Guideline Development Group Meeting on Targeted Next-Generation Sequencing for Detection of TB Drug Resistance

Background

Drug-resistant TB is a major threat to global TB control. Cumulatively, the number of people started on MDR/RR-TB treatment regimens from 2018-2020 was almost 483,000 people, less than a third of the 5-year target of 1.5 million people (2018-2022) set at the UN High Level Meeting on TB in 2018. Substantial improvements in treatment coverage of DR-TB at the global level will require an intensification of efforts to diagnose DR-TB.

After a long period of stagnation in TB treatment, the introduction of new drugs and repurposing of existing antimicrobial agents for the treatment of TB have generated new TB treatment regimens at a comparatively rapid rate, providing a quick improvement to treatment options, outcomes, and quality of life during treatment among DR TB patients. As resistance to these new and repurposed drugs in the community gradually increases, however, concern has been raised about the lack of options for rapid detection of resistance.

Gene sequencing technologies provide an option for rapid, accurate genetic analysis and detection of genetic mutations indicating resistance in a fraction of the time required for culture-based methods for detecting resistance. Several various commercially available “End-to-End Solutions” for targeted next-generation sequencing (tNGS) for detection of drug resistance have become available in recent years. These solutions offer the potential for higher throughput, a significantly faster time to result, and a greater accuracy across more TB drugs than current WHO-recommended molecular technologies, and offer the potential to rapidly assimilate new information on genetic markers for resistance as they become known.

To address the question of the use of tNGS technologies in clinical care and programmatic management of DR-TB, the WHO Global TB Programme will convene a Guideline Development Group meeting from 2-5 May 2023, in Geneva, Switzerland.

Objectives

- To assess the available evidence on the diagnostic accuracy of tNGS solutions for detection of TB drug resistance among TB patients; the impact of tNGS solutions for detection of TB drug resistance on patient-important outcomes including TB treatment success and cure, mortality, time to detection of TB resistance and initiation of appropriate treatment regimen; the available evidence of the costs and cost-effectiveness of the introduction of tNGS solutions for detection of TB drug resistance in LMIC settings; and the available
evidence of the feasibility, acceptability, and user preferences regarding the use of tNGS solutions for detection of TB drug resistance among TB patients.

- To issue global recommendations and guidance on the use of tNGS solutions for detection of TB drug resistance.

Biographies of members of Guideline Development Group

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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.
ARINAMINPATHY, Nimalan

Constituency: Technical expert, epidemiologist
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Nim Arinaminpathy is Professor of Mathematical Epidemiology at Imperial College London. In his research he applies mathematical modelling to study the spread and control of infectious diseases, with a focus on human tuberculosis (TB). He works closely with national TB programmes in high-burden countries, particularly India and Kenya. He also works with the WHO South-East Asian Regional Office (SEAR) on TB control priorities for the region, and serves on the WHO Strategic and Technical Advisory Group for TB. Additionally, during India’s COVID-19 response, he worked closely with public health authorities in India, providing advice in support of their decision-making.

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.

CIRILLO, Daniella

Constituency: Technical expert, microbiologist
Title: MD, PhD
Current position: Board-certified clinical microbiologist, Head of the Emerging Bacterial Pathogen Research unit
Institutional affiliation: IRCCS San Raffaele Scientific Institute, Fondazione Centro San Raffaele
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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.

DE HAAS, Petra

**Constituency:** Technical experts, microbiologist  
**Title:** B.Sc, M.Sc, PhD  
**Current position:** Senior Laboratory Technical Advisor  
**Institutional affiliation:** KNCV TB plus  
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Petra de Haas worked for almost 20 years at the Mycobacteria department at the RIVM, in the Netherlands as a laboratory manager and researcher in the development of new diagnostics and the epidemiology for tuberculosis. Then she joined LSHTM in the position of a laboratory manager and was based in Zambia for four years, hereafter she worked with MSF as laboratory advisor. Currently she is positioned at KNCV as Senior Laboratory Technical Advisor. In this role she provides technical assistance, trainings and advise on laboratory network systems, TB diagnostics and innovations through National TB programs and other TB partners within countries.

