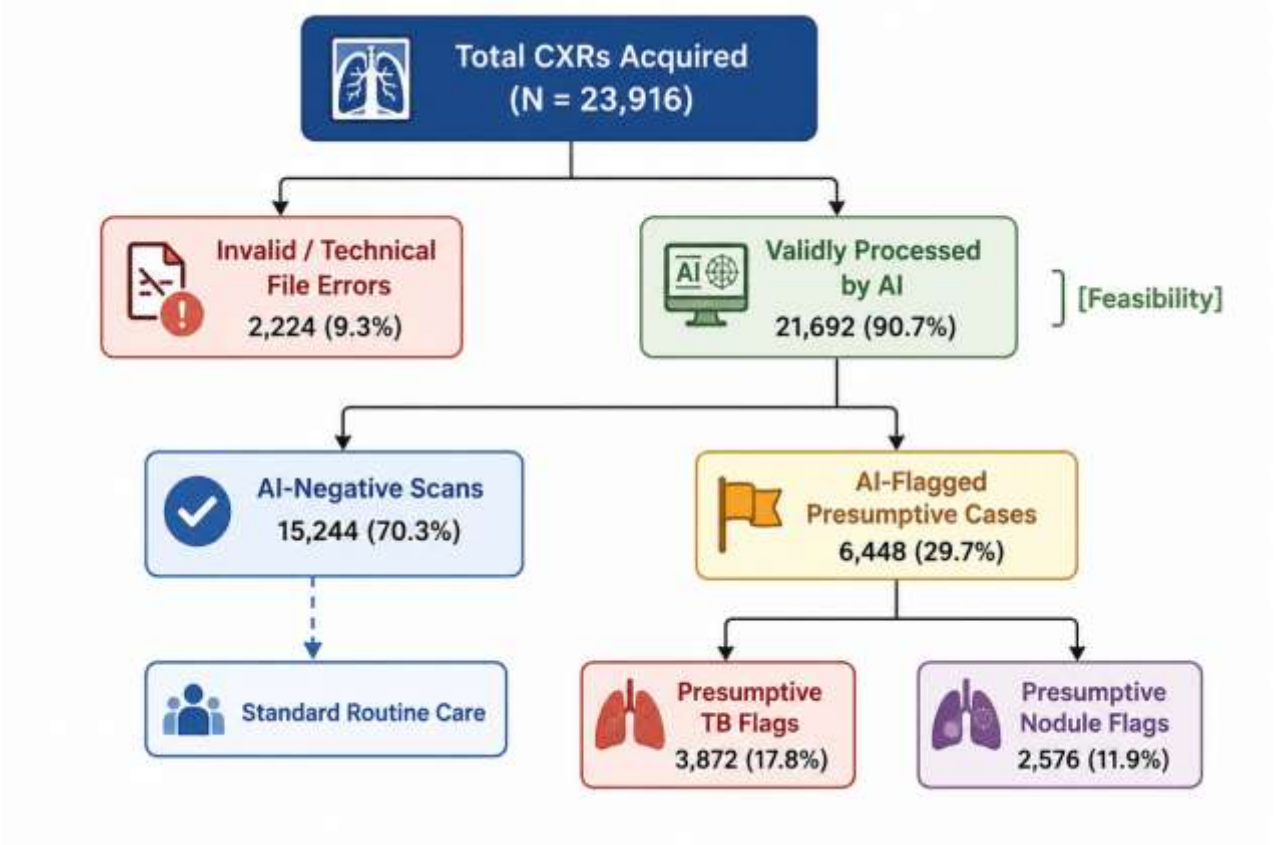

Figure 3: Implementation cascade of AI-Enabled Chest X-Ray Analysis

Site-Specific Screening Outputs

Tikur Anbessa Specialized Hospital (TASH): A total of 7,606 CXRs were processed. The AI system flagged 797 pulmonary nodules (156 high-risk, 641 low-risk), 391 TB-only cases, 322 nodule-only cases, and 540 dual-flagged cases (TB + pulmonary nodule).

