

**Integration of CAD-enabled X-ray into diagnostic algorithms
and monitoring & evaluation frameworks**

MODULE 5



Introduction

This module will help national programs to track and monitor the impact of their usage of computer-assisted diagnosis and digital x-ray to screen for pulmonary tuberculosis

Course Outline

→ Connecting screening to confirmatory diagnostics

→ Monitoring & evaluation across the cascade of care

→ Indicators for a screening program

→ Closure

Learning Objectives

By the end of this module, participants should be able to:

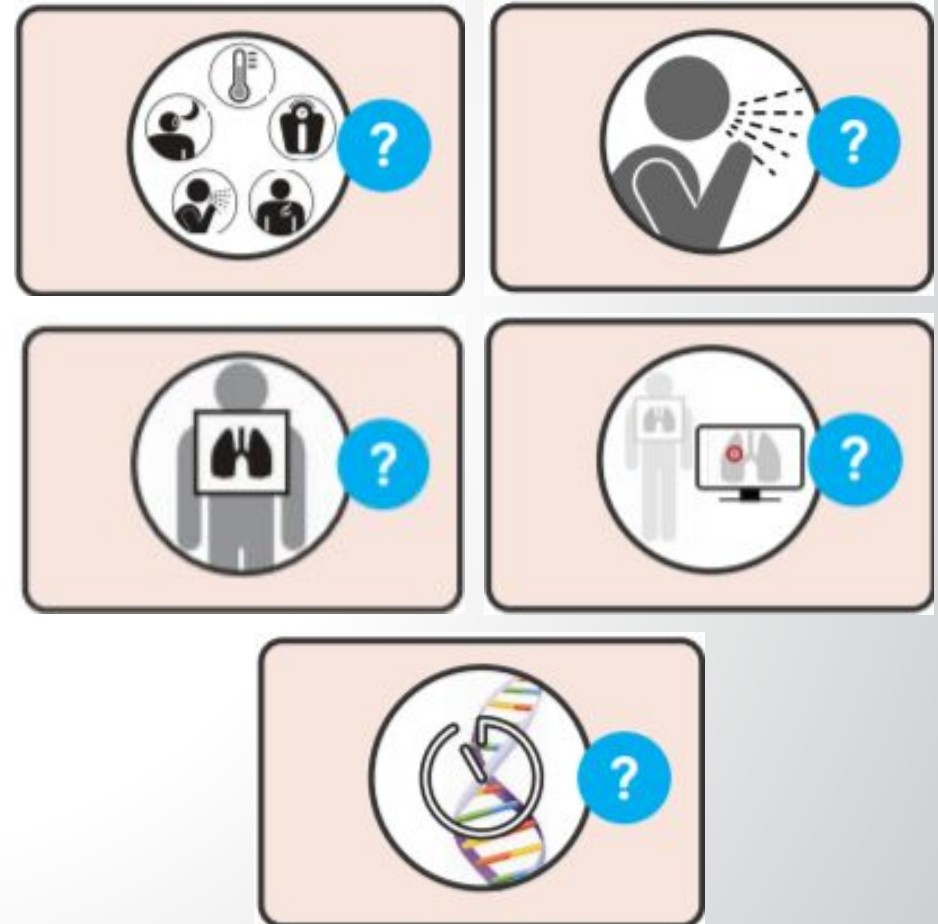
- Describe how to integrate CAD-enabled X-ray into the diagnostic algorithm.
- Describe monitoring & evaluation requirement for a CAD-enabled X-ray system.
- Select indicators to use when establishing a screening program using CAD-enabled X-ray.
- Describe how they would do these in their own country.

Reminder: WHO guidelines on Systematic Screening



In general populations without HIV aged 15 years and older where TB screening is recommended...

