**Public call for data to inform WHO policy updates on tools for screening for TB disease**

*17 March 2026*

The WHO End TB Strategy calls for systematic screening to ensure early diagnosis of tuberculosis (TB). Accurate, accessible and affordable screening tools are essential for systematic TB screening to be brought to the scale needed to help reduce TB incidence and mortality.

To support the implementation and scale-up of systematic TB screening, WHO is preparing to update WHO guidelines on TB screening through a Guideline Development Group (GDG) meeting in late 2026 to evaluate the performance of new and existing screening tools.

In preparation for this, **WHO is issuing a public call for data**, appealing to national TB programmes, implementers, researchers, and other stakeholders to provide evidence that could inform the guideline process. This call has separate requests for

1. Data for new and established tools for screening for TB; and
2. Data for pediatric computer-aided detection (CAD) software products for TB.

The full Population-Intervention-Comparator-Outcome (PICO) questions guiding this call for data can be found in Annex 1.

Data should be received by 30 May 2026. Researchers who have data to contribute to this call are requested to contact WHO (Cecily Miller at cmiller@who.int and Dennis Falzon at falzond@who.int) by 31 March 2026 to indicate their interest. Appropriate data templates will then be provided upon request.

If researchers are interested in contributing data that will become available *after* 30 May 2026, please contact us as soon as possible and let us know further details about what data are expected and when they will become available.

## 1. Evaluation of novel and established tools for screening for TB

The current WHO consolidated guidelines on TB screening, released in 2021, recommend specific tools for systematic screening, including symptom screening, chest X-ray (CXR) with and without computer-aided detection (CAD), C-reactive protein (CRP) for screening people living with HIV, and rapid molecular diagnostic tests (specifically low-complexity automated nucleic-acid amplification tests (LC-aNAATs)).

In recent years, the technological landscape for molecular TB detection has expanded to include moderate-complexity nucleic-acid amplification tests (MC-aNAATs) for high volume, centralized laboratory-based detection of TB, rifampicin resistance, and isoniazid resistance, as well as near point-of-care (NPOC) tests designed for decentralized use outside of the laboratory. Alongside these, collection of tongue swabs as an alternate sample type for NPOC or LC-aNAAT tests offer a potential solution to sputum scarcity (inability to produce adequate sputum samples), facilitating molecular screening in populations unable to produce respiratory samples.

In addition, rapid advancements in artificial intelligence-based technology in recent years have given rise to new digital tools for detection of TB disease, including AI-based cough analyzers, digital stethoscopes, point-of-care ultrasound with computer-aided interpretation, and more. These

technologies have the potential to improve screening for TB through the development of inexpensive, easy-to-use tools that can be rapidly applied to large populations undergoing screening.

*Review question*: What is the accuracy and effectiveness of established and newly developed tools for screening among populations undergoing systematic screening for TB disease? Please note the following:

- Data must be from complete (locked) datasets. Both individual participant and aggregate data are eligible for this call. A template for either type of data will be provided upon request.
- Data must be generated from populations undergoing systematic screening, as specified in the PICO and as defined in WHO guidelines, not diagnostic evaluation of individuals already identified to have presumptive TB. Individuals included in the test evaluation must have not been pre-selected by symptom status or any other form of pre-screening.
- Studies should have a minimum of 20 participants with TB (as defined by the reference standard in use).
- Data from adult and pediatric populations are accepted. Data on the accuracy and/or effectiveness of CXR for screening among pediatric populations living with HIV are of particular interest.
- Accuracy data must include a valid reference standard, as specified in the PICO, with results available on all individuals included in the evaluation to allow for the calculation of sensitivity and specificity.
- Tests undergoing evaluation must have received regulatory approval from one of the founding members of the Global Harmonization Task Force or from a WHO Listed Authority and be commercially available for procurement by member states.
- Only independent evaluations[1] will be eligible. Studies conducted through manufacturer sponsorship will not be admissible

Outcomes of interest include diagnostic accuracy, patient-important outcomes (e.g., mortality, time to diagnosis), feasibility, acceptability, resource requirements and cost-effectiveness of the interventions outlined below. To review the PICO question that may guide data suitability and preparation efforts, see Annex 1. Further, for parameters on economic, acceptability, and feasibility data see Annex 2 below.