St. Paul's Hospital Millennium Medical College (SPHMMC): A total of 8,901 CXRs were processed. The AI system categorized 5,184 (58.2%) as abnormal and 3,717 (41.8%) as normal. Flagged findings included 1,051 pulmonary nodules (160 high-risk, 891 low-risk) and 1,882 presumptive TB cases (1,221 TB-only; 661 dual-flagged).

Kidus Petros Hospital: A total of 5,185 CXRs were processed. The AI system categorized 2,967 (57.2%) as abnormal and 2,218 (42.8%) as normal. Flagged findings included 728 nodules (76 high-risk, 652 low-risk) and 1,058 presumptive TB cases (606 TB-only; 451 dual-flagged).

Implementation Outcome 2: Adoption and AI–Radiologist Concordance

Adoption was evaluated by measuring radiologist review completion rates and diagnostic agreement (concordance) between radiologist interpretations and automated AI automated flags. (Table 1)

Table 1: AI versus Radiologist concordance rates

Diagnostic category	AI-flagged, n	Radiologist reviewed, n (%)	Aligned/Concordant, n (%)
Presumptive TB	3,872	3,652 (94.3%)	443 (12.1%)
Pulmonary nodules	2,576	1,523 (59.1%)	172 (11.3%)
Total	**6,448**	**5,175 (80.3%)**	**615 (11.9%)**

Tuberculosis Triage:

Senior radiologists completed reviews for 3,652 out of 3,872 AI flagged TB cases (94.3% review adoption). Radiologists concurred with the AI flags in only 443 cases, corresponding to a concordance rate of 12.1%. Radiologists did not confirm the AI-flagged finding in 3,209 cases (87.9%), citing algorithmic overcalling of prominent vascular markings and non-specific cardiac shadows (Table 1).

Pulmonary Nodule Triage:

Senior radiologists completed reviews for 1,523 out of 2,576 nodule-flagged cases (59.1% review adoption). Radiologists confirmed true nodules in 172 cases, corresponding to a concordance rate of 11.3%. Misclassifications were primarily attributed to nipple shadows, rib crossings, and calcified granulomas (Table1)

Implementation Outcome 3: Diagnostic Cascade Fidelity and Case Detection

Table 2: Diagnostic cascade attrition

Stage	TB pathway	Nodule pathway
AI flagged	3,872	2,576
Radiologist reviewed	3,652	1,523
AI–radiologist concordant	443	172
Diagnostic evaluation completed	268 GeneXpert	77 LDCT
Further diagnostic procedure	—	3 biopsies
Confirmed outcome	17 microbiologically confirmed TB	2 malignancies

Tuberculosis Yield: Among 443 concordant TB cases, only 268 patients (60.5% cascade fidelity) completed secondary bacteriological evaluation via GeneXpert testing. GeneXpert confirmed microbiological TB in 17 patients. An additional seven patients were initiated on anti-TB therapy based on strong clinical/radiological features, bringing the total yield to 24 detected TB cases. (Table 2)

Pulmonary Nodule Yield: Among 172 concordant nodule cases, 77 patients (44.8% cascade fidelity) completed follow-up low-dose CT (LDCT) imaging. (Table 2)

Table 3: Distribution of Lung-RADS Categories and Clinical Outcomes in Patients Undergoing LDCT Evaluation (n=76)

Lung-RADS Category	Frequency (n)	Percentage (%)
0	27	35.5
1	**21**	**27.6**
2	**8**	**10.5**
3	**8**	**10.5**
4A	**4**	**5.3**
4B	**5**	**6.6**
4X	**3**	**3.9**
Total	**76**	**100**

Tissue biopsies were completed in three high-risk patients. Histopathological examination confirmed 2 primary lung cancer malignancies (one Stage II adenocarcinoma and one Stage IV non-small cell carcinoma).

