

# PUBLIC NOTICE

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## Guideline Development Group meeting on *M. tuberculosis* antigen-based skin tests (TBST) for the diagnosis of TB infection

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### Background

A new class of *M. tuberculosis* antigen-based skin tests (TBST) have been developed combining the simpler skin-test platform used in tuberculin skin tests (TST) with the specificity of blood-based interferon gamma release assays (IGRAs) that use *M. tuberculosis* specific antigens. Emerging evidence suggests that compared to IGRA, the tests may have similar specificity and provide more reliable results in children and in HIV-infected cohorts. However, the evidence has not been systematically reviewed.

### Objectives

- To assess the available data related to the impact of TBST on patient important outcomes: efficacy of TB preventive treatment (TPT) based on diagnostic tests results, predictive value for progression to TB disease, correlation with exposure gradient, proportion started on TPT.
- To assess the available data on the diagnostic accuracy (sensitivity and specificity) of TB antigen-based skin tests (TBST) for diagnosis of TB infection.
- To assess the available data on the concordance of TBST with TST and IGRAs.
- To conduct a review of the published qualitative data on feasibility, accessibility, equity and end-user values related to TBST implementation.
- To conduct a review of the published economic data on affordability, cost, and cost-effectiveness of TBST implementation.
- To determine questions for future research and issues to be addressed by WHO in subsequent policy recommendations.

### Questions to guide evidence reviews related to WHO guidance on tests of TB infection (2021)

#### ***Overarching patient-intervention-comparator-outcome (PICO) question for guideline development process:***

Should *Mycobacterium tuberculosis* antigen-based skin tests (TBST) for TB infection be used as an alternative to tuberculin skin tests (TST) or WHO-endorsed interferon- $\gamma$  release assay (IGRA) to identify individuals most at risk of progression from TB infection to TB disease?

#### ***The following specific PICO and research questions will be used to support the overarching PICO:***

1. ***Diagnostic performance:***  
Do *Mycobacterium tuberculosis* antigen-based skin tests for TB infection have similar or better diagnostic performance to TST or IGRA to detect infection with *M. tuberculosis*?

| Population  | Intervention  | Comparison        | Outcome  |
|---|---|-------------------|--|
| <ul style="list-style-type: none"> <li>- PLHIV;</li> <li>- &lt;5 years</li> <li>- Household and other close contacts;</li> <li>- Other at-risk groups;               <ul style="list-style-type: none"> <li>o Immune compromised ( individuals receiving anti-TNF-<math>\alpha</math> treatment, dialysis, under preparation for an organ or haematological transplant, patients with silicosis, pregnant women, malnourished, diabetes mellitus, steroid use, smoker);</li> <li>o High risk of prior TB exposure ( prisoners, health workers, immigrants from high TB burden countries, individuals with CXR abnormalities; homeless people and people who use drugs, inhabitants of high TB burden settings)<sup>1</sup></li> </ul> </li> <li>- BCG vaccinated vs non-vaccinated (in identified groups at risk of TB infection-stratified or in combination, as appropriate)</li> </ul> | <p><i>M. tuberculosis</i> antigen-based skin tests:</p> <ul style="list-style-type: none"> <li>- Diaskintest</li> <li>- C-Tb</li> <li>- EC skin test</li> <li>- DPPD</li> <li>- Others</li> </ul> | TST<br>or<br>IGRA | <ul style="list-style-type: none"> <li>- Efficacy of TB preventive treatment (TPT) based on diagnostic tests results;</li> <li>- Predictive value for progression to TB disease;</li> <li>- Correlation with exposure gradient;</li> <li>- Sensitivity/Specificity<sup>2</sup> for TB infection<sup>3</sup>;</li> <li>- Concordance with TST;</li> <li>- Concordance with IGRA;</li> <li>- Proportion started on TPT.</li> </ul> |

## 2. Safety:

Do TBST for TB infection cause more adverse reactions compared to TST or IGRA?

- What is the risk of adverse events compared to current TST or IGRA ?
- Consider data on both local and systemic reactions graded by type, severity and seriousness and stratified by sub-group.
- Compute relative risks where possible, however, if a control group receiving a comparator test is unavailable, to report frequency (%) of adverse events.

## 3. Health Economics:

What are economic aspects of TBST for compared to TST or IGRA?

