REPUBLIC OF KENYA

MINISTRY OF HEALTH



OPERATIONAL HANDBOOK
for Computer-Aided Detection and Chest X-ray Introduction

2026

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

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Foreword



It is with great anticipation and commitment to innovation that I introduce the *Operational Handbook for CAD and Digital X-ray (DXR) Introduction 2025*. This resource is designed to support the Division of National Tuberculosis, Leprosy and Lung Diseases Program (DNTLD-P) and its partners in advancing the use of Computer-Aided Detection (CAD) technologies for TB screening and diagnosis.

Kenya is among the high-burden countries for TB and TB/HIV globally. TB remains one of the leading causes of morbidity and mortality in Kenya, especially among men and adults aged 25–44 years. Despite our efforts, the country still misses about 30% of TB cases. In addition, we are witnessing a rising burden of chronic respiratory conditions, including post-TB lung disease. These challenges call for high-impact, people-centred interventions including expanding access to molecular WHO-recommended rapid diagnostic tests (mWRD) and the introduction and optimization of innovative tools (such as digital chest X-ray with CAD) to enhance the early detection of individuals at risk of TB disease.

As Kenya intensifies efforts to reduce the burden of tuberculosis and TB/HIV co-infections, this handbook offers a strategic roadmap for the effective introduction, integration, and scale-up of CAD solutions within the national TB and lung health ecosystem. Chest X-ray (CXR) has a long history of use in the screening and diagnosis of TB. It remains one of the most sensitive tools for detecting TB-related abnormalities in the lungs, making it highly effective as a triage and screening tool, especially in high-burden settings.

The development of this guideline was a collaborative effort, led by the Division of National Tuberculosis, Leprosy and Lung Disease Program (DNTLD-P), with valuable input from TB experts, researchers, implementing partners, and frontline health workers.

Let us all commit to the effective use of this handbook. Its adoption will be key in accelerating progress toward our national and global targets, as outlined in the Kenya National Strategic Plan for TB, Leprosy and Lung Health (2022–2026), and in the global End TB Strategy.

Together, we can build a healthier, more resilient Kenya, where every person has the opportunity to breathe freely and live with dignity.

Dr. Patrick Amoth, CBS

Director General for Health,
Ministry of Health

Acknowledgement



The Ministry of Health, through the Division of National Tuberculosis, Leprosy, and Lung Disease Program (DNTLD-P), extends its sincere appreciation to all individuals and institutions who contributed to the development and review of the Operational Handbook for CAD and Digital X-ray (DXR) Introduction 2025. This handbook marks a pivotal milestone in Kenya's journey to strengthen TB detection and lung health services through the strategic deployment of digital chest X-ray technologies integrated with Computer-Aided Detection (CAD) software.

We acknowledge the steadfast support and visionary leadership provided by the Office of the Cabinet Secretary, the Principal Secretary, the Director General for Health, the Heads of the State Departments for Medical Services and Public Health, and the Head of the Department of National Strategic Public Health Programs. Their guidance has been instrumental in shaping a forward-looking approach to digital innovation in public health.

Special thanks go to the technical teams within DNTLD-P, County TB coordinators, and frontline healthcare workers whose insights from early deployments of portable and ultraportable systems enriched the operational guidance in this handbook. Their dedication to equitable, patient-centered care—especially in resource-limited settings—continues to drive meaningful progress in TB control.

We are deeply grateful to our technical and development partners for their financial and strategic contributions. These include the World Health Organization (WHO), Global Fund, Market Access Africa (MAA), Clinton Health Access Initiative (CHAI), Centre for Health Solutions (CHS) – Tamatisha TB, AMREF Health Africa in Kenya, Centers for Disease Control and Prevention (CDC), Kenya Medical Research Institute (KEMRI), Stop TB Partnership, Network of TB Champions, Respiratory Society of Kenya, and many other implementing and academic institutions whose collaboration made this work possible.

We also recognize and thank the communities and individuals affected by TB and other lung diseases. Their lived experiences and voices have helped shape this handbook to be more inclusive, responsive, and grounded in the realities of access, stigma, and continuity of care.

To all who contributed—whether named here or not—your support is deeply appreciated. May this handbook serve not only as a technical guide but as a catalyst for innovation, collaboration, and sustained impact in the fight against TB and the advancement of lung health in Kenya.

Dr Immaculate Kathure,OGW

Head, Division of National Tuberculosis, Leprosy and Lung Diseases Program

Abbreviations and Acronyms

ACF	Active case finding
CAD	Computer aided detection
CAB	Conformity assessment body
CE	Conformité Européene
CMMS	Computerized maintenance management system
CR	Computed radiography
CXR	Chest X ray
dCXR	Digital chest X ray
DHIS2	District Health Information Software 2
DICOM	Digital imaging and communications in medicine
DL	Deep Learning
DNTLD-P	Division of National Tuberculosis, Leprosy and Lung Diseases Program
DPA	Data processing agreement
DR	Digital radiography
EHR	Electronic health record
EMR	Electronic medical record
EU	European Union
IVDR	In Vitro Diagnostics Regulation
FSE	Field service engineer
GDF	Global Drug Facility
KHIS2	Kenya Health Information Software 2
KNRA	Kenya Nuclear Regulatory Authority
IAEA	International Atomic Energy Agency
iNTP	Introducing new tools project
mWRD	Molecular WHO - recommended rapid diagnostic tests
PACS	Picture archiving and communication systems
PMS	Post market surveillance
PPB	Pharmacy and Poisons Board
PRC	Precision recall curve
QA	Quality assurance
RIS	Radiology information systems
ROC	Receiver operating characteristics
SaMD	Software as a medical device
SLA	Service level agreement
TB	Tuberculosis
TPP	Target product profile
US	United States
FDA	Food & Drug Authority
WHO	World Health Organization

Executive Summary

Since 2021, the WHO has recommended digital chest X-ray radiography (dCXR) with CAD for TB diagnostics and supports using CAD software as a replacement for human readers in TB screening and triage. Kenya faces significant challenges in TB detection, with 31% of cases missed annually and a high rate of TB/HIV co-infection. The National Tuberculosis Strategic Plan aims for a 90% reduction in TB incidence by 2028 through high-impact interventions, including CAD. Chest X-rays (CXR) and CAD software are crucial in TB screening and diagnosis, providing high sensitivity for detecting pulmonary TB, although their specificity remains a limitation.

The Kenyan government, led by the NTP, has launched initiatives to introduce and expand CAD technologies nationwide. The document covers all aspects from product selection to implementation to facilitate the integration of these technologies. It builds upon existing national policies and frameworks, including the Integrated Guideline for Tuberculosis, Leprosy, and lung disease (2021) and the National Plan for TB (2023–2028). The NSP aims to reduce the TB burden through widespread deployment of dCXR and CAD across counties by 2028. Integrating ultra-portable digital X-ray systems with CAD software will address the shortage of trained radiologists in primary healthcare settings. Teleradiology solutions will enable remote QA and QC, which are critical for areas with limited healthcare resources. Community outreach via portable digital X-ray systems will facilitate TB screening in hard-to-reach populations.

This document supports Kenya's Division of National Tuberculosis, Leprosy and Lung Diseases Program (DNTLD-P) and other stakeholders in implementing CAD solutions for TB detection, to overcome the high burden of tuberculosis and TB/HIV co-infections. It serves as a strategic guide to inform decision-making regarding introduction and scaling up of Computer-Aided Detection (CAD) solutions within Kenya's TB and broader lung health ecosystem.

It outlines the vision, current landscape, and implementation strategy for deploying digital chest X-ray (dCXR) technology integrated with Computer-Aided Detection (CAD) software, and guides on selecting and implementing CAD software for TB screening and triage, focusing on facility readiness and product selection.

It encompasses both analogue and digital X-ray equipment selection, planning, and implementation, and explores the advancements in chest X-ray (CXR) technology, classifying it by technology type and mobility characteristics, and highlights the benefits and limitations of each type for TB screening. It also outlines the critical considerations for selecting and implementing CAD software for TB screening and triage, focusing on certification, interoperability, and performance.

Facility selection and readiness assessments will be carried out to evaluate suitability for deployment of digital chest X-ray and CAD technologies. Considerations include political support, TB burden, infrastructure, and resource availability. Key technical factors are the presence of a functional X-ray machine for CAD retro-fitting, availability of a radiographer, electricity and internet connectivity, access to molecular WHO-recommended rapid diagnostics (mWRDs) and integration with national health systems.

The document also provides the criteria for product selection including digital capability, the capability to screen for multiple pulmonary conditions, compatibility with existing X-ray equipment, PACS, and RIS, and existence of regulatory approval.

This Document also outlines critical considerations for selecting and implementing CAD software for TB screening and triage, focusing on certification, interoperability, and performance. CAD software should be certified by recognized bodies like the CE mark/EU-IVDR or US-FDA. Locally, the Pharmacy and Poisons Board (PPB) is the authority responsible for approving such software, supported by Kenya Bureau of Standards (KEBS) for standards and conformity assessment. Compliance with ISO 13485, ISO 14971, and IEC 62304 is essential for registration. These certifications confirm that the software meets safety and effectiveness standards. Consider CAD products that are certified and validated for specific indications.

Additional considerations for selecting digital X-ray equipment include, focusing on technical parameters, lifespan, image quality, disposal, and mobility. Ensuring these factors align with the facility's requirements will enhance TB diagnostics and overall healthcare delivery.

Interoperability with Health Information Systems is key to ensure the CAD software can integrate with national health systems like Kenya's KHIS2 and TIBU. Standardization and harmonization will ensure seamless data integration and accessibility.

The document outlines key criteria for selecting and validating CAD software for TB screening. Threshold scores and performance metrics should be informed by real-world data and local validation studies, with ROC and PRC curve analyses used to assess diagnostic accuracy. These curves support performance evaluation but are not used to set threshold scores.

CAD software must be validated for the appropriate age groups and settings, in alignment with WHO recommendations. Selection should also consider the diagnostic scope (TB-only or multiple pulmonary conditions), compatibility with existing X-ray infrastructure (including PACS and RIS), and certification by recognized regulatory bodies such as CE mark/EU-IVDR or US FDA. Regulatory approval, digital capability, and integration with national systems are essential, alongside evidence of diagnostic efficacy in operational settings.

As of 2024, Kenya had 197 digital X-ray units under the Managed Equipment Services program. An initial 70 units were retrofitted with CAD software, with assessments for further integration conducted. Additional funding to support the procurement and deployment of these technologies includes the Global Fund and the US Government (through USAID/ the State Department, DOD, CDC, and PEPFAR). These Investments will accelerate the scale-up of CAD technologies, contributing to Kenya's goal of reducing TB Incidence by 90% by 2028.

1

Introduction – Purpose, Scope and Target Audience

Since the World Health Organization (WHO) updated its TB diagnostic guidelines in 2021 to recommend digital chest X-ray radiography (dCXR) with Computer-Aided Detection (CAD), the Kenyan government, led by the DNTLD-P and supported by various partners, has launched several initiatives to introduce and expand CAD technologies nationwide.

This guidance is designed to support the NTP and other stakeholders in TB and lung health with informed decision-making processes regarding the introduction and scaling up of CAD solutions in Kenya. Although primarily focused on CAD, the guidance also addresses practical considerations for selecting and implementing both analogue and digital X-ray equipment. It serves as a comprehensive end-to-end resource, covering all aspects from product selection to planning and implementation, to facilitate the successful integration of these technologies at the national and subnational levels.

1.1 Scope

This document covers product selection, implementation planning, and monitoring and evaluation for CAD solutions in TB screening and triage in Kenya. It is designed to reinforce and build upon existing national policies and frameworks, including, but not limited to:

- Integrated Guideline for Tuberculosis, Leprosy, and Lung Disease (2021) *https://nltp.co.ke/patient-management/*
- National Plan for TB (2023 – 2028) *https://nltp.co.ke/national-strategic-plan-2019-2023-3/*

- Quality Improvement Framework
  https://nltp.co.ke/patient-management/
- Program Quality and Efficiency Implementation Handbook
  https://nltp.co.ke/patient-management/
- Nuclear Regulatory Act
  https://knra.co.ke/download/the-nuclear-regulatory-act-no-29-of-2019/
- Guidelines for Registration of Medical Devices Including In-Vitro Diagnostics -
  https://web.pharmacyboardkenya.org/download/guidelines-for-registration-of-medical-devices-including-in-vitro-diagnostics/

1.2 Target Audience

This document is intended for stakeholders directly or indirectly engaged with CAD solutions, including national, county, and sub-county decision-makers; National Tuberculosis, Leprosy, and Lung Disease (NTLD) Technical Working Groups (TWGs); program managers; healthcare providers; managers of imaging departments; procurement and regulatory agencies; policymakers and planning officers; as well as biomedical and clinical engineering professionals, IT professionals, medical physicists, diagnostic technicians, and radiographers. It is also relevant to civil society organizations (CSOs), the private health sector, the medical device industry, and intergovernmental and international agencies.

By addressing the needs of this diverse audience, this guidance aims to foster coordinated, informed and effective implementation of CAD technologies across Kenya's TB response ecosystem.

2

Background

Kenya is ranked among the top 30 high-burden countries for tuberculosis (TB) and HIV-associated TB. Despite notable progress in combating the TB epidemic, significant challenges remain in identifying individuals at risk. Approximately 23% of TB cases, including those in children, are still missed each year. In 2023, people living with HIV accounted for 28,000 new cases of TB/HIV co-infection, with 8,000 deaths reported among TB-HIV coinfected patients, underscoring the need for more effective screening and diagnostic strategies across all populations.

The National Tuberculosis Strategic Plan 2023/2024–2027/2028 sets an ambitious target of achieving a 90% reduction in TB incidence by 2028, compared to 2015 levels. To achieve this, the plan prioritizes high-impact, people-centred interventions including expanding access to molecular WHO-recommended rapid diagnostic tests (mWRD) and the introduction and optimization of innovative tools TB screening tools, including chest X-ray (CXR) with computer-aided detection (such as CAD) to enhance the early detection of individuals at risk of TB disease.

The 2016 National TB Prevalence Survey revealed a higher TB prevalence in Kenya than previously estimated, with about half of TB cases going undetected each year. In response, Kenya ramped up its efforts to find missing people with TB through the active case-finding (ACF) strategies at both health facility and community levels. The introduction of more sensitive TB screening tools and WHO-recommended rapid molecular diagnostic platforms has been pivotal in accelerating progress toward improved TB detection.

2.1 Chest X-ray and CAD Software for TB Screening

Chest X-ray (CXR) has a long history of use in the screening and diagnosis of TB. It is one of the most sensitive tools for detecting pulmonary TB, making it a useful triage and screening tool. In addition, recent studies have shown that a substantial proportion of people with active TB disease do not present with symptoms and TB is detected through CXR or culture alone[1-3]. This underscores the importance of CXR in identifying cases that would otherwise go unnoticed, particularly in community-based screening initiatives.