Implementation Determinants (CFIR 2.0 Mapping)

Table 4: CFIR 2.0 Determinants and Their Operational Impact During Implementation

CFIR 2.0 domain	Observed determinants	Operational impact
Intervention Characteristics	Rapid AI analysis (<1 min); non-calibrated thresholds	Efficient image processing, but contributed to a high false-positive rate and low AI–radiologist concordance
Outer Setting	GeneXpert cartridge shortages; cloud data-governance requirements; CT scanner downtime	Delayed or limited confirmatory testing and follow-up of AI-flagged cases
Inner Setting	Extended server downtime (2 months at TASH); PACS integration gaps; X-ray machine breakdowns	Interrupted AI workflow, reduced availability of images for AI analysis, and delayed implementation.
Individuals Involved	Reader fatigue; staff turnover at Kidus Petros; radiologist skepticism related to low concordance	Reduced consistency of AI use and increased reliance on conventional radiologist interpretation
Implementation Process	Effective pilot testing; robust weekly monitoring; loss to follow-up after AI triage	Facilitated early identification and resolution of implementation problems, but incomplete downstream follow-up limited the diagnostic cascade

Discussion

This large-scale implementation of an AI-enabled chest X-ray decision-support system for tuberculosis (TB) and pulmonary nodule detection across three Ethiopian referral hospitals demonstrated the technical practicality of integrating qXR into routine radiology services. By structuring our evaluation using CFIR 2.0 and Proctor's implementation outcomes, we move beyond basic diagnostic accuracy to provide a comprehensive analysis of health system integration. The system was successfully deployed within existing hospital infrastructure, enabling routine DICOM-based image processing, stable operation under most conditions, and incorporation of AI outputs into radiologists' daily workflow. The implementation also demonstrated operational value by providing rapid image processing, facilitating prioritization of AI-flagged examinations for radiologist review, and supporting standardized referral pathways for confirmatory investigations. These findings demonstrate the feasibility of implementing AI-enabled radiology within routine hospital workflows, while also highlighting important health-system constraints

The system processed nearly 24,000 CXRs with an average processing time off less than one minute, supporting its potential utility as a rapid screening tool in high-volume, resource-limited settings. The dual-disease approach is particularly relevant, as it concurrently addresses TB (the world's leading infectious killer) and lung cancer, a leading cause of non-communicable disease mortality; this strategy may increase the public health utility of a single, widely available imaging platform (36, 37). Critically, the detection of 24 new TB cases and two primary lung cancers (one at Stage II) highlights the potential of AI-assisted screening to facilitate identification of cases that might otherwise be missed or diagnosed late, complementing evidence from other settings (38).

However, AI–radiologist agreement was limited. Of 3,872 AI-flagged TB cases, only 443 (12.1%) were considered concordant with radiologist interpretations. This low concordance increased the radiologist review burden and was compounded by limited GeneXpert cartridge supply, a challenge consistent with findings from other high-burden settings (21, 39). Observed misclassifications included cardiac shadows being flagged as TB and nipple shadows and calcified granulomas being flagged as pulmonary nodules, suggesting that local radiographic characteristics may affect AI performance in this setting. This underscores the importance of evaluating and, where appropriate, calibrating AI thresholds for specific patient populations and clinical contexts (19, 40).

Patient loss to follow-up and incomplete diagnostic cascades substantially reduced the case detection yield. Although AI identified 3,872 potential TB cases and 2,641 pulmonary nodules, only 268 and 77 patients, respectively, completed the planned secondary investigations. Systemic barriers, including GeneXpert shortages, CT service interruptions, and the need for return visits, diminished the downstream impact of AI-assisted triage. This experience mirrors the broader lesson that technology must be paired with robust linkage-to-care pathways to translate screening outputs into clinical benefit (10, 41, 42).

Implementation challenges further reflected broader systemic fragilities in digital health adoption within LMICs. Prolonged AI server downtime and frequent X-ray machine failures illustrated how infrastructural vulnerability disrupts continuity (9). Human resource barriers, including staff turnover and initial resistance among radiographers, IT staff, and radiologists, echo well-documented challenges that require continuous training, sensitization, stakeholder engagement, and demonstration of workflow benefits to overcome (20).

Comparison with global experience reinforces these lessons. AI tools such as qXR and CAD4TB have demonstrated high sensitivity and feasibility in studies from India, South Africa, and Bangladesh, yet have also faced similar limitations related to specificity, confirmatory testing bottlenecks, and downstream diagnostic capacity (20, 43, 44). Systematic reviews emphasize that much of the existing evidence comes from retrospective or controlled studies, with relatively limited data from real-world perspective implementations (19). Our Ethiopian experience contributes to this prospective evidence base, particularly regarding the implementation of integrated dual-disease screening for TB and Pulmonary nodules.