- What is the unit cost of a single skin-based in vivo test in LMI countries?
- What are the resource requirements for health services to implement these tests at scale (cost description)?
- Incremental resource considerations and costs of implementing TBI tests as replacement test to TST or IGRA (these should be considered for different levels of health system)

<sup>1</sup> > 100/100,000 population

<sup>2</sup> For estimation of specificity, the ideal population is the one with very low likelihood of prior exposure to *M. tuberculosis*.

<sup>3</sup> TB disease is used as a proxy diagnosis for TB infection

- What is the certainty of the evidence of resource requirements (costs)?
- Is the intervention cost-effective compared to other tests (TST, IGRAs), in terms of:
  - o Increase in TPT uptake
  - o TB cases averted or DALYs lost

#### **4. Qualitative:**

What are end-user<sup>4</sup> views and perspectives on use of novel skin-based in vivo tests for TB infection use?

- What are the key attributes or characteristics of skin-based TB testing that people value (correct/incorrect diagnosis of TB infection)? How does this vary between different stakeholder groups ?
- What would be the potential impact of this class of technologies on health equity?
- Is the intervention acceptable to key stakeholders<sup>6</sup>?
- Is the intervention feasible to implement?
- What is a certainty of the qualitative evidence according to GRADE-CERQal approach?

## **Biographies of members of Guideline Development Group**

### ***Disclaimer on personal information on GDG members***

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<sup>4</sup> health care provider, lab technician/manager, programme staff, community workers, person offered test, and family

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Helen Ayles is a Reader in Infectious Diseases and International Health in the Clinical Research Department in the Faculty of Infectious and Tropical Diseases at the London School of Hygiene and Tropical Medicine, and the Director of Research at Zambia AIDS Related TB (ZAMBART) project in Lusaka, Zambia. After training in clinical infectious and tropical diseases in the UK she trained in epidemiology at the London School of Hygiene and Tropical Medicine. In 1998 she moved to Zambia where she has since lead the ZAMBART research team. Zambart is a multidisciplinary research group with over 650 staff. Helen's research interest is in the combined epidemics of TB and HIV and in the evaluation of large public health interventions. She is the Zambia principal investigator for the PopART trial (HPTN071), a large community-randomised trial of treatment as prevention for HIV.

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David Branigan is the TB Project Officer at Treatment Action Group (TAG) in New York, where he leads TAG's TB diagnostics advocacy portfolio, researches the latest developments in TB diagnostics, and engages external partners and affected communities to advocate for equitable access to TB diagnostics. He previously worked as a journalist covering intellectual property and global health policy, and as a researcher in the field of economic and social rights. David holds an MS in International Affairs from The New School, and has more than a decade of experience working in international development.

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Dr Chakaya has been a leader in TB control throughout his career, in his home country of Kenya and on the global stage. Until recently the Chief Research Officer for the Kenya Medical Research Institute, he has led the National TB Control Programme as its head from 2003 to 2006 and continues to act as a technical expert for the National Programme. Dr. Chakaya is President of the Board of Directors of the International Union Against Tuberculosis and Lung Disease. Until recently, he was the chief research officer for the Kenya Medical Research Institute, and led the National TB Control Programme as its head from 2003 to 2006, and continues to act as a technical expert for the National Programme. Dr. Chakaya is also technical advisor and executive director of the Kenya Association for the Prevention of Tuberculosis and Lung Disease. On the international stage, Dr. Chakaya has been active in both the Stop TB partnership and at the World Health Organization, serving as the chair of the DOTS Expansion Working Group of the STOP TB Partnership as well as chair of the Strategic and Technical Advisory Group for Tuberculosis at WHO.

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Daniela Maria Cirillo is a Technical Expert, Microbiologist, Group leader, Emerging bacterial pathogens Unit, San Raffaele Scientific Institute, Division of Immunology, Transplantation and Infectious Diseases. Her recent professional experience includes Director of the WHO Collaborating Centre on TB laboratory strengthening (ITA-98) (2013-now); Head of TB Supranational Reference Laboratory at the IRCCS Ospedale San Raffaele, Milan, Italy (2006-now). The main research focus of Emerging bacterial pathogens Unit includes tuberculosis and other mycobacterial diseases with multiple lines of research: Investigation of the determinants of drug resistance at genomic level and the correlation between specific SNPs in relevant genes and an increase in the phenotypic resistance by quantitative methods; Investigation of the pathogen's associated determinants leading to the progression of the disease with a focus on the role of non-coding genomic regions; Design and evaluation of new diagnostic assays; Investigation of TB transmission dynamics among vulnerable population and the best strategy to be implemented for an early detection; Use of whole genome sequencing (WGS) and in-house bioinformatic pipelines for the surveillance of TB outbreaks and others.