## 2. Evaluation of pediatric computer-aided detection (CAD) software for screening and diagnosis for TB

The advent of computer-aided detection (CAD) software products for automated interpretation of digital chest radiography for TB screening represented a major technological advancement for scaling up TB screening. However, when CAD products were first recommended by WHO in 2021, there were

[1] Independent evaluation: Research study evaluating the diagnostic test that is conducted by investigators who are not involved in the development, optimization, manufacture, marketing, or regulatory approval of the test, and who have no conflicts of interest that could bias the study design, conduct, analysis, or interpretation of results. Having received donated test kits and loaned equipment to conduct a study does not usually constitute a conflict of interest.

not yet products available with proven performance in pediatric and adolescent populations (under 15 years of age). Since 2021, many more CAD products have become available for TB evaluation, including some with a manufacturer indication for use in pediatric populations. WHO is preparing to evaluate these products for potential recommendation for screening and for aid in diagnosis for those under 15 years of age. WHO is issuing a call for complete (locked) datasets that can contribute to an individual patient data analysis for assessing the accuracy and performance of CAD products for evaluation of children for pulmonary TB.

*Review question*: What is the diagnostic accuracy of computer-aided detection (CAD) software products for the detection of TB in children?

Only individual participant data will be eligible to inform the PICO questions 2-3 on diagnostic accuracy for this call.

For this evaluation there are two use cases:

- Children undergoing systematic screening for TB (PICO 2),
- Children undergoing diagnostic evaluation for TB (PICO 3).

Please note the following:

- Individual patient datasets are required. Datasets must be complete and include the following:
    - Demographic and clinical data including comorbidities (age, sex, HIV, weight-for-age Z-scores, other relevant clinical data)
    - Reference standard outcomes for TB, using consensus clinical case definitions for classification of pediatric TB from 2015 (https://pubmed.ncbi.nlm.nih.gov/26409281/)
    - CAD interpretation scores from interpretation of chest radiograph images, as a continuous score (from 1-100 or 0-1)
    - Human radiologist interpretations of the same chest radiograph images, with a minimum of any abnormality distinguished from normal (suggested to include: abnormal not TB, abnormal suggesting TB, normal)
- It is essential that the data included in the dataset (including chest radiography images and associated clinical data) have not been previously exposed to any CAD products under evaluation or used to train any CAD products included in the evaluation.
- Evaluations must have been conducted on at least one CAD product with stringent regulatory approval for use for screening or detection of TB (please provide details of the regulator providing marketing authorization of the CAD product).
- Only independent evaluations[2] will be eligible. Studies conducted through manufacturer sponsorship will not be admissible

[2] Independent evaluation: Research study evaluating the diagnostic test that is conducted by investigators who are not involved in the development, optimization, manufacture, marketing, or regulatory approval of the test, and who have no conflicts of interest that could bias the study design, conduct, analysis, or interpretation of results. Having received donated test kits and loaned equipment to conduct a study does not usually constitute a conflict of interest.

In addition to datasets that can inform a systematic review of diagnostic accuracy, data that address feasibility, acceptability, resource requirements and cost-effectiveness of the intervention are sought. To review the PICO questions that may guide data suitability and preparation efforts see Annex 1 below. For parameters on economic, acceptability, and feasibility data see Annex 2 below.

**Annex 1. Specific Population-Intervention-Comparator-Outcome (PICO) questions**

***PICO question for new and existing screening tools for TB***

**PICO 1:** What is the accuracy and effectiveness of existing and newly developed tools that can be used for TB screening among populations undergoing systematic screening for TB disease?