From a clinical practice perspective, our findings suggest that AI-enabled chest X-ray interpretation can serve as a practical decision-support tool to assist radiologists in prioritizing patients with suspected tuberculosis and pulmonary nodules, particularly in high-volume, resource-constrained settings where radiology expertise is limited. At the health system level, successful implementation requires more than AI deployment alone; it depends on reliable digital infrastructure, uninterrupted access to confirmatory diagnostic services, standardized referral pathways, and continuous workforce training. The implementation process and the findings provide important evidence for policymakers and hospital administrators considering the scale-up of AI-assisted radiology services, emphasizing that investments in health-system readiness are essential to realize the potential benefits of AI in routine clinical care.

From a policy perspective, this initiative aligns with Ethiopia's National TB Strategic Plan (2021–2025) and National Cancer Control Plan, both of which emphasize early detection, digital innovations, and capacity building (10, 45). Dual-disease screening represents a pragmatic method to maximize the utility of routine CXRs and is consistent with international recommendations to leverage existing infrastructure for early detection of lung cancer (46). However, achieving sustainability will require consideration of AI-related costs within national and instructional budgets, diversified financing models, and integration of the technology into existing hospital infrastructure (47-49). Prerequisites for scalability include reliable imaging and IT infrastructure, secure supply chains for confirmatory tests, appropriate local evaluation and calibration of AI thresholds, comprehensive workforce training, and robust stakeholder engagement (19, 20).

Limitation of the study

This implementation study has several limitations that should be considered when interpreting the findings. First, it was designed as a prospective multicenter implementation study to evaluate the real-world integration of an AI-enabled chest X-ray system into routine radiology services rather than as a diagnostic accuracy or validation study. Consequently, AI-negative chest radiographs were not systematically verified using an independent reference standard, precluding estimation of sensitivity, specificity, negative predictive value, and overall diagnostic accuracy. Furthermore, only a subset of AI-positive cases completed radiologist review and confirmatory investigations, introducing the potential for verification bias. Operational challenges, including temporary AI server downtime, X-ray equipment failures, shortages of GeneXpert cartridges, staff turnover, and patient loss to follow-up, affected completion of the implementation pathway and may have influenced the observed case detection. In addition, the study was conducted in three tertiary referral hospitals with established digital radiology infrastructure, which may limit the generalizability of the findings to lower-level health facilities or settings with more limited resources. Finally, formal evaluation of key implementation outcomes, such as acceptability, adoption, fidelity, and sustainability, was beyond the scope of this quantitative study and should be explored in future mixed-methods implementation research.

Conclusion

AI-enabled CXR screening demonstrated high technical feasibility and operational value in routine clinical practice; however, its real-world impact was constrained by limited AI–radiologist concordance, infrastructure fragility, diagnostic bottlenecks, and sustainability challenges. AI should be positioned as a decision-support and triage aid to augment, rather than replace, radiologist expertise. Sustainable implementation requires human oversight, robust digital and diagnostic infrastructure, strengthened health system capacity, and seamless workflow integration through harmonization with existing digital radiography systems, DICOM protocols, Picture Archiving and Communication Systems (PACS), and routine radiologist reporting workflows. Long-term financing and sustained health-system support will be essential to achieve meaningful and sustainable public health impact.