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Prof. Frank Cobelens MD MSc PhD (1959) studied medicine in Amsterdam and communicable disease epidemiology in London, and earned his PhD at the University of Amsterdam. He worked for several years in HIV/AIDS control and tropical and travel medicine. He became involved in epidemiological research on tuberculosis in Asia, Africa and Latin America as Senior Epidemiologist with the Dutch NGO KNCV Tuberculosis Foundation, one of the world's leading technical agencies for tuberculosis control. Since 2008 he has led the tuberculosis research group at what later became AIGHD and the Department of Global Health of the Amsterdam UMC, Amsterdam, where he was appointed Full Professor of epidemiology and control of poverty-related infectious diseases in 2011. Since 2013 he has combined this position with that of KNCV's Scientific Director.

Cobelens works closely with research groups around the world, and has supervised numerous junior researchers and doctoral students at home and abroad. His scientific interest is in multidisciplinary approaches to problems at the interface of biomedical aspects of infectious diseases, socioeconomic context and control policy. Recent work includes causes and spread of anti-tuberculosis drug resistance, development and evaluation of novel interventions for tuberculosis control, and biomedical mechanisms that define the relation between poverty and infectious diseases.

Cobelens has served on several expert panels and advisory bodies for global infectious disease control, in particular tuberculosis, including the World Health Organization's Strategic and Technical Advisory Group for Tuberculosis.

### **DATE, Anand**

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Dr Anand Date is a physician trained in preventive medicine and applied epidemiology. He currently works as a medical epidemiologist with the Division of Global HIV/AIDS at the US Centers for Disease Control and Prevention (CDC). His main focus is on TB/HIV, and he has conducted programme evaluations and operational research on TB/HIV and has collaborated with the World Health Organization (WHO) on developing global policies and guidelines. As Vice Chair, Dr Date hopes to increase the number of abstract-driven sessions at The Union World Conference on Lung Health in order to improve the scientific rigor and to increase the participation of HIV care and treatment implementing partners in the HIV Section.

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### **HAAS de, Petra**

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KNCV consultant Petra de Haas worked for close to 20 years at the Mycobacteria department at the National institute of public Health in the Netherlands (RIVM), as a laboratory manager and as researcher in the development of new diagnostics and the epidemiology for tuberculosis. In 2007 she started as a TB/HIV laboratory manager in the ZAMSTAR project, where she was based in Zambia via the London school of Hygiene and Tropical Medicine (LSHTM). When she returned to the Netherlands she worked as a laboratory advisor for doctors without borders (MSF) for two years after which she joined KNCV Tuberculosis Foundation (KNCV) in 2015 as Laboratory Technical Advisor. In this role she is providing technical assistance and advice on laboratory network systems through National TB programs and other TB partners within countries KNCV is involved in. The role of technical advisors at KNCV is to ensure that countries are up to date with new guidelines and endorsed diagnostic tools and support them with the implementation of these new tools and help with future strategic planning to reach the END TB strategy.

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Rumina Hasan has acquired FRC degree in pathology from Royal College of Pathologists, UK in 2000; PhD in Immunology from London School of Hygiene and Tropical Medicine, University of London in 1990; MSc from London School of Hygiene and Tropical Medicine and The Royal Post Graduate Medical School, University of London, in 1983 and MBBS, University College Hospital, University of London in 1980. She has research interests in Tuberculosis and Antimicrobial resistance. Currently she maintains position of Professor in Department of Pathology and Laboratory Medicine, The Aga Khan University, Pakistan.