| **Population** | **Intervention/Index** | **Comparator** | **Outcome** |
|---|---|---|---|
| Populations undergoing systematic screening for TB:<br>*WHO-recommended populations*<br>• Contacts of TB patients<br>• Persons living with HIV<br>• Prisoners<br>• Miners<br>• People attending health facilities with TB risk factors in settings with general prevalence at or above 100/100,000<br>• Populations with increased risk of TB and limited access to care (urban poor populations, homeless communities, refugees, internally displaced persons, etc.)<br>• General population in settings with TB prevalence at or above 500/100,000<br>*Children recommended for screening*<br>• Child contacts of TB patients<br>• Children living with HIV<br><br>*Other groups at increased risk of TB who may undergo screening, for example but not limited to:*<br>• People with diabetes mellitus<br>• Heath workers | • Chest radiography<br>○ With human interpretation<br>○ With computer-aided detection (CAD) interpretation<br>• Molecular rapid diagnostics, distinguished by class and sample type (*WHO-approved products are listed below, other products may now be available and can be included in data if they have received regulatory approval*):<br>○ Low complexity automated nucleic acid amplification tests (LC-aNAATs) with sputum samples, including<br>▪ Xpert MTB/RIF Ultra (Cepheid)<br>▪ Truenat MTB Plus, MTB-RIF Dx (Molbio)<br>○ LC-aNAATS with swab samples, including:<br>▪ Truenat MTB Ultima (Molbio)<br>▪ Xpert MTB/RIF Ultra (Cepheid)<br>○ Low complexity manual automated nucleic acid amplification tests (LC-mNAATs) including<br>▪ TB-LAMP (Eiken Chemical)<br>○ Moderate-complexity NAAT (MC-aNAATS) including:<br>▪ BD MAX™ MDR-TB (Becton Dickinson) | Reference standard:<br>1. Microbiologic Reference Standard (MRS; TB liquid automated culture)<br>2. Composite reference standard (CRS; Decision to treat)<br>3. Molecular rapid diagnostic test can be accepted as a reference standard if the index test under consideration is not another molecular rapid diagnostic test<br><br>Comparator test(s):<br>1. Symptom screen for TB | Individual-level outcomes<br>- Diagnostic accuracy (sensitivity/ specificity)<br>- Failure rate (error, invalid, other)<br>- Effectiveness on patient-important outcomes – treatment outcomes, mortality, time to diagnosis<br><br>Population-level outcomes<br>- Effectiveness on population-level outcomes of screening – TB prevalence, incidence, transmission, incidence/prevalence of infection |

| | | | |
|---|---|---|---|
| • Populations with severe acute malnutrition<br>• General population with lower TB prevalence than the currently-recommended 0.5%<br>• Others as data is available | ▪ cobas MTB & cobas MTB-RIF/INH (Roche)<br>▪ FluoroType MTB & FluoroType MTBDR (Bruker-Hain)<br>○ Near point-of-care nucleic acid amplification tests (NPOC-NAATs) with swab samples (from tongue or sputum), including:<br>▪ MTB NAT Card (Pluslife)<br><br>• Biomarker tests<br>○ C-Reactive protein (CRP)<br>○ LF-LAM on urine<br>○ Blood-based biomarker tests (other than CRP)<br>○ Breath-based biomarker tests<br><br>• Digital tools<br>○ Digital cough analyzers<br>○ Digital stethoscopes<br>○ Point-of-care ultrasound (POCUS) | 2. Any other comparator that has been used | |

*Current screening guidelines for tools and adult risk groups for screening apply to individuals age 15 years and above for most populations and age 10 years and above for people living with HIV. Future guideline updates will seek to align recommendations to age classifications that consider pediatric populations to include those up to 10 years of age, and adolescents and adults as those aged 10 years and above, to better align with other WHO guidelines

**See WHO screening guidelines

***PICO questions for potential evaluation of pediatric CAD products for TB detection***

PICO 2. Among children and adolescents under 15 years of age undergoing screening for tuberculosis (TB) disease, should CAD software be used in place of human readers for interpretation of digital chest radiography for TB screening?

| POPULATION | INTERVENTION | COMPARATOR | OUTCOME |
|---|---|---|---|
| Children and adolescents under 15 years of age who are undergoing systematic screening for TB disease in health facilities or communities, including:<br>• Close contacts of people with TB<br>• Children and adolescents living with HIV<br>• Children underdoing screening due to other risk factors for TB (malnutrition)<br><br>Age groups:<br>- 0-<2<br>- 2 - <5<br>- 5 - <10<br>- 10 - <15 | CAD software interpretation of digital CXR* | Comparator test: Human interpretation of digital CXR<br><br>Reference standard: Composite reference standard based on CID 2015 clinical case definitions for classification of TB in children** | - Accuracy (sensitivity, specificity)<br>- Patient-important outcomes (time to diagnosis, treatment outcomes, mortality, safety) |