Across all populations, CXR plays an important role in the early detection and treatment of TB in both children and adults at higher risk of TB. When combined with timely treatment and other public health interventions, CXR contributes significantly to reducing the overall burden of TB and supports active case-finding efforts by identifying radiological abnormalities even in asymptomatic individuals. (Table 2.1)[4].

Table 2.1: Diagnostic accuracy symptoms, chest X-ray, and molecular WHO-recommended rapid diagnostic tests or screening for TB disease. (WHO Consolidated Guidelines on Tuberculosis, 2021)

Screening test	No. of studies (no. of participants)	Sensitivity	No. of studies (no. of participants)	Specificity
WHO target product profile	NA	> 0.90	NA	> 0.70
Prolonged cough (≥ 2 weeks)	40 (6 737)	0.42	40 (1 284 181)	0.94
Any cough	21 (2 734)	0.51	21 (768 291)	0.88
Any TB symptoms (cough, haemoptysis, fever, night sweats, weight loss)	28 (3 915)	0.71	28 (460 878)	0.64
Chest radiography (any abnormality)	22 (4 243)	0.94	22 (1 012 752)	0.89
Chest radiography (suggestive abnormality)	19 (2 152)	0.85	19 (464 818)	0.96
Molecular WHO-recommended rapid diagnostic test	5 (337)	0.69	5 (8 619)	0.99

NA: not applicable

Advances in artificial intelligence-based image recognition have driven the development of software for analyzing CXR to detect pulmonary TB. Computer-aided detection (CAD) offers a potential solution to challenges posed by the lack of trained personnel to interpret the images and the substantial intra- and inter-reader variability[5,6]. CAD utilizes machine learning and deep neural networks for automated image interpretation, producing an abnormality score indicative of the likelihood of TB. TThe diagnostic accuracy and overall performance of WHO-approved CAD software are comparable to the interpretation of digital CXRs by human readers[7–9].

However, it is important to recognize that a CXR lacks sufficient specificity to confirm pulmonary TB. Similarly, CAD software may fail to flag some lesions that may be TB-related while also failing to detect other lung pathologies beyond TB[4,6]. Additionally, there is substantial variation in diagnostic accuracy across different contexts, implying that the use of CAD requires calibration for the purpose and setting in which it is implemented.

Considering the potential and risks associated with CAD, clear national guidance is essential to support CAD product selection, appropriate deployment and integration with existing tools. This guidance should accompany the ongoing expansion of CAD technologies to ensure their effective and equitable use in Kenya's TB response.

2.2 WHO's Position on CAD in the Screening Algorithm

Since 2021, WHO has recommended the use of CAD products as an alternative to human readers in the interpretation of antero-posterior or postero-anterior views of digital plain CXR for pulmonary TB screening and triage in people aged 15 years and older. CAD can serve as an alternative to human readers in two primary contexts[4]:

- **Screening:** CAD is effective in screening individuals who may or may not exhibit symptoms or possess significant risk factors for TB. This is particularly useful in prevalence surveys or active case-finding initiatives, targeting early disease detection in populations that have a low risk of TB or limited access to healthcare services.
- **Triage:** In triage, CAD is used for individuals presenting with TB symptoms, signs, risk markers, or test results. This application is typically for those seeking medical care in healthcare facilities or referred for further investigation through screening or contact tracing efforts.

In both scenarios, the ultimate objective is to utilize CAD to determine whether an individual should undergo confirmatory diagnostic testing for TB.

3

Overview of CXR Technology

The field of medical imaging has made significant advances over the years, especially in X-ray technologies, which have revolutionized diagnostic practices in healthcare. CXR technologies can be classified based on their technology types and mobility features.

3.1 Classification by Technology Type

Analog radiography, the foundation of radiology since its inception, involves capturing images on traditional photographic film. The process begins with X-rays passing through the patient's body and hitting the film, creating varying levels of exposure based on tissue density. This exposed film is then developed to produce visible images that reveal anatomical structures and abnormalities. The exposed X-ray film requires wet processing, either manually in a darkroom or using an automatic processor[10].

However, reliance on a darkroom-based process that uses chemicals, complex accessories like X-ray cassettes, and additional personnel, along with the challenge of maintaining quality assurance standards, restricts the widespread use of this method for quick and effective TB screening at the population level. These factors make large-scale, efficient deployment of analog radiography difficult.



Figure 3.1: Analog Radiography – Automated and manual film processing (Photo: Courtesy)

Digital radiography represents a significant leap forward in imaging capabilities. There are three distinct approaches within the realm of digital X-ray technologies, each offering unique advantages and applications. Understanding the nuances of these categories is essential for making informed decisions in medical imaging.

- **Computed radiography (CR)** is a digital imaging technique that combines features of traditional film radiography while incorporating digital technology. CR systems use a cassette-based method to capture X-ray images, similar to traditional film radiography. However, CR cassettes containing photostimulable phosphor plates are used in place of film[10].

  Although both CR and DR are digital imaging technologies, they differ significantly in several key aspects. CR uses cassette-based photostimulable phosphor plates to capture and store X-ray images, requiring manual handling and scanning by a CR reader. In contrast, DR employs flat-panel detectors or charge-coupled devices to capture X-ray images directly, converting X-ray photons into electronic signals instantly without intermediate processing. Importantly, the radiation dosing for this technology is very low compared with the former two described above.

  Workflow efficiency also differentiates them. CR, although faster than traditional film radiography, still involves manual cassette handling, which can slow the process down, but provides good quality images with potential for digital enhancement. While DR offers immediate image capture and processing, it speeds up the workflow by enabling real-time image viewing and analysis, providing superior quality images which is crucial in fast-paced medical settings where efficiency is paramount.

Cost considerations also impact the choice. CR typically requires a lower initial investment, making it attractive for facilities with limited budgets or those gradually transitioning to digital imaging. Despite its higher upfront cost, DR offers long-term savings through reduced film and processing expenses, lower radiation exposure for patients, and increased efficiency.



Figure 3.2: Computed Radiography. Images are captured and stored on cassettes which are scanned on a computed radiography reader (Photo: Courtesy)

- **Digital radiography (DR)** is a state-of-the-art imaging technology that employs electronic sensors to capture X-ray images directly. Unlike traditional analog systems that use film, DR systems utilize flat-panel detectors to convert X-ray photons into electronic signals. A computer then processes these signals to create high-quality digital images[10].

  The advantages of DR are many. First, DR offers superior image quality with higher resolution and clearer details than analog systems. This better image quality helps make more accurate and detailed diagnoses, especially for subtle abnormalities. Second, DR systems allow faster image capture and transfer, enabling real-time viewing and immediate analysis. This quick process is especially useful in high-volume TB settings where quick diagnosis is essential.

  DR systems also facilitate image manipulation, such as adjusting brightness and contrast, zooming in on specific areas, and applying various filters to improve visualization. These features enhance diagnostic accuracy and decrease the need for retakes, thereby reducing patient exposure to radiation. Additionally, DR eliminates the necessity for chemical processing and film storage, resulting in long-term cost savings and environmental advantages.



Figure 3.3: Digital Radiography Equipment. Electronic sensors are used to capture X-ray images which are viewed and analysed on a dedicated computer (Photo: Courtesy)

- **Analog Retrofit DR-based Imaging:** Analog retrofit DR-based imaging represents a hybrid approach, designed to upgrade existing analog X-ray systems to digital capabilities without replacing the entire setup. This process involves integrating a digital detector into an existing analog X-ray machine, effectively transforming it into a digital system[10].

  The main benefit of analog retrofit DR is its cost-effectiveness. Upgrading an existing analog system is usually cheaper than buying a new DR system. This allows healthcare facilities to use their current infrastructure while gaining many benefits of digital imaging, such as better image quality and quicker processing times.

  However, there are some limitations to consider. While retrofit DR systems offer significant improvements over pure analog systems, they may not achieve the same level of image quality and advanced functionality as dedicated DR systems. The performance of a retrofit system is often constrained by the limitations of the original analog equipment. For instance, the mechanical components and overall design of the analog machine may not fully support the capabilities of the digital detector, leading to suboptimal results compared to a purpose-built DR system.

3.2 Classification by Mobility

X-ray machines are categorized by their mobility, which affects their appropriateness for various clinical environments and deployment situations.

1. **Fixed X-ray Systems**: These are traditional X-ray machines permanently installed in dedicated rooms within hospitals, clinics, or imaging centers. Fixed systems offer high image quality and often include advanced features for specialized imaging procedures. They are suitable for facilities with a high workload that need precise positioning and stability[10].



Figure 3.4: Fixed or Stationary X-ray Equipment (Photo: Courtesy)

2. **Portable X-ray Systems** are designed for easy mobility within healthcare facilities, such as patient rooms, intensive care units (ICUs), or operating theatres. These systems are mounted on wheeled carts or stands, allowing healthcare providers to bring imaging capabilities directly to patients who cannot be moved to a radiology department. Portable X-ray equipment is considerably lighter (usually < 100 kg), with output power in the range of 5–10 kW. It can be easily assembled and disassembled and fits into large carry-on cases, making it simple to transport in a mid-size car or van for temporary use at a local facility. It only requires a household power supply or equivalent[10].



Figure 3.5: Portable X-ray Equipment (Photo: Courtesy)

3. **Ultraportable X-ray Systems** represent the latest evolution in mobility, characterized by their compact size, lightweight design, and ease of maneuverability. These machines are fully battery operated, have an output power < 5kW, and can produce digital diagnostic-quality CXR images when used with a recommended, highly sensitive detector. These handheld or small-form-factor devices can be carried by healthcare providers directly to the point of care, making them useful for TB screening in outreach programs, temporary clinics, or for event-based screenings with a small number of people to be X-rayed[10].



Figure 3.6: Ultra-Portable X-ray Equipment (Photo: Courtesy)

3.3 General Considerations for Selecting CXR Equipment

Selecting appropriate X-ray equipment is a critical decision that requires a thorough evaluation of the existing technology, healthcare needs, and program goals, particularly regarding the transition to DR. The decision to upgrade existing equipment or procure new machines will depend on several factors, including the age, technology level, and condition of the current X-ray systems.

Globally, medical imaging is shifting towards DR due to its superior image quality, faster processing times, and reduced radiation exposure. For the NTP, adopting DR can significantly enhance diagnostic accuracy and operational efficiency. Digital systems enable rapid image acquisition and immediate availability, which are crucial for the timely diagnosis and treatment initiation.

The transition from analog to Computed Radiography (CR) systems, and eventually to DR, can be complex. While CR systems offer improvements over traditional film radiography, they still require manual cassette handling and are less efficient than DR systems. Retrofitting CR systems with digital upgrade kits can be a cost-effective temporary solution, extending the utility of existing equipment. However, aging CR technologies face increasing challenges related to compatibility, service support, and part availability, eventually making ongoing updates impractical or uneconomical. This makes DR a more appealing long-term investment.

In 2021, the WHO-International Atomic Energy Agency (IAEA) working group developed minimum technical specifications for portable and ultraportable X-ray systems[11]. These guidelines emphasize that choosing between fixed, mobile, or portable equipment should be based on factors such as the local epidemiological situation, geographic considerations, health infrastructure, workforce availability, and decentralized services

Portable X-ray systems are primarily designed for use in settings where diagnostic and screening activities are located far from health facilities. They provide benefits for various outreach interventions, offering social and economic advantages. However, portable systems should not replace hospital radiology departments for patients who can be transported to fixed units. According to IAEA Safety Standards Series No. SSG-46, portable units should only be used when transferring patients to a fixed unit is impractical or medically unacceptable. These devices are generally used for standard 2D radiographic studies, such as chest X-rays, orthopedic imaging of small body parts, and other specific clinical diagnostics[12].

Selecting appropriate X-ray equipment is a critical decision that requires a thorough evaluation of the existing technology, healthcare needs, and program goals, particularly regarding the transition to DR.

3.4 Key Considerations to Upgrade or Replace Existing X-ray Equipment

When deciding whether to upgrade or replace existing X-ray equipment, several critical factors must be taken into account to ensure that the chosen solution meets the specific needs of DNTLD-P and enhances patient care in the context of the broader primary health care[12].

- **Local needs and context**: The decision should account for the specific healthcare requirements, infrastructure, and availability of trained healthcare workers in the area. In rural or underserved regions, portable and ultraportable X-ray systems can greatly improve diagnostic capabilities by enabling remote diagnostics and allowing for immediate decision-making and treatment. However, these systems may produce lower image quality compared to fixed or standard portable systems and need robust training and maintenance support to ensure proper functioning.
- **Patient outcomes and efficiency goals**: The decision to upgrade or replace equipment should align with the program's diagnostic algorithms and overall TB patient management objectives. DR systems, whether fixed or portable, can deliver faster and more accurate TB diagnoses, which are essential for improving patient outcomes and achieving efficiency targets.
- **Age and condition of existing equipment**: The current state of the X-ray machines should be carefully assessed. Older systems may not only require frequent repairs but also may not be compatible with newer technologies, making retrofitting less viable or cost-effective.
- **Economic factors**: The cost implications of each type of system must be assessed. Fixed systems, though requiring a higher initial investment and more extensive infrastructure, offer long-term reliability and high-quality imaging. In contrast, portable and ultraportable systems, while potentially more expensive to operate, provide critical flexibility and reach, especially vital for comprehensive TB programs in diverse and geographically challenging settings.
- **Service and support**: The availability of technical support and replacement parts for each system type is a key consideration. Portable and ultraportable systems may demand more frequent maintenance and skilled technicians, particularly in remote areas. Fixed systems, while generally more stable, still require robust service agreements to ensure continuous and reliable operation.
- **Transport considerations**: Portable and ultraportable systems are particularly relevant in situations where transporting patients to fixed X-ray units is impractical or medically inappropriate. This consideration is especially important in resource-limited settings where patient mobility may be constrained. Equitable service delivery requires that deployment strategies go beyond technology placement to address key components of access. This includes strengthening community outreach, providing transport support for clients, establishing clear referral pathways, and integrating with sample transport systems for confirmatory testing. These measures are critical to ensure that individuals screened for TB are seamlessly connected to diagnostic and treatment services.

4

The Evolving Landscape of CAD Solutions for TB and Lung Health Diseases

CAD technologies for tuberculosis (TB) are transforming the field of TB diagnostics by utilizing artificial intelligence (AI) to analyze CXR images for abnormalities suggestive of pulmonary TB. CAD systems generate an abnormality score that helps determine whether an individual should undergo confirmatory diagnostic testing and evaluation, thereby enhancing the efficiency and reach of TB screening and triage efforts.

These technologies significantly improve the feasibility and accuracy of CXR interpretation, either supplementing or replacing human expert analysis, which can reduce inter-reader variability and minimize delays, particularly in settings with limited access to skilled personnel.