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Dr Farzana Ismail is a Clinical Microbiologist and worked initially as consultant at a tertiary level Microbiology laboratory attached to the Steve Biko Academic Hospital and provided specialist services in both infectious diseases and infection control. These services extended to regional and district hospitals covering the Northern region of South Africa. She is a senior lecturer at the University of Pretoria involved in training medical undergraduate and postgraduate students as well as registrars in clinical microbiology and infection control. In 2017, she was appointed as the pathologist at the Centre for tuberculosis and now leads the WHO Supranational TB Reference laboratory section of the Centre providing support to other National TB reference laboratories in the region as well as conducting an external quality assurance program for high burden TB reference laboratories in Africa. She has a keen interest in drug resistant TB, diagnostic technologies, and patient centred care for TB. An important initiative has been reference laboratory support to clinicians managing difficult to treat and highly resistant TB patients in SA. She also plays an important role in surveillance activities trying to monitor new drug resistance as well as patient pathways to TB diagnosis among drug susceptible TB.

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Following my specialist registrar training in Clinical Microbiology and Virology in London in 2015 I became clinical director of the Supranational and National Tuberculosis Reference Laboratory in Germany. I have trained as an epidemiologist at the London School of Hygiene and Tropical Medicine in 2007, followed by a Wellcome Trust funded PhD. During my PhD I investigated the role of active case finding and antiretroviral therapy for tuberculosis control in high HIV and TB prevalence settings in South Africa. I continued to work in sub-Saharan Africa with my research mainly focusing on tuberculosis and HIV, including specifically interventions to improve linkage to care, operational and implementation research and diagnostics. More recently my role as director of the WHO Supranational Tuberculosis Reference Laboratory my research interests have expanded to multi-drug resistant tuberculosis in Eastern Europe and Central Asia, as well as laboratory quality management and laboratory networks.

My research to date has informed WHO Guidelines on “Systematic Screening for Active Tuberculosis” and “Management of Latent Tuberculosis Infection”. I have served on several WHO expert panels and provided expert advice to the European Centre of Disease Control and national public health institutions such as the Robert Koch Institute.

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Graduated in Medicine from Faculdade Evangélica do Paraná (1980), Master's in Pulmonology and Phthysiology from Federal University of Rio de Janeiro (1990), Ph.D. in Infectious and Parasitic Diseases from Federal University of São Paulo (1995) and Post-doctorate from Royal Tropical Institute of the Netherlands (2006). He held the following positions: a) Head of the Department of Internal Medicine from August 2006 to May 2010; b) Vice Director of the Faculty of Medicine (FM) from May 2010 to December 2015; c) coordinator of the Diagnostic Area of the Brazilian Network for Research on TB (REDE TB) from 2001 to 2014; d) Coordinator of the CNPq Advisory Committee - Medicine from August 2010 to August 2012; e) Adjunct Editor of the International Journal of Tuberculosis and Lung Disease (1027-3719) from 2001 to 2011; f) Elected representative of the full professors of the Health Science Center at the University Council of UFRJ from September 2011 to 2015; g) Adjunct Editor of J. Bras. Pneumol 2004-2018; h) member of the Task Force for TB Research of the World Health Organization from 2009-2019; i) President of REDE TB 2014-2018; He currently holds the following functions: a) coordinator of the Academic TB Program at FM-UFRJ since August 2006; b) deputy coordinator of the National Institute of Science and Technology - Tuberculosis (INCT-TB), since 2008; c) member of the Ministry of Health's Technical Advisory Committee on TB since 2007; d) Professor of Phthysiology and Pulmonology at the Faculty of Medicine of UFRJ since 2010; e) consultant to the CAPES/MEC Evaluation Committee since 2014, f) representative of the Academy in the BRICS TB Research Network from September 2017 to September 2019; g) Member of the International Editorial Board of the Brazilian Society of Tropical Medicine since 2019; h) Member of the Scientific Advisory Board of the Global Center for Health and Tropical Medicine, Institute of Hygiene and Tropical Medicine, University of NOVA Lisbon-Portugal, period 2020-2024; i) member of the MCTIC Virus Network in

the fight against COVID -19 since April 2020; j) Member of the CNPq Advisory Committee - Medicine from August 2020 to August 2023. Has experience in Medicine, with an emphasis on Phthisiology, Infectious Diseases, and Pulmonology, acting on the following topics: tuberculosis/HIV, diagnosis, immunopathogeny , molecular biology, molecular epidemiology, treatment, clinical trials, operational studies, biosafety, cost-effectiveness and impact of technological incorporation.