*Also including digitized scans of CXR on analogue film

**Composite reference standard based on CID 2015 clinical case definitions for classification of TB in children (https://pubmed.ncbi.nlm.nih.gov/26409281/): Confirmed TB = bacteriological evidence of *M. tuberculosis* on any respiratory (expectorated sputum, induced sputum, gastric aspirate, nasopharyngeal aspirate) or stool specimen collected at baseline or follow-up from any WHO-approved rapid molecular test (including Xpert MTB-RIF Ultra Trace as positive) or MTB culture or a positive LF-LAM test on urine for children with HIV. Other molecular tests used on induced or expectorated sputum are also acceptable. Non-respiratory specimens such as CSF or lymph node are acceptable if the patient also has respiratory symptoms. Unconfirmed TB = bacteriological confirmation NOT obtained AND at least 2 of the following: -Symptoms/signs suggestive of tuberculosis (cough >2 weeks, history of weight loss/failure to thrive/weight-for-age Z-score ≤ -2, fever >1-2 weeks, lethargy/reduced playfulness, neonatal pneumonia, sepsis-like illness); -Unexplained hepatosplenomegaly; -Chest radiograph

or other imaging from initial evaluation suggestive of tuberculosis disease; -Documented history of close TB exposure or immunologic evidence of M. tuberculosis infection; -Positive response to TB treatment (requires documented positive clinical response on tuberculosis treatment—no time duration specified). Unlikely TB = bacteriologic confirmation is not obtained, and criteria for "unconfirmed tuberculosis" are not met, with or without immunologic evidence of *M. tuberculosis* infection.

PICO 3. Among children under 10 years of age with presumptive TB, should CAD software be used in place of human readers for interpretation of digital chest radiography for aiding in diagnosis of TB disease?

| POPULATION | INTERVENTION | COMPARATOR | OUTCOME |
|---|---|---|---|
| Children under 10 years of age with presumptive TB (with signs and symptoms or screened positive) being evaluated for TB disease<br><br>Age groups<br>- 0-<2<br>-2 - <5<br>-5 - <10 | CAD software interpretation of digital CXR* | Comparator test: Human interpretation of digital CXR<br><br>Reference standard: Composite reference standard based on CID 2015 clinical case definitions for classification of TB in children** | - Accuracy (sensitivity, specificity)<br>- Patient-important outcomes (time to diagnosis, treatment outcomes, mortality, safety)<br>- Severity of disease for treatment decision-making |

*Also including digitized scans of CXR on analogue film

**Composite reference standard based on CID 2015 clinical case definitions for classification of TB in children (https://pubmed.ncbi.nlm.nih.gov/26409281/): Confirmed TB = bacteriological evidence of *M. tuberculosis* on any respiratory (expectorated sputum, induced sputum, gastric aspirate, nasopharyngeal aspirate) or stool specimen collected at baseline or follow-up from any WHO-approved rapid molecular test (including Xpert MTB-RIF Ultra Trace as positive) or MTB culture or a positive LF-LAM test on urine for children with HIV. Other molecular tests used on induced or expectorated sputum are also acceptable. Non-respiratory specimens such as CSF or lymph node are acceptable if the patient also has respiratory symptoms. Unconfirmed TB = bacteriological confirmation NOT obtained AND at least 2 of the following: -Symptoms/signs suggestive of tuberculosis (cough >2 weeks, history of weight loss/failure to thrive/weight-for-age Z-score ≤ -2, fever >1-2 weeks, lethargy/reduced playfulness, neonatal pneumonia, sepsis-like illness); -Unexplained hepatosplenomegaly; -Chest radiograph or other imaging from initial evaluation suggestive of tuberculosis disease; -Documented history of close TB exposure or immunologic evidence of M. tuberculosis infection; -Positive response to TB treatment (requires documented positive clinical response on tuberculosis treatment—no time duration specified). Unlikely TB = bacteriologic confirmation is not obtained, and criteria for "unconfirmed tuberculosis" are not met, with or without immunologic evidence of *M. tuberculosis* infection.

**Annex 2: Parameters of the economic and qualitative acceptability/ feasibility data**

For the above-mentioned PICO questions, WHO is also seeking data on costs, cost-effectiveness, feasibility, acceptability and impact on equity. The specific questions to be addressed are as follows:

*Parameters of the economic data*

- How large are the resource requirements (costs)?
- What is the certainty of the evidence on resource requirements?
- Does the cost-effectiveness of the intervention favor the intervention or the comparator?

*Parameters of the qualitative data*

- What are views and perspectives from the key stakeholders[3] on the use of the intervention?
- Is the intervention acceptable to key stakeholders?
- Is the intervention feasible to implement?
- Is there important uncertainty about, or variability in, how much people value the main outcomes? In case important variability is identified on any of the above research questions within a class of technologies or within a strategy, details should be provided by technology or strategy use case.
- What is the impact on health equity?

[3] Health care providers, testing technicians, laboratory/ testing managers, patients and their caregivers, and health program staff.