



## PUBLIC NOTICE

Guideline Development Group Meeting on nucleic acid amplification tests (NAATs) for detection of TB and DR-TB

May 6-10, 2024

Geneva, Switzerland

## Background

In 2022, 7.5 million were diagnosed with TB. <sup>1</sup> Globally, the estimated number of people who developed MDR-TB or RR-TB (MDR/RR-TB) in 2022 was 410 000; 95% UI: 370 000–450 000).

WHO's End TB Strategy calls for the early diagnosis of TB and universal drug-susceptibility testing (DST), highlighting the critical role of laboratories in the post-2015 era in rapidly and accurately detecting TB and drug resistance. <sup>2</sup> WHO has endorsed a range of new diagnostic technologies during the past 10 years.

The WHO assessment process for TB diagnostics currently focuses on evaluating classes of TB diagnostic technologies rather than specific products. However, several individual technologies-based recommendations exist. The objectives of the current update are the following:

- Consolidate individual technologies-oriented recommendations into class-based recommendations;
- Update existing recommendations for technologies falling into above mentioned classes;
- Evaluate parallel use of currently WHO recommended rapid diagnostic tests for diagnosis of TB in children and PLHIV.

To address the question of the use of molecular technologies in clinical care and programmatic management of TB and DR-TB, the WHO Global TB Programme will convene a Guideline Development Group meeting from 6-10 May 2024, in Geneva, Switzerland.

## Biographies of members of Guideline Development Group

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<sup>1</sup> Global tuberculosis report 2023. Geneva: World Health Organization; 2023.

<sup>2</sup> Global strategy and targets for tuberculosis prevention, care and control after 2015 (Resolution WHA67.1, Agenda item 12.1). Geneva: World Health Assembly; 2014 ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_R1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R1-en.pdf)).

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The list of participating experts, a summary of relevant interests disclosed by such experts, and any appropriate mitigation measures taken by WHO relating to the management of conflicts of interests, will be reported publicly in accordance with WHO policies.

## BRANIGAN, David

**Constituency:** Technical expert, community based research and policy, patients' rights advocate

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David Branigan is the TB Project Officer at Treatment Action Group (TAG) where he advances TAG's advocacy to promote increased investment in TB research and improved access to TB tools. David closely follows scientific developments relevant to TB diagnosis, treatment, and prevention; creates resources to sensitize activists, policymakers, and other stakeholders to these developments; and coordinates advocacy campaigns to promote equitable access to the highest standard of TB care. David holds a Masters in International Affairs with a focus on Governance and Rights from The New School.

## CHOUB, Sok Chamreun

**Constituency:** Technical expert, community based research and policy, patients' rights advocate

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Sok Chamreun CHOUB is currently working with the Khmer HIV/AIDS NGO Alliance, known as KHANA in the Kingdom of Cambodia, as the Executive Director, but also the Chief of Party for the five-year USAID-funded Community Mobilization Initiative to End TB (COMMIT) under the USAID TB-Local Organization Networks mechanism. Chamreun has been working with KHANA, the local non-governmental organization over the past twenty-years, that works, and focus are on the prevention, care support and treatment for HIV/AIDS, Tuberculosis, sexual reproductive health, other health related issues including non-communicable diseases, promote and address the human rights and gender and the universal health coverage for key marginalize and vulnerable populations in Cambodia. He has started his public health career, since early 1993 focused on community and health system strengthening, as part of the health reforms and the roll-out of primary health care services.

Chamreun is an active advocate/activist for HIV and for TB. He is currently the Co-Chair of the Activists Coalition on TB for Asia and Pacific or known as ACT! AP hosted by APCASO in Bangkok and funded by the Stop TB Partnership and he is also the Developing Country NGOs Representative of the Stop TB Partnership Board. He was also serving as one of the members of the WHO Civil Society Taskforce for TB for a two-year term: 2021-2022.

