



ERS | *monograph*

Tuberculosis

Edited by
Giovanni Battista Migliori,
Graham Bothamley,
Raquel Duarte and
Adrian Rendon

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Editor in Chief
Robert Bals

This book is one in a series of *ERS Monographs*. Each individual issue provides a comprehensive overview of one specific clinical area of respiratory health, communicating information about the most advanced techniques and systems required for its investigation. It provides factual and useful scientific detail, drawing on specific case studies and looking into the diagnosis and management of individual patients. Previously published titles in this series are listed at the back of this *Monograph*.

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Contents

Tuberculosis	Number 82 December 2018
Preface	ix
Guest Editors	x
Introduction	xiv
List of abbreviations	xviii
1. The patients' perspective <i>Gabi Spita, Helen Clegg, Marius Dumitru, Paul Sommerfeld, Courtney Coleman and Pippa Powell</i>	1
2. History of tuberculosis <i>Robert Loddenkemper, John F. Murray, Christoph Gradmann, Philip C. Hopewell and Midori Kato-Maeda</i>	8
3. Epidemiology and socioeconomic determinants <i>Raquel Duarte, João V. Santos, André Santos Silva and Giovanni Sotgiu</i>	28
4. Evolution of the strategies for control and elimination <i>Mario C. Raviglione</i>	36
5. Aetiopathogenesis, immunology and microbiology <i>Palmira Barreira-Silva, Egidio Torrado, Hanna Nebenzahl-Guimaraes, Gunilla Kallenius and Margarida Correia-Neves</i>	62
6. Clinical diagnosis <i>Jean-Pierre Zellweger, Pedro Sousa and Jan Heyckendorf</i>	83
7. Laboratory diagnosis <i>Elisa Tagliani, Vlad Nikolayevskyy, Enrico Tortoli and Daniela Maria Cirillo</i>	99
8. Imaging for diagnosis and management <i>Dumitru Chesov and Victor Botnaru</i>	116
9. Bronchoscopy and other invasive procedures for diagnosis <i>Angshu Bhowmik and Felix J.F. Herth</i>	137
10. Treatment of drug-susceptible and drug-resistant tuberculosis <i>José A. Caminero, Anna Scardigli, Tjip van der Werf and Marina Tadolini</i>	152

11. New and repurposed drugs	179
<i>Maria Krutikov, Judith Bruchfeld, Giovanni Battista Migliori, Sergey Borisov and Simon Tiberi</i>	
12. Adverse anti-tuberculosis drug events and their management	205
<i>José A. Caminero, Paula Lasserra, Alberto Piubello and Rupak Singla</i>	
13. Surgery as a treatment	228
<i>Anne Olland, Pierre-Emmanuel Falcoz, Sophie Guinard, Joseph Seitlinger and Gilbert Massard</i>	
14. Challenges in childhood tuberculosis	234
<i>H. Simon Schaaf, Ben J. Marais, Isabel Carvalho and James A. Seddon</i>	
15. Pregnancy and the elderly	263
<i>Alice Repossi and Graham Bothamley</i>	
16. Comorbidities	276
<i>Cecile Magis-Escurra, Anna Cristina C. Carvalho, Afrânio L. Kritski and Enrico Girardi</i>	
17. Access and adherence to prevention and care for hard-to-reach groups	291
<i>Kerri Viney, Tom Wingfield, Liga Kuksa and Knut Lönnroth</i>	
18. Monitoring during and after treatment	308
<i>Jan-Willem C. Alffenaar, Onno W. Akkerman and Graham Bothamley</i>	
19. Sequelae assessment and rehabilitation	326
<i>Marcela Muñoz-Torrico, Silvia Cid-Juárez, Susana Galicia-Amor, Thierry Troosters and Antonio Spanevello</i>	
20. Towards a new vaccine	343
<i>Morten Ruhwald, Peter L. Andersen and Lewis Schragar</i>	
21. Transmission control: a refocused approach	364
<i>Edward Nardell and Grigory Volchenkov</i>	
22. Diagnosis and treatment of latent tuberculosis infection	381
<i>Adrian Rendon, Delia Goletti and Alberto Matteelli</i>	
23. Nontuberculous mycobacteria	399
<i>Sanne Zweijpfenning, Wouter Hoefsloot and Jakko van Ingen</i>	
24. What next? Basic research, new treatments and a patient-centred approach	414
<i>Graham Bothamley</i>	
25. Opportunities for training and learning	430
<i>Caterina Casalini, Alberto Matteelli, Albert Komba, Lia D'Ambrosio and Jan van den Hombergh</i>	
Clinical cases	446
<i>Simon Tiberi, Marie Christine Payen, Katerina Manika, Inês Ladeira, Marta Gonzalez Sanz and Marcela Muñoz-Torrico</i>	



Preface

Robert Bals

While most European chest physicians have little contact with TB patients, the disease is still of outstanding importance in our field, for a number of reasons.

- 1) TB was a major killer in Europe for hundreds of years, and phthisiology has helped develop many aspects of pulmonology.
- 2) TB is still a major cause of mortality and morbidity, and its prevalence in developing countries highlights the political dimensions of the disease.
- 3) TB is present in Europe and the clinical context of its presentation has changed in recent decades. Patients from a migratory background, those who are immunosuppressed and those with chronic lung diseases are now within the focus of care.
- 4) Diagnosis and treatment of TB is still a complicated issue. TB can mimic most other lung diseases and treatment has become a challenge in the age of multidrug resistancy.



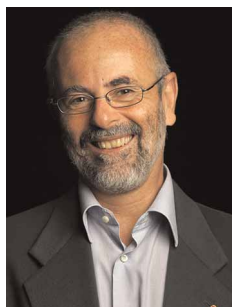
With these issues in mind, the United Nations General Assembly initiated concerted action and developed new guidelines. This *ERS Monograph* considers such guidelines, and provides a comprehensive and detailed overview of all aspects of TB. As such, it represents a unique source of information. The book covers the field's historical development, epidemiology, basic science and the clinical approach to the TB patient. It also includes chapters on drug therapy and special patient populations, as well as comorbidities.

The broad ranging and comprehensive topