

WHO consolidated guidelines on tuberculosis

Module 2: Screening

**Systematic screening for
tuberculosis disease**

Web Annex A.

Methods and Expert Panels



World Health
Organization

WHO consolidated guidelines on tuberculosis. Module 2: screening – systematic screening for tuberculosis disease. Web Annex A. Methods and expert panels

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*Web Annex A.
Methods and Expert Panels*

Web Annex A. Methods and Expert Panels

1. Methods used to develop the guidelines

In conformity with the process recommended by the Guideline Review Committee¹, three expert groups were established: 1) a Guideline Steering Group, composed of WHO staff; 2) the Guideline Development Group (GDG), including a guideline methodologist, external content experts, national TB programme managers, other implementers, academics, researchers and representatives of patients and civil society; and 3) the External Review Group (ERG), composed of peer-reviewers.

The WHO Guideline Steering Group prepared the background document for the guidelines and initially drafted the PICO questions to be addressed for the update and the composition of the expert panels. The scoping document was submitted to the WHO Guideline Review Committee and approved. The background material inclusive of the biographies of the GDG members were placed on a public website ahead of the Guideline Development Group meeting². Once the GDG was established, the PICOs to be addressed were finalized and evidence reviews commissioned. A list of potential outcomes of interest for each PICO question relating to screening effectiveness (questions 1–7) was circulated to all members of the GDG, who scored the importance of each outcome on an incremental scale from 1 to 9: 1–3: “not important”; 4–6: “important”; and 7–9: “critical”. The average of the scores for each outcome was used to prioritize the outcomes and to select the most important outcomes for each PICO question. Nearly all outcomes proposed were ultimately scored as “critical”. The outcomes for PICO questions related to diagnostic accuracy (questions 8–12) were pre-specified to the sensitivity and specificity of the tools and thus not scored (see also the GRADE tables in the **Web Annexes B and C**).

GDG meetings were conducted virtually, as a series of three-hour webinars held between June and October 2020 (13 webinars in total). A number of preparatory webinars were also held with GDG members and observers to discuss the guideline scope, finalize the PICOs and outcomes and review preliminary findings of the evidence. The meetings were co-chaired by a technical expert and a guideline methodologist who facilitated the discussions to reach consensus, which was defined as unanimous or majority agreement. For a session to proceed a quorum of 50% GDG members had to be reached. The GDG agreed in advance that for a recommendation to be made, and should consensus not be reached, approval by voting was required by at least 80% of the GDG members.

Evidence summary tables were drafted for each of the PICO questions using the GRADE (“grading of recommendations assessment, development and evaluation”) approach³. The estimates and the judgements on the quality of evidence were reviewed by the GDG members during the online discussions. GRADE evidence-to-decision tables were used to guide discussions on benefits and harm, the quality of the evidence, cost, feasibility, acceptability, equity, values and preferences. The direction

¹ WHO handbook for guideline development. 2nd ed. Geneva, World Health Organization; 2014. Available from: http://www.who.int/publications/guidelines/handbook_2nd_ed.pdf

² <https://www.who.int/docs/default-source/hq-tuberculosis/gdg-biographies-tb-screening-guidelines-2020-cm-v2-edit-23-june-2020.pdf>

³ Guyatt et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*, 2008.

of the recommendations and their strength (strong or conditional) were determined by these factors. GRADEpro⁴ was used to document the decisions made.

As part of the 2021 update of the guidelines, the wording of the recommendations from the previous guidance was reviewed for clarity, applicability in different settings, and alignment to other WHO guidance.

2. Certainty of the evidence and accuracy and strength of the recommendations

The certainty of the evidence (or quality of evidence) and the strength of the recommendations were assessed with the GRADE method³. The certainty in the body of evidence is defined as the degree of confidence that the estimates of effect (desirable or undesirable) or accuracy (sensitivity and specificity) are close to the actual effects of interest. The usefulness of an estimate of effect depends on the level of confidence in that estimate: the higher the certainty in the evidence, the more likely a strong recommendation can be made. A decision on the strength of the evidence also depends on other factors. The strength of a recommendation reflects the degree of confidence of the GDG that the desirable effects outweigh the undesirable effects. The desirable effects included beneficial health outcomes (e.g. prevention and early diagnosis of TB, reduced TB-related morbidity and mortality), a smaller burden of TB and more savings; whereas the undesirable effects include harm, a greater burden and more costs. The “burdens” included adherence to the recommendations by programmes, patients and caregivers – formal or informal – such as more frequent tests and taking additional medications.

The certainty in the estimates of effect (quality of evidence) was categorized into four levels:

<i>High</i>	The GDG is very confident that the true effect lies close to that of the estimate of the effect.
<i>Moderate</i>	The GDG is moderately confident that the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
<i>Low</i>	The confidence of the GDG in the effect estimate is limited: the true effect may be substantially different.
<i>Very low</i>	The GDG has very little confidence in the effect estimate: the true effect is likely to be substantially different.

The recommendations are either strong or conditional:

A *strong recommendation* is one for which the GDG was confident that the desirable effects of adhering to it would outweigh the undesirable effects. This could be either in favour of or against an intervention.

A *conditional recommendation* is one for which the GDG concluded that the desirable effects of adhering to it would probably outweigh the undesirable effects, but the GDG was not confident about the trade-off. The reasons for lack of confidence included: absence of high-quality evidence (few data to support the recommendation); imprecise estimates of benefit or harm (new evidence might change the ratio of risk to benefit); uncertainty or variation in the value of the outcomes for different individuals (applicable only to a specific group, population or setting); and small benefits or benefits that might not be worth the cost (including the cost of implementing the recommendation).

⁴ GRADEpro – Guideline Development Tool. Available from: <http://www.guidelinedevelopment.org/>

The recommendations in the guidelines are structured in two parts: target populations and screening tools. The recommendation text is followed by sections that summarise the evidence (justification), discuss their rationale, and highlight key considerations on implementation and subgroups. Separate chapters are devoted to monitoring and evaluation and to research gaps identified by the GDG.

3. Publication, implementation, evaluation, and expiry

The guidelines and the supporting documents were reviewed and endorsed by all GDG members. Remarks from the External Review Group were assessed by the WHO Guideline Steering Group and incorporated in the final version of the guidelines. Final approval of the guidelines by the Guideline Review Committee was received on 5 March 2021.

The guidelines will be published on the WHO website for free download and will be communicated widely at international and regional conferences and meetings of programme managers in all regions. The recommendations will also feature on the online *WHO eTB guidelines* (<https://who-tb.qa.evidenceprime.com/>). WHO will release an operational handbook alongside these guidelines with more practical details to support programmatic implementation of the updated recommendations on systematic screening for TB disease. This will also be incorporated in a knowledge sharing platform (“microsite”) of the Global TB Programme.

National programmes will be supported by WHO and technical and funding partners to plan for systematic screening for TB disease. Implementers should create a conducive policy and programmatic environment, including national and local policies and standard operating procedures to facilitate implementation of the recommendations in these guidelines. This should include promoting universal health coverage. Furthermore, dedicated resources should be allocated, including for human resource development and service delivery in the community. Training of frontline healthcare staff and students on critical areas such as identification of populations at risk, choice of test and administration of the tests, and counselling is important. National programmes should ensure meaningful engagement with affected populations, their communities, the private sector, other relevant health programmes and ministries in both planning and implementing the interventions. The process should articulate with other guidance on TB preventive in people with relevant risk factors for TB, and access to comprehensive care for people with these risks.

The uptake of these WHO recommendations will be monitored in the annual data collection of WHO Global TB Data Monitoring. Moreover, the number of downloads of the document from the WHO website will be monitored. Its citation in other websites will also be monitored (e.g. Medline). The impact of the guidelines will also be assessed during meetings with national TB programme managers and representatives held periodically by the WHO regional offices, during periodical programme reviews/joint monitoring missions, and during other specific country missions. A review of the implementation of WHO guidelines using surveys is being planned in early 2021 as a means for assessing TB guideline “adoption”⁵.

WHO will update the guidelines 5 years after their publication or earlier if new evidence becomes available that necessitates a revision. Meanwhile the WHO Global TB Programme will continually monitor the availability of new evidence and assess the need to change the recommendations earlier if necessary.