WHO has outlined minimum requirements for TB triage and systematic screening. These requirements include a sensitivity of 90% and a specificity of 70%. The optimal criteria, as per the WHO target product profile (TPP), are a sensitivity of 95% and a specificity of 80%[4]. Numerous studies have investigated whether CAD tools meet these standards using real-world data. Although CAD tools have only partially satisfied the TPP, the WHO has endorsed their use in place of human readers for interpreting chest radiographs for tuberculosis screening and triage, given their similar accuracy to human readers.

As of December 2023, at least 16 CAD software products specific to TB screening were available globally, reflecting rapid innovation and growing market interest.

Some of the CAD data that is currently in use was obtained from the national prevalence data (2016) and the iNTP data.

4.1 Historical Development and WHO Endorsement

CAD technologies for TB were initially developed between 2008 and 2010, with Delft Imaging in the Netherlands being one of the pioneers. The WHO first reviewed CAD for TB detection in 2016, but due to the limited evidence available at the time, no recommendation was issued.

However, in 2020, the WHO's Global TB Programme held a Guideline Development Meeting to update TB screening guidelines. The Guideline Development Group (GDG) re-evaluated the performance of CAD software in the automated reading of digital CXR for detecting pulmonary TB, comparing it to human readers in the context of screening and triage. Based on this review, the WHO updated its guidelines in 2021 to recommend the use of CAD for individuals aged 15 years and older, endorsing CAD as an alternative to human readers for interpreting digital chest radiographs in both screening and triage for pulmonary TB disease[4].

4.2 Current Applications and Deployment

CAD technology has since become integral to various TB case detection strategies, including:

- Systematic Screening in High-risk and vulnerable population: CAD is used in systematic screening of high-risk and vulnerable populations, often in community-based health initiatives.
- ACF in Health facilities: Systematic screening to identify presumptive for further testing and treatment. In healthcare facilities, CAD assists in identifying patients who need further testing and treatment.
- ACF in outreach programs: CAD facilitates TB screening in remote and underserved areas through portable and mobile radiography solutions.

Since the WHO's endorsement in 2021, CAD technologies have seen widespread adoption particularly through initiatives like the Introducing New Tools Project (iNTP) supported by USAID and the Stop TB Partnership. To assist with decision-making on selecting and purchasing CAD products, FIND and the Stop TB Partnership launched an open access online resource *(https://www.ai4hlth.org/)* that provides detailed information on commercially available CAD solutions for TB.

As of December 2023, at least 16 CAD software products specific to TB screening were available globally, reflecting rapid innovation and growing market interest. At least 10 CAD solutions for TB have since received CE-Mark certification, reflecting the growing acceptance and regulatory approval of these technologies.

In June 2025, WHO approved six software products for use in the computer-aided detection (CAD) of tuberculosis (TB) on chest X-rays during TB screening. An updated policy guidance was released following an independent evaluation of CAD software

for TB screening. This assessment, conducted by the Foundation for Innovative New Diagnostics (FIND) and reviewed by WHO's Technical Advisory Group (TAG), evaluated eight CE-marked CAD products using standardized image libraries for both community and facility screening use cases. Based on diagnostic accuracy—specifically partial area under the curve (pAUC) and specificity at 90% sensitivity—six CAD software products met WHO's performance standards for use in individuals aged 15 years and older. These include: CAD4TB v7 (Delft Imaging), DrAid for TB screening v2.4.4-6 (VinBrain), Genki Edge v3.4.2 (DeepTek), InferRead DR Chest v1.0.1.1 (Infervision), Insight CXR v3.1 (Lunit) and qXR v4.0 (Qure.ai) (WHO approves six software products for computer-aided detection of TB on chest X-ray)

WHO does not currently recommend CAD use for children under 15 years of age. Importantly, CAD is intended for screening and triage—individuals flagged by CAD must undergo confirmatory testing before treatment initiation.

5

Country Context

5.1 DNTLD-P's Vision for CXR and CAD Deployment

The National Strategic Plan (NSP) for Tuberculosis, Leprosy, and Lung Diseases 2023/24–2027/28 has set forth an ambitious agenda to substantially reduce the burden of TB and other lung health conditions in Kenya. Central to this goal is the expansion of community outreach activities through the widespread deployment of dCXR technology integrated with CAD software across all counties by 2028.

This strategy is based on the findings of the Patient Pathway Analysis conducted in 2017, which showed that most patients with TB symptoms initially seek care at primary healthcare facilities. Unfortunately, these facilities often lack adequate X-ray services and have a limited number of radiographers or other skilled X-ray readers. The integration of ultra-portable digital X-ray systems with CAD software addresses these gaps by providing a solution that compensates for the shortage of trained radiologists, particularly in primary healthcare settings.

Furthermore, the ability to share images electronically supports the implementation of teleradiology solutions, enabling remote quality assurance (QA) and quality control (QC) by radiologists based at central locations. This is especially critical in remote areas

As of Jan 2024, Kenya had 197 digital X-ray equipment procured through the government Managed Equipment Services (MES) program and distributed to level 4, 5, and 6 health facilities.

where healthcare resources are limited. The portability of these digital X-ray systems is also vital for targeted community outreaches as part of the Active Case Finding (ACF) strategy, facilitating TB screening in hard-to-reach populations.

To ensure comprehensive care at the primary health care (PHC) level, this deployment will be complemented by other essential services for individuals presenting with TB symptoms—including sample transportation networks for molecular testing (e.g. mWRD), access to microscopy, and linkage to diagnostic and treatment services. Together, these efforts aim to strengthen early detection, streamline diagnostic pathways, and improve treatment outcomes nationwide.

This approach has been demonstrated by the USAID-supported Introducing New Tools Project (iNTP), where 30% of patients with a CAD4TB score exceeding 60 were subsequently confirmed bacteriologically using molecular WHO-recommended rapid diagnostic tests (mWRDs). This is a significantly higher yield compared to patients referred for molecular tests based on clinical symptom screening alone. The use of CAD could potentially save the program on cost by reducing the number patients needed to test to diagnose a case of TB.

5.2 Healthcare Services Landscape

Kenya's healthcare system is structured into six levels, ranging from community-based services (level 1) to national referral hospitals (level 6), and is further divided into 47 counties and 308 TB control zones. The ongoing pursuit of universal health coverage underscores the importance of ensuring equitable access to high-quality healthcare services at all levels of the system. However, several challenges persist, including geographical barriers, inconsistent electricity supply, and limited human resource capacity, all of which hinder the optimal delivery of healthcare services.

The findings from the National TB Prevalence Survey 2016 revealed a significant gap in TB case detection, with 52% of TB cases potentially missed if relying only on symptom-based screening. Due to the limited availability of X-ray equipment, the use of CXR has mainly been confined to TB diagnosis and is often promoted as a screening tool during outreach efforts. To overcome these challenges, it is essential that investments in X-ray technology are not only directed toward TB and lung conditions but also enable the diagnosis of a wider range of conditions, thereby strengthening the overall capacity and resilience of the healthcare system.

The number of health facilities is outlined in Tables 5.1 and 5.2.

Table 5.1: All Healthcare Facilities in Kenya

Level	Level 2	Level 3	Level 4	Level 5	Level 6	Total
Faith-Based Organization	911	233	111	5	0	**1,260**
Ministry of Health	5,226	1,134	363	13	6	**6,742**
Non-Governmental Organizations	420	68	13	0	0	**501**
Private Practice	6,219	1,054	452	5	0	**7,730**
Total	**12,776**	**2,488**	**939**	**23**	**6**	**16,233**

Table 5.2: TB Treatment Facilities

Level	Level 2	Level 3	Level 4	Level 5	Level 6	Total
Faith-Based Organization	226	120	91	5	0	442
Ministry of Health	1,694	912	346	12	5	**2,969**
Non-Governmental Organizations	60	15	6	0	0	**81**
Private Practice	218	95	124	2	0	**439**
Total	**2,198**	**1,142**	**567**	**19**	**5**	**3,931**

5.3 Digital X-ray and CAD Software Landscape in Kenya

As of Jan 2024, Kenya had 197 digital X-ray equipment procured through the government Managed Equipment Services (MES) program and distributed to level 4, 5, and 6 health facilities. They are not ultra-portable and therefore are stationed within the health facilities. An initial 70 of these were retrofitted with CAD software after which an assessment was undertaken to determine the suitability of the remaining 127 for CAD software integration. The existing digital X-ray platforms in Kenya are as outlined in Table 5.3.

Table 5.3: Existing Digital X-ray Platforms and CAD Software for TB as of Dec 2024

Source of Funding	pDXR	pDXR+AI (Qure AI & CAD4TB)	# retrofitted with CAD Software for TB (MES equipment)	Total
iNTP (USAID)		**8**		**8**
GF-TNT		**55**		**55**
GF-Amref		**25**	**69**	**94**
CDC	**2**	**15**	**5**	**22**
State Department and DoD		**14**		**14**
Grand Total	**2**	**113**	**74**	**189**

Kenya projects a need for 715 Ultra-Portable Digital X-Ray systems with AI to expand equitable TB screening across priority populations which includes TB control zones, high-burden HIV counties, FBO facilities, and prisons. With only 189 units currently available, the country faces a shortfall of 526 systems, underscoring the strategic investment to close diagnostic gaps and accelerate early case detection.

Table 5.4: Proposed Country needs for Ultra-Portable Digital X Ray Systems and AI

Criteria	Number of zones	Number of equipment proposed	Remarks
TB control zones	308	308	Based on the current TB program implementation structures
Hard-to-reach counties	105	70	15 counties based on the current TB program implementation structures
Counties with high burden of PLHIV, contributing 90% PLHIV burden	70	197	27 counties based on Kenya preliminary 2024 PLHIV estimates
FBO sites	0	109	TB treatment FBO sites that are level 2 and 3 contributing 80% of TB cases in 2022
Prisons	0	31	Prisons that account for 90% of notified TB cases in Prisons
Total Need		**715**	
Available		**189**	
Country Gap		**526**	

6

Considerations for Selecting a CAD Software

6.1 Facility Selection and Readiness Assessment

The facility must be assessed to determine its suitability for CAD deployment. A site assessment tool has been developed to assist in facility selection and the key considerations related to the site's readiness to implement CAD for TB screening and triage (Annex 1)[13].

The key considerations for facility selection and readiness are:

- Political will of county.
- Location of the facility.
- Burden of disease in the facility's location/catchment area.
- Workflow of patient care and high workload.
- Availability (on-site/sample referral network) of molecular testing e.g. Gene Xpert, TrueNat.
- Presence of an X-ray machine with regulatory approval.
- Presence of a radiographer.
- Secure room for the X-ray.
- Presence of personal protective equipment for the radiographer/technician and patients.
- Presence of radiation monitoring protocols and functional monitoring equipment.

- Ability to move the X-ray system to nearby communities.
- Reliable electricity supply and backup power system.
- Internet connectivity.
- Ability to integrate CAD product with existing X-ray machines.
- Ability to integrate with the national health information system.

The facility assessment is a critical step in ensuring readiness before deploying CAD technology. Each selected site must undergo a rigorous evaluation to confirm its suitability. It is highly recommended to adapt the assessment tool to local county requirements.

6.2 Product Selection

The considerations for CAD product selection are highlighted below:

6.2.1 Multi-Disease Considerations

Some CAD software is designed explicitly for TB screening and produces abnormality scores solely for TB, while others have been developed to help identify various pulmonary and thoracic conditions, including lung diseases like TB. Additionally, many CAD software companies have created products to detect COVID-19, often offering these tools free of charge. The current CAD solutions available in the market can classify common chest X-ray abnormalities such as calcification, cardiomegaly, lung masses, nodules, pleural effusion, pneumothorax, as well as bone and heart abnormalities.

Before choosing a particular CAD software, it is essential to consider whether it will be used solely for TB screening or also for other pulmonary conditions, who will be using it (healthcare workers or radiologists), and the environment where it will be deployed (in a modern facility or rural communities with limited infrastructure and no internet connection). Additionally, it is crucial to evaluate the disease profile in different regions and select CAD software that can identify multiple pulmonary and thoracic conditions, ensuring versatility and comprehensive diagnostic capabilities.

The ability of CAD software to identify other abnormalities with CXR-CAD, suggestive of pathologies beyond TB, would benefit the country by ensuring equitable and accessible healthcare. Since multi-disease CAD software can be integrated with diagnostic tools, it can be effectively utilized in various applications such as thoracic and multi-organ imaging, as well as in vascular and skeletal systems.[14]

However, there are several tradeoffs, including weighing the impact on detection rates and patient outcomes, costs and financial incentives, time saved from double reading, increased recall rates, and radiologist perceptions that need to be factored as part of key considerations.

6.2.2 Compatibility of CAD with Existing X-ray Equipment, RIS and PACS

To reduce the gap in access to CXR for TB detection, it is essential to consider not only new equipment but also the existing X-ray machines currently in use, along with the picture archiving and communication systems (PACS) and radiology information systems (RIS) that support them.

Given the variety of tools to consider (CAD, PACS, RIS), it is recommended to perform thorough analyses to clarify the role of each system and prevent redundancies that could impede the adoption and effective use of solutions. PACS is used to securely store and transmit patient medical images, while RIS are specialized systems that manage radiology-specific workflows, including the storage and distribution of radiology reports. RIS are typically intra-hospital systems. All these technologies must support interoperability standards like digital imaging communications in medicine (DICOM) and HL7 communications to work co-operatively[15].

A key prerequisite for including and operating existing X-ray equipment in the implementation of CAD is determining whether the equipment is digital or can be upgraded with digital retrofit. This information should be captured during the baseline facility assessment. It is also important to validate if existing equipment is approved by relevant regulatory authorities for routine CXR. Once the equipment meets digital standards and is approved by the regulator, its compatibility with CAD can be assessed.

Most CAD products are compatible with a wide range of X-ray equipment, meaning they can work with any digital radiography (DR) or computed radiography (CR) equipment if the digital input is in a compatible format. The most used format in medical imaging is DICOM and most CAD process data in this format.

The TB program must engage with the CAD software supplier to discuss the existing X-ray systems present in facilities and determine compatibility with the CAD software under consideration. This compatibility is essential because the image quality must be sufficient for the software to accurately analyze the CXR image.

6.2.3 Deployment mode

There are two modes of deployment available for CAD software: online and offline. The deployment mode selected for use is dependent on the available infrastructure in the facilities.

Online mode connects to a cloud platform for image processing and storage, and the CAD output is reviewed on a dedicated laptop. This can be viewed on the X-ray workstation, but in some cases, a second device is required for the CAD software, as some X-ray systems limit the installation of third-party software. This should be discussed with the X-ray system manufacturer before installing the CAD software. The DICOM files of the CXR images are very large (approximately 10 to 30 MB); therefore, a reliable, low-cost internet connection with the appropriate bandwidth and unlimited data plan is required to analyse CXR images[13].