References

1. World Health Organization. (2023). Global tuberculosis report 2023. Geneva: World Health Organization. Available at: https://www.who.int/teams/global-programme-on-tuberculosis-and-lung-health/tb-reports/global-tuberculosis-report-2023.
2. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021;71(3):209-49.
3. International Agency for Research on Cancer (IARC). (2024). Lung cancer fact sheet. Lyon: IARC/WHO. Available at: https://www.iarc.who.int/cancer-type/lung-cancer.
4. Walzl G, Goletti D, Zumla A. The Global Epidemiology of Tuberculosis: Burden, Trends, and Determinants. Cold Spring Harb Perspect Med. 2026.
5. Le Monde. 2024. “Tuberculosis: Millions of Undiagnosed Cases Jeopardize Control Efforts.” Le Monde. March 25, 2024. https://www.lemonde.fr/en/environment/article/2024/03/25/tuberculosis-millions-of-undiagnosed-cases-jeopardize-control-efforts_6652894_114.html. [
6. World Health Organization. (2024, February 1). Global cancer burden growing, amidst mounting need for services. https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services [
7. International Agency for Research on Cancer. (n.d.). Lung cancer. World Health Organization. Retrieved August 30, 2025, from https://www.iarc.who.int/cancer-type/lung-cancer/ [
8. Union for International Cancer Control. (n.d.). Lung cancer. Retrieved August 30, 2025, from https://www.uicc.org/what-we-do/thematic-areas/lung-cancer().
9. Zhou J, Xu Y, Liu J, Feng L, Yu J, Chen D. Global burden of lung cancer in 2022 and projections to 2050: Incidence and mortality estimates from GLOBOCAN. Cancer Epidemiol. 2024;93:102693.
10. Ethiopia Ministry of Health. National Tuberculosis Strategic Plan 2021–2025. Addis Ababa: MoH; 2021.
11. International Agency for Research on Cancer. Global Cancer Observatory: Ethiopia fact sheet. Lyon: International Agency for Research on Cancer; 2024.
12. National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011;365:395–409.
13. World Health Organization. (2016). Chest radiography in tuberculosis detection: Summary of current WHO recommendations and guidance on programmatic approaches (WHO/HTM/TB/2016.20). Geneva: World Health Organization. Retrieved from WHO IRIS.
14. Kim J, Kim KH. Role of chest radiographs in early lung cancer detection. Transl Lung Cancer Res. 2020;9(3):522-31.
15. Ait Nasser A, Akhloufi MA. A Review of Recent Advances in Deep Learning Models for Chest Disease Detection Using Radiography. Diagnostics. 2023;13(1):159.
16. Lakhani P, Sundaram B. Deep Learning at Chest Radiography: Automated Classification of Pulmonary Tuberculosis by Using