## CIRILLO, Daniella

**Constituency:** Technical expert, microbiologist

**Title:** MD, PhD

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Daniela Maria Cirillo is a board-certified clinical microbiologist, Head of the Emerging Bacterial Pathogen Research unit at San Raffaele Scientific Institute in Milan. Dr. Cirillo is also the Director of the WHO CC in tuberculosis (TB) laboratory strengthening ITA-98 and of the ESCMID Collaborating Centre at Ospedale San Raffaele. Her research focuses on mechanisms of detection of drug resistance in MDROs of nosocomial origin and mycobacteria and application of NGS based technology in clinical microbiology. Areas of expertise include clinical bacteriology and infection control, next generation sequencing based diagnostic tools, diagnostic capacity building in high burden TB countries, research on new diagnostics for active TB and Infection, nosocomial infection. She and her collaborators provide technical support to more than 12 Countries in Africa, Asia and Europe. She is Co-Chair of the New Diagnostic Working Group of the StopTB partnership, core group member of European Laboratory Initiative and ERI, PI of the European laboratory network (ERLN-TBnet), Elected member of the Disease Network Coordination Committee (DNCC) for Tuberculosis at ECDC and President of the European Society of Mycobacteriology since 2016. Awardee of G Middlebrook prize in 2017. She is currently member of or has contributed to several international Research Consortia: EU-Seq MyTB, ReSeq TB, Cryptic, E-detect TB, EU-PEARL, Unite4TB. Her scientific production includes more than 330 original papers published in peer-reviewed journals.

## DHEDA, Keertan

**Constituency:** Technical expert, clinician, researcher

**Title:** Professor

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Keertan Dheda is a hospital-based respiratory physician and clinician scientist with professorial appointments at the University of Cape Town and the London School of Hygiene and Tropical Medicine. His research work has focussed on the pathogenesis, diagnosis and management of respiratory infections including TB, and his clinical interest includes difficult to treat asthma. He serves or has served on several international academic and advisory bodies including those of the WHO, NIH, Wellcome

Trust, and the editorial boards of the American Journal of Respiratory and Critical Care Medicine, Lancet Respiratory Medicine, and the British Medical Journal. He has published over 380 peer-reviewed manuscripts (H index of 100).

## FIELDING, Catherine

**Constituency:** Technical expert, epidemiologist, researcher

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Prof Katherine Fielding joined the School in January 2000 and previously worked at the Centers for Disease Control and Prevention in Atlanta, US and University of Nottingham and University of Edinburgh. Currently she is a chair of the TB Centre steering committee and deputy chair of the DL MSc Epidemiology exam board. Prof Katherine Fielding gives lectures and run practicals on the Statistical Methods in Epidemiology and Advanced Statistical Methods in Epidemiology.

Her research focuses on the design of intervention studies and evaluation of interventions to reduce the burden of tuberculosis (TB), particularly in settings of high HIV prevalence. Previously Prof Katherine Fielding have collaborated with researchers in The Gambia, Guinea and Guinea-Bissau on work investigating the role of genetic and environmental factors in susceptibility to TB. She has been senior statistician and co-investigator on various cluster randomized trials (CRTs) in South Africa and an individually randomized non-inferiority trial in conducted West and Southern Africa. The CRTs include an evaluation of Xpert MTB/RIF in South Africa embedded within their national rollout of the new TB diagnostic.

## HALL-EIDSON, Patricia

**Constituency:** Technical expert, laboratory strengthening

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Dr. Patricia Hall-Eidson leads the Tuberculosis and Clinical Monitoring Team in the International Laboratory Branch of the Division of Global HIV and TB (Global Health Center) at US CDC, manages the WHO Supranational Tuberculosis (TB) Reference Laboratory in Atlanta, GA USA, and serves as Vice Chair of the Stop TB Partnership Global Laboratory Initiative. She holds a PhD in Microbiology and Molecular Genetics from Emory University and a Master of Science in Evolutionary Development. Patricia applies her 20 years of laboratory research and project management experience to: oversee TB testing network strengthening activities across more than 20 CDC partner countries, inform and review TB/HIV testing guidance and performance for US President's Emergency Plan for AIDS Relief (PEPFAR) country

programs, and supervise development of practical guidance and tools to enhance implementation of, and improve patient access to, TB and advanced HIV disease testing services.