⁵ Schünemann HJ, Wiercioch W, Brozek J, Etxeandia-Ikobaltzeta I, Mustafa RA, Manja V, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. *Journal of Clinical Epidemiology*. 2017 Jan;81:101–10.

4. Composition of Guideline Development Group and External Review Group⁶

Guideline Development Group

Name	Area of expertise	Affiliation	Sex	Region
Denise Arakaki-Sanchez	National TB Programme, clinical	Ministry of Health, Brazil	F	South America
Omolola Atalabi	Clinical	University College Hospital (Ibadan), Nigeria	F	Africa
Helen Ayles	Epidemiology, clinical	Infectious Diseases and International Health, London School of Hygiene and Tropical Medicine, Zambia	M	Western Europe
David Branigan	Gender, equity and rights	Treatment Action Group, USA	M	North America
Jeremiah Chakaya	Clinical, public health, Co-chair	UNION, Kenya	M	Africa
Gavin Churchyard	Epidemiology, trials	The Aurum Institute, South Africa	M	Africa
Elizabeth Corbett	Epidemiology, trials	Liverpool School of Tropical Medicine and Hygiene, Malawi	F	Western Europe
Anand Date	Clinical, public health	Centers for Disease Control and Prevention, USA	M	North America
Esty Febriani	Gender, equity and rights	Civil Society Task Force, Indonesia	F	South East Asia
Celine Garfin	National TB Programme	National TB Programme, Philippines	F	Western Pacific
Amir M Khan	Private sector	Association for Social Development, Pakistan	M	Eastern Mediterranean
Katharina Kranzer	Epidemiology, public health	London School of Hygiene and Tropical Medicine, UK	F	Western Europe
Tamara Kredo	Guideline methodologist, Co-chair	University of Cape Town, South Africa	F	Africa
Knut Lönnroth	Epidemiology, public health	Karolinska Institute, Sweden	M	Western Europe
Guy Marks	Epidemiology, trials	University of Sydney, Australia	M	Western Pacific
Andrey Maryandyshev	National TB Programme, clinical	Northern State Medical University, Russian Federation	M	Eastern Europe
David Mungai	Clinical	Civil Society Task Force, Kenya	M	Africa

⁶ See Acknowledgements in main text for affiliations and countries of experts

Name	Area of expertise	Affiliation	Sex	Region
Iveta Ozere	Paediatrics	Centre of Tuberculosis and Lung Diseases, Latvia	F	Central Europe
Alena Skrahina	National TB Programme, clinical	National TB Programme, Belarus	F	Central Europe
Marieke van der Werf	Epidemiology, public health	European Centre for Disease Prevention and Control, Sweden	F	Western Europe

External Review Group

Name	Area of expertise	Affiliation	Sex	Region
Grania Brigden	Public health	UNION, France	F	Western Europe
Connie Erkens	Public health	KNCV, Netherlands	F	Western Europe
Andrew Kerkhoff	Epidemiology, trials	University of California San Francisco, USA	M	North America
Giovanni B. Migliori	Public health, clinical	Maugeri Care and Research Institute, Tradate, Italy	M	Western Europe
Ikushi Onozaki	Epidemiology, public health	Japan Anti-TB Association, Japan	M	Western Pacific
Srinath Satyanarayana	Epidemiology, public health	National Institute of TB and Respiratory Diseases, India	M	South East Asia
James Seddon	Paediatrics	Imperial College London, UK	M	Western Europe
Ivan Solovic	National TB Programme, clinical	National TB Programme, Slovakia	M	Central Europe
Sabira Tahseen	National TB programme	National TB Reference Laboratory, Pakistan	F	Eastern Mediterranean

5. Declaration of interests and management of conflicts of interest

The members of the Guideline Development Group (GDG) and External Review Group (ERG) completed a WHO declaration of interests form. All declarations were evaluated by the WHO Guideline Steering Group for any financial conflict of interest that might warrant exclusion from membership or from certain discussions of the GDG. The completed forms were summarised and presented to all GDG members at the first meeting, at which point the members were requested to update their declarations. Intellectual conflict of interest was not considered a motive for exclusion from the GDG as expertise on the topic was considered an important criterion for selection and the diversity and representation in the Group was large enough to balance any individual member's intellectual interest. The biographies of the GDG members were made public alongside the background document outlining the 2019 update on 1 July 2019, ahead of the GDG meetings.