In offline mode, the CAD software is installed on a dedicated processing box or laptop to analyse the CXR image, and the CAD output is reviewed on the dedicated device. Third-party software is restricted on X-ray system workstations; therefore, an additional device with greater processing power may be required[13]. There is an option to combine the two and operate in a hybrid deployment mode, whereby the data and CXR images are uploaded to an online server.

There are some aspects to consider when selecting the mode of deployment. Firstly, online mode requires cloud storage; therefore, the program must consider data privacy and protection of patient data. Most CAD suppliers offer the option to set up the software using in-country servers, cloud, or physical, to ensure data sovereignty and compliance with country data privacy laws (see Section 7.5 on Data Privacy). Secondly, a strong, high-speed Internet connection is needed to avoid interruptions during use. Lastly, offline mode requires additional hardware to be procured, such as a dedicated laptop and external hard drives for the storage of CXR images, which has implications on the overall cost of deployment.

6.2.4 Certification

CAD software should be certified by a conformity assessment body (CAB), and the certification is directly linked to a specific indication or disease condition. The CE-mark/ European Union In Vitro Diagnostics Regulation (EU-IVDR) is currently the most common certification for CAD software on the market, indicating conformity to those standards, and allows for the sale and clinical use of the product within Europe.

CAD-AI software has a medical purpose as it is intended to process, analyze, create, or modify medical information that may impact patient outcomes. It is also considered a medical device. As such, it must conform to specific safety standards. Medical devices, including in-vitro diagnostic medical devices, are subject to pre-market authorization by a regulatory authority. The CAB uses a risk-based approach to classify the devices with different classes from low risk (Class I) to high risk (Class III). The regulatory pathway includes having common specifications, post-market surveillance (PMS), periodic safety update report (PSUR), clinical evaluation consultation, European Union (EU) declaration of conformity, and CE marking.

CAD products under the EU are mostly classified as Class II b. Class II b applies to software that intends to impact diagnosis or monitor vital physiological processes, with a higher risk of harm than Class II a when the software falls short. Class II b certificates are issued by a Notified Body, which assesses validation, conformity, and clinical evaluation for the product.

In addition to the CE mark, the United States Food & Drug Authority (US-FDA) certification is also used for CAD/AI products. The FDA clearance indicates conformity to those standards and allows for the sale and clinical use of the product within the United States. The risk classification is the same as in the EU, and most software as a medical device (SaMD) is also categorized as Class II.

It is important to understand at this stage that the CE or US-FDA certification of CAD products does not necessarily mean that the software will perform well in all settings or use cases, or can process images produced by any equipment. Careful consideration

is needed for the selection of CAD products based on validation studies specific to the geographical location, use case, and combination with equipment where it will be used.

The CE mark and FDA clearance have been the most extensively covered certifications for CAD solutions used for TB and are often included in procurement specifications and evaluation criteria of CAD product tendering documents.

However, certifications by any of the other Global Harmonization Task Force (GHTF) founding members are usually considered sufficient. Different certification options are available and are dependent on the country's policy adoption of AI-enabled diagnostics. Australia, the United Kingdom (UK), and Korea have comprehensive policies.

Recognizing that these policies are new and the technologies are rapidly evolving, having the most appropriate certification is critical when considering which technology to adopt and scale up. There are a considerable number of CAD products on the market that can detect TB on CXR (including for comprehensive chest pathologies) and which are pending CE or US-FDA certification.

In addition to the broader regulatory frameworks of the EU and FDA, the WHO Prequalification (PQ) and Global TB Program offer targeted recommendations to ensure the quality and performance of digital X-ray and CAD software specifically for TB screening. This WHO PQ process involves independent evaluation by FIND and the Technical Advisory Group (TAG), guided by Technical Specification Series (TSS) documents that define minimum diagnostic accuracy and safety standards. Unlike the EU and FDA, which regulate a wide range of medical devices, WHO PQ focuses on public health applications in low-resource settings, maintaining a prequalified list of devices and requiring ongoing monitoring of software changes. These recommendations are tailored to support national TB programs by ensuring CAD tools are fit-for-purpose, reliable, and contextually calibrated for effective screening and triage.

In the landscape assessment report published by the STOP TB partnership in 2021, only six of eleven CAD products had the CE-mark and out of the 5 products with pending certification, 3 were already on the market and 2 were in validation. An ideal CAD solution should hold CE-mark or equivalent regulatory approval and demonstrate robust validations for its specific indications.

CAD products under the EU are mostly classified as Class II b. Class II b applies to software that intends to impact diagnosis or monitor vital physiological processes, with a higher risk of harm than Class II a when the software falls short.

6.2.5 Interoperability with the National Health Information System

The interoperability of Electronic Medical Records (EMR) and Electronic Health Records (EHR) is crucial for the ongoing digitalization of healthcare. The challenge for health systems is to ensure that all interventions can be captured within a single Health Information System (HIS), where any stakeholder, depending on their access rights, can seamlessly access and utilize health data in an appropriate format for various purposes.

To achieve this goal, it is necessary to design a coherent information system architecture that spans data entry, validation, and accessibility for users and decision-makers, while considering the integration of various data collection tools tailored to the country's programs and needs. This requires a high level of standardization, harmonization, and above all, a capacity for continuous integration and evolution.

Kenya adopted the District Health Information Software 2 (DHIS2), now known as the Kenya Health Information Software 2 (KHIS2), alongside several digital tools to enhance the management, monitoring, and oversight of health programs. The web-based Kenya Tuberculosis Surveillance System, known as TIBU, was developed and deployed in 2012, providing a mobile application available to all sub-county TB coordinators for real-time TB data collection at the point of care.

TIBULIMS, a middleware developed and implemented to address data reporting challenges, facilitates the connection of applications from different instruments that were not originally designed to connect, into a single interface where data is centralized before being transferred to the TIBU information system and then to KHIS2. TIBULIMS reduces the number of interfaces that need to be connected to TIBU to just one, as the data centralization is done upstream. With the TIBULIMS interface, DNTLD-P can centralize information from GeneXpert, Truenat, CAD screening outputs, and many other tools that will be included in the package of tuberculosis screening and diagnostic solutions in Kenya.

It is important to discuss with CAD suppliers the ability of their software to connect to TIBULIMS or relevant health management systems available in the country.

6.2.6 Threshold Score and Performance

The performance of the CAD software is an important aspect to consider as this determines the abnormality score for the likelihood of TB assigned to the CXR that is analysed by the software. The real-world performance of the software should be evaluated to help ascertain its effectiveness in the local setting. The threshold score selected for assessing CXR images and assigning the abnormality score influences the CAD software's sensitivity and specificity. A universal score cannot be used as the software is developed differently and abnormality scores will differ in different populations depending on local TB prevalence and the setting in which it is used[15].

When reviewing CAD software for selection, it is also important to note the version used in the evaluations as the newer versions have improved performance than the older versions.

In addition, the Receiver Operating Characteristic (ROC) and Precision-Recall Curve (PRC) can be used to evaluate and compare the CAD software for selection purposes but they should not be used to determine the threshold score. The ROC curves plot the CAD's sensitivity against the false positive rate, while the PRC curves plot the positive predictive value against the sensitivity. As such, the area under the ROC and PRC curves relates to the accuracy of CAD to identify TB and other lung pathologies, should the software be validated for these[13].

Many CAD softwares are validated for a specific age group, limiting their ability to diagnose patients below that age. Selecting CAD validated for the appropriate age range recommended by WHO for TB screening is important. Also consider other population parameters for which the CAD software was validated (or not) e.g., HIV status, based on the intended population for use.

6.2.7 After-Sales Support

After-sales support, also known as after-sales service, is any assistance provided to a customer after a product or service has been purchased. This support includes installation, user training, preventive and corrective maintenance, spare parts delivery and installation, and life cycle management support. These activities can be provided by the manufacturer, an authorized partner or representative (like a distributor), or a third-party customer service provider with relevant expertise.

The value of after-sales support is directly related to the perceived product quality and the supplier's reputation. High-quality after-sales support is essential when implementing new technologies, and **the supplier's customer service policy**, which typically describes their service level agreement (SLA), is considered a critical document for decision-makers.

Performance evaluation of after-sales support can be assessed using three key indicators: 1) the cost of after-sales service, 2) the time gap between a service request and its delivery, and 3) the average time required to deliver the service.

Considering the rapid development around CAD, the most crucial point in the field of after-sales service is undoubtedly the updates and upgrades of the software. As these technologies are used, developers learn and improve the tools, expand the scope of applications, and address the growing demand for security. This dynamic will result in performance differences for the same tools depending on whether the tool has received updates or not. It is important to note that the implementation of updates and upgrades will differ depending on the deployment mode.

CAD deployed online will benefit from updates more quickly than CAD deployed offline. Therefore, it is advisable to opt for a hybrid deployment, even if you want to maintain complete control of your local database. Thus, the offline mode could temporarily allow updates to be retrieved in a short timeframe. Importantly, any new version of CAD software—whether updated or newly released—must undergo appropriate regulatory review and approval before use. This ensures continued compliance with safety and performance standards, particularly as software modifications may affect diagnostic accuracy. Implementers should verify that updated versions retain certification from recognized regulatory bodies (e.g., CE mark/EU-IVDR, US FDA) and are validated for the intended population and use case. Furthermore, when selecting CAD software, consider

the developers' plans to expand its capabilities for screening and diagnosing tuberculosis in broader populations and for identifying conditions of strategic importance to the program.

The review of the challenges in the implementation of digital X-rays and CAD outlined in Table 7.1 provides insights into some important elements to validate in **the supplier's customer service policy** when selecting these tools. It is therefore important to discuss these aspects to understand how they provide support to address these challenges, and how this support will impact the total cost of ownership.

Qualified field service engineers (FSE) are essential for providing support for CAD. It is recommended to ask the supplier for a map showing coverage of region and country to know how many FSE are available in the area. While support remains important, the programs should assess suppliers based on their ability to provide responsive, context-appropriate support—whether remote or on-site. This approach will avoid excluding innovative vendors and promote inclusive, sustainable adoption. Delivery time for parts is another important metric when evaluating a service provider, as it determines the overall average time needed to deliver the service. Implementers should require suppliers to commit to a specific delay for spare parts delivery when an instrument is covered by a SLA.

When selecting a provider for digital chest X-ray (DCXR) systems, the availability of replacement parts within the country is a critical consideration. Locally available parts significantly reduce turnaround time (TAT) for maintenance, minimize service downtime, and lower the cost of repairs and replacements. This ensures continuity of essential diagnostic services, particularly for TB and other lung diseases and enhances the long-term sustainability and responsiveness of the imaging infrastructure within the health system.

A warranty is essential when procuring Digital Chest X-ray (DCXR) systems with Computer-Aided Detection (CAD) because it protects against costly repairs, minimizes equipment downtime, and ensures continuity of TB screening services. It should cover both hardware and software components, including detectors, generators, CAD licenses, and AI updates and include on-site servicing, spare parts, and technical support. A strong warranty also guarantees timely issue resolution, preferably with local service teams, ensuring reliable system performance and sustainability over time.

6.2.8 Pricing

Considering costs is an essential element when planning the implementation of new healthcare technologies. In the absence of historical data on purchases and operational expenses, DNTLD-Ps face a gap in reference information needed to guide their decision.

Fortunately, an innovative market-shaping approach was developed by the Stop TB Partnership through the establishment of the Global Drug Facility (GDF) in 2001. This is an integrated pooled procurement mechanism aimed at facilitating worldwide, equitable access to TB products, including new tools across both the public and private sectors. Portable digital X-ray and CAD have now been included in this mechanism since 2021. They have been listed in the GDF catalog, GDF Diagnostics Medical Devices and Other Health Products Catalog.

However, it is important to note that, in addition to the costs specified in the GDF catalog, including equipment acquisition, installation and commissioning, training, and service contracts, DNTLD-P must anticipate additional costs that may influence project implementation for CXR-CAD solutions for TB.

These additional costs, associated with mandatory needs but not directly provided by the manufacturers of X-ray and CAD products, significantly impact the overall budget and, consequently, the cost per interpretation of X-rays. They also include importation costs, acquisition costs of additional materials or infrastructures, and costs related to the accessories and human resources required for implementing these tools.

a. Deployment mode

Three options are available depending on connectivity: offline, online, or hybrid. Each mode has its unique cost implications, affecting both initial setup and ongoing operational expenses - WHO Operational Handbook on Tuberculosis: Module 3 – Diagnosis (2023). Below is a detailed analysis of the cost impact of each deployment mode:

Table 6.1: Cost Impact Analysis of Deployment Mode Selected

	Offline	Online	Hybrid
Initial Costs	High (hardware)	Low (subscription)	Moderate
Operational Costs	Moderate	High (recurring)	Moderate
Scalability	Limited	High	Moderate to High
Flexibility	Low	High	Moderate to High
Security	High (local)	Moderate (cloud)	Moderate
Maintenance	High (mostly local)	Low (mostly remote)	Moderate

b. Type of license

Two options are available depending on the prospective numbers of reads anticipated by the program for each site.

i. **Perpetual License**: a one-time payment fee to use the software indefinitely.

ii. **Subscription-Based License**: requires regular payment (monthly, annually, etc.) to access the software or payment per read. Payment per read should be considered carefully, as it may contradict the principle of budget optimization if the cost per interpretation is not rigorously negotiated, especially if the site performs many radiographs. The costs can become very high over time if the cost per interpretation is high. Lastly, a subscription-based license requires more efficient administrative organization to ensure continuity of services.

6.2.9 Training Requirements

Training for CAD should not be delivered in isolation but embedded within broader instruction on acquiring high-quality chest X-rays (CXR), as image quality is foundational to effective CAD performance. Integrating CAD training with CXR acquisition training can enhance diagnostic accuracy and, from a cost-efficiency perspective, offers opportunities for streamlined delivery and potential savings.

Setting up CAD systems, particularly in lower levels of care, requires significant training and upskilling of healthcare and non-healthcare workers that will be using the system, such as radiographers, clinicians, community healthcare workers and IT support staff. The technology providers typically provide training support as part of the installation package, although the cost of the training packages varies based on the technology provider selected. The training can be in-person, virtual or hybrid. When deciding to select a provider, the training cost, the format and rigor of the training programme should therefore be one of several considerations in determining total cost of ownership.

The ability of the technology provider to provide ongoing training, capacity building, and technical support post-installation is another important consideration in selecting a CAD system. It is important to select a provider that has a technical partner in the country with the resources to provide ongoing timely support to DNTLD-P.

6.2.10 Value Added Services

The rapid evolution of Artificial Intelligence (AI) and Deep Learning (DL) has significantly enhanced the performance and accuracy of computer-aided detection (CAD) solutions in identifying anomalies for various conditions from chest X-rays and other medical imaging modalities.