## HASAN Rumina

**Constituency:** Technical experts, microbiologist

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Dr. Hasan's areas of interest focuses on antimicrobial resistance and diagnostics including for tuberculosis. In this context, she has contributed to a number of national and International Strategic Technical Advisory Expert Groups and Committees including as a part of the WHO Strategic Technical Advisory Group on Antimicrobial Resistance (STAG-AMR). Dr. Hasan continues to serve on consultations and guideline development groups at WHO working on the development and positioning of new TB diagnostics. She also a part of the WHO Eastern Mediterranean Regional Green Light Committee (RGLC) for prevention and control of drug resistant tuberculosis in the region.

## JITTIMANEE, Sirinapha

**Constituency:** Nursing, patient care, groups affected by potential recommendations

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Dr. Jittimane is a lecturer at Faculty of Nursing, Chulalongkorn University, Bangkok, Thailand. She graduated with a master's and a PhD in community health nursing from the School of Nursing at Case Western Reserve University in Ohio, USA in 2005. Dr. Jittimane joined the faculty in 2022 and currently teaches nursing courses for master's students with a focus on interventions such as symptom management, self-management, case management, continuing care, and health behavior modification. Her areas of interest include person-centred care, providing health services for prisoners and migrants, and conducting systematic review and meta-analysis.

Dr. Jittimane has over 20 years of experience as a civil servant in the National Tuberculosis Program in Thailand, which has given her extensive expertise in the field. She has also published 20 articles related to TB and HIV in peer-reviewed international journals. Additionally, from 2016 to 2017, she served as a monitoring and evaluation officer at HIV, Health and Development Unit, UNDP, Asia and the Pacific.

## KOURA, Kobto

**Constituency:** Technical expert, end-user, public health practitioner

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Kobto Koura is a Medical Doctor and public health specialist with 16 years of professional experience. His expertise is in planning, designing, implementing, monitoring and evaluating strategies and prevention, detection and management of TB in adults and children. His background includes research, technical assistance, and delivering international courses for health professionals.

## KRANZER, Katharina

**Constituency:** Technical expert, end-user, bacteriologist, epidemiologist, public health practitioner

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Katharina Kranzer is a Professor of Infectious Disease Epidemiology at the London School of Hygiene and Tropical Medicine and the Co-director of the Health Research Unit Zimbabwe at the Biomedical Research and Training Institute. She is a clinical microbiologist and epidemiologist who previously directed the National and WHO Supranational Tuberculosis Reference Laboratory In Germany. She has more than two decades of experience in research, clinical care and diagnostic service provision for people affected by tuberculosis in Europe, Central Asia and Southern Africa. She has contributed to many WHO tuberculosis guidelines including those on systematic tuberculosis screening.

## MARYANDYSHEV, Andrei

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Professor Andrey Mariandyshev is the head of the phthisiopulmonology department of the Northern State Medical University, vice-president of the Russian TB Association, main TB specialist of the Ministry of Health of the North-Western Federal District of the Russian Federation. Participant of training courses organized by WHO. Chair of the WHO European Green Light Committee from 2011 to 2018. Consultant for tuberculosis program in eleven regions of Russia and other countries funded by a non-governmental organization. Author 73 publications in international scientific journals.