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Blessina Kumar is a health activist with a background in Community Health and Health Systems Management and is the co-founder of the Global Coalition of TB Activists (GCTA). She has extensive experience of working with varied marginalised communities in India and the internally displaced populations in the Sudan. While working in the Sudan she was responsible for 5 clinics and ran a very successful community health promoters training programme among the IDPs. This was recognized and accepted by the Government of Sudan. She also has experience of working with TB communities in Cambodia, Indonesia and India and provides technical support to countries in South East Asia region. She has endeavoured to bridge the patient - practitioner divide through patient literacy at community level and policy advocacy at macro level. Blessina's last decade has been focused on TB, passionately advocating for inclusion of affected community in TB policy and implementation globally. The impact of her leadership and global advocacy over a decade is visible in the understanding and inclusion of community and has shaped the TB response nationally and globally making it more people centred. Presently, Blessina is the CEO of Global Coalition of TB Activists, the first and the only global network of people affected by TB and is in the forefront of advocacy and capacity building of advocates and activists globally. She is also the co-founder of 'Touched by TB' the National Coalition in India, of people affected by TB. She is also a member of the Civil Society Task Force on TB. She serves on several boards and committees contributing richly to ensure people-friendly, rights-based and community led response for TB.

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Dr.N. Kumarasamy is a clinician and a researcher in infectious diseases with more than 20 years' experience in the field of HIV medicine. He is the Chief Medical Officer at YRGCARE Medical Centre, and directs the clinic which provides medical care for more than 20,000 people with HIV in Chennai, southern India. He is the Chief and Site Leader of the Chennai Antiviral Research and Treatment clinical research site (CART) of the US National Institutes of Health, which conduct multisite clinical trials on therapeutics (ACTG) and prevention (HPTN). He is also involved as Clinical Investigator in several on-going clinical research projects with the University of California, San Diego, and Brown University.

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Professor Andrei Mariandyshev is the head of the Phthisiopulmonology Department of the Northern State Medical University, Arkhangelsk, Russian Federation. Mariandyshev A. is the main TB expert of the Ministry of Health of the Arkhangelsk region and Northwest Federal District of the Russian Federation (11 regions). He has been graduated as a medical doctor from Arkhangelsk State Medical Institution. In 1986, did his Master of Science in Tuberculosis in 1989 and PhD in Tuberculosis 1999 at Northern State Medical University. He has been a chair of the European Green Light Committee WHO since 2010 to 2018 years and continue to be a member EurGLC now. Mariandyshev A. participated as an international expert implementation DOTS and MDR TB programs funded by the Global Fund in the Central Asia countries.

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Director of the WHO Collaborating Centre for TB/HIV activities and TB elimination at Brescia University Hospital from 31/10/2015 up to date. Previously Co-director of the WHO Collaborating Centre for TB and HIV activities at Brescia University Hospital –January 2010 to September 2013. Chair of the Technical Advisory Group on Tuberculosis Control (TAG-TB) of the European Region of WHO (EURO) and TB/HIV co-infection expert – since August 2016. Co-chair of panel of experts designated by the WHO for the preparation of the “Management of latent tuberculosis infection for people living with HIV, household contacts, and other at-risk populations: consolidated guidelines” - since September 2016 Chair of the Task Force for Latent Tuberculosis Infection of the New Diagnostic Working Group of the STOP-TB Partnership – since December 2015. Member of the Expert Panel on rapid diagnosis and effective treatment of drug-resistant TB jointly established by WHO/Europe and by the European Respiratory Society – since January 31st , 2013. Member of the expert panel for preparation of the ECDC Refugee and Migrant Health Infectious Disease Guidelines Screening (Tuberculosis group) (TB) since July 2016. Member of the “ad hoc” scientific panel for developing a guidance on programmatic latent tuberculosis infection control in the EU/EEA and candidate countries since May 2016.

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I worked for the development of TB diagnostics for more than 25 years. The major objectives are to improve the specimen collection efficiency, specimen concentration techniques, nucleic acid

amplification technology, and drug susceptibility testings. I also worked for drug resistance surveys in Japan and in other countries as a supra-national reference laboratory in WHO Western Pacific Region. I am currently working still for the development of sensitive TB diagnostics mainly using nucleic acid amplification methods. The current topic is specimen concentration efficiency. We evaluated several different types of concentration techniques, including magnetic beads, dielectrophoresis, and so on. They have increased the current sensitivity of any nucleic amplification methods. In addition, our team is working for molecular epidemiological analysis of TB transmission and AMR diagnosis by genome sequencing. I am much interested in the growth control of *Mycobacterium tuberculosis*. It is well known that growing tubercle bacilli contains semi-dormant bacillus group. The mechanisms are totally unclear, but if we can analyse the mechanism, it will be useful to prevent the development of TB disease from latent infection phase.