Convolutional Neural Networks. Radiology. 2017;284(2):574-82.
17. Showkatian E, Salehi M, Ghaffari H, Reiazi R, Sadighi N. Deep learning-based automatic detection of tuberculosis disease in chest X-ray images. Pol J Radiol. 2022;87:e118-e24.
18. World Health Organization. WHO consolidated guidelines on tuberculosis: module 2: screening: systematic screening for tuberculosis disease. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240022676.
19. Harris M, Qi A, Jeagal L, Torabi N, Menzies D, Korobitsyn A, et al. A systematic review of the diagnostic accuracy of artificial intelligence-based computer programs to analyze chest x-rays for pulmonary tuberculosis. PLoS One. 2019;14(9):e0221339.
20. Qin ZZ, Ahmed S, Sarker MS, Paul K, Adel ASS, Naheyan T, et al. Tuberculosis detection from chest x-rays for triaging in a high tuberculosis-burden setting: an evaluation of five artificial intelligence algorithms. Lancet Digit Health. 2021;3(9):e543-e54.
21. Han ZL, Zhang YY, Li J, Gao S, Liu W, Yang WJ, et al. A systematic review and meta-analysis of artificial intelligence software for tuberculosis diagnosis using chest X-ray imaging. J Thorac Dis. 2025;17(5):3223-37.
22. Ardila D, Kiraly AP, Bharadwaj S, Choi B, Reicher JJ, Peng L, et al. End-to-end lung cancer screening with three-dimensional deep learning on low-dose chest computed tomography. Nat Med. 2019;25(6):954-61.
23. Nam JG, Park S, Hwang EJ, Lee JH, Jin KN, Lim KY, et al. Development and Validation of Deep Learning-based Automatic Detection Algorithm for Malignant Pulmonary Nodules on Chest Radiographs. Radiology. 2019;290(1):218-28.
24. Hwang EJ, Park S, Jin KN, Kim JI, Choi SY, Lee JH, et al. Development and Validation of a Deep Learning-Based Automated Detection Algorithm for Major Thoracic Diseases on Chest Radiographs. JAMA Netw Open. 2019;2(3):e191095.
25. Vijayan S, Nair AM, Dominic N, Chiramal JA, Pawar S, Goswami L. Artificial intelligence-assisted chest X-ray for tuberculosis case finding in low- and middle-income countries: implementation experiences and impact. BJR Open. 2026;8(1):tzag007.
26. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.
27. Zeleke TA, Nora WT, Denberu MT, Adal O, Demisse LB. Length of stay and associated factors among pediatric patients in the pediatric emergency unit of the Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. BMC Emergency Medicine. 2024;24(1):170.
28. Schluger NW. Dr. Neil Schluger marks milestone in treating pulmonary disease in East Africa. New York Medical College; Available from: https://www.nymc.edu/newsroom/stories/dr-neil-schluger-milestone-in-treating-pulmonary-disease-in-east-africa.php.
29. Ethiopian Accreditation Service. Accreditation certificate: Addis Ababa University College of Health Sciences Tikur Anbessa Specialized Hospital Laboratory [certificate]. Addis Ababa: EAS; 2023. Available from: https://eas-eth.org/wp-content/uploads/2023/11/Black-Lion-Hospital-min.pdf.
30. International Atomic Energy Agency. IAEA holds Rays of Hope forum to increase access to cancer care. Vienna: IAEA; 2025 Jul 1.
31. International Atomic Energy Agency. Ethiopia is expanding access to radiation medicine and earlier detection of adult and childhood cancer. News; 26 Mar 2024. Vienna: IAEA; 2024.
32. Das M. Expansion of radiotherapy access in Ethiopia. The Lancet Oncology. 2024;25(5):542.
33. Ministry of Health. St. Peter's TB Specialized Hospital. Addis Ababa: Ministry of Health; 2024. Available from: https://www.moh.gov.et/index.php/en/St_Peter_TB_Specialized_Hospital?language_content_entity=en.
34. Beshaw MA, Siraj EM, Demass TB, Lakew AM. Chest x-ray features and their associated factors among rifampicin/multi-drug-resistant tuberculosis patients in drug-resistant tuberculosis treatment initiating centers in Addis Ababa, Ethiopia: a retrospective study. BMC Infectious Diseases. 2025;25(1):974.
35. Tusho AR, Mokoboto-Zwane ST. Treatment completion of drug-resistant tuberculosis in Ethiopia: A perspective from healthcare users. PLOS Glob Public Health. 2025;5(2):e0004110.
36. Ahmad K, Rehman HU, Shah B, Ali F, Hussain I. Dual-model approach for accurate chest disease detection using GViT and swin transformer V2. Scientific Reports. 2025;15(1):31717.
37. The U.S. CDAS “Utilization of Deep Learning Architectures for the Automated Detection of Pulmonary tumor and Tuberculosis in Thoracic Radiographic Imaging” describes efforts to build a multimodal deep-learning model to discriminate TB and lung cancer from chest imaging.
38. Codlin AJ, Dao T, Trinh P, Nguyen B, Pham H, Le L, et al. 607P Results from a feasibility pilot for integrated TB & lung cancer screening in Vietnam. Annals of Oncology. 2024;35:S1620-S1.

