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# Guideline Development Group for the update of the WHO consolidated guidelines on the treatment of drug resistant tuberculosis, 2022

WHO headquarters, Geneva, Switzerland February-March 2022

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# WHO Consolidated Guidelines on Tuberculosis. Module 4: Drug-resistant Tuberculosis Treatment. (2022 update)

# **Background**

Tuberculosis (TB) remains a threat to global public health and is one of the major infectious causes of death in the world (1). In 2020, an estimated 10 million people developed TB and 1.5 million died from the disease (1). About 465,000 new cases of rifampicin-resistant or multidrug-resistant¹ tuberculosis (MDR/RR-TB) are estimated to emerge each year. While all of these would have been eligible for a second-line TB treatment regimen, just over 150,000 enrolments on treatment were reported by countries in 2020. Despite this, significant improvements in the availability of enhanced diagnostics and more effective medicines have occurred in recent years and this has led to earlier detection and higher success rates among patients with MDR/RR-TB in several national programmes. However, these successes have not been reproduced in the rest of the world, and the overall treatment success rate only reached 59% for MDR/RR-TB patients who started on treatment in 2018 worldwide.

The current World Health Organization (WHO) recommendation for treating persons with drug resistant TB is included in the WHO consolidated Guidelines for treatment of drug-resistant tuberculosis, released in 2020. In recent years, several combinations anti-TB medicines as well as various durations of the overall treatment have been tested by the researchers and national programmes. These regimens include the use of a new 6-month regimen including pretomanid, bedaquiline and linezolid in combination with moxifloxacin (BPaLM), a 6-month regimen using bedaquiline, pretomanid, linezolid and clofazimine (BPaLC) and 6-9-month regimens based on the BPaL regimen with less exposure to linezolid (lower dosing or shorter duration) that have undergone clinical trials for treatment of patients with MDR/RR-TB or pre-XDR-TB; modified all-oral shorter regimens (6-9 months or 9-12 months) containing all three Group A medicines for MDR/RR-TB patients that have been tested in a clinical trial or implemented by the national TB programme in South Africa. In addition, co-administration of Hepatitis C virus infection (HCV) and MDR-TB treatment becomes important in several countries in the regions with high prevalence of MDR/RR-TB and HCV co-infection that requires an evidence assessment on efficacy and safety if it can improve treatment outcomes. As the use of new regimens or co-administration of treatment offers the possibility of improved outcomes for patients, it is imperative that WHO reviews new evidence in a timely manner to determine if new recommendations on MDR/RR-TB treatment can be made. Therefore, these data from the national programmes as well as clinical trials will constitute the body of evidence for review by the Guideline Development Group (GDG). The guidelines will update the recommendation on the treatment of drug resistant TB, incorporating related guidance from other WHO guideline documents to aid clinicians, nurses, users and member countries in implementing a comprehensive package of patient treatment and support.

To advise WHO on the guideline update, a GDG composed of external experts is being convened in early 2022 to review the evidence and formulate evidence-based recommendations (see list and bios in the later section of this document). The GDG members are involved in the finalization of the guideline questions, scoring of outcomes, commenting on the evidence to be reviewed, completion of the GRADE tables, formulation of any new or updated recommendations and approval of the final guidelines document.

The GDG meeting is being held virtually in a series of webinar sessions in three five-day sessions on three non-consecutive weeks (21 to 25 February 2022; 7 to 11 March 2022; and 21 to 25 March 2022).

 $<sup>^{\</sup>rm 1}$  Combined resistance to both rifampicin and isoniazid, the two most important first line anti-TB drugs.

Before finalization, the guidelines will be reviewed by other experts serving in an External Review Group.

### **Key questions**

The guidelines update will be framed by the following PICO questions.

- 1. Should a shorter all-oral regimen (less than 12 months) containing at least three Group A medicines be used in patients with MDR/RR-TB (fluoroquinolone resistance excluded)
- 2. Should a 6-to-9-month shorter all-oral regimen containing Lzd, Bdq, Lfx, Z, Eto/Hh/Trd be used in patients with MDR/RR-TB (fluoroquinolone resistance excluded)?
- 3. Should BPaL regimens with lower linezolid exposure (dose or duration) be used instead of the original BPaL regimen in patients who are eligible for BPaL regimen?
- 4. Should 6-month regimen using bedaquiline, pretomanid, linezolid be used in patients with pulmonary pre-XDR-TB (MDR/RR-TB with fluoroquinolone resistance)
- 5. Should 6-month regimen using bedaquiline, pretomanid and linezolid be used in patients with pulmonary MDR/RR-TB and without fluoroquinolone resistance?
- 6. Should 6-month regimen using bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) be used in patients with pulmonary MDR/RR-TB (with or without fluoroquinolone resistance)?
- 7. Should 6-month regimen using bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) be used in patients with pulmonary pre-XDR-TB (MDR/RR-TB with fluoroquinolone resistance)?
- 8. Should 6-month regimen using bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) be used in patients with pulmonary MDR/RR-TB and without fluoroguinolone resistance?
- 9. Should 6-month regimen using bedaquiline, pretomanid, linezolid and clofazimine (BPaLC) be used in patients with pulmonary pre-XDR-TB (MDR/RR-TB with fluoroquinolone resistance)?
- 10. Should 6-month regimen using bedaquiline, pretomanid, linezolid and clofazimine (BPaLC) be used in patients with pulmonary MDR/RR-TB and without fluoroquinolone resistance?
- 11. Should HCV treatment be co-administered with MDR-TB treatment in patients co-infected by MDR/RR-TB and HCV? (subject to the availability of evidence)

In addition, two background questions are also included for the GDG review:

- 1. What is the safety profile of BPaL regimens with different levels of exposure to linezolid when used in MDR-TB patients?
- 2. What is the prevalence of chronic viral hepatitis infection (HBV and HCV infection) among patients diagnosed with TB (including MDR/RR-TB)?