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Dr Lindiwe Mvusi is the Director in the TB Control and Management Cluster within the National Department of Health. She is a medical practitioner with post graduate training in occupational and public health. She had 11 years experience in clinical work both in the private and public sectors prior to joining the Department of Health in 2001. In the current position she is responsible for TB policy development, training, monitoring and evaluation of the implementation of the national policies and overall coordination of the TB programme. She has been involved in the development of TB and Drug Resistant TB policies and the scale up TB and HIV collaborative activities in the country and has served as technical advisor on the WHO DOTS Expansion Working Group, TB/ HIV and MDR-TB Working Groups.

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### NICOL Mark

**Constituency:** Technical experts, Microbiologist  
**Title:** MB ChB, MMed, FCPATH (SA) Micro, DTM&H, PhD  
**Current position:** Professor  
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Professor Mark Nicol is a medical microbiologist in the Division of Infection and Immunity in the School of Biomedical Sciences. He also holds an honorary appointment at the University of Cape Town, South Africa. He has a passion for using modern molecular tools to understand complex microbial communities, investigating how imbalances in these communities cause illness and to develop and test better diagnostics for infections, particularly for diseases relating to poverty. Specific focus areas of Dr Nicol's research are the pathogenesis and diagnosis of respiratory infection in children, development, evaluation and implementation of novel diagnostic tests for tuberculosis, the cascade of care for patients with drug-resistant tuberculosis and the role of the microbiome in early childhood development and illness. Professor Nicol has done seminal work on diagnostics for tuberculosis in children and adults, which has provided an evidence base for the new molecular tuberculosis tests used worldwide, and has contributed to many WHO policy recommendations and guidelines. Dr Nicol has successfully competed for grants from major international funders, including recent funding from the National Institutes of Health, the Bill and Melinda Gates Foundation and Wellcome Trust. He is a member of the advisory board for several large biotech companies and grant consortia, and a member of the International Interview Panel for the Wellcome Trust. A major emphasis is placed on the development of the next generation of researchers, and many of Dr Nicol's students have received international fellowships as well as awards at scientific meetings.

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### SHINNICK, Thomas

**Constituency:** Technical experts, Microbiologist  
**Title:** BS, PhD, Post-doc  
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Dr Shinnick is focused on understanding the biology, and genetics of the pathogenic mycobacteria, elucidating mechanisms of pathogenicity and drug resistance of *Mycobacterium tuberculosis*, developing rapid methods for the diagnosis of mycobacterial infections, using genotyping to support TB control programs and elucidate the dynamics of transmission. His programmatic work focuses on building laboratory capacity for the diagnosis of tuberculosis in resource-limited settings and in high burden countries. Got his PhD in 1978 at the Massachusetts Institute of Technology, Cambridge, MA. Now he is an Independent TB Consultant.

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### SOHN, Hojoon

**Constituency:** Technical experts, Health economic expert



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**Current position:** Assistant Scientist  
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My research focuses on an inter-disciplinary agenda that aims to combine methodologies and topics across disease disciplines, including translational epidemiology, operations research, health economics, health systems, and technology assessment. Through my research, I seek to streamline health economic and epidemiology methods in both model-based and field-based studies that can supplement evidence-based decisions in global and national-level policies and innovate new data-gathering methods/studies. I have more than 10 years of experience conducting tuberculosis and HIV/AIDS studies in various low and middle-income countries (India, Lesotho, Malawi, Nepal, Peru, Philippines, South Africa, Thailand, Zambia, Uganda, Morocco, Timor Leste) as well as in high income countries (Canada, South Korea, United States). During my off-time, I enjoy spending my time with my son, Haewon, and playing the clarinet.