For countries aiming to adopt these innovative technologies, the main challenge increasingly lies in the ability of CAD suppliers to meet all the needs related to deployment projects, ensuring smooth adoption and long-term sustainability of these solutions.

Therefore, the selection of CAD, depending on their intended use case, should consider the following supplier-related criteria:

- The ability to offer a comprehensive solution that includes equipment (dCXR and CAD), licenses, installation, training, and maintenance.
- The availability of necessary skills, ideally local, to implement a national-scale cloud solution that allows for the archiving, consultation, and processing of data generated by dCXR and CAD, enabling the generation of reports and dashboards for decision support.
- Integration expertise that provides turnkey solutions covering various areas such as mobility solutions for community screening (trucks or motorcycles), energy solutions (solar panels), and internet connectivity solutions.

These aspects, among others, can be discussed with CAD suppliers to identify those offering the most comprehensive and competitive value-added services, thus enabling the delivery of more robust projects.

6.3 Additional Considerations for Selecting Digital X-ray Equipment

6.3.1 Technical Parameters

There are key technical parameters that must be considered when selecting the appropriate digital X-ray machine to deploy, particularly for portable and ultra-portable systems. In addition to WHO recommendations, the country-specific context remains a critical consideration. Factors such as access to electricity, hard-to-reach areas, and workload during outreaches are important and inform some of the recommendations below.

Table 6. 2: Technical Parameters to be Evaluated for Portable and Ultra-Portable Digital X-rays

	Portable	Ultra-Portable
Exposures per day	100 – 300	≥200
Weight	< 100 kg	< 35kg
Output power	5 – 10 kW	<5 kW
Generator Voltage		Must include the range from 40kV to not less than 90kV
Transportation	Fits into a large case and can be transported in a vehicle.	Fits into a small case or back-pack
Use/Placement	Primary healthcare facilities, mobile vans with intermittent supply	Community Outreach/ level 2 / level 3

These parameters are important to consider particularly for facilities without reliable electricity supply and machines used for community outreach initiatives for active case finding.

6.3.2 Lifespan

The lifespan of ultraportable X-Ray devices remains uncertain due to limited long-term data. While their portability enables outreach and decentralized screening, it also introduces risks such as physical damage, environmental exposure, and wear from frequent transport that can be mitigated through proper handling, use of protective casing, and adherence to manufacturer guidelines. Implementing these measures can help extend device longevity and safeguard investments in diagnostic infrastructure.

However, the lifespan for general/standing X-ray equipment is 10 to 14 years for 10,000 – 20,000 examinations per year. For mobile X-ray equipment, the lifespan is 10 to 14 years for 3,000 – 6,000 examinations per year. Machines older than 10 years are considered outdated, with reduced image quality, high maintenance costs, and increased radiation emission risks.

Regular maintenance, including function checks and cleaning, is essential to prolong the lifespan and ensure high performance and image quality. CAD software's lifespan depends on advancements in AI and regular updates to maintain accuracy and performance. A service and maintenance schedule must be implemented and enforced either after a set number of examinations or at the end of a specified period to ensure high performance of the X-ray machine and high image quality. It is crucial to maintain a register of exposures conducted daily to ensure timely maintenance.

6.3.3 Image Quality

The X-ray images generated by the X-ray system for CAD software analysis must be of high quality. Therefore, it is crucial to assess image quality before starting enrollment in the implementation. It is recommended to collect some CXR images from existing equipment and test them with the CAD software to ensure the images can be processed effectively. For chest and abdomen exams, factors such as detector size and noise reduction are critical to image quality. The involvement of X-ray equipment suppliers is essential to address any questions related to image enhancement and ensure compatibility.

6.3.4 Disposal of X-ray Equipment

Disposal of an X-ray machine can be defined as

i. Transferring ownership by donation or sale;

ii. Returning to the manufacturer or

iii. Recycling parts or usable machines.

When recycling or disposing in landfills (not recommended), there are some components of the X-ray machine that must be assessed. These are included below and must be determined for appropriate hazardous waste disposal.

i. Polychlorinated biphenyls (PCBs) are found in the tube oil or transformers (typically found in older models).

ii. Tubes with beryllium,

iii. Housing that contains lead or cast steel with lead lining.

As these machines produce ionising radiation, they must be rendered inoperable by ensuring they cannot be restored, removing the electric cord, or destroying components in the X-ray generator. These components and chemicals must be removed and disassembled by a specialist before they are sent for recycling; this includes draining the oil and removing and disposing of harmful metals appropriately.

To ensure safe disposal, consultation with the Kenya Nuclear Regulatory Authority (KNRA) for approval to dispose of X-ray equipment must be sought. Disposal of X-ray machines must also be in accordance with the National Environment Management Authority's (NEMA) Waste Management Regulations under the Radiation Protection Act, appropriately classifying the type of radiation and disposal requirements. Moreover, the Central Radioactive Waste Processing Facility (CRWPF) in the Materials Testing and

Research Laboratory can safely store and dispose of all radioactive components of X-ray machines.

Should the X-ray machine be donated, sold, or returned to the manufacturer/supplier, a similar approval must be sought. Furthermore, an updated inventory must be kept to track all X-ray machines in use, those that have been disposed of, and the manner in which they are disposed of.

6.3.5 Mobility considerations

Stakeholders should assess the geographic and infrastructural context when selecting X-ray systems. Fixed systems should be prioritized for stable, well-equipped facilities, while portable and ultraportable systems should be deployed in remote or underserved areas to maximize accessibility and coverage.

7

Radiographers Role and the Standard Operation Procedures

Radiographers are responsible for upholding radiation safety by serving as Radiation Safety Officers (RSOs) and strictly applying the ALARA principle to minimize exposure. Despite low doses from ultra-portable machines, protective measures remain essential. These include screening only eligible individuals, maintaining safe distances (8–10 meters in field settings) and using physical or natural shielding.

7.1 Radiation Safety

Radiographers must wear dosimeter badges, 0.5 mm Pb aprons, and thyroid shields. They should also maintain a 2–3-meter distance from the panel detector.

Patient safety involves confirming identity, ensuring proper positioning and collimation, using the correct source-to-image Distance (SID), minimizing repeat exposures, and shielding unwanted areas from radiation.

Safety measures for the public, especially in an outreach activity, require a clearly marked radiation zone with a cordon tape adhering to the stipulated 10 x 10 m demarcation by KNRA, correct placement of radiation warning signages, designated assistants to secure the area, and shielding off bystanders from both primary and scattered radiation.



Radiographers must wear dosimeter badges, 0.5 mm Pb aprons, and thyroid shields. They should also maintain a 2–3-meter distance from the panel detector.

Regular dose monitoring and compliance with KNRA safety audits are mandatory to ensure sustained safety standards.

7.2 Technical and Diagnostic Qualities of Chest X-ray for AI CAD Interpretation

A standard chest X-ray (CXR) must meet both technical and diagnostic quality criteria to ensure accurate interpretation, particularly for TB and lung-related abnormalities. Technically, the image should be clear, properly exposed, and reproducible, with correct patient positioning, adequate inspiration, proper centering and alignment, optimal penetration, absence of artifacts, and proper documentation.

Diagnostically, the image must allow full visualization of relevant anatomy, clear visibility of the lung parenchyma, and sufficient detail to detect signs indicative of tuberculosis or other lung conditions.

7.3 Standard Operating Procedure during the Acquisition of a Good Chest X-ray

During imaging, the radiographer is responsible for guiding the patient through proper positioning- typically a posteroanterior (PA) chest view, though alternative views may be used when clinically indicated. This includes adjusting the height, source-to-image distance (SID) to 150–180 cm, and ensuring correct anatomical alignment. Clear instructions must be given to the patient to stand still, take a deep breath, and hold it during exposure. Image capture should follow locally approved exposure parameters, with strict adherence to safety protocols.

7.4 Care and Maintenance of the Equipment

Daily equipment maintenance is essential to ensure safe and reliable imaging operations. Radiographers must begin by inspecting the unit for physical damage and confirming that it powers on correctly, addressing any troubleshooting needs.

The flat panel detector should be tested for functionality, and all components, including accessories, must be cleaned and high-contact areas disinfected regularly.

Equipment should be installed on stable, level ground to support smooth mechanical movement. Daily inspection outcomes, including system calibrations and checks, must be performed. This should be documented along with any corrective actions taken.

Periodic machine servicing by the vendor or the designated local maintenance team should be performed according to their prescribed schedule.

8

Additional Consideration for Planning & Implementation

8.1 Effective Inventory Management

For ultraportable CXR devices, it is important to establish a clear mechanism for tracking equipment location and utilization. This may involve designating a central "base site" where the device is primarily housed, along with a documented list of all service delivery points that regularly access or are supported by the device. Such an approach enhances visibility, accountability, and planning for maintenance, redeployment, and performance monitoring across multiple sites.

To ensure a comprehensive and up-to-date understanding of the medical devices (hardware and software) used within the DNTLD-P networks, it is essential to conduct a detailed inventory. This inventory should provide a real-time national overview of all installed equipment. Below is a non-exhaustive list of critical information that should be collected and recorded:

- **Equipment type and configuration:** Document the type of equipment (e.g., fixed, mobile, portable, ultraportable radiography equipment) and its complete configuration. This includes all components that make up the equipment, particularly those whose malfunction would render the equipment inoperative (e.g., server, central control unit, monitor, voltage generator).
- **Manufacturer contact details:** Record comprehensive contact information for the equipment's manufacturer.
- **Supplier information:** Identify the supplier, whether it be the manufacturer, distributor, funding agency, government entity, NGO, or other sources.

- **Serial number:** Capture the unique serial number for each piece of equipment.
- **Installation details:** Include the installation date, a copy of the installation report, and the equipment's age.
- **Operational status:** Indicate whether the equipment is currently active or inactive.
- **Location:** Specify the precise location where the equipment is installed.
- Software version: Record the current software version installed on the equipment.
- **Maintenance records:** Include the date of the last maintenance, along with copies of reports from both preventive and corrective maintenance activities.
- **Upcoming maintenance:** Note the scheduled date for the next maintenance activity.
- **Service contract details:** Document the scope of the service contract, including the contact information for the contractor or the designated contact person in case of equipment breakdown.
- **Service contract documentation:** Maintain a copy of the service contract, clearly specifying the obligations of all parties involved.
- **Infrastructure requirements:** Provide a summary of the necessary infrastructure required for the optimal operation of the equipment.

Given the complexity and scale of equipment management within Kenya's TB diagnostic network, the adoption of a robust, digitized solution is not just recommended—it is essential. The TIBU Laboratory Information Management System (TIBU LIMS), enhanced under the Secure Sync project, is purpose-built to address precisely these operational and life-saving needs. TIBU LIMS now incorporates features traditionally associated with a Computerized Maintenance Management System (CMMS), but customized for the TB diagnostic ecosystem.

TIBU LIMS consolidates equipment data from across all TB diagnostic platforms into a centralized, secure, and interoperable database. With its newly developed real-time synchronization and device monitoring modules, the system supports preventive maintenance, calibration tracking, repair ticketing, inspection documentation, and asset lifecycle management. These enhancements allow maintenance planners, regional engineers, super users, and MOH oversight teams to proactively monitor equipment health, set reminders, generate maintenance checklists, and track key performance indicators (KPIs). Importantly, it also digitizes claims for maintenance-related activities by Subcounty Lab Coordinators, Quality Controllers, and Super Users through integration with TIBU Cash, streamlining financial accountability.

By embedding CMMS functionality directly into TIBU LIMS, the TB program ensures that diagnostic instruments remain functional, downtime is minimized, and life-saving services for TB patients are not interrupted. This solution not only supports Kenya's End TB strategy but also strengthens resilience and sustainability within the broader health informatics landscape.

8.2 Robust Service Level Agreements

Effective maintenance of medical equipment requires a well-structured approach, with clear roles for all stakeholders, including suppliers, biomedical engineers, technicians, healthcare facilities, and operators. Central to this approach is the development of robust Service Level Agreements (SLAs) with manufacturers and service providers.

SLAs are critical because they define the expectations, responsibilities, and performance metrics for maintaining equipment. However, maintenance contracts are often underfunded, and their performance is rarely evaluated rigorously, leading to gaps in service quality and equipment uptime.

Programs should prioritize SLA negotiations early in the planning process when introducing new medical technologies. These agreements should cover not just immediate post-installation support but extend for a minimum of three to four years to ensure long-term reliability. During negotiations, it is essential to clearly define the services to be covered, such as routine inspections, preventive maintenance, and emergency repairs. The SLA should also specify critical spare parts, with provisions for either full coverage during breakdowns or maintaining a basic stock based on reliability metrics like Minimum Time Before Failure (MTBF).

Moreover, the qualifications of the engineers provided by the service contractor should be verified, and their performance should be tracked through detailed intervention reports. These reports are key indicators of the quality of service provided under the SLA.

Programs should also ensure that the SLA includes comprehensive training for healthcare personnel. This training will empower staff to use the equipment properly, identify issues early, and take corrective actions promptly, all of which contribute to better patient care and equipment longevity.

When developing a Service Level Agreement (SLA) for Digital Chest X-ray (DCXR) systems with Computer-Aided Detection (CAD), it is critical to include provisions on data safety, privacy, and sharing regulations. These should clearly define how patient images and diagnostic data are collected, stored, transmitted, and accessed, ensuring compliance with national data protection laws and global standards such as GDPR or HIPAA where applicable. The SLA should specify data ownership, storage locations (especially in cloud-based CAD solutions), consent requirements, access controls, encryption standards, and protocols for cross-border data sharing or export restrictions. This safeguards patient confidentiality, builds public trust, and protects the health system from legal and ethical risks associated with misuse or unauthorized access to sensitive health data.



SLAs are critical because they define the expectations, responsibilities, and performance metrics for maintaining equipment.

8.3 Effective Resource Planning

Effective resource planning is crucial for the successful introduction, maintenance, and disposal of medical devices, particularly when integrating new technologies into existing health systems. This process involves carefully considering human, financial, and material resources, especially in contexts without historical usage of similar technologies. Strong collaboration between health programs, funders, and manufacturers is essential to manage these resources effectively.

a. Human Resources

The deployment of new medical devices, such as dCXR combined with CAD systems, demands the development of new skills among healthcare professionals. Training programs must be comprehensive, covering device operation, maintenance, troubleshooting, and software updates, as well as essential IT skills like programming and cybersecurity. Ongoing support to users of the devices, including mentorship and refresher courses, is vital, particularly in lower levels of the health systems where the lower healthcare working cadres may be engaged. Workforce planning should also consider the need for additional staff (e.g., radiologists) or the upskilling of existing personnel.