- Systematic screening for TB disease may be conducted using a **symptom screen, chest X-ray with computer-aided detection (CAD) software, or molecular WHO-recommended rapid diagnostic tests**, alone or in combination.
- **CAD software** may be used in place of human readers for interpreting digital chest X-rays for screening and triage for TB disease





**CONNECTING CAD-ENABLED X-RAY TO
CONFIRMATORY DIAGNOSIS**

→ Reminder: How is CAD-enabled X-ray being used?

CAD-enabled X-ray screening needs to be integrated into the diagnostic algorithm for tuberculosis.

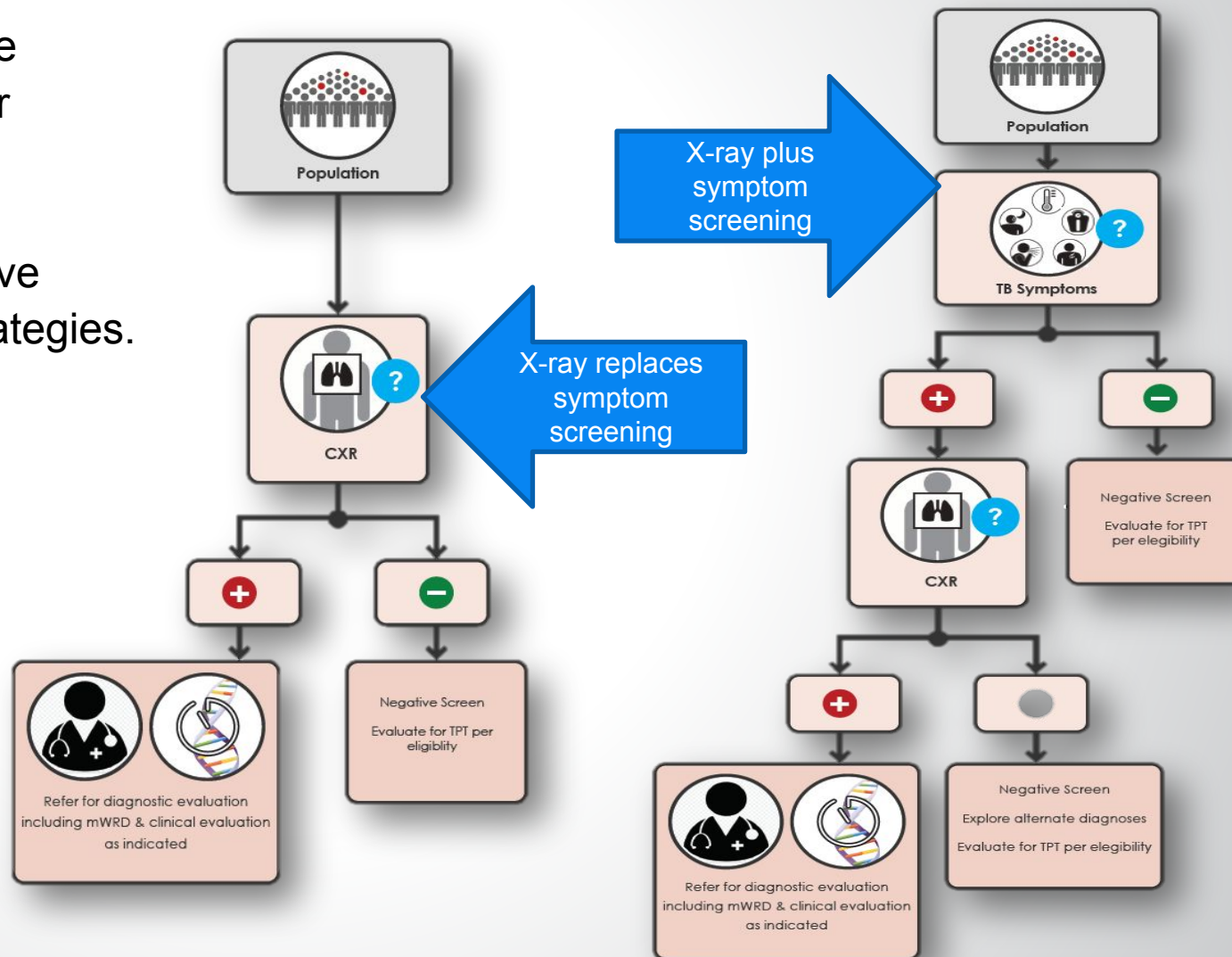
This integration may look different for active case-finding and passive case-finding strategies.