## MUHWA, Jeremiah Chakaya

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Jeremiah Chakaya qualified as doctor and internal medicine specialist from the University of Nairobi in 1985 and 1992 respectively. He is a practicing pulmonologist based in Kenya. He has previously worked with the Kenya Medical Research Institute where he was the Director at the Centre for Respiratory Diseases Research. He has also previously managed the National TB Program in Kenya. He is the immediate past president of the IUATLD ( the Union). Other previous roles include chair of the DOTS expansion working group, vice chair of the Stop TB Partnership Coordinating Board, Chair of WHO's Strategy and Technical Advisory Group for TB (STAG- TB) and chair of the Global Fund's Technical Review Panel.

## NDJEKA, Norbert

**Constituency:** National TB Programme, technical expert, end-user, TB clinician and NTP manager

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Dr. Norbert Ndjeka has been the Director, Drug-Resistant TB, TB & HIV at the National Department of Health in South Africa since May 2009. His vision is to strengthen the programmatic and clinical management of Drug-Resistant TB (DR-TB). Under his leadership, there has been a decline in the number of cases of DR -TB in South Africa and a remarkable improvement in the proportion of patients successfully treated for DR- TB. He is a Specialist Family Physician with an interest in TB and HIV. He is currently the Chairperson of the Afro-GLC (African Green Light Committee), a committee that advises WHO on how to manage drug-resistant tuberculosis. He recently received an Honorary Doctorate from UCT in recognition of his outstanding contribution to the fight against DR-TB locally and globally.

## OMAR, Shaheed Vally

**Constituency:** Technical expert, microbiologist

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Dr Shaheed Vally Omar MSc(Med) PhD(Med), is a Medical Scientist with specialisation in Microbiology, focusing on Mycobacterium tuberculosis research since his post-graduate training. He currently leads the following scientific programmes in the Centre for Tuberculosis at the National Institute for Communicable Diseases in Johannesburg, South Africa; diagnostic evaluations for both active and latent



disease state; drug resistance determination and surveillance; molecular epidemiology of drug resistance tuberculosis; and the application of novel technologies for these purposes. He further is the lead scientist of the National TB Reference Laboratory as well as the WHO TB Supranational Laboratory Network. He has over 50 peer-reviewed publications and has participated as a presenter or invited speaker at over 60 local and international conferences preceding. He further serves as a peer reviewer for several accredited journals.

## SHARMA, Sangeeta

**Constituency:** National TB Programme, technical expert in pediatric TB, end-user, TB clinician

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Dr Sangeeta Sharma, MD, working in the premier National TB Institute for more than 25 years, an apex quaternary referral centre for North India serving a population of 100 million. With a career devoted to pediatric TB, has treated more than 150,000 children with TB including MDR/XDR and complicated TB patients referred from tertiary care centres. Actively involved in conducting both clinical and operational research for tuberculosis diagnostic techniques, novel regimes and prevention. She has been assisting in the Govt of India's National TB Elimination program in formulation and updation of guidelines and modules., policy development and implementation strategies and training of trainers. As a member of the WHO GDGs and GDI Core group, Dr. Sharma has contributed to the formulation of WHO guidelines besides being an author of more than 100 peer-reviewed publications.

## SHINNICK, Thomas

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Thomas M. Shinnick, Ph.D. is an independent TB consultant with more than thirty years of experience in strengthening TB laboratory capacity. As the former Associate Chief, International Laboratory Branch, Division of Global HIV and TB, Center for Global Health, Centers for Disease Control and Prevention, Dr. Shinnick led CDC's global TB laboratory activities. Dr. Shinnick has served on numerous expert groups for the World Health Organization, the core groups of the Global Laboratory Initiative of the Stop TB Partnership and GLI-Africa, the TB and Immunology Subsection of the International Union Against TB and Lung Diseases, the Scientific Advisory Board for the Heiser Program and the Scientific Advisory Group for the Center for Translational Research. He is the author/co-author of more than 200 publications and the editor of one book.