Key personnel to consider and their roles and responsibilities include:

i. **Clinicians:** Clinical assessment of patients, send for x-ray and laboratory test, diagnose and treat.

ii. **Radiologist:** operates X-ray equipment and reviews CAD-generated reports for quality assurance.

iii. **X-ray technician:** sets up and operates X-ray equipment.

iv. **Nurse:** Patient triage, treatment initiation, registration, and follow-up.

v. **Community healthcare worker:** Community mobilization and patient follow-up.

vi. **IT staff:** support with IT and CAD-related matters.

b. Financial Resources

A detailed financial plan should be developed to cover both the initial and ongoing costs associated with maintaining an optimal CAD and X-ray infrastructure. The plan should cover the purchase, installation, training, infrastructure upgrades, and operational expenses such as maintenance, software licensing, and consumables/parts. It is also important to distinguish between manufacturer warranties, which offer limited coverage, and maintenance contracts that provide comprehensive support, including regular inspections. Financial risk management strategies, such as securing warranties, service contracts, or insurance, should be employed to mitigate unexpected costs.

A structured analysis of these additional costs is crucial for an objective assessment of the impact. Below is a non-exhaustive list of cost items to be estimated:

Table 8.1: Additional Costs to be Considered Before CAD Implementation

Cost Categories	Items
Import logistics & Customs clearance	**Shipment conditions** 1. Freight & insurance costs for Portable digital X-ray system 2. Customs Duties & Taxes 3. Freight forwarder fees and other transit charges
	Shipment conditions 1. Freight & insurance costs for Computer-Aided Detection hardware and accessories 2. Customs Duties & Taxes 3. Freight forwarder fees and other transit charges
Overhead acquisition	Full detailed list of intrants (equipment, infrastructures) mandatory need but not supplied by the portable digital X-ray system supplier as per supplier indication on the pre-installation report
	Full detailed list of intrants (equipment, infrastructures) mandatory need but not supplied by the CAD system supplier as per supplier indication on the pre-installation report
	IT Support (Internalization & Externalization) 1. On-site integration with PACS/RIS (If applicable) 2. Internet connection annual subscription (If applicable) 3. Interoperability with the National Health System (If applicable)
	Additional Power supply systems (If necessary)
	Addition drive for storage and backup or any other backup strategy
Human resources	Senior radiologist salary / stipend
	Junior radiologist salary/ stipend
	Radiographer salary/ stipend
Logistics & security of equipment	Active outreach (If applicable)

When considering procurement of CAD software, the price can vary significantly depending on the deployment mode and type of software license.

c. Material Resources

A precise and well-planned budget is essential for acquiring the necessary tools and equipment for both preventive and corrective maintenance. In particular, medical imaging devices often require specialized toolkits for fine-tuning, which must be used within specific time frames or after a set number of uses. Additionally, preventive maintenance kits, which are sometimes included in service contracts or need to be purchased separately from manufacturers, are crucial to ensuring the ongoing functionality of these devices. Properly anticipating these costs and incorporating them into the overall budget is vital for securing the necessary funding and maintaining the operational integrity of the equipment

8.4 Registration, Licensing, and Quality Assurance

8.4.1 Regulation of X-ray Equipment

X-ray equipment is regulated by the Kenya Nuclear Regulatory Authority (KNRA), under the Nuclear Regulatory Act No.29 of 2019. The Act provides the overarching legal framework that governs the regulation of safe, secure, and peaceful development, production, possession, use, storage, transport, transfer, disposal, or handling of nuclear and radioactive materials, activities, facilities, and other apparatus generating radiation. In addition to KNRA, the Pharmacy and Poisons Board (PPB) plays a complementary role in regulating medical devices, including diagnostic imaging equipment, under the Pharmacy and Poisons Act (Cap 244). PPB ensures that imported medical devices meet safety, efficacy, and quality standards before they are approved for use in the public or private sector.

Before any X-ray equipment can be imported and deployed in a public or private sector health facility in Kenya, the importer must obtain a license from KNRA. The licence application must describe the device, cost (in KSh), the manufacturer's certificate, and any other global certification. The import permit is valid for 30 days. Importers must also ensure that the equipment is registered with the Pharmacy and Poisons Board (PPB). For more information, please refer to the KNRA website

8.4.2 Regulation of CAD Software

CAD is regulated as a medical device when it is used for diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, injury or disability. Most products considered medical devices and that rely on AI/ML are categorized as Software as a Medical Device (SaMD). CAD software falls under the SaMD category. The regulatory framework governing these tools is complex and many regulators around the world are having to play catch up. In Kenya, the regulation of AI-enabled medical devices is nascent but fast-evolving. The PPB is tasked with ensuring the safety and effectiveness of any AI-enabled medical device used in the country, based on its intended use and the level of risk to patients if it is inaccurate. It is important to ensure that the CAD software has gotten the necessary approvals from PPB. As part of the review process, PPB may request further evidence to validate performance claims.

Further details about regulations of AI-enabled medical devices can be found on the PPB website.

In Kenya, the Office of the Data Protection Commissioner (ODPC) plays a central role in regulating AI data in health, applying the principles of the Data Protection Act (DPA) (2019). The ODPC issues guidelines, handles complaints, and enforces DPA provisions to ensure lawful, transparent, and ethical processing of personal health data used in AI systems. Its functions include promoting data protection by design, providing sector-specific guidance for health entities, and supporting compliance with existing data protection frameworks for health-related AI applications.

8.4.3 Quality Assurance

Advancements in medical imaging, from analogue to digital systems and from basic fluoroscopy to advanced angiography, highlight the critical need for robust quality assurance (QA) in X-ray and diagnostic imaging. The reliability of the hardware and software device is critical, as errors or malfunctions can significantly impact patient health. The International Atomic Energy Agency (IAEA) has developed standardized quality control procedures to address these challenges, incorporating the latest advancements in the field.

In Kenya, a strong QA system for molecular tests and diagnostic tools operates at the county level, supported by the national TB quality improvement framework and aligned with the Kenya Quality Model for Health (KQMH). The Nuclear Regulatory Act provides specific guidance on QA for medical radiation facilities, ensuring detailed implementation guidelines. To enhance diagnostic quality across Kenya's dCXR and CAD systems, a comprehensive QA system must be integrated into existing national QA activities within the TB diagnostic network.

Below, we outline a few critical steps to be considered in developing and implementing a QA strategy for X-ray and CAD:

- **Governance:** Establish clear roles and procedures at national, county, and sub-county levels. Involve medical physicists, radiological practitioners, and technologists under KNRA guidelines to effectively plan, implement, and monitor the QA system.
- **National strategic planning:** Conduct a situational analysis to assess current diagnostic quality and QA initiatives. Develop a prioritized action plan with measurable steps for phased implementation and impact assessment based on these findings.
- **Equipment procurement and installation:** Select reputable vendors with a track record of reliable equipment and excellent after-sales service. Ensure proper installation following manufacturer specifications and regulatory guidelines. Conduct comprehensive acceptance testing and periodic measurements by medical physicists to verify performance and safety.
- **Training and certification:** Implement structured training programs and competency assessments for radiologists and support staff to ensure proficiency with dX-ray and CAD systems.

- **Routine quality control:** Establish daily checks for critical parameters, regular inspections, and annual QA tests. Develop standardized protocols and engage external experts for impartial assessments as needed.
- **Maintenance and calibration:** Schedule regular preventive maintenance and use certified calibration tools to maintain accuracy. Establish service contracts for timely maintenance and issue resolution.
- **Incident reporting and management:** Develop a system for documenting and analyzing equipment malfunctions and errors. Conduct root cause analysis and implement corrective actions to prevent recurrence.
- **Monitoring and auditing:** Conduct regular internal audits to ensure compliance with QA protocols and engage external auditors for unbiased reviews. Establish key performance indicators (KPIs) to monitor QA strategy effectiveness.
- **Continuous improvement:** Use feedback from audits, incident reports, and user input to continuously improve QA processes. Regularly update protocols and provide training on new standards and technologies.
- **Patient and staff safety:** Implement stringent radiation safety protocols to protect patients and staff. Educate on the importance of QA for health and safety to enhance the effectiveness of the QA strategy.
- **Clinical-laboratory interface:** Strengthen coordination between clinical and laboratory functions to ensure adherence to national testing algorithms. Ensure correct test ordering, accurate result reporting, and prompt initiation of appropriate therapy.

8.5 Data Privacy, Storage, and Ownership

The need for transparent data governance in CAD implementation is essential to ensure that all patient data collected through CAD systems is handled in accordance with Kenya's data protection laws, including the Data Protection Act (2019). Programs should prioritize solutions that offer secure, locally hosted storage options or clearly define data residency protocols. Strengthening local data stewardship and ensuring that the Ministry of Health retains full ownership and control over health data is critical to building trust, safeguarding patient rights, and supporting long-term system sustainability. For effective data management and protection in the DNTLD-P, a robust data infrastructure must be established to ensure data ownership and prevent potential privatization by external entities.

During the selection process for the CAD and/or dCXR solution, it is crucial to evaluate whether data processing will occur on local cloud servers or the provider's proprietary or third-party servers. This decision should be made with input from data experts to determine the best approach for the NTP, considering factors such as data sovereignty and system capabilities. Privacy policies of CAD providers must be thoroughly reviewed to ensure compliance with national data privacy laws. The Office of the Data Protection Commissioner (ODPC) plays a key role in enforcing data protection regulations and must authenticate the security protocols implemented by CAD developers.

In the initial agreement of sale, it must be clearly stated that all data processed by the CAD software belongs to the NTP or facility. Moreover, it must be a clear indication of where the data obtained will be stored (local cloud, physical servers, or the CAD supplier's cloud server). In addition to this, a Data Processing Agreement (DPA) must be in place to ensure the data security of all patient information. The DPA must outline the obligations of the users/NTP and the CAD supplier, including de-identification measures to maintain confidentiality, prior authorization of any third-party cloud services, and to ensure all CAD-generated reports will only be used as intended. A non-disclosure agreement (NDA) should be signed before use to help safeguard the data privacy of all patients.

Given the sensitivity of patient health data, it is essential to implement robust security measures to safeguard against breaches. This includes encrypting stored data, enforcing strict access controls during data transmission and storage, and securing systems with antivirus software, firewalls, and detection systems. Regular data vulnerability checks should be conducted to identify and address potential weaknesses.

Training for all staff in data security, handling, and storage is critical. Staff must be educated about data management risks, including cybersecurity threats such as phishing, malware, and ransomware. Additionally, computer systems used for managing patient data should be dedicated to that purpose only, avoiding personal use to reduce the risk of data breaches.

8.6 Integration with Existing X-ray Systems

Before implementation, it is imperative to ensure the CAD software is fully integrated with the existing PACS and/or RIS systems. Moreover, it is recommended to run a validation process of the CAD software with the existing equipment.

For CAD systems with integrated PACS features, deployment can follow a simplified workflow for image capture and routing, requiring only a connection interface between the X-ray equipment and the CAD console, even if a PACS is not present. Some CAD suppliers offer these interfaces as part of their solution.

For CAD systems without integrated PACS features, deployment will typically require a PACS if one is not available. The workflow for image capture and routing will involve the X-ray equipment, the CAD console, and finally, the display on PACS.

For hospital structures that also use an RIS, it will be essential to develop procedures to ensure data is accurately entered into both the local RIS and the national health information system. This will require developing APIs to automate these processes, minimizing the risk of errors or omissions. Communication with CAD, PACS, and RIS here will be dependent on appropriate interfacing and a high-speed data network.

8.7 Validation and CAD Cut-off Threshold Selection

It is important to reiterate that CAD threshold settings must be re-evaluated whenever there is a system update, software upgrade, or change in CAD technology or provider. These changes can affect algorithm performance and calibration, requiring renewed validation to ensure diagnostic accuracy and alignment with programmatic goals.

As the implementation of the CAD-CXR solutions begins, it will be critical for DNTLD-P or facilities to undertake validation studies in their localities and for their intended use cases rather than the wholesale adoption of validation studies that might have been conducted in other markets, geographic regions, or different use cases. Most importantly, given the huge investments required to deploy this technology, it will be imperative for users of the facilities to consider the multi-disease application capabilities of CAD products to meet their universal health coverage and program-specific goals.

In addition, it is imperative to select a suitable threshold for the local setting and intended use, as this would represent an optimized accuracy for interpretation. The threshold can differ between regions within a country; thus, facility-specific calibration studies must be conducted upon start.

The cut-off threshold can differ between regions within a country based on local epidemiology, program goals, and operational realities; thus, facility-specific calibration studies are strongly recommended upon start.

WHO and the Special Programme for Research and Training in Tropical Diseases has developed a toolkit to guide the calibration study and selection of the local threshold that can be accessed here. *(https://tdr.who.int/activities/calibrating-computer-aided-detection-for-tb)*

A threshold score can be adjusted lower for high sensitivity, thereby requiring more confirmatory tests to be done. In contrast, an adjustment higher than this will result in low sensitivity, resulting in missed TB cases. This can be the difference between detected and missed TB cases, and meeting screening and public health targets. The adjustment of the selected threshold depends on the program or facility targets.

The performance of CAD algorithms can decrease over time when the original training conditions change, such as differing and decreasing image quality from various X-ray equipment or clinical environments. This can lead to incorrect diagnoses and treatments. It is crucial to conduct continuous calibration of the threshold and recommended software updates to maintain accuracy and performance and ensure consistency in results. More so it is critical to have a periodic validation of reports based on expert human readers working in those settings, and thresholds adjusted accordingly.

8.8 Post-Marketing Surveillance

Post-market surveillance (PMS) is a systematic process to continuously monitor the safety and effectiveness of a medical device after it has been launched on the market. This is done by collecting information and deriving necessary corrective and preventive actions. AI-enabled devices have unique attributes that require more proactive PMS than the typical medical device system. This is because there is limited user experience with AI-enabled tools as the technology is relatively new, AI models are sensitive to bias, and version updates to the software might cause the solution to drop in performance.

Ongoing surveillance and monitoring of complaints and adverse events related to harm caused to users of CAD technologies are essential, given that the technology is still emerging. Manufacturers need to allocate time and resources to investigate, respond, and notify regulatory authorities, thereby reducing risks from adverse events or issues. They should also establish channels to contact local agents or distributors when complaints are received or when regulatory action is necessary. Communication channels for updates, patches, and recall actions should be set up with end users and healthcare providers.

The PPB guideline for post-marketing surveillance of medical products and health technologies in Kenya provides a comprehensive framework for PMS for medical devices in the country. It outlines the roles and responsibilities of all stakeholders, including the patient/public, healthcare providers, the county vigilance focal person, the county health management team, public health programs, the market authorization holders, manufacturers, the quality control testing laboratory, and procurement agencies. The guideline also elaborates on how, when, and when adverse events should be communicated. Further details about PMS can be found on the PPB website.