The outcome should be the same:

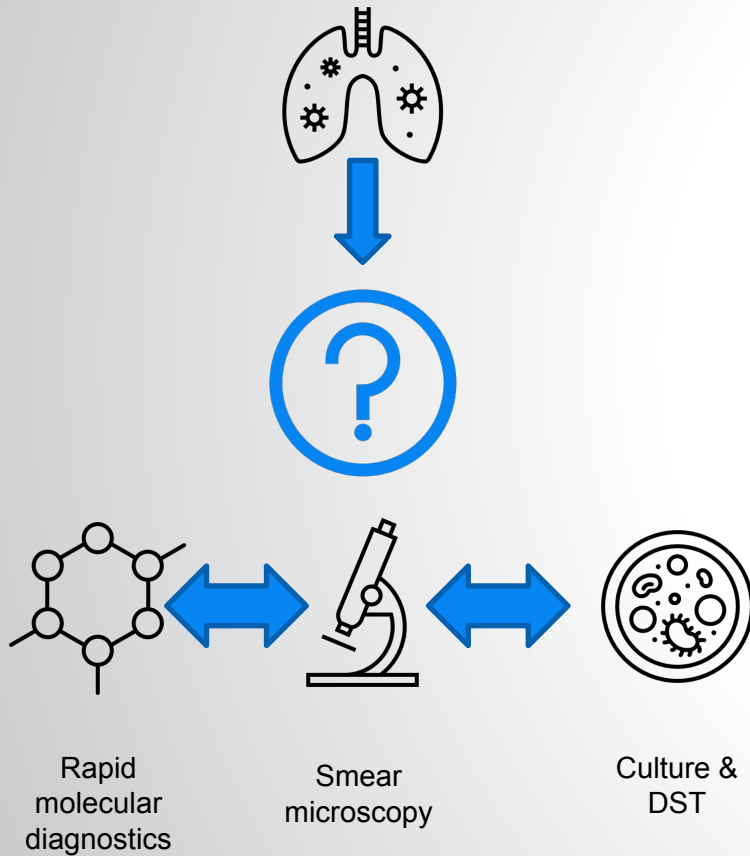
X-ray results inform diagnostic decision-making

X-ray can also augment or replace symptom screening.

Consider: Does the expansion of X-ray as a screening tool change the working definition of “presumptive TB”?



→ CAD-enabled X-ray results lead to confirmatory testing by the reference standard



- How to make the connection between screening and diagnosis?
 - Do patients have to go to nearby lab, or
 - Can specimens be collected at screening site & transported to labs?
- How are CXR & CAD results transmitted to patients / health provider?
 - Should the X-ray/CAD report be printed?
 - For all patients or only for those above the threshold score?
- How to link the X-ray data with diagnostic data?
 - How are patients registered for X-ray screening?
 - How are patients registered for lab diagnosis?
 - Are unique patient identifiers used for both system and are linked?

Who is responsible for this process?



SETTING UP AN M&E SYSTEM FOR CAD

What is needed for an M&E system for CAD?

➤ A data register is needed to capture chest X-ray data and link to follow-up testing, notification and treatment enrollment.

A unique, national patient identifier is ideal for this link, but these are not always available.

Question:

What alternatives exist in the absence of a unique patient indicator?

Linking to National M&E systems

➤ Chest X-ray data register must link to national notification systems, specimen referral systems, diagnostic testing, etc.