39. 39. Marquez N, Carpio EJ, Santiago MR, Calderon J, Orillaza-Chi R, Salanap SS, et al. Performance of chest X-ray with computer-aided detection powered by deep learning-based artificial intelligence for tuberculosis presumptive identification during case finding in the Philippines. BMC Glob Public Health. 2025;3(1):74.
40. Kazemzadeh S, Kiraly AP, Nabulsi Z, Sanjase N, Maimbolwa M, Shuma B, et al. Prospective Multi-Site Validation of AI to Detect Tuberculosis and Chest X-Ray Abnormalities. Nejm ai. 2024;1(10).
41. Qure.ai. AI-Driven Chest X-Ray Tool Boosts Lung Cancer Detection [Internet]. Qure.ai; 2025 Mar 31. Available from: https://www.qure.ai/news_press_coverages/AI-Driven-Chest-X-Ray-Tool-Boosts-Lung-Cancer-Detection.
42. Akhter Y, Singh R, Vatsa M. AI-based radiodiagnosis using chest X-rays: A review. Front Big Data. 2023;6:1120989.
43. Codlin AJ, Dao TP, Vo LNQ, Forse RJ, Van Truong V, Dang HM, et al. Independent evaluation of 12 artificial intelligence solutions for the detection of tuberculosis. Sci Rep. 2021;11(1):23895.
44. Qin ZZ, Van der Walt M, Moyo S, Ismail F, Maribe P, Denkinger CM, et al. Computer-aided detection of tuberculosis from chest radiographs in a tuberculosis prevalence survey in South Africa: external validation and modelled impacts of commercially available artificial intelligence software. Lancet Digit Health. 2024;6(9):e605-e13.
45. Ethiopia Ministry of Health. National Cancer Control Plan of Ethiopia 2016–2020. Addis Ababa: MoH; 2016.
46. International Agency for Research on Cancer. Cancer screening in five continents: lung cancer screening recommendations. Lyon: IARC; 2020.
47. Kagujje M, Kerkhoff AD, Nteeni M, Dunn I, Mateyo K, Muyoyeta M. The Performance of Computer-Aided Detection Digital Chest X-ray Reading Technologies for Triage of Active Tuberculosis Among Persons With a History of Previous Tuberculosis. Clin Infect Dis. 2023;76(3):e894-e901.
48. WHO digital health/AI governance guidance stresses that for sustainability, AI and digital tools should be integrated into national health budgets and policy frameworks, not remain donor-dependent pilots.
49. Alami H, Rivard L, Lehoux P, Hoffman SJ, Cadeddu SBM, Savoldelli M, et al. Artificial intelligence in health care: laying the Foundation for Responsible, sustainable, and inclusive innovation in low- and middle-income countries. Globalization and Health. 2020;16(1):52.

Annex

DATA USE AGREEMENT (DUA)

This Data Use Agreement ("**Agreement**") is entered into by and between **Ethiopian Thoracic Society**, with a place of business at Tracon Tower, second floor, Churchill Ave, Addis Ababa, Ethiopia (hereafter referred to as "**Data Provider**") and **Qure.ai Technologies Private Limited** with a place of business at 6th Floor, Wing E, Times Square, Andheri-Kurla Road, Marol, Andheri (East), Mumbai - 400059, Maharashtra (hereinafter referred to as "**Recipient**").

RECITALS

Data Provider and Recipient desire to set forth the terms and conditions under which Data Provider will disclose to Recipient de-identified data relating to the IRB titled **Evaluation of the performance of Artificial Intelligence enabled Chest X-Ray interpretation to detect Tuberculosis and lung nodule in Ethiopia project** (the "**Data Set**") for the limited use described in this Agreement.

In consideration of the mutual promises below, and Data Provider's disclosure of the Data Set to Recipient under this Agreement, the parties agree as follows:

ARTICLE I
RECIPIENT'S OBLIGATIONS

Recipient may use the De-Identified Data Set, subject to all applicable laws/regulations, only in relating to the **Evaluation of the performance of Artificial Intelligence enabled Chest X-Ray interpretation to detect Tuberculosis and lung nodule in Ethiopia project**, *Addis Ababa University, College of Health Science, Institutional Review Board Protocol number 078/23/IM* ("Study").

The Recipient shall only share the Data Set with Qure Employees who shall be bounded by terms of this Agreement, and Recipient shall be responsible for their acts in connection with this Agreement. Recipient shall not share the Data Set with any other person or entity without Data Provider's prior written consent.

Recipient will (i) not use or disclose the Data Set for any purpose other than permitted by this Agreement pertaining to the Study or as required by law; (ii) include authors from the data provider side and clearly communicate with Dr. Amsalu Bekele, the principal investigator (PI) when publishing abstracts or original articles using the shared data set; (iii) use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Data Set other than as provided for by this Agreement; (iv) report to the

Qure.ai Technologies Private Limited Mumbai

Data Provider any use or disclosure of the Data Set not provided for by this Agreement of which the Recipient becomes aware within five (5) days of becoming aware of such use or disclosure; (v) not identify the information contained in the Data Set; and (vi) not contact (or attempt to do so), either directly or through another person, the individuals who are the subject of the Data Set.