Guideline Development Group

The following GDG members declared no interests that could conflict with the objectives of the guidelines:

Denise Arakaki-Sanchez, Omolola Atalabi, David Branigan, Jeremiah Chakaya, Anand Date, Celine Garfin, Amir M Khan, Andrey Maryandyshev, David Mungai, Iveta Ozere, and Alena Skrahina.

The following GDG members declared interests that were judged not to conflict with the objectives of the guidelines:

Tamara Kredo declared research support of US\$1000 to her organization (the South African Medical Research Council) for helping in one of the systematic reviews for this guideline. She contributed to develop a search strategy and to run a search. This was sent to the lead authors at the University of Cape Town. She also expected to be consulted on the conduct of the review.

Marieke van der Werf works for the European Centre for Disease Prevention and Control (ECDC) and part of her job is to communicate on her work. ECDC has worked on TB screening and she has presented on this work in international meetings. Her employer pays her salary and contributes to her travel expenses. Her views cannot go against ECDC policy.

Esty Febriani declared payment from WHO SEARO as consultant to lead community training at Timor Leste in 16–18 September, 2019.

Gavin Churchyard declared past grants from various sources to his employer (The Aurum Institute) for about US\$10 million for implementation or research as follows: Bill & Melinda Gates Foundation to evaluate the national rollout of Xpert MTB/RIF starting in 2011 (XTEND) (>4 years ago); UNOPS, funded by TB Reach (1 year) to implement TB screening in peri-mine communities (>4 years ago); South Africa Department of Health as part of a grant from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) for community based TB screening using symptoms and Xpert MTB/RIF for symptomatic (within the past 4 years); Global Fund funding for screening in correctional facilities using digital chest radiography and computer-aided detection (within the past 4 years); Free State Province to evaluate chest radiography screening in primary health clinics (within the past 4 years); and UNOPS, funded by TB Reach, to evaluate chest radiography screening in prisons (within the past 4 years).

Elizabeth Corbett declared research support from Wellcome Trust for the following fellowships: GB£3 million over 5 years until 2021, to London School of Hygiene and Tropical Medicine (LSHTM), as Principal Investigator; GB£1 million over 5 years until 2022, to Liverpool School of Tropical Medicine and Hygiene, as co-investigator; GB£350,000 over 3 years until 2022, as supervisor. All 3 grants include some form of digital radiography and CAD (two products: CAD for TB and qure.AI). The largest grant relates to HIV self-testing (the bulk of expenditure) as well as to TB active case finding in general populations of urban settings. She also declared that she has been invited to talk for FIND and WHO New Diagnostics Working Group at the 2018 Union World Conference on Lung Health in The Hague, Netherlands. She received no financial remuneration or travel grants. She also was involved in the systematic review on behaviour change that was presented at the meeting (author on the report). The other smaller grants relate to systematic screening in health facilities.

Katharina Kranzer reported employment (about GB£85000; LSHTM) and research support (€3.9million; the European & Developing Countries Clinical Trials Partnership (EDCTP)). One study funded by EDCTP, starting to recruit in October 2020, is following up household contacts and will validate several new tests and no particular technology has been privileged in the research.

Knut Lönnroth declared grants for research (EU H2020) on effectiveness and cost-effectiveness of TB community screening in high TB burden settings (focus on Nepal and Viet Nam), and other grants for screening of TB infection and active TB in migrants in low TB incidence settings, Sweden and other European countries, as follows: Swedish Heart and Lung Foundation – SEK 1500000 (2016–2020);

Swedish Research Council for Healthy Working Life and Welfare – SEK 3600000 (2015–2019); EU Horizon 2020 – €600000 (2016–2019); CHAFEA EU Health Programme – €180000 (2016–2020). One CAD product (Delft) was in one of the grants but he was not involved in that component. He has reviewed the FIND protocol assessing CAD that was used to inform the 2020 GDG on screening.