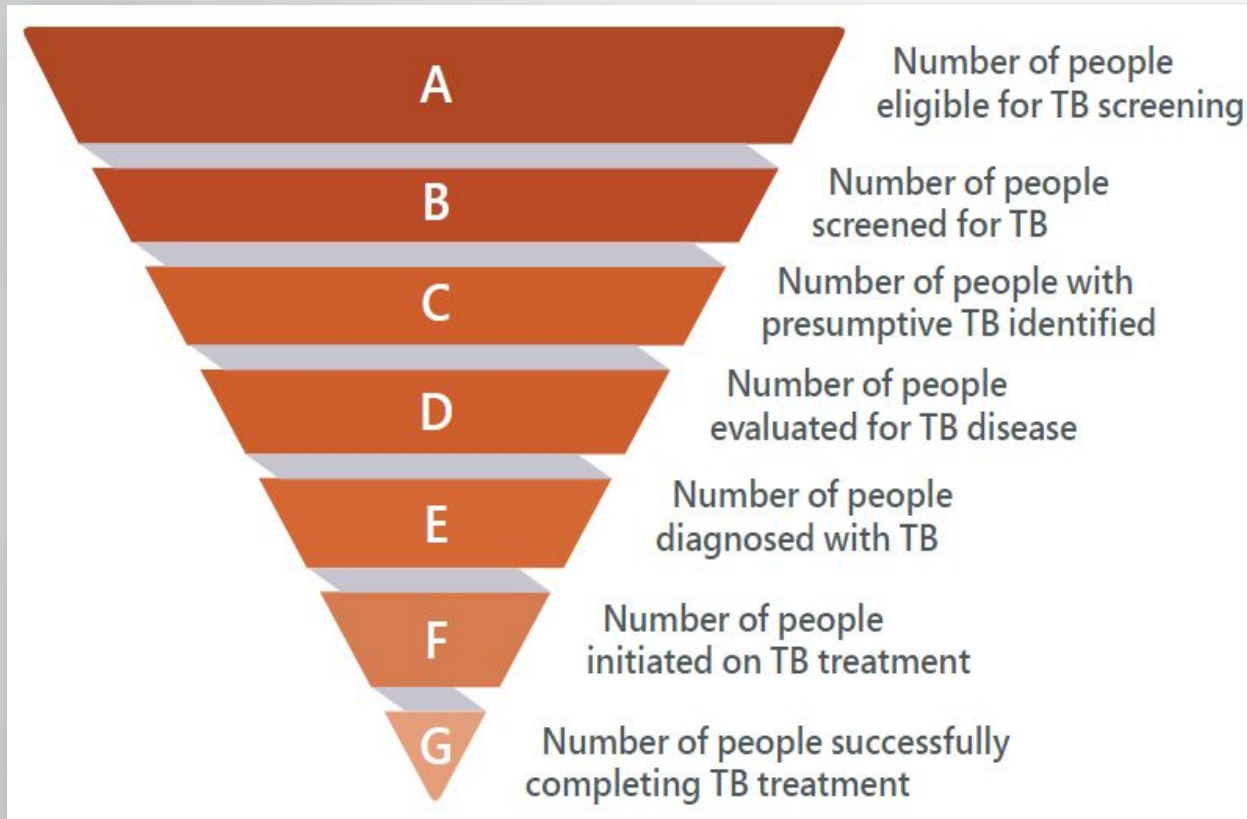
CAD software should be calibrated to send outputs directly to national M&E systems*

- Is software linked in real-time (through SMS, or internet) to system?
- If offline running is possible, how is data uploaded when connection is restored?



SELECTING INDICATORS FOR A CHEST X-RAY AND CAD SCREENING PROGRAM

Cascade of Care – Indicators



Consider the cascade of care for tuberculosis:

What are the standard indicators used in your context?



Calculations from the indicators for each screened group:

- **Acceptability:** the proportion of people screened for TB among those eligible;
- **Screened positive:** the proportion of people screened by CAD with a score above the selected threshold score;
- **Testing retention:** the proportion of people tested or evaluated for TB with a confirmatory diagnostic test among patients presumed to have TB;
- **NNS and number needed to treat:** the proportion of people diagnosed with TB among those screened and tested;
- **Linkage to care:** the proportion initiating TB treatment among those diagnosed; and
- **Treatment success:** the proportion of people who successfully complete TB treatment among those who initiated treatment.