# **Key documents**

- 1. Global tuberculosis report 2021. Geneva, World Health Organization; 2021. https://www.who.int/tb/publications/global\_report/en/
- 2. World Health Organization. The End TB Strategy: Global strategy and targets for tuberculosis prevention, care and control after 2015. Geneva, 2014.
- 3. United Nations General Assembly. Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. New York: United Nations, 2018.
- 4. World Health Organization. WHO Consolidated Guidelines on Tuberculosis. Module 4: Treatment. Drug-resistant tuberculosis treatment. Geneva, 2020.

# **Guideline Development Group members**

| SCHÜNEMANN, Holger Jens (Co-chair) | 1  |
|------------------------------------|----|
| CHAKAYA, Jeremiah Muhwa (Co-chair) | 1  |
| ARAKAKI Denise                     | 2  |
| CHANDRASEKARAN, Padmapriyadarsini  | 2  |
| CIRILLO, Daniela Maria             | 3  |
| DALEY, Charles                     | 3  |
| DAVIES, Geraint (Gerry)            | 4  |
| GUPTA, Amita                       | 5  |
| GURBANOVA, Elmira                  | 5  |
| HESSELING, Anneke                  | 6  |
| LANGE, Christoph                   | 7  |
| LIENHARDT, Christian               | 7  |
| MAGSAYO-SALON Leslie Christine     | 8  |
| MARKS, Guy Barrington              | 8  |
| MEINTJES, Graeme                   | 8  |
| MUJTABA, Asif                      | 9  |
| NASEHI, Mahshid                    | 9  |
| NGUYEN, Viet Nhung                 | 10 |
| NUNN, Andrew                       | 10 |
| SCHOEMAN Ingrid                    | 11 |
| TAHSEEN, Sabira                    | 11 |
| TUN, Ye                            | 12 |
| VAMBE, Debrah                      | 12 |
| VASILYEVA, Irina                   | 13 |
| VERNON, Andrew                     | 14 |
| WINARNI, Paran                     | 14 |
| 7HAO Yan-Lin                       | 15 |

# Brief biographies of the Guideline Development Group members

SCHÜNEMANN, Holger Jens (Co-chair)

**Constituency: GRADE** methodologist Qualifications: M.D., Ph.D., M.Sc., FRCP(C)

**Current position:** Professor and Chair, Department of Health Research Methods, Evidence

and Impact; Professor of Clinical Epidemiology and Medicine and Director,

Cochrane Canada and McMaster GRADE Centre

Institutional affiliation: Departments of Health Research Methods, Evidence and Impact and of

Medicine, McGRADE Centre, McMaster University Health Sciences Centre

Holger Schünemann is professor in the Departments of Health Research Methods, Evidence, and Impact and of Medicine, McMaster University. He received his MD and Dr. med. from Hannover Medical School and trained in lung biology, epidemiology, internal medicine and preventive medicine/public health at SUNY Buffalo (M.Sc. & Ph.D.). In 2009, he joined McMaster University fulltime, widely considered the birthplace of evidence-based health care and problem-based learning to become Chair of Clinical Epidemiology and Biostatistics. He completed his final term as chair in 2019 and now leads the Michael G DeGroote Cochrane Canada Center and the McMaster GRADE center. He also is director of Cochrane Canada, co-chair of the GRADE working group and co-director of the WHO Collaborating Center for Infectious Diseases, Research Methods and Recommendations. He has led evidence synthesis and guideline methodology projects and has been advisor and chair of many guideline expert groups for WHO, the European Commission, ministries of health, other governmental organizations, and professional societies. As author of over 700 publications (h-index 160/102 google scholar/web of science) he is among the 500 most cited scientists globally (www.webometrics.info). Maintaining an active internal medicine practice fulfils his passion for patient care and ensures his guideline work is people oriented.

CHAKAYA, Jeremiah Muhwa (Co-chair)

Constituency: Clinician

Qualifications: MBChB, MMed, DThM

**Current position:** Technical Director and Chief Executive Officer, Respiratory Society of Kenya

Professor, Global Respiratory Health, Liverpool School of Tropical Medicine, UK

**Institutional affiliation:** NTP Kenya

Muhwa Jeremiah Chakaya, is a Professor, Global Respiratory Health, at the department of clinical sciences, Liverpool School of Tropical Medicine. Prof. Chakaya hails from Kenya where he was born and educated and where he practices and teaches respiratory medicine. He graduated from the University of Nairobi with a basic degree in medicine and surgery (MBChB) in 1985 and a master's

degree in internal medicine (M.Med) in 1992. He then went on to study lung medicine at the National Lung and Heart Institute, University of London at the Royal Brompton Hospital and at the Kyorin University Hospital in Tokyo, Japan. Professor Chakaya worked as a TB and lung disease researcher at the Centre for Respiratory Diseases Research at the Kenya Medical Research Institute and later served as the TB Program Manager at the Ministry of Health between 2003 and 2006. At the international level, Professor Chakaya has held several positions including, Vice Chair of the Stop TB Partnership Coordinating Board, Chair of the Strategic and Technical Advisory Group for TB (STAG-TB) of the World Health Organization (WHO), Chair of the Global Fund's Technical Review Panel (TRP) and President of the International Union Against Tuberculosis and Lung Disease (The Union). Professor Chakaya is a founder member of the Respiratory Society of Kenya (ReSoK) and has remained closely engaged with this organization. He is a member of the Pan African Thoracic Society and serves in the executive committee of this organization. He has honorary teaching position at the school of medicine, Kenyatta University, Nairobi, Kenya.