8.9 Common Challenges Faced During Implementation

Based on lessons learned from early deployments of portable and ultraportable digital X-ray and CAD systems, a table has been developed to summarize the most common after-sales service requests and their impact on deployment and operational processes.

Table 7.2: Common Challenges Facilities may face with Ultra-Portable Digital X-rays and CAD and the Associated Implications

Challenges	Portable & Ultra-Portable Digital X-Ray	Computer-Aided Detection Software for TB	Implications
Power Supply	Generators and detector batteries are not as reliable as claimed by manufacturers.	The battery life of computers is insufficient for a full day of work.	High-quality supplementary power supply solutions are necessary.

Challenges	Portable & Ultra-Portable Digital X-Ray	Computer-Aided Detection Software for TB	Implications
Installation and Field Service Engineer (FSE) Training	Assembly of the digital X-ray system can be complex for an inexperienced radiographer.	Installation varies depending on the deployment mode (Online, Offline, Hybrid) and different components to connect	Efficient field service engineer training is required. A project IT specialist (systems, application, or network engineer) is needed.
Connectivity Issues	The connection of CAD systems may vary depending on the digital X-ray used.	Loss of connection from the console's wireless transmitter can cause delays or failed uploads of chest X-rays (CXR) to CAD.	A Local Area Network (LAN) is necessary if the CAD software is installed on a different computer than the one connected to the CXR machine (two-device mode).
Storage Capacity and Integration with PACS	Integration of different data systems is challenging and requires IT capabilities	Due to the large size of X-ray files (approximately 10–30 MB), the CAD data storage capacity can quickly reach its maximum, preventing image uploads.	An application programming interface (API) may be needed to address interoperability issues. An external drive may be necessary for data backup.
Complaint Handling Process	Unexpected defects may occur at any time on hardware and devices.	Unexpected defects may occur any time on software and devices.	A clear procedure for contacting supplier service is required (24/7 technical support from product experts via online case submission, live chat, and phone support). It is highly recommended to sign an SLA granting access to 24/7 service support.
Spare Parts Delivery and Instrument Calibration Needs	Defective device (Hand switch and detector) required replacement (at different times).	Software is pre-installed on a laptop and in case of default, the equipment had to be returned to the manufacturer for recalibration.	Local spare part stock for sensitive parts is required. SLA is recommended to obtain a priority shipment route for spare parts. Additional laptops with full configuration could be considered in procurement planning.
End-user Training & Improvement	Multiple remote technical support is needed during installation, and for troubleshooting as needed.	Suppliers provide support for results interpretation and threshold selection when needed.	Continuous education along with sharing best practices is required in the rapidly evolving environment.

9

Monitoring and Evaluation

Monitoring and Evaluation (M&E) in TB care plays a vital role in tracking and improving diagnostic and treatment outcomes. A key focus of this framework is leveraging X-ray technology as a diagnostic tool, particularly through the use of Computer-Aided Detection (CAD) systems. This chapter highlights the integration of X-ray-based indicators into the M&E process, which enables healthcare workers to identify presumptive TB cases more effectively and optimize patient management.

X-ray diagnostics, supported by CAD scoring, provide a robust method for early detection of TB and other respiratory conditions. The indicators detailed in this chapter cover the entire spectrum of X-ray diagnostics—from the number of presumptive cases screened using X-ray to the analysis of CAD scores across three key ranges (60 and above, 40–59, and below 40). These metrics are further enhanced by disaggregation into laboratory results, radiologist interpretations, and diagnostic outcomes. This granular approach ensures that the system captures essential data for assessing the accuracy and efficiency of X-ray diagnostics.

By embedding X-ray-related metrics within the M&E framework, healthcare teams can evaluate trends in TB diagnosis, identify gaps in service delivery, and refine diagnostic protocols.

X-ray diagnostics, supported by CAD scoring, provide a robust method for early detection of TB and other respiratory conditions. The indicators detailed in this chapter cover the entire spectrum of X-ray diagnostics—from the number of cases screened using X-ray to the analysis of CAD scores. These metrics are further enhanced by disaggregation into laboratory results, radiologist

interpretations, and final diagnostic outcomes. This granular approach ensures that the system captures essential data for assessing the accuracy and efficiency of X-ray diagnostics.

By embedding X-ray-related metrics within the M&E framework, healthcare teams can evaluate trends in TB diagnosis, identify gaps in service delivery, and refine diagnostic protocols. The chapter also outlines the roles of key actors, including radiographers, health workers, and program officers, in managing and utilizing these indicators. Regular monitoring cycles—monthly, quarterly, and annually—allow for timely feedback and data-driven decision-making to strengthen TB control initiatives.

This Chapter aims to provide an in-depth understanding of how X-ray diagnostics are operationalized and monitored within the broader M&E framework, emphasizing their pivotal role in enhancing TB detection and treatment outcome.

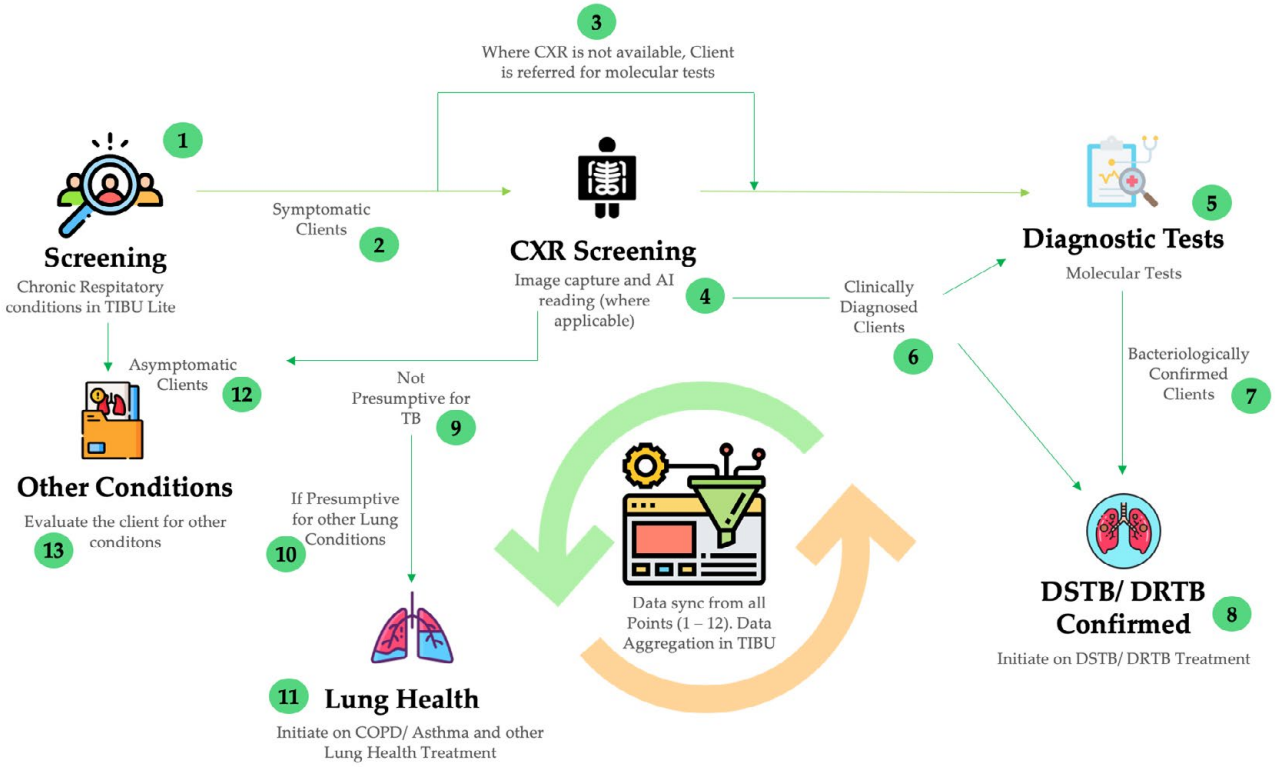


Figure 9.1: Data Flow

Table 9.1: Indicators to Monitor

Monthly Monitoring and Evaluation Indicators							
Code	**Indicator**	**Source of data**	**Frequency**	**Primary Actor(s) and Access Level**	**Supporting Actors (read only access)**	**Geographical filter**	**Category**
101	Facility Work load (OPD)	MoH 204 B >15 years	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
102	Number of patients screened for respiratory symptoms	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
103	Number of patients with respiratory symptoms	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
104	Number of patients screened for Lung Conditions using Chest X-ray	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
105	Number with abnormal CXR suggestive of TB	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload

Code	Indicator	Source of data	Frequency	Primary Actor(s) and Access Level	Supporting Actors (read only access)	Geographical filter	Category
106	Number with abnormal CXR suggestive of other conditions	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
107	Number of CXR with Lung Nodules	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
108	Number with Normal CXR	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
109	Number with abnormal CXR suggestive of TB with Positive laboratory results disaggregated by type of test	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
110	Number with abnormal CXR suggestive of TB with Negative laboratory results disaggregated by type of test	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload

Code	Indicator	Source of data	Frequency	Primary Actor(s) and Access Level	Supporting Actors (read only access)	Geographical filter	Category
111	Number with abnormal CXR suggestive of other Lung Conditions offered lung function assessment (spirometry /peak-flow tests)	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
112	Number with abnormal CXR suggestive of other Lung Conditions with obstructive features by final diagnosis	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload
113	Number of CXR with lung Nodules referred for lung cancer screening	TIBULIMS	Monthly Quarterly Annually	Primary Health Care Worker; Write and Read	Health Care Workers SCTLC CTLC Partner Program Officers	Facility Sub County County National	Workload

ANNEXES

Annex 1: Facility Readiness and Site Assessment Tools

Name of Health Facility:			
Type of facility: Government NGO Private Academia			
If facility is privately owned, has it been registered with the NTLP under PPM Yes/No			
MLF Code:			
Location of health facility: City/Town County/Sub County/District			
TB control zone			
TB/HIV Partner(s) supporting the facility			
List persons interviewed			
Full Name	Position/Title	Contact Details	
1.			
2.			
3.			
4.			
5.			
6.			
Assessors' names and contact details (phone & email):			
1.			
2.			
3.			
Date of assessment: (DD/MM/YYYY)			

Facility Demographics and Services	
1. Catchment population	Facility Sub-county
2. List the services offered	…… …… …… …… ……

3. Operation times (is it 24 hours)?	24-hour facility Yes/No Operating Time: …… to…… Days of the week: …….
4. Does the facility have admission facilities?	Yes / No If yes, indicate applicable bed capacity below: Maternity ward No. of beds…… General ward No. of beds…… Paediatric ward No. of beds…… Surgical ward No. of beds…… Other specify ……..
5. Laboratory Services What TB diagnostics services are available?	Tick all that apply: 1. Light microscope 2. FM microscope 3. GeneXpert machine (how many modules) 4. Truenat 5. LF LAM 6. Other specify ……
6. Do you offer testing/screening for diabetes at the facility?	Yes /No If yes, at what point are they available. Specify……..……
7. Do you offer blood pressure monitoring at the facility?	Yes/No If yes, at what point are they available. Specify…….
8. Does the facility use an automated patient identification and validation system?	Yes/ No

9. Total number of healthcare workers at the facility?	Pulmonologist/ TB Specialist…… Radiographers…… Radiologists…… Doctors …… Clinical officers…… Nurses…… Laboratory technologists…… Pharmacists…… Pharmacy technologists ……... IT officer…… Biomedical engineer…… Medical Physicist …… Others……...

Outpatient Workload	
1. Average daily OPD workload (all) *Check the last 3 busiest days*	…….. …….. ……... Average ……
2. Monthly OPD workload	Month 1……. Month 2……. Month 3……. Month 4……. Month 5…….
3. CXR performed at this facility *Average number of tests performed daily*	……
4. How are people referred for CXR in this facility?	Tick all that apply: Doctor/Clinical Officer/Nurse Pulmonologist/TB specialist NGO/Community worker Self-referral Active case finding campaign Other
5. Estimated monthly number of CXRs to be read using CAD based on planned algorithm for TB screening	……

6. Imaging Workload (if applicable)	Month 1…… Month 2 …… Month 3 ……
7. Monthly numbers of persons with respiratory illnesses (*Check in MOH 705 a/b*)	

	Children (under 5 yrs.)	Children & Adults (5 yrs. and above)
Month 1		
Month 2		
Month 3		
Month 4		

TB Screening and Community Outreach		
1. Is the health facility conducting TB screening at the outpatient department? *Check the availability of screening tools.*	Yes/No	Comments
2. Where is the documentation of TB screening done? *Check the availability of presumptive registers or note other tools.* *Note use and completeness*	1. …… 2. …… 3. …… 4. …… 5. ……	
3. Where are people referred for CXR investigations currently?	Private Public NGO	
4. How much do they pay for CXR services?	……..	
5. Does this facility offer TB preventive therapy treatment (TPT)?	Yes/No	

6. Is the health facility covered by a community health unit?	Yes/No If yes, how many health facilities are attached to this health facility? ……	
7. Are there community health volunteers available?	Yes/No If yes, how many are they?..... Who supports their stipend? …… …….....	
8. Does the facility conduct community outreaches?	Yes/No *If yes, provide more details/frequency, target populations reached etc.*	

Readiness For the Digital X-ray and Computer Aided Detection Software		
Existence of a safe and functional X-ray Unit/Department		
1. Is there secured storage for X-ray machines (particularly portable ones) *Let the facility show you- check for security, lockability etc.*	Yes/No *Comment on what needs to be improved* *Is the facility willing to foot the cost of improvements?*	
2. Is there adequate space to perform CXR investigations compliant with the Kenya Nuclear Radiation Authority (KNRA requirements?	Yes/No *Check for availability of a room/space to do this*	
3. What is the space size available for CXR investigations?	Provide measurements of available space ------- x ------(metres)	

4. What is the structural integrity of the space? For enclosed spaces *Provide layout diagram including the adjacent spaces*	Stone Brick Wooden Iron Sheet Tent Other (specify)……..…	
5. For outdoor spaces describe nearby structures/ landmarks. If no fixed structure – a tent or dedicated outdoor space? Demarcation to avoid high traffic?	Yes / No	
6. Does the facility provide privacy to patients who need to remove any clothing with metallic components, or accessories, before taking a CXR?	Yes/No	
7. Is the facility connected to the electricity grid?	Yes/No	
8. Are there sufficient sockets available for battery charging of essential devices: CXR detector, generator, PACS laptop, CAD laptop/box? *(At least 4 sockets or an extension cable required)*	Yes/No	
9. Do you experience power outages? If yes, what is the frequency of power outages at the facility? Is there a power backup solution including solar?	Yes/No How many times weekly……? Yes/No	
10. Would a solar panel system or storage battery need to be procured to provide the required electricity?	Yes/No	
11. Is available electricity adequate to run CAD software and charge batteries? (three-phase)	Yes/No	

12. Does the facility have internet connectivity? If No, is the location of the facility covered with a 4G network?	Yes/No Yes/No	*Specify* *Specify*
13. Does the facility already have existing radiology systems? e.g. Picture Archiving and Communication System (PACS) or Radiology Information System (RIS)	Yes/No	*Specify*
14. Was the ambient temperature recorded in the X-ray unit below +10°C or above +50°C?	Temperature Yes/No	
15. Was the relative humidity recorded in the X-ray unit below 15% or above 80%	Humidity Yes/No	
16. Does the testing site use appropriate disinfectants and are they prepared correctly?	Yes/No	
17. Is suitable personal protective equipment (PPE) provided at the CXR unit and are staff trained in its correct use?	Yes/No	
18. Does the facility monitor radiation within the X-ray department? *(MOV- radiation monitoring report)*	Yes/No	
19. On average, how many CXRs are done/referred to every month?	……..	
20. Who reads the CXR at the referral site?	Resident radiologist Outsourced radiologist Clinician Radiographer Other specify	
21. How are the CXR results currently sent back to clinicians?	Written Report Digital report Word of mouth	

22. On average, what is the turnaround time (TAT) for getting the results back to the clinicians?	Hours…… Days…….. Weeks……	
23. Are clinicians at this facility trained on CXR reading? *Verify proof of training*	Yes/No	
24. Does the CXR unit have relevant job aids, work instructions, SOPs and algorithms?	Yes/No	
25. In case of findings of other abnormalities other than TB, would the patient be managed at the facility or referred out? In case of referral, to what facility would that be?		