Considerations when selecting M&E indicators

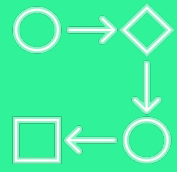


What indicators are already in use?

What indicators are captured in current electronic monitoring systems?

What indicators will you need to add?

Selecting indicators for a screening program



PROCESS ORIENTED

Enable you to evaluate the performance of the screening solution (e.g., CAD-enabled X-ray) during roll-out and maintenance

Adaptable over time (without losing integrity of information)



IMPACT ORIENTED

Evaluate the impact of the solution on case finding and other health outcomes, as well as program targets



Proposed indicators

for Monitoring the Performance of CAD Technology

1. Positivity rate of chest X-ray and CAD for TB diagnosis at implementation sites
2. Percentage of people screened positive for TB with X-ray and CAD that were referred for confirmatory testing
3. Positivity rate of confirmatory test for people screened positive for TB with X-ray and CAD
4. Percentage of people screened positive for TB with X-ray and CAD and received clinical diagnosis

Where to place CAD in the TB screen algorithm

➤ CAD can be used **with** trained human readers as a decision support tool or **in place of** trained human readers.

Alongside human readers

CAD can work **with** human readers:

- ➔ Helping radiologists to optimize their workflow
- ➔ Alerting human readers to abnormal images requiring prioritization
- ➔ Providing reporting assistance
- ➔ Providing quality control
- ➔ Performing pre-reading assistance

In place of human readers

The WHO recommends CAD to **replace** human readers in two broad situations in individuals aged 15 and above:



Screening: CAD can be a valuable tool for screening asymptomatic individuals without significant risk factors (e.g., active case finding).



Triage: CAD can be useful in identifying TB in individuals with TB symptoms, risk markers, or other positive test results (e.g., in healthcare facilities).

The CAD software used must be to the same standard as those evaluated in by the WHO Guidelines Development Group.

In either situation, there is insufficient evidence to support the use of CAD with CXR alone for TB diagnosis

Where to place CAD in the TB screen algorithm



There are a number of advantages to either technique

Alongside human readers

The entire output of CAD, or parts of the output, may be used to inform triage decisions by trained human readers alongside clinical information.

Advantages:

- CAD can be used to supplement decision making, potentially improving upon human reader performance.
- While human readers' judgement can be used:
 - where a CAD reading is not conclusive/near the threshold score.
 - in populations where CAD is not approved, e.g., in children < 15 years.
 - alongside CAD for reading X-ray that show non-TB abnormality.

In place of human readers

The CAD output may be used by trained non-radiologist personnel to decide the triage outcome. A threshold score is set and everyone assigned a CAD score higher than this receives confirmatory diagnostic testing.

Advantages:

- Increased access to chest X-ray where there is a scarcity of trained human readers or no human readers.
- May be used to rapidly triage people by non-radiological personnel in high throughput settings.
- CAD does not become exhausted when reading large quantities of images.
- No intra- and inter-reader variability.

ASK YOURSELF...



1. What changes would be needed to adopt CAD-enabled X-ray?
2. How will you track CAD-enabled X-ray outputs and link them to confirmatory testing?
3. What screening threshold would you use?
4. What indicators will you use?
5. What adaptations to your current system would be needed to capture these indicators?

ASK YOURSELF...



1. Will CAD-enabled X-ray be used in active and / or passive case finding strategies?
 - Does the strategy impact the implementation?
2. How will you inform stakeholders about the opportunities from and availability of CAD-enabled X-ray?
3. What do clinicians need to trust the outputs?

CLOSURE

- Review exercise
- Team presentations
- Next steps
- Installation plans
- Monitoring
- Ongoing support