# **ARAKAKI** Denise

Constituency: Clinician Qualifications: MD

**Current position:** Head of Reference Center of Infectious Diseases, federal district of Brazil

Institutional affiliation: National TB programme, Brazil

Dr Arakaki-Sanchez is an Infectious Disease Specialist, in the last years she has worked in Mozambique for scaling up for antiretroviral therapy, Pan American Health Organisation Brazil as TB national Officer, she also has coordinated the Brazilian TB Program. Currently, she is the head of a Reference Centre of Infectious Diseases at Federal District in Brazil and a consultant of National TB Program. She is also a member of WHO STAG TB.

# CHANDRASEKARAN, Padmapriyadarsini

Constituency: Clinician

Qualifications: MBBS, DNB, MS (CR), Ph.D

Curent position: Director

Institutional affiliation: National Institute for Research in Tuberculosis, Chennai

Chandrasekaran Padmapriyadarsini is a Clinician by training and is currently the Director of ICMR-National Institute for Research in Tuberculosis (NIRT) (formerly known as the Tuberculosis Research Centre), Chennai. She has a Short-term Fellowship in HIV epidemiology from University of California, Los Angeles; a master's degree in clinical and translational research from Tufts University Boston, USA and recently completed Ph.D. in Pediatrics.

Over the last 20 years, she has been involved in multiple clinical studies and trials of HIV and TB among adults and children. She is the Principal Investigator of multiple collaboratives, multicentric projects, both at national and international level. She has more than 85 publications in peer reviewed National and International journals and 4 book chapters to her credit. She has been involved in framing National Guidelines for Management of Extra-pulmonary TB (INDEXTB Guidelines) and for the Introduction of Bedaquiline for Drug resistant TB patients in India and Nutritional Guidelines for TB patients. She was awarded the Lupin-TAI Oration Award at the National TB Conference in 2016, Lucknow, and again in 2020 in Indore by the TB Association of India. She is a member of the National Technical Expert Group of RNTCP under Central TB Division, Ministry of Health and Family Welfare, Government of India and the Regional Green Light Committee of WHO for the South-east Asia region. She is also currently the Senate member of the Tamil Nadu Dr. MGR Medical University, Chennai.

CIRILLO, Daniela Maria

**Constituency:** Technical experts, Microbiologist

Qualifications: MD, PhD

**Current position:** Group leader, Emerging Bacterial Pathogens Unit

Institutional affiliation: San Raffaele Scientific Institute, Division of Immunology, Transplantation

and Infectious Diseases

Daniela Maria Cirillo is a board-certified clinical microbiologist and the Head of the Emerging Bacterial Pathogen Research unit at San Raffaele Scientific Institute in Milan. Dr. Cirillo is also the Director 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 and latent TB Infections, 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, Member of the Core Group of the ERLN-TB and of core group of WHO-SRL network, 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.

DALEY, Charles

**Constituency:** Pulmonologist; TB expert

Qualifications: M.D.

**Current position:** Professor of Medicine, Chief of the Division of Mycobacterial and

Respiratory Infections and Director of NTM Center of Excellence

Institutional affiliation: National Jewish Health

Charles L. Daley, M.D., is Professor of Medicine at National Jewish Health (NJH), the University of Colorado, and Icahn School of Medicine at Mount Sinai. He is Chief of the Division of Mycobacterial and Respiratory Infections at NJH. Dr. Daley has served on expert panels for the WHO, CDC, IDSA, and ATS including those addressing diagnosis and treatment of drug susceptible and drug resistant TB. He served as Chair of the Green Light Committee, rGLC and Global Drug Resistant TB Initiative and received the ATS Global Lung Health Award in 2016 for his work with MDR-TB. Dr. Daley was an Associate Editor for the American Journal of Respiratory and Critical Care Medicine and now serves an Associate Editor for the European Respiratory Journal. As a scientist, Dr. Daley is actively involved in clinical, epidemiologic, and translational investigations of mycobacterial infections and bronchiectasis that has resulted in over 200 research publications, chapters and reviews. As a clinician, he focuses on the care of patients with NTM infections and drug resistant tuberculosis.