## SOHN, Hojoon

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Dr Hojoon Sohn, an Associate Professor at the Seoul National University, is an infectious disease epidemiologist with multidisciplinary expertise in health economics. Dr. Sohn has over 10 years of experience in evaluating novel diagnostics for TB, conducting empiric and model-based economic evaluations of TB, HIV/AIDS, and other types of public and social protection interventions in resource-limited settings and in South Korea. Dr. Sohn is keen on advancing novel data collection and analysis methods in the context of the implementation science discipline to improve 'real-world' evidence on costs, cost-effectiveness, and cost-benefits of novel strategies for TB and HIV/AIDS.

## TAHSEEN, Sabira

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Dr Sabira Tahseen is a TB laboratory expert and 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.

## VASSILIEVA, Irina

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Chief TB specialist of the Ministry of Health of Russia, chairman of the certification qualification commission for the specialty "Phthysiology", member of the scientific and practical council of the Ministry of Health of Russia, president of the Russian Society of Phthysiatricians (ROF), president of the Association of Phthysiatricians (AF), editor-in-chief of the journal "Tuberculosis and Lung Diseases", Member of the Council for Therapeutic Sciences of the Russian Academy of Sciences. Member of the advisory group on tuberculosis of the WHO European Bureau, head of the WHO Collaborating Center for

Research on Tuberculosis and HIV Infection in the Russian Federation, representative of Russia in the BRICS research network on tuberculosis.

## WALKER, Tim

**Constituency:** Technical expert, TB clinician, epidemiologist, researcher

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Associate Professor Tim Walker is conducting a series of observational studies based in Ho Chi Minh City to understand how we best preserve the efficacy of what is still our most effective and shortest treatment regimen for any kind of TB. Seeking to understand how patients get MDR-TB, Professor Tim Walker is performing pathogen whole genome sequencing for a comparative genomic analysis of the burden of MDR-TB transmission, and at the same time, seeking to understand the contribution of different factors related to the de novo emergence of resistance to first-line drugs. To this end, two case-control studies are assessing potential selection pressures, including undiagnosed resistance to other drugs and pharmacogenomic and pharmacokinetic factors.  
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## XICHAO, Ou

**Constituency:** Technical expert, microbiologist, National TB Programme, end-user

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Currently employed at the National Tuberculosis Reference Laboratory of China CDC, specialize in the molecular epidemiology of tuberculosis, as well as the development and implementation of novel TB laboratory diagnostics. Supervisor of Chinese Field Epidemiology Training Program. Presided over a provincial natural science fund project, managed a sub-task of the major national infectious disease technology projects during 13th Five-Year plan, and led sub-tasks of two national key research and development plan project. Won the second prize of the Huaxia Medical Science and Technology Award. Published over 40 academic papers in world-class medical journals such as the New England Journal of Medicine and Nature Microbiology, and published 4 academic monographs as either the chief editor or associate editor.

## MBUAGBAW, Lawrence

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Dr Lawrence Mbuagbaw is a Research Methods Scientist in Clinical Epidemiology and Biostatistics. He trained at the Faculty of Medicine and Biomedical Sciences (FMBS) in Cameroon (MD; 2005); the Hebrew University of Jerusalem (MPH; 2009); and McMaster University (PhD in Health Research Methodology; 2014). He is an associate professor at McMaster University where he teaches courses in biostatistics and randomized trials; associate professor extraordinary of Epidemiology and Biostatistics at Stellenbosch University. He holds the title of University Scholar at McMaster University. He works as a research methods scientist at the Research Institute of St Joseph's Health Care Hamilton (SJHH) where he provides methodological and statistical support for other researchers as the Director of the Biostatistics Unit. This includes research question formulation, study design, data analysis and reporting. He is the principal investigator of numerous research projects covering a wide variety of research designs including evidence syntheses, randomized trials, mixed-methods studies, and qualitative studies. He also the co-Director of Cochrane Cameroon. He has authored over 300 peer-reviewed publications on topics as diverse as infectious diseases, mother and child health, mHealth, methodology, health systems strengthening and the intersection of these fields.