Health Facility Processes (Tick what applies)						
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Remarks
The communication and feedback mechanism at the health facility is adequate						
The facility has active quality improvement teams that meet regularly (*Check for evidence, minutes, charts etc.*)						
TB is incorporated as an agenda item during monthly facility meetings (*verify with meeting agenda, and minutes*)						
There are discussions of TB during data review meetings						

Data Demand and Information Use						
Health facilities can analyze and consume their data						
Current TB data management practices						
Health facility staff have been trained in data management and use (D4D)						
Health facility has used data for decision making (***if yes, depict an example)***						

Questions to the County Health Administration/ Radiologists	
1. If the facility being assessed has no radiographer, would the county provide one to run these screening activities?	Yes/No
2. What mechanism is in place in the county, for radiation monitoring of all staff working in the radiation area every month? *This should include the submission of radiation doses. (MOV-Radiation monitoring reports)*	
3. What radiation protection gear is available for all patients and staff in the county?	Patients: • Lead shields/gown • Thyroid shield Staff • Lead gown • Thyroid shield • Other……
4. Are radiation monitoring instruments available?	Monitoring equipment • Dosimeter
5. How would the radiology department conduct quality assurance for this facility?	
6. Any other comments?	

Radiation Safety[12]	
1. Particulars of the X-ray unit: the manufacturer, model, serial number, date of installation, purpose and location of the X-ray unit together with the peak tube potential (kVp) and current (mA). Include the serial number of the control panel.	
2. What is the purpose of the unit? *(e.g. radiography, fluoroscopy, computerized tomography (CT), digital subtraction angiography, dental intraoral, dental panoramic, mobile fluoroscopy, mobile radiography, etc.)*	
3. Visually inspect the unit for cleanliness, ease of use, state of cables and parts, and any signs of wear or damage is also essential in ensuring the proper functioning of the X-ray unit.	
4. Does the existing unit have a radiation safety assessment done by a certified radiation safety provider and a compiled report submitted to KNRA	Yes/No
5. Does the facility have a valid operator license?	Yes/No
6. Does the facility have a radiation safety officer? *(Verify appointment letter)*	Yes/No
7. Do the existing X-ray units have a valid operating license? *(verify previous annual renewals)*	Yes/No
8. Does the existing unit have a documented regular maintenance and calibration schedule?	Yes/No
9. Does the facility maintain records for the measurement of performance characteristics against the applicable regulations i.e. dose, dose rate, exposure time, tube output, collimation, and image quality is necessary to verify that the X-ray unit is operating within acceptable limits?	Yes/No
10. Does the design and construction of the physical location conform with required standards - wall thickness, window placement, physical characteristics of the doors, windows, and the operator's cubicle	Yes/No
11. Was the Factory acceptance test (FAT) report provided by the supplier? FAT: the system, before shipment, shall be tested for conformity of the system with the manufacturer's performance specifications and the minimum requirements specified.	Yes/No
12. Did the supplier perform, when applicable: installation, calibration, safety and operation checks before the handover	Yes/No
13. Was an on-site acceptance test (SAT) performed on the system, after delivery, by the contractor together with the user to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified as determined by WHO, IAEA and users *(Check if the facility has an acceptance test protocol)*	Yes/No

Annex 2: Sample Specifications for DCXR and CAD

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
Ultra-Portable Digital X-ray Unit			
Clinical Purpose	Ultra-portable digital X-ray system that provides X-ray *images* of all parts *of the* body (X-ray generator and flat panel detector can be positioned to image required body part).		
Capability	Can work completely offline for image acquisition and processing and has capability for cloud syncing.		
Technical Characteristics			
User interface	Digital		
Data management	Has an X-ray acquisition software that allows for pre population of X-ray work list using Dicom Modality Worklist (MWL) software capable of integrating with generic smartphones, tablets or other electronic device	Compliance sheet	
Weight	Total weight of the complete system not higher than 35kg, including at least: generator, detector, stands (for both detector and generator), laptop		
Accessories	Should be supplied with a transport Case and a transport Bag which allow for easy and safe transportation of the entire portable digital X-ray system (including Generator, Detector and laptop)	Compliance sheet/ brochure	
	Should be supplied with two lead aprons that are (1) shoulder to knee length; (2) material should be lead-based composite or lead-free materials with high atomic numbers and low densities) (3) at least 0.35 mm Pb protection equivalence (measured @ 90 kVp at least); (4) adult size / adjustable front lead apron with Velcro / buckle;		
	Should be supplied with two thyroid shields or collars		
	Should be supplied with a tape measure for measuring the SID		

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
System composition requirement	~~Core system should be composed of the following devices/ elements:~~		
	- X-ray Generator		
	- X-ray Generator Stand / Frame		
	- X-ray Detector panel		
	X-ray Detector Panel Stand/ Frame OR a detector universal portable mounting system		
	-X-ray Detector Panel protector		
	One laptop computer pre-installed with both the X-ray acquisition software and computer-aided Detection (CAD) software with Qtrack or capable of interoperating with TIBULIMS	Compliance sheet	- One laptop computer pre-installed with both the X-ray acquisition software and Computer-aided Detection (CAD) software with Qtrack or capable of interoperating with TIBULIMS
X-ray Generator	High frequency X-ray generator:		
	-Should be powered by detachable lithium ion battery.	Compliance sheet	
	-X-ray Generator total weight (with battery) < = 20 kg.		
	- Voltage range must include the range from 40kV to not less than 90kV, preferably digitally displayed		
	- X-ray generator current-time range must include the range from .02 to 20 mAs		

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
	- Maximum current: at least 10mA @ 90kV (or calculated on the product voltage available)		
	- X-ray Generator to be supplied with all needed cables and connectors including X-ray tube and collimator.		
	Either a fixed or a Rotating anode with focal spot between 0.8mm to 1.3mm in size		
	Heat storage capacity of the anode >= 9,000HU		
	Pre-installed mandatory duty cycle preventing exposures over heat limits		
	Multileaf collimator with a) patient centering light and b)Total filtration with collimator not lower than 2.5 mm @ 70kV (or calculated on the product voltage available)		
	Generator shall be supplied with TWO detachable/replaceable Lithium ion batteries ech with exposure capacity when fully charged (battery autonomy time) of at least 200 exposures	compliance sheet/ brochure	
	Exposure features:		
	- Time range must include the range from 0.02 to at least 1.0 seconds		
	Detachable exposure release switch with a cable > = 200cm in length (one that can be stacked/stored in the generator is preferred)		
X-ray Generator/ Frame	**Stand/frame with at least the following main characteristics:**		
	Lightweight (should be less than 2.5kg)		
	- Vertical movements range is from 60cm to > = 180 cm from ground	compliance sheet	

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
		compliance sheet	- The stand/frame shall be capable of setting the best generator's position for all the clinical applications/ uses/interventions requested and available
	Has a rotation of at least 90 degrees around vertical axis	compliance sheet	- Has a rotation of at least 90 degrees around vertical axis
X-ray Detector panel	Dimension: - Active detector area not less than 35cm*43cm		
	Powered by a detachable Lithium ion battery.		
	-X-ray Detector total weight less than 5 kg (with battery but excluding protective cover).		
	- Time to display image after exposure no longer than 10 sec	compliance sheet	
	- Preferably, pixel pitch <= 150pm.		
	_Spatial resolution not less than 3 lp/mm		
	- DQE (detective quantum efficiency) @ RQA5 at least 60%		
	- Dynamic range of A/D converter at least 14 bit or at least 10 pixels resolution Detectcr should have wireless connectivity to the workstation laptop/console		
	- Automatic Exposure Detection feature available		
	Shall be supplied with TWO detachable/replaceable Lithium ion batteries each with exposure capacity when fully charged (battery autonomy time) of at least 200 chest X-rays @ 90KV		

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
X-ray Detector panel Protective cover	Detector panel provided with a light-weight (less than 1.5kg), weight-bearing protective cover (detector panel must be capable of withstanding dropping multiple times from a height of 90cm while in protective cover). Protective cover should be capable of being sanitized between patients. Preferrable if the protective cover doesn't have to be removed for xrays to be taken		Can be supplied separately
X-ray detector stand/ Frame or Holder	A lightweight of less than 1kg, universal portable mounting system for the detector panel that can be attached to nearly all types of doors, hooks, screws, tree branches and other sturdy structures. It should allow for height adjustment. This is the preferred option.		
	OR		
	A stand/frame with at least the following main characteristics: Lightweight (should be less than 2.5kg), Vertical movements range from 60cm to 180 cm from ground.		
Energy Source			
Power Requirements	X-ray Generator powered by a removable, rechargeable Lithium-ion battery	compliance sheet/ brochure	
	Recharge power source: AC power input to be 120 or 220 VAC +/-10%, 50/60Hz, single phase, fitted with compatible type G mains plug		
	Battery recharging time less than 6 hours (both for Generator and Detector).		
	Low battery indicator.		
	The battery back-up related to the whole system (Generator, detector and workstation) allows at least 200 chest X-ray exposures @90KV with imaging transmission/storage.		
	Can operate for 6-8 hours without the need to recharge		

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
External charging system (battery charging box)	**External charging system (battery charging box) shall have the following characteristics:**		
	1)Able to charge all electric components (generator, detector and workstation) of the portable digital X-ray system		
	2)Is compatible with AD/DC/Solar power		
	3)Has at least > =500Wh		
	4)AC power input to be 100-120VAC"4 or 220-240VAC"2, single phase, fitted with compatible type G mains plug		
Environmental			
Ambient storage temperature	Temparature at least between -20°C to +50°C (can be higher than +50°C) Relative humidity at least between 10°/o to 90°/o (can be higher than 90°/o]		
Ambient operating temperature	Capable of operating continuously in ambient temperature from +10°C to +35°C (can be higher than +35°C) Relative humidity at least between 30% to 75 °/o (can be higher than 75 °/o)		
Disinfection	Parts of the device that come into contact with the patient or the operator should be capable of easy disinfection	compliance sheet	
Standards, Certifications and Safety			
Standards, for the manufacturer and the equipment	Manufacturer must have ISO 13485:2016 certification for quality standards– Medical devices – Quality management systems.		
	Should provide a certificate of calibration and inspection of parts from the manufacturer		
Regulatory approval/ certification	Proof of regulatory compliance per the product's risk classification, as appropriate to the intended use: either the US Food and Drug Administration [FDA] OR Conformité Européenne [CE])		
	Should have certification from the Kenya Nuclear Regulatory Authority		

Area of Consideration	Specifications during evaluation	To be captured in the tender document	Items for confirmation during delivery
Operating manuals and other user manuals	Should be provided with at least two sets (hard and soft copy) of the following in English:	compliance sheet	
	1. User and technical manuals with diagrams of the equipment		
	2. User specifications *for* calibration		
	3. Routine maintenance, service and operation manuals		
	4. Specifications for the laptop hosting both the X-ray acquisition software and the CAD software with Qtrack or capable of interoperating with TIBULIMS	compliance sheet-laptop should be open to host the functionality of both acquisition and CAD software (both software in one laptop)	
Parts and spares	Should be provided with a list of essential spares, their part numbers, their costs and where they are found		
Installation, Warranty and Maintenance			
Warranty	3-year equipment warranty including all spares and calibration.		
	Must include a drop protection warranty for the detector panel with associated costs		
Training	Training package should be included with the associated costs of training the sites on operating the equipment and CAD software	List of facilities to be installed	
Service support	In-country support should include 1) Availability of spare devices in-country AND 2) An active loaner program for immediate deployment in case of breakdown	compliance sheet	
	Must provide contact details of the manufacturer, supplier and local service agent as applicable including physical address, telephone contact and email address	letter indicating local service agent	

Annex 3: Radiation Safety Checklist for Ultra-Portable CXR Outreach

1. Before Start of Screening

a. Survey the outreach area and carefully select the most appropriate X-ray screening area considering shielding and distances for radiation safety.

b. Designate the X-ray area and clearly demarcate and cordon off a Controlled Zone of 8-10 m radius around the X-ray device using highly visible tape, cones or improvised barriers.

c. Check all X-ray device components: batteries, X-ray tube detector, cables.

d. Set up the X-ray apparatus selecting the safest direction for the Chest stand

e. Post "Radiation Caution" signs at entry and other points around the X-ray area.

f. Ensure no bystanders or unauthorized persons are inside controlled zone.

2. Patient Safety during Screening

a. Position detector and tube at correct distances and height to the patient.

b. Properly align and collimate the X-ray beam to the patient's ROI only.

c. Apply low-dose protocols where needed.

d. Provide the patient with lead shielding for critical parts.

e. Endeavor to avoid repeat exposures.

3. Operator Safety During Exposure

a. Radiation workers must properly wear radiation dosimeters

b. Always wear lead apron with 0.25 - 0.5 mm lead equivalent

c. Stand at least 3 m away from X-ray tube and behind a lead barrier.

d. Use the longest length of trigger/exposure cable.

e. Confirm that X-ray area and controlled zone is clear before making exposure.

f. Review image quality.

4. After Screening

a. Check device, detector and other components for any faults or damages.

b. Ensure all X-ray device components are packed back in their containers.

c. Secure the X-ray package during transport.

d. Perform periodic QA tests.

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