# DAVIES, Geraint (Gerry)

Constituency: Trials expert; Pharmacologist

MB, DTM&H, MRCP, MSc Epidemiology, PhD Pharmacology, FRCP Qualifications: Professor of Infection Pharmacology, Honorary Consultant in Infectious **Current position:** 

Diseases and Associate, Liverpool of Tropical Medicine

**Institutional affiliation:** University of Liverpool

Gerry Davies is Professor of Infection Pharmacology and Honorary Consultant in Infectious Diseases at the University of Liverpool. He is the TB lead clinician for Liverpool and an advisor to the British Thoracic Society MDR-TB Clinical Advice Service. He ran the TB programme at Hlabisa hospital, Kwazulu/Natal, South Africa from 1994-1998, later obtaining an MSc in Epidemiology from the London School of Hygiene and a PhD in Pharmacology from the University of Liverpool. From 2007-2009, he was based at the Mahidol-Oxford Research Unit in Bangkok where he worked on antituberculosis and influenza therapy and subsequently as theme leader in HIV-TB pharmacology at the Malawi-Liverpool-Wellcome Research Unit in Blantyre (2012-2014). He is an editor for the Cochrane Infectious Diseases Group, specialising in tuberculosis and has extensive experience of Phase II and III clinical trials in tuberculosis in differing roles. He played a prominent role in the EU Innovative Medicines Initiative product development partnerships PreDiCT-TB and UNITE4TB and has served on numerous WHO policy taskforces and guidelines development groups over the last decade related to treatment of tuberculosis. Since 2018, he has been Specialty Lead for Infection for the NIHR NW Coast CRN, chairing the cross-specialty group co-ordinating local delivery of COVID-19 research.

#### GUPTA, Amita

**Constituency:** Clinician Qualifications: MD, M.H.S

**Current position:** Deputy Director; Professor of Medicine and Public Health

Institutional affiliation: Johns Hopkins University School of Medicine, USA

Amita Gupta is Faculty Chair of the Johns Hopkins India Institute, Deputy Director of the Johns Hopkins Center for Clinical Global Health Education, and Professor of Medicine (Infectious Diseases) and Public Health (International Health) at Johns Hopkins University. Dr. Gupta has 25+ years of experience in international public health, clinical research, and 18 years of working in infectious diseases in India. She serves as the US chair of the NIH-DBT funded TB research consortium RePORT, leads several clinical trials of new HIV/TB therapeutics, serves on global TB preventive trials leadership, and collaborates with more than 15 Indian institutions. She is actively engaged in the NIH funded ACTG and IMPAACT trial networks. She serves on the Johns Hopkins COVID precision medicine center of excellence analyzing data from the Hopkins health system and has cared for inpatients with COVID. She and her Indian collaborators receive grant funding from the US NIH, CDC, UNITAID, Indian government, foundations, and philanthropy. She is an author of more than 200 peer-reviewed research publications and has mentored more than 35 junior scientists in India and the US. She serves on Anthony Fauci's NIAID Advisory Council and the Indo-US Science and Technology Foundation's Governing Board.

# GURBANOVA, Elmira

Constituency: Clinician MD, PhD Qualifications:

Current position: Clinician at the University of Tartu Clinic, Tartu, Estonia.

Head of World Health Organization (WHO) Collaborative Centre (CC) on TB

control and prevention in prisons

**Institutional affiliation:** University of Tartu Clinic, Tartu, Estonia

Elmira Gurbanova has gained practical experience of TB/M/XDR-TB clinical and programmatic management in Azerbaijan. From 2011 she was a member of the clinical committee on TB and MDR-TB functioning in penitentiary system. In 2011 Dr Gurbanova joined the project implementation unit of the Global Fund TB project in Azerbaijan. During her tenure rapid tests were introduced into TB case finding and diagnostics algorithms in prisons, treatment policies for TB/MDR-TB were revised in line with WHO recommendation. Dr Gurbanova contributed to establishment of the unique WHO Collaborative Centre on TB control and prevention in prisons, with the main aim to spread an exemplary model for TB care in prisons and to generate new data for future decisions. Dr Gurbanova also has 7 years' international experience in more than 10 countries as a WHO TB consultant and as an international trainer in related fields. Dr Gurbanova holds a PhD degree in Medicine from the

University of Tartu, Estonia and she is the main/principal author of >10 publications in the field of TB/MDR-TB. Since 2018 Dr Gurbanova is practicing clinician at the University of Tartu Clinic, Estonia.

HESSELING, Anneke

Constituency: Paediatrics and clinical management of TB, end-user

Qualifications: MD, MSc, PhD

**Current position:** Professor in Paediatrics and Child Health, Director of the Desmond Tutu TB

Centre

**Institutional affiliation:** The University of Stellenbosch

Anneke Hesseling is a South African clinician scientist dedicated to research in tuberculosis and HIV in children and adolescents and other special populations, including pregnant women and young people. She is a Distinguished Professor in Paediatrics and Child Health, Department of Paediatrics and Child Health, Faculty of Medicine and Health Sciences, Stellenbosch University, where she is the Director of the Desmond Tutu TB Centre and has 20 years' experience in designing and conducting translational pediatric TB research in South Africa and in other high-burden settings and holds the first South African National Research Foundation SARChi chair in Paediatric Tuberculosis. Professor Hesseling has published more than 260 peer-reviewed papers and her Scopus H index is 50.