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### TAHSEEN, Sabira

**Constituency:** Technical experts, Microbiologist/Public Health Practitioner  
**Title:** MBBS, PhD  
**Current position:** National Technical advisor (National TB Reference laboratory)  
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Dr Sabira Tahseen is a TB laboratory expert, a medical graduate with specialization in clinical pathology. She started her professional carrier in 1989 and has remained affiliated with TB diagnostic laboratories since 1993. She joined National TB control Programme Pakistan in 2003 and is heading the National TB reference laboratory. Her key contribution includes technical guidance for scale up of QA diagnostic services and successful implementation of National TB disease and drug resistance surveys. As Technical advisor (NTP), she provides guidance on policy making, planning for roll out of new diagnostics, programmatic management of drug resistant TB and surveillance of drug resistance. As a core group member of Global laboratory initiative (GLI) and regional Green Light Committee (rGLC) for Eastern Mediterranean region, she also contributes in the development of various handbooks and tools and international TB Review and monitoring missions.

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## TAVORA, Ezio

**Constituency:** Groups affected by potential recommendations, Patients  
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**Current position:** Director  
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Since 2015, Ezio is the Coordinator of the Community Engagement component of the STREAM study, by The Union/ Vital Strategies (VS) in Mongolia, Moldova, Georgia, India, South Africa, Uganda and Ethiopia, under USAID TREAT-TB grant. Has recently establish a Brazilian National TB CAB; is a member of the Global TB CAB since 2012; member of the REFLATE Scientific Committee; was a member of the CDC's TB Trials Consortium (TBTC) Community Research Advisory Board (CRAG) for five years. He has long experience in Community Engagement in TB since 2002 both in Brazil and internationally. He has served in different International organizations and institutions: member of the Regional Green Light Committee by the Pan-American Health Organization (2011-12); member of the Stop TB Partnership Coordinating Board (2006-09); served as the Country Focal Point to organize the Global TB Partners' Forum in Rio de Janeiro in March 2009; member of the Brazilian NTP Technical Advisory Panel (2009-2012).

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## TUDOR, Carrie

**Constituency:** Groups affected by potential recommendations, Nurse  
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**Current position:** TB Project Director  
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Dr Carrie Tudor, has worked in global health for nearly 20 years. She earned a BA from Indiana University, a MPH from the Rollins School of Public Health at Emory University, and a BSN and PhD from the Johns Hopkins University School of Nursing. Following her PhD, she completed a Fogarty Global Health Post-doctoral research fellowship based at K-RITH in Durban, South Africa. Her research interests are focused on occupational risk factors for TB among healthcare workers and preventing TB in healthcare workers. She has published several articles on infection, prevention and control and occupational TB in healthcare workers. She is experienced in both quantitative and qualitative research methods. Dr Tudor is currently the TB Project Director for the International Council of Nurses (ICN) working to build the capacity of nurses related to TB/MDR-TB and patient-centered care in China, Russia, and six sub-Saharan African countries. Prior to joining ICN she

was a Senior Research Coordinator at the John Hopkins University School of Medicine based in South Africa. She currently serves as the Chair of the Stop TB Partnership's End TB Transmission Initiative working group and the Chair of the Nurses and Allied Professionals Sub-section of the Union.

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### van der WERF, Marieke

**Constituency:** Technical experts, Epidemiologist, Public Health  
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Dr. Marieke J. van der Werf is the head of disease programme sexual transmitted infections, blood-borne viruses and tuberculosis at European Centre for Disease Prevention and Control in Stockholm. She was trained as a biomedical scientist (MSc, 1997) and medical doctor (MD, 1997) at the University of Leiden, The Netherlands, did her Master of Public Health in 2001 at the Netherlands School of Public Health and obtained her PhD in Medicine in 2003 at the Erasmus University in Rotterdam. She has provided technical assistance and built capacity for epidemiological and operational research in Europe, Africa and Asia, and coordinated European Union guidance development, surveillance, and training on sexual transmitted infections, blood-borne viruses and tuberculosis. She (co-)authored 150 articles in international peer-reviewed journals and participates in the work of international policy advisory groups and guidance developments groups from the World Health Organization and other organizations.