Unless specifically stated otherwise in this Agreement, Recipient's obligations with respect to the Data Set apply to the whole and to any part of the Data Set.

Recipient shall not use or disclose the Data Set in any manner that would violate any law or regulation.

ARTICLE II
AMENDMENT AND TERMINATION

When Data Provider reasonably concludes that an amendment to the Agreement is necessary Data Provider shall notify Recipient in writing of the proposed modification(s). Data Provider shall request Recipient's written approval in the form of an amendment to this agreement at the time of notification. Either party to this Agreement may terminate this Agreement without cause upon thirty (30) days written notice.

On termination of the Agreement for any reason, Recipient shall, at Data Provider's option, return or destroy the Data Set. Recipient will certify in writing destruction of Data Set to Data Provider.

The terms of this Agreement shall be effective as of the date of the last party to sign this Agreement and shall remain in effect until all of the Data Set provided to the Recipient is destroyed or returned to Data Provider.

Upon Data Provider's knowledge of a material breach of this Agreement by the Recipient, Data Provider may provide an opportunity for Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time period specified by Data Provider, Data Provider shall discontinue disclosure of the Data Set to the Recipient and report the problem as permitted by law. Data Provider shall immediately discontinue disclosure of the Data Set to the Recipient if Data Provider determines cure of the breach is not possible.

Qure.ai Technologies Private Limited Mumbai

2

ARTICLE III
MISCELLANEOUS

This Agreement may be modified by the parties at any time pursuant to a writing executed by both parties. No use or disclosure different from that permitted hereunder may be made unless this Agreement is amended in writing.

Any ambiguity in this Agreement relating to the use and disclosure of the Data Set by Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

All notices required or permitted under the Agreement to be in writing delivered by electronic facsimile (with a confirmation by registered or certified mail, return receipt, postage prepaid, placed in the mail no later than the following day), or by registered or certified mail, postage prepaid, return receipt requested addressed to a party as indicated below:

If to Recipient: Qure.ai Technologies Private Limited 6th Floor, Wing E, Times Square, Andheri-Kurla Road, Marol, Andheri (East), Mumbai - 400059, Maharashtra Email: partner@qure.ai	If to Data Provider: Ethiopian Thoracic Society Tracon Tower, second floor, Churchill Ave, Addis Ababa, Ethiopia. Po Box: 10646, Addis Ababa, Ethiopia. Email: ethiopianthoracicsociety@gmail.com

Notice shall be deemed to have been given on receipt of communications personally delivered or transmitted by electronic facsimile (delivery confirmed), and electronic mail (delivery acknowledged) on the third (3rd) day after mailing. The above addresses may be changed by giving written notice as described in this section.

This Agreement shall be governed by Indian Law.

This Agreement shall not be assigned by Recipient without the prior written consent of the Data Provider.

Recipient shall be fully liable to the extent permitted by law for its acts, and the acts of any affiliates, subcontractors, agents and any other individuals or entities to whom Recipient provides the Data Set, and the results thereof.

Qure.ai Technologies Private Limited Mumbai

3

In the event of any conflict between terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties related to the data, the terms of this Agreement shall govern. Recipient warrants that it has obtained all necessary permission and has the authority to receive the Data Set. This Agreement may be executed in one or more counterparts, each of which when executed and delivered will be deemed to be an original, but all of which taken together will constitute one and the same agreement. This Agreement will become effective when counterparts have been signed by each of the parties and delivered by facsimile or other means to each other party.

IN WITNESS WHEREOF, the parties agree as follows:

Qure ai Technologies Limited	Data Provider: Ethiopian Thoracic Society
By:	By:
Name: Vivek Anand	Name: Dr Amsalu Bekele
Title: Data Privacy Officer	Title: Principal Investigator
Date: December 17, 2024	Date: 09/12/2024

Read and Understood:
By: _____
Name: Safa Mariyam T K
Date: December 17, 2024

Read and Understood:
By: _____
Dr. Amsalu Bekele (PI)
Date: 09/12/2024

Read and Understood:
By: _____
Dr. Rahel Argaw, ETS President
Date: 07/10/24

Qure.ai Technologies Private Limited Mumbai