Professor Hesseling chairs the NIH IMPAACT TB Scientific Committee and leads or co-leads several IMPAACT protocols including IMPAACT P1108, PHOENIX (A5300/I20013), IMPAACT 2020 and IMPAACT 2024. She is the PI for the Stellenbosch DAIDS-funded Clinical Trials Unit (SUN-CTU) network renewal application and the IMPAACT CRS leader for the Desmond Tutu TB Centre (DTTC, CRS 31790). She is also the PI for the CDC-funded TB Trial Consortium (TBTC) Stellenbosch site (CDC Site 33) 10-year grant and protocol chair for TBTC Study 35 (rifapentine pharmacokinetics and safety for TB prevention in HIV-infected and uninfected children) and a core member of the WHO Stop TB Pediatric and Adolescent Core Group. She has been the PI and co-investigator on several paediatric diagnostic and biomarker studies, paediatric phase I/II trials of delamanid and bedaquiline in children and is the PI of the TB-CHAMP phase 3 TB prevention trial of MDR-TB in children, and the South African PI on the SHINE treatment shortening trial in children with drug-susceptible TB. Her group's research has a strong focus on novel strategies to prevent TB in children with and without HIV co-infection, the evaluation of novel therapeutic strategies, and a special interest in diagnostic and biomarker research in young and HIV-affected children. Her group also conducts rigorous epidemiolocal and implementation science research, socio-behavioral research coupled with strong collaboration with programmes and community stakeholders to advance the health of children affected by TB or HIV.

# LANGE, Christoph

Constituency: Clinician Qualifications: MD

Medical Director and Chief of the Medical Clinic **Current position:** 

Institutional affiliation: Research Centerl, Leibniz Lung Center, Borstel, Germany

Christoph Lange is a German pulmonologist and infectious diseases specialist. He is the Medical Director of the Research Center Borstel, Leibniz Lung Center, and Professor of Respiratory Medicine & International Health at the University of Lübeck, Germany.

He leads the clinical tuberculosis unit of the German Center for Infection Research (DZIF).

Professor Lange holds international academic affiliations with the Baylor College of Medicine in Houston, TX (USA), the University of Umeå (Sweden) and the State University for Medicine and Pharmacy in Chisinau (R. Moldova). His research interests include the epidemiology, prevention, diagnosis and treatment of tuberculosis, especially MDR-TB. Recent work focusses on the development and application of precision medicine technologies to improve the management of patients with mycobacterial diseases.

# LIENHARDT, Christian

Constituency: Researcher Qualifications: MD, MSc, PhD Current position: Research Director

Institutional affiliation: French Institute for Research on Sustainable Development (IRD), France

Christian Lienhardt, MD, MSc, PhD, is Research Director at the French Institute for Research on Sustainable Development (IRD), in Montpellier, France. He is an Infectious and Tropical Diseases specialist and Clinical Epidemiologist, graduated from the Universities of Strasbourg (France), and London (UK). He worked several years as a clinician in France and undertook medical relief and health development work with various NGOs in the Middle East and in Africa (1981-1989). He started his research work on leprosy at the London School of Hygiene and Tropical Medicine (UK) and in Bamako (Mali) (1990-1994). He then carried out clinical and epidemiological research on TB in The Gambia with the Medical Research Council (UK) and in Senegal with IRD (1994-2004). His research work included case-contact and cohort studies, multicenter randomized controlled trials, and operational research studies. He headed the Clinical Trial Division at the International Union Against Tuberculosis and Lung Diseases (The Union) in Paris from 2004 to 2008, and then joined the World Health Organisation in Geneva (Switzerland) as Senior Scientist and then Team Leader, Research for TB Elimination, at the Global TB Programme (2009-2018).

MAGSAYO-SALON Leslie Christine

Constituency: Clinician Qualifications: MD

Current position: medical specialist

Institutional affiliation: Northern Mindanao Medical Center, Philippines

Leslie Christine Magsayo-Salon is a medical specialist at the Northern Mindanao Medical Center (NMMC) and consultant for Department of Internal Medicine Residency Training Program. She is the head of the TB-DOTS/PMDT clinic as well as the Chair for the HIV/AIDS Core Team and the HIV Treatment Hub of the said hospital. She is also a faculty member at Xavier University (XU), Jose P. Rizal School of Medicine where she lectures on TB and HIV/STI. She is also the chair of the TB Medical Advisory Committee (MAC) for Region X (Northern Mindanao) and a member of the National TB MAC. Dr. Salon's experience started in 2011 as clinic physician and eventually as clinic head for XU-Community Health Care Center TB treatment facility which allowed her to work on the diagnosis, treatment, and management of Drug Resistant and Drug Susceptible Tuberculosis. In 2015, she became part of the 9-month Treatment Regimen (9MTR) Operational Research: Feasibility, Effectiveness, and Safety of the 9MTR for MDRTB in the Philippines. In 2016, she was involved in the research and assessment of Bedaquiline as a treatment for drug-resistant tuberculosis in the Philippines. Currently, she is part of the BPAL OR of the National TB program of the country.

MARKS, Guy Barrington

Constituency: Researcher Qualifications: **MBBS** 

Professor, South Western Sydney Clinical School Current position:

**Institutional affiliation**: University of New South Wales Sydney

Guy Marks is a respiratory and public health physician and epidemiologist. He is President and interim Executive Director of the International Union Against Tuberculosis and Lung Disease. In this capacity he also serves on the Board of the NCD Alliance and the STOP TB Partnership. He is a member of the steering committee of the Global Asthma Network. He has led the Centre for Air pollution, energy and health Research (CAR, an NHMRC Centre of Research Excellence) since 2012. His main research interests are in chronic respiratory disease (asthma and COPD), tuberculosis control and the adverse health effects of exposure to air pollution.