Guy Marks declared that he is currently President of the International Union Against Tuberculosis and Lung Disease. He also declared that he has received public research funds (NHMRC Australia) for research on TB control. He has led a trial in which Xpert MTB/RIF was used for TB screening but the manufacturer did not fund this work.

The following GDG member declared interests that were judged to conflict with one of the PICO questions of the guidelines (on use of computer-aided detection of TB on chest radiography):

Helen Ayles declared that she is a serving member of the Technical Review Panel of the Global Fund, which provides technical input into proposals including HIV testing modalities. She also declares leading a consortium that looks at the impact of an active TB case finding strategy for TB and HIV funded by EDCTP (EUR12,902,000). Delft is part of the EDCTP grant and consortium and provides some in-kind services at reduced costs. This includes the use of the CAD4TB at a reduced rate, training and the use of an experimental back-pack radiography unit. She declared a long-standing relationship with Delft and worked with them to develop the early CAD products. Based on this support she was recused from the session on recommendations on CAD products.

External Review Group

The following ERG members declared no interests that could conflict with the objectives of the guidelines:

Grania Brigden, Judith Bruchfeld, Giovanni B. Migliori, Ikushi Onozaki, Srinath Satyanarayana, James Seddon, Ivan Solovic, Sabira Tahseen.

The following ERG members declared interests that were judged not to conflict with the policy of WHO or the objectives of the guidelines:

Connie Erkens declared that a study she was involved in on LTBI screening in migrants to the Netherlands received 1,800 QuantiFERON-TB Gold Plus from the manufacturer QIAGEN (value EUR24,000) in 2016–2018⁷.

Andrew Kerkhoff declared being a collaborator in one of the reviews (screening in PLHIV) but received no funding for this work.

Evidence reviewers

The evidence reviewers provided the estimates for the evidence summaries but did not participate in formulating the recommendations for policy.

The following reviewers declared no interests that could conflict with the objectives of the guidelines:

Modupe Amofa-Seki, Hannah Alsdurf, Rafia Bosan, Jacob Creswell, Cyrus Daneshvar, Ashar Dhana, Pamela Delgado, Brianna Empringham, Helen Feasey, Gregory Fox, Paul Garner, Sifrash Gelaw, Maged Hassan, Mikashmi Kohli, Ramya Kumar, Miranda Langendam, Gary Maartens, Peter Macpherson, Tila Mainga, Lawrence Mwenge, Marriott Nliwasa, Anna Mandalakas, Hector Manzo, Nancy Medley, Fahd Naufal, Zhi Zhen Qin, Maria Ruperez, Adrienne Shapiro, Lily Telisinghe, Anja van't Hoog, Kavindhran Velen, Mariana Velleca Bryan Vonasek, Bada Yang, Alice Zwerling.

⁷ Spruijt I, Erkens C, Suurmond J, Huisman E, Koenders M, Kouw P, et al. (2019) Implementation of latent tuberculosis infection screening and treatment among newly arriving immigrants in the Netherlands: A mixed methods pilot evaluation. *PLoS ONE* 14(7): e0219252. <https://doi.org/10.1371/journal.pone.0219252>

The following reviewers declared interests that were judged not to conflict with the policy of WHO or the objectives of the guidelines:

Faiz Ahmad Khan and Gamuchirai Tavaziva declared research support from:

- Canadian Institutes of Health Research provided \$487,000 operating grant 2016–2020 for a prospective study evaluating CAD software, qure.ai, Lunit, Delft provided access to their software for research & evaluation purposes only (since 2016)
- Observatoire international sur les impacts sociétaux de l'intelligence artificielle et du numérique (publicly funded multi-institutional research observatory, financed by Fonds de Recherche Quebec). Provided CAD159,850 operating grant for interdisciplinary study on potential health equity impact of CAD 2020–2022

Lelia Chaisson declared owning 230 shares of Merck & Co

Jonathan Golub declared research support inclusive of 20% salary support from the US National Institute of Health amounting to US\$500,000 per year for 5 years for a RCT (TB Aftermath), investigating two case finding strategies to detect recurrent TB among people who have recently completed TB treatment. The RCT started in July 2020 in India and will end in June 2025. The content of this trial is not directly related to the subject of the PICO's driving the update of the WHO guidelines.