HALL-EIDSON, Patricia

**Constituency:** Technical exert, laboratory strengthening  
**Title:** PhD, MS  
**Current position:** TB and Clinical Monitoring Team Lead  
**Institutional affiliation:** US Centers for Disease Control  
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**Email:** igg5@cdc.gov

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
Title: MBBS, PhD, FRCPath
Current position: Professor and Consultant Clinical Microbiologist
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Honorary Professor, Faculty of Infectious and Tropical Diseases, London
School of Hygiene and Tropical Medicine
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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
Title: PhD, MS
Current position: Lecturer
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Dr. Jittimanee 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. Jittimanee 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. Jittimanee 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
Title: MD
Current position: Director, Tuberculosis Department
Institutional affiliation: International Union Against Tuberculosis and Lung Disease (The Union)
Address: Paris, France
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.

KUMAR, Blessina

Constituency: Affected communities and patients’ rights advocate
Title: MS
Current position: CEO
Institutional affiliation: Global Coalition of TB Advocates
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Blessina Kumar is a health activist with a bachelor’s degree in nursing and midwifery and a postgraduate in health systems management and advanced TB Diagnostics and Research. She has worked with varied communities across India and Sudan. She has endeavoured to bridge the patient – practitioner divide through patient literacy at the community level and policy advocacy at a macro level. For the last 18 years, Blessina has been focused on TB. She has built capacity of affected community members and advocated for their inclusion in TB policy and implementation bodies, globally. In India she has led the civil society movement against TB, lobbied decision makers and worked with parliamentarians to raise TB awareness among them for better care and support for patients and accountability from the TB programme. Her strong advocacy highlighting the issue of stigma has contributed richly to make addressing stigma and discrimination a top global priority. She continues to serve on many global and regional boards and committees bringing the community perspective to the table. She is a proud member of the WHO Civil Society Task Force (CSTF) TB, Global Community Advisory board member UNITE4TB, Co-Chair of Indian Council for Medical Research National Community Advisory Board (CAB), Member of the International Scientific Advisory Group -ICMR, Member of CAB Benefit Kids Stellenbosch TB Centre South Africa, Technical Advisor for WHO Southeast Asia Region for TB, Technical Advisor Community Engagement, National TB Programme, India. Presently, Blessina heads the Global Coalition of TB Advocates, a body that is in the forefront of ensuring a people centred and rights-based TB response.

KUMARASAMY, Nagalineswaran

Constituency: Technical experts, HIV clinician
Title: MD, PhD, MBBS
Current position: Chief & Director, VHS-Infectious Diseases Medical Centre
Institutional affiliation: Voluntary Health Services Infectious Diseases Medical Centre
Address: Chennai, India
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Dr Kumarasamy is the Chief & Director of Infectious Diseases Medical Centre at Voluntary Health Services (VHS) Hospital in Chennai and directs the clinic which provides medical care for persons with HIV, Hepatitis, Tuberculosis, COVID and other infectious Diseases in Chennai, Southern India. Dr Kumarasamy is the Director of the Chennai Antiviral Research and Treatment (CART) Clinical Research Site which conducts therapeutics and biomedical prevention clinical trials in infectious
diseases. He is involved as Clinical Investigator for several ongoing clinical research projects with University of California San Diego, Brown University, Harvard University, and University of New South Wales/Kirby Institute in Sydney, Australia. Dr Kumarasamy is a clinician and a researcher in infectious disease with more than 25 years of experience and has published more than 450 manuscripts in peer reviewed medical journals. He has conducted several landmark antiretroviral clinical trials which have impacted treatment guidelines. His publications on the impact of antiretroviral therapy have led to several antiretroviral scale-up programs in developing countries. Dr Kumarasamy is an advisor and expert panel member for World Health Organization, ARV Treatment guidelines committee member, and a Clinical advisor to Clinton Health Access Initiative. He has a particular interest on the long term impact of antiretroviral therapy in resource limited settings. He is serving as a member of COVID National Task Force for Clinical Research and Drug Development.

MENEZES DE SOUZA, Nicole

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<td>Title</td>
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Nicole graduated in Pharmacy with a Master’s in Biotechnology and Biosciences and a qualification in Clinical Analysis, and as a specialist in Pharmaceutical Assistance Management. She has been working as a technician for the Ministry of Health since 2013 and is currently a focal point in the area of care and diagnosis at the General Coordination of Surveillance of TB, endemic mycosis and MNT, focusing on the promotion, organization and strengthening of the national networks for the diagnosis of this three diseases.

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  
**Title:** MD  
**Current position:** Director, Drug-Resistant TB, TB & HIV  
**Institutional affiliation:** National Department of Health in South Africa  
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**Email:** norbertndjeka@gmail.com

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.