MEINTJES, Graeme

Constituency: Researcher

Qualifications: MBChB, MRCP, FCP, PhD, MPH

Professor and Deputy Head of the Department of Medicine **Current position:** 

**Institutional affiliation:** University of Cape Town

Graeme Meintjes is the Second Chair and Deputy Head of Medicine at the University of Cape Town, and also holds the DST/NRFSARChI Chair of Poverty related Diseases. He leads a research programme that focuses on the clinical conditions affecting patients with advanced HIV disease including disseminated HIV-associated tuberculosis and cryptococcal meningitis. His group also investigates drug-resistant tuberculosis and diagnostics for TB. He has been the PI or local PI of several clinical trials and conducts observational cohort studies that address questions related to disease pathogenesis. He has contributed to the development of management guidelines for HIV, TB and cryptococcal meningitis at a provincial and national level and in WHO Guideline Development Groups. He is a member of the South African National Clinical Advisory Committee for drug-resistant TB. He undertakes clinical work at Groote Schuur Hospital and Khayelitsha Hospital in Cape Town.

# MUJTABA, Asif

Constituency: Clinician

MBBS, DTCD, PhD, FCCP Qualifications:

Current position: Senior Consultant, Respiratory Medicine & Tuberculosis

**Institutional affiliation**: Asgar Ali Hospital, Dhaka, Bangladesh

Asif Mujtaba Mahmud is presently working as Senior Consultant and Head of Respiratory Medicine at the Asgar Ali Hospital, Dhaka. He retired as an Associate Professor of Respiratory Medicine after completion of 33 years of service under the Government of Bangladesh. He serves as the Secretary General of Bangladesh Lung Foundation and Joint Secretary, National Anti-TB Association of Bangladesh (NATAB). He graduated from Chittagong Medical College in 1983. He obtained Diploma in Tuberculous & Chest Diseases (DTCD) and Ph. D in Respiratory Medicine from Tohoku University, Japan. He has been involved in the formulation of various guidelines, particularly National Guidelines and Operational Manual for Programmatic Management of Drug-Resistant TB (DR-TB). Dr. Mujtaba is acknowledged as the pioneer of clinical and programmatic management of MDRTB in Bangladesh since 2000. He served as Advisor, Regional Advisory Committee on MDR-TB in WHO South- East Asia Region (r-GLC) from 2012 to 2018. He also served as the Senior Technical Advisor of the USAID funded Challenge TB project. He is advising the National TB Control Program as Member of CCM Oversight Committee and Technical Working Group. He has total 91 publications including 15 in international journals.

NASEHI, Mahshid

Constituency: Clinician Qualifications: MD, MPH, PhD

Director, National Director for TB and Leprosy control department Current position:

**Institutional affiliation**: National TB & Leprosy programme, Iran

Mahshid Nasehi is a medical doctor who has been working as National Director of TB and Leprosy Control Department in Iran since 2000 and simultaneously as an academic member and researcher in Department of Epidemiology and Biostatistics, in Iran University of Medical Sciences (since 2005). She started her work as a GP in a PHC center (Primary Health Care Center). Then, she has been working consecutively as District TB coordinator, Provincial TB coordinator, Director of Disease Control Office at Provincial level in Capital City, and finally she joined the national level in 2000 as National Director of TB and Leprosy Control Department.

# NGUYEN, Viet Nhung

Constituency: TB expert Qualifications: MD, PhD Current position: Manager

Institutional affiliation: National TB programme, Vietnam

Nguyen Viet Nhung is an expert in the field of TB and TB/HIV diagnosis and treatment with more than 25 years' experience. As the first Manager of the Vietnam National Tuberculosis (TB) Program and Director of the National Lung Hospital, he participated in the development of strategic research on TB and lung diseases. In 2009, he established the Clinical Trials Unit (CTU) in Hanoi, Vietnam for the CDCfunded TB Trials Consortium (TBTC). He completed a number of collaborative studies with universities and research centers from the United States, Australia, France, the Netherlands, South Korea, and Japan. In the last four years, he has led the site to conduct a number of studies on treatment of multidrug resistant TB (MDR-TB), Pre-XDR and XDR TB. These studies included piloting shorter regimen (9 months) for MDR, regimens including Bedaquiline for pre- XDR, XDR and severe MDR-TB, and Delamanid for XDR-TB.

# NUNN, Andrew

Constituency: Researcher, Scientists Qualifications: BSC (Maths), MSc (statistics)

Current position: Senior scientist, Professor of Epidemiology

**Institutional affiliation:** MRC Clinical Trials Unit at University College London

Andrew Nunn worked as senior statistician with Wallace Fox and Denny Mitchison as part of the team that conducted the landmark trials which led to the worldwide adoption of short course chemotherapy. Following the closure of the tuberculosis unit he joined the MRC's Uganda AIDS programme which investigated the dynamics of the HIV epidemic in a rural African setting documenting for the first time the high attributable mortality of HIV-infection in that population. On returning to the UK he became a founder member of the MRC Clinical Trials Unit with responsibility for the development of trials in neglected disease areas including musculoskeletal disease and dermatology. Subsequently he played a leading role as senior statistician in a series of trials in tuberculosis treatment including REMoxTB and RIFAQUIN. Currently he is co-chief investigator on the multi-centre STREAM phase III trial in MDR-TB, Stage 1 of which demonstrated the non-inferiority of a shorter regimen for rifampicin-resistant TB when compared to the long WHO recommended regimen. Stage 2, which is includes a fully oral regimen, is expected to report by mid-2022. He is a member of a number of scientific advisory groups for TB research including the TB Alliance.

# **SCHOEMAN Ingrid**

Constituency: **TB Survivor** Qualifications: **MSc Dietetics** 

Current position: Director of Advocacy and Strategy

Institutional affiliation: TB Proof South Africa

Ingrid Schoeman is the Director of Advocacy and Strategy at TB Proof, a Advocacy organisation based in South Africa. In 2012, she was working as a dietitian in public hospitals where she developed extensively drug-resistant (XDR) tuberculosis. The TB treatment resulted in liver failure and she fell into a coma. She was in ICU for over a month and hospitalised for 75 days. This experience changed her life and today she is a passionate about advocating for person-centered high quality TB care for all, free from stigma and discrimination. She completed her MSc Dietetics on "Knowledge, attitudes and experiences of dieticians in relation to tuberculosis at the workplace". She serves as a board member for the International Union Against Tuberculosis and Lung Disease and is a national TB Ambassador in South Africa.

# TAHSEEN, Sabira

Constituency: TB laboratory expert Qualifications: Clinical pathologist **Current position:** Technical advisor

**Institutional affiliation:** National TB Reference Laboratory, Pakistan

Sabira Tahseen is a TB laboratory expert, a medical graduate with specialization in clinical pathology. She started her professional carrier in 1989 as clinical pathologist in large tertiary care chest hospital specialized in Tuberculosis care. After serving for ten years in this hospital, she joined National TB control Program, Pakistan in 2003 and is currently serving as Technical advisor for the National TB reference laboratory. Her key contribution includes technical guidance for scale up of QA diagnostic services in the country, establishment of National TB reference laboratory, successful implementation of National TB disease and drug resistance surveys and capacity building for TB culture and DST services in the public sector. As advisor (NTP) and head of NTRL, she provides guidance in policy making, planning for roll out of new diagnostics, programmatic management of drug resistant TB and surveillance of drug resistance. She has served as a core group member of Global laboratory initiative (GLI) and regional Green Light Committee (rGLC) for Eastern Mediterranean region, and currently serving as member of WHO Advisory group on Tuberculosis Diagnostics and Laboratory Strengthening. She has also contributed in the various guidelines and handbooks development convened by WHO, participated in international TB reviews/monitoring missions and collaborative research projects.

TUN, Ye

Constituency: Clinician

Qualifications: M.B.B.S, PhD, Dip.Med.ed

Professor/Head of department of respiratory medicine **Current position:** 

Institutional affiliation: Yangon Specialty Hospital, Myanmar

Ye Tun, graduated from Institute of Medicine Yangon for MBBS in 1987 and received Master degree for Internal Medicine in 1994 and PhD degree (Internal Medicine specialized on Respiratory Medicine) from School of Medicine, Tohoku University, Japan in 2001. He a Consultant Chest Physician caring the patients with various respiratory diseases including respiratory infections and Tuberculosis. Ye Tun, participated in a pilot phase of programmatic management on MDR-TB which had been started at two major cities: Yangon and Mandalay in 2009.

He is a Chairperson of National Expert Committee for drug resistant TB, Myanmar since 2017 as well as a member of international societies (American Thoracic Society, European Respiratory Society, and Asia Pacific Society of Respirology) for respiratory medicine. Currently, he is acting as a president of Tuberculosis Society of Myanmar Medical Association.

VAMBE, Debrah

**Constituency:** Clinician

Qualifications: M.B.B.S, MPH (health systems and policy)

**Current position:** Technical advisor for PMDT

Institutional affiliation: National TB Programme, Eswatini

Debrah Vambe has 15 years of professional experience, a holder of Bachelor of Medicine and surgery degrees, MPHIL in HIV/AIDS management, MPH (health systems and policy) from University of Zimbabwe, Stellenbosch, and Witwatersrand respectively. Currently working as a National Programmatic Management of Drug Resistance TB(PMDT) Technical advisor in Eswatini. Her area of focus is strategic planning, health care provider capacity building, implementation of new medicines

and shorter regimens, monitoring and evaluation of the diagnostics and treatment cascades, operational research, innovations, advocacy, and resource mobilization towards improved treatment outcomes. She has participated in different research studies including drug resistance survey, TB and lung cancer prevalence survey, shorter MDR-TB regimen, DR-TB preventative therapy and community MDR-TB. She has shared country 's experience through national and international conferences as well as publications. She is a recognised WHO consultant who has provided technical assistance to other countries such as Malawi, Uganda, South Sudan, Tanzania, Kenya to implement new drugs, shorter regimen, aDSM, developing mortality audit tools, transition plans, develop guidelines, recording and reporting tools to adopt WHO key changes. She was a member of the WHO guideline review team for the 2020 WHO DR-TB guidelines. Debrah has also flexibly integrated COVID 19 into her portfolio and coordinates Eswatini case management pillar.

### VASILYEVA, Irina

**Constituency:** Clinician Qualifications: MD, Professor Current position: Chief TB Expert

**Institutional affiliation:** Ministry of Health, Russian Federation

Irina Vasilyeva is a professor of medicine and currently the Chief TB Expert of the Ministry of Health of the Russian Federation. She is the President of the Russian Society of Phthisiologists/Association of Phthisiologists and Director of National Medical Research Center of Phthisiopulmonology and Infectious Diseases of the Ministry of Health of the Russian Federation. Dr Vasilyeva was a member of WHO Strategic and Technical Advisory Group (STAG) from 2014 till 2016. At present time she is a member of the Technical Advisory Group on Tuberculosis (TAG-TB) for the WHO European Region. She has worked in different capacities in TB control since 1990. Dr. Vasilyeva's research expertise includes various aspects of M/XDR-TB treatment, comorbidity (TB/HIV, TB, and diabetes mellitus), development of TB chemotherapy regimens based on molecular genetic methods for DST, and the development of measures for the prevention of tuberculosis in patients with HIV and diabetes.