Claudia Denking, Sandra Kik, Stefano Ongarello and Morten Ruhwald declared that they benefited from:

- Free use of qXR licence, free installation of the software and technical advice provided by the company.
- Free use of Lunit Insight CXR licence, free installation and use of a laptop with the application installed for the duration of the research and technical advice provided by the company.
- Free technical advice provided by Delft Imaging during the duration of the research (note: FIND paid research licence fee to the CAD4TB software).
- These three software products were the ones included in the analysis undertaken for the WHO TB screening guidelines.

Eveline Klinkenberg declared work for KNCV and consulting for active TB case finding and other aspects of TB control

Katherine Robsky declared research support for:

- A project on a comprehensive snapshot of tuberculosis transmission in an urban Ugandan community US\$575,698 (current)
- Johns Hopkins Center for Global Health Established Field Placement Grant (PhD research funding) for herself US\$3000 in 2017
- Fogarty-Fulbright Fellowship in Public Health for the association of spatio-temporal patterns with tuberculosis in urban sub-saharan Africa (PhD research funding) for herself US\$26,950 (current)

Karen Steingart declared consulting work and research support related to the area of her reviews for the screening guidelines.

- Systematic review author on two reviews for GDG meeting on Nucleic acid amplification tests to detect TB and DR-TB: Cartridge-based nucleic acid amplification tests of low-complexity for the detection of resistance to isoniazid and second-line anti-tuberculosis drugs; User perspectives on cartridge-based diagnostic tests, 2020 (US\$24,500, of which US\$13,000 was distributed to others on the review team)
- Systematic review author for current meeting WHO guidelines on the systematic screening of TB disease: Screening tests for active pulmonary tuberculosis in children, 2020 (US\$6,000)

- Systematic review author for a suite of reviews on the accuracy of Xpert Ultra and Xpert MTB/RIF, 2019 (US\$35,900, of which US\$25,000 was distributed to others on the review team)
- Lateral flow urine lipoarabinomannan assay for detecting active tuberculosis in people living with HIV, 2019 (US\$20,000, of which US\$10,000 was distributed to others on the review team)
- Travel support and *per diem* to participate in WHO meetings and a US\$250 honorarium to participate as faculty in the Advanced TB Diagnostic Research Course, McGill University, Montreal

Ongoing:

- READ-It & CIDG consultancy, Liverpool School Tropical Medicine Role: Mentoring and technical support for Cochrane Reviews US\$11,200 (2019–2020)
- Stellenbosch University Consulting, projects involving systematic review methods, tailoring guideline development to country, PhD supervisor US\$2634 (2019–2020)

Completed 2016–2019:

- WHO Role: Preparation of GRADE tables US\$6,400
- FIND Role: Preparation of GRADE tables US\$3,200
- McGill University Role: Systematic review author, Xpert MTB/RIF and Xpert MTB/RIF Ultra for pulmonary tuberculosis and rifampicin resistance in adults (US\$16,970)
- University of Washington Department of Medicine, Seattle Role: Systematic review author, Symptom screening for active tuberculosis in pregnant women living with HIV US\$1000
- FIND Role: Systematic review author, Commercial products for preserving clinical specimens (US\$3200)
- WHO Role: Systematic review author, GenoType® MTBDR *sl* assay (US\$12,000)
- WHO Role: Guideline Development Group member, LAMP assay, Webinar 27 January 2016 (no remuneration)

She is a co-author on a three-year grant from Canadian Institutes of Health Research (CIHR) through McGill University, Montreal entitled "Evaluating diagnostic accuracy of tests and decision rules in the absence of a perfect reference standard", 2018 to 2020. In 2018, she received support from McGill University to attend two conferences, Methods for Evaluating Medical Tests & Biomarkers, 2–3 July 2018 in Utrecht, and the Union World Conference on Lung Health, 24–27 October 2018, in The Hague. In 2019 and 2020, she received support to attend the Union World Conference on Lung Health. In 2020, she received support to purchase a laptop and software (US\$2400). Otherwise, did she not receive remuneration. The project was completed in October 2020.



For further information, please contact:

World Health Organization

20, Avenue Appia CH-1211 Geneva 27 Switzerland

Global TB Programme

Web site: www.who.int/tb