NICOL, Mark

**Constituency:** Technical expert, 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.

SHINNICK, Thomas

**Constituency:** Technical expert, laboratory strengthening, microbiologist  
**Title:** MD
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

Constituency: Health economist
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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

Constituency: Technical expert, microbiologist, National TB Programme, end-user
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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.
TAVORA DOS SANTOS, Ezio

Constituency: Groups affected by potential recommendations, patients’ rights advocate
Title: PhD, MS
Current position: Community Engagement Projects Coordinator
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Ezio Tavora dos Santos Filho, Brazilian, holds a PhD in Health Policies by the Medical School of the Federal University of Rio de Janeiro, a master’s in international Relations (IRI-Pontifical Catholic University in Rio de Janeiro), and is a Lawyer by formation (Law School, Rio de Janeiro State University). As a member of the Brazilian TB Research Network, REDE-TB, he coordinates the STREAM study Community Engagement (CE) component, as well as the SimpliciTB study CAB in Brazil and the TB Alliance CE Forum. He is an emeritus member of the WHO-CSTF (Civil Society Task Force), an emeritus member of the Global TB CAB and is a co-founder of the Brazilian National TB CAB. He serves as a consultant for PAHO and has served as a member of the Brazilian Technical Advisory Committee for the NTP; at the Coordinating Board of the Global Fund and the Stop TB Partnership; the AMRO Regional Green Light Committee; and the Community Research Advisory Board of the CDC’s Tuberculosis Trials Consortium (TBTC).

VIET NHUNG, Nguyen

Constituency: Technical expert, microbiologist, public health practitioner
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Current position: President, Vietnam Lung Association; Vice President, Vietnam Medical Association
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Dr Nguyen Viet Nhung is the emeritus Director of the National Lung Hospital and emeritus 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 was 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. Dr Nhung’s 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.
WALTERS, Elisabetta

Constituency: Technical expert, paediatrician
Title: MD, PhD
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I am a paediatrician with extensive experience in clinical research in the field of paediatric tuberculosis (TB). My primary area of interest is TB diagnostics. My doctoral thesis (2018) examined alternative approaches for the microbiological confirmation of TB in children. In 2019, I obtained an international fellowship in paediatric infectious diseases and clinical immunology from the Great North Children’s Hospital, Newcastle-upon-Tyne, United Kingdom. I am currently an associate clinical researcher at Newcastle University in the Directorate of Integrated Laboratory Medicine (Institute of Human Genetics, John Walton Muscular Dystrophy Research Centre). I remain affiliated to Stellenbosch University as a clinical research fellow, and I am currently involved in a number of projects including diagnostic biomarker work, treatment response and functional outcomes of TB in children.

ZHAI, Yanlin

Constituency: National TB Programme, end-user, technical expert
Title: MD, PhD
Current position: Director, National Center for Tuberculosis Control and Prevention
Institutional affiliation: Chinese Center for Disease Control and Prevention
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Dr Yanlin Zhao is responsible for technical management of Chinese tuberculosis control and prevention network, capacity building-up and nationwide anti-TB drug resistance surveillance. His research areas focus on: molecular epidemiology and epigenetics of tuberculosis mycobacterium, drug resistance surveillance, new diagnostics. He has published more than one hundred publications in international journals.

KREDO, Tamara

Constituency: Methodologist
Title: MD, PhD
Current position: Director
Institutional affiliation: Health Systems Research Unit, South African Medical Research Council
Associate Professor Extraordinary, Stellenbosch University, Department of Medicine, Department of Global Health
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Dr Tamara Kredo is a health policy and guidelines specialist, with training as a medical doctor and specialist in Clinical Pharmacology. She is the Director of the Health Systems Research Unit and previously held the position of Chief Specialist Scientist at Cochrane South Africa. She is an Associate Professor Extraordinary at Stellenbosch University in the Department of Medicine and Department of
Global Health. She works in the field of evidence-based healthcare practice and training, rational therapeutics and clinical practice guidelines. Her research explores the methods, quality and content of clinical practice guidelines in Southern Africa. She is also involved in conducting reviews on COVID-19 treatments and other medicines informing national standard treatment guidelines for the South African Department of Health. She has fulfilled several leadership roles including co-directing Cochrane Africa, co-lead of the South African GRADE Network, and has been on several strategic and advisory committees including being a member of the South African National Essential Medicines List Committee. She also consults to the World Health Organization as a guideline methodologist; was a member of the Cochrane Centre Directors Executive (now Geographic Groups); was a co-opted Trustee of the Guidelines International Network Governing Board; and in 2020 was elected to the Cochrane Board.