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### VARAINE, Francis

**Constituency:** Technical experts, TB physician / researcher  
**Title:** MD  
**Current position:** TB medical adviser  
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Medical doctor graduated in 1982, after a long field experience with Médecins Sans Frontières, Dr. Varaine joined the headquarters as medical adviser on TB. In this position he worked towards the integration of DR-TB as a part of regular TB management. He was the chair of the MSF TB Working Group that gathers expertise and coordinates various actors of

TB management within MSF. He promoted an ambitious operational research agenda and set up a mechanism for compassionate use of new anti-TB drugs. Dr. Varaine was until 2021 the leader of the endTB project for MSF and is co-investigator of the endTB trials.

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## VIET NHUNG, Nguyen

**Constituency:** National TB Programme; MDR-TB physician; end-user  
**Academic degrees:** M.D., Ph.D.  
**Institutional affiliation:** Vietnam National Tuberculosis Programme  
**Current position:** Director of the National Lung Hospital, Manager of the National TB Control Programme  
**Primary residence:** Hanoi, Vietnam

Associate professor Nguyen Viet Nhung is currently Director of the National Lung Hospital, Manager of the National Tuberculosis Control Program, President of the Vietnam Association against TB and Lung Diseases and Head of TB and Lung Diseases Faculty of Ha Noi Medical University, Viet Nam. Dr. Nhung is an active member of ATS, ESMO, IASLC and IUATLD. He obtained his medical degree from Hanoi Medical University and did his 3-year residency specialized in tuberculosis and lung diseases at the National Lung Hospital in Hanoi and completed his PhD scholarship in the Charles University in Prague, Czech Republic in 2000 with thesis on “the role of immunohistochemistry in typing and prognosis of lung cancer”. He was appointed as associate professor of the Ha Noi Medical University in 2012 and he is also a guest lecturer in Army Medical University, Hanoi School of Public Health. He has been a member of regional Green Light Committee (rGLC) Western Pacific from 2011-2015 and a current member of WHO Task Force on development of policies for the rational introduction of new TB drugs and a member of the WHO STAG TB from 2016. Prof Nhung research interests are primarily in the areas of lung cancer, tuberculosis, asthma and COPD. Since 2010, he is deputy editor in chief of National Journal of Tuberculosis and Lung Diseases. His research interests are primarily in the areas of TB, lung cancer, asthma and COPD and published 137 scientific articles, 45 scientific abstracts and 41 books.

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## WALTERS Elisabetta

**Constituency:** Technical experts, Paediatrician  
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Experienced Clinical Researcher with a demonstrated history of working in the higher education industry. Skilled in Clinical Research, Medical Education, Epidemiology, Pediatrics, and Scientific Writing. Strong research professional with a PhD in paediatric tuberculosis, and Master's Degrees in Paediatrics and Clinical Epidemiology from Stellenbosch University. She is the clinical lead for the paediatric TB diagnostic research program at the Desmond Tutu TB Centre, (director: Anneke Hesselning). She has completed a PhD in 2018 on strategies to improve the diagnosis of pulmonary tuberculosis in children, including the use of stool and other samples. Since her early medical career, she has had a keen interest in clinical research in the field of infectious diseases, specifically tuberculosis (TB) and HIV. Elisabetta has obtained an MMed (Paed) degree cum laude from SU: my research project was the first study to document a significant reduction in TB incidence after introduction of antiretroviral therapy in HIV-infected children (Walters et al, BMC Pediatrics 2008). She has joined the DTTC in 2009 to dedicate myself to a career in clinical research on paediatric TB, in an environment which is exceptionally supportive and internationally recognized for its academic outputs. Elisabetta has a Master's degree in Clinical Epidemiology, which I was awarded cum laude. She published the first study to document the utility of GeneXpert MTB/RIF on pediatric stool samples. Due to her experience in the field of TB diagnosis in children, she was an invited speaker at a Pediatric TB Diagnostics Workshop at the Union World Lung Health Conference in Barcelona, Spain in 2014, as well as at 2 local conference (TB Conference, Durban 2014 and Southern African Thoracic Society Congress August 2015). She is a member of faculty for the annual International Childhood TB Training course run by Stellenbosch University, offered to 60 international participants, on which lecture on the diagnosis of TB in children.

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## ZHAO, Yanlin

**Constituency:** National TB Programme; MDR-TB physician; end-user  
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Zhao Yanlin is Full professor of Chinese Center for Disease Control and Prevention. Vice-Director of National Tuberculosis Control and Prevention Center of China CDC. Director of National Tuberculosis Reference Laboratory of China CDC.