As a Chief TB Expert, Dr. Vasiyleva contributes significantly to solving issues with TB care management in the Russian Federation. Under her leadership, the following documents have been developed: a strategy for the development of TB care in the Russian Federation, a national plan for the prevention of M/XDR-TB and TB/HIV spread, modern approaches to drug supply and TB treatment management, and an update of legal TB documents. She has been instrumental in guiding efforts to introduce modern medical and organizational technologies to TB practice.

# VERNON, Andrew

**Constituency:** Researcher Qualifications: MD, MHS

**Current position:** Chief, Clinical Research Branch

Institutional affiliation: Division of TB Elimination, National Center for HIV, Viral Hepatitis, STD and

TB Prevention, Centers for Disease Control & Prevention (CDC), USA

Andrew Vernon's expertise lies in clinical research in tuberculosis. Throughout his career he has sought to advance the relationship of clinical and translational research to public health practice in the domain of infectious diseases. Dr Vernon began work in TB as trial coordinator for USPHS Study 22, testing a once-weekly rifapentine-based continuation regimen in drug-sensitive tuberculosis. From 1995-2002 he served as project officer, and from 2004-2021 as Chief in the Clinical Research Branch, Division of TB Elimination, at CDC. The branch guided, supported and participated in the activities of CDC's TB Trials Consortium (TBTC), which arose from the USPHS Study 22 effort. TBTC is a multinational collaboration among local TB control programs, academic investigators, and CDC scientists, whose mission is to conduct programmatically relevant research in tuberculosis. The group has conducted a dozen major studies, and multiple PK and other sub-studies, enrolling over 18,000 persons worldwide. TBTC has collaborated with other major trials groups, including ACTG, IMPAACT, and the British Medical Research Council. TBTC's most recent major trial (S31/A5349), performed in collaboration with NIH's AIDS Clinical Trials Group, demonstrated the non-inferiority of a 4-month regimen for drugsensitive TB. Dr Vernon currently works on CDC's COVID-19 Response.

# WINARNI, Paran

**Constituency:** TB survivor

Qualifications: Faculty of law, social & political sciences

Current position: member of CSTF and TB CAB

Institutional affiliation: Civil Society Task Force (CSTF), The Global Tuberculosis Community

Advisory Board (TB CAB).

Paran Sarimita Winarni experienced Tuberculosis twice. In 2008, she was diagnosed with drugsensitive TB merely based on chest x-ray result from a doctor in a private health center. She had 2 years of treatment until the doctor said she was cured. Four years after that, in 2012, Paran had the same symptoms and the doctor gave the same medicine but doubled the doses. She did not get better at all and Paran sought help at a public primary health center and referred to Persahabatan Hospital where she had her first test with GeneXpert. It was then Paran was diagnosed with multi-drug resistant TB. On 28 August 2012, she began her MDR-TB treatment at Persahabatan hospital. Every day Paran took fifteen pills and injections to fight the disease. Some of the side effects that she experienced were vomiting, feeling nausea for hours, insomnia, little appetite to eat and repeatedly want to end her life.

However, with the support from her family and best friends, Paran finished her treatment on 25 April 2014. Since 2014 and until now, Paran is active in MDR-TB patient organization named PETA (Pejuang Tangguh) TB RO Jakarta. Their organization work in five districts of DKI Jakarta province. PETA's activities are mainly in the treatment phase of TB care. Paran works as the Peer Educator in this organization that empowers ex-TB patients to become treatment supporters for those who are still on treatment. These treatment supporters educate and motivate MDR-TB patients in DKI Jakarta to continue their treatment since baseline until the end of their care. PETA members regularly do visits to hospital, public primary health centers and homes of patients. At the global level, currently, Paran is also a member of GCTA (Global Coalition of TB Activist), Vice chair of South East Asia rGLC (Regional Green Light Committee), and initiate Youth Movement Against TB Indonesia (IMUT). Recently she also joined with another global platform such as Civil Society Task Force (CSTF) WHO and The Global Tuberculosis Community Advisory Board (TB CAB).

# ZHAO, Yan-Lin

Constituency: TB expert Qualifications: MD, PhD

**Current position:** Director, National Tuberculosis Control and Prevention Center,

Director, National Tuberculosis Reference Laboratory

Institutional affiliation: Chinese Center for Disease Control and Prevention P.R China

Zhao Yan-Lin (M.D and Ph.D) is a full professor of Chinese Centers for Disease Control and Prevention P. R. China. He is the director of National Tuberculosis Control and Prevention Center, Chinese Center for Disease Control and Prevention, and the director of National Tuberculosis Reference Laboratory of China CDC. He is a board member of National Infectious Disease Control and Prevention expert panel of P. R. China, Board Member of State health standard committee of P. R. China. He is appointed as visiting professor at medical health school of Harvard medical university. He is the Chairperson of research branch of the Chinese Anti-TB Association from 2009 to now, and the head of TB research branch of Chinese Medical Association since 2010.

Dr. 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 and new diagnostics. He has published more than one hundred publications in international journals, such as NEJM, LANCET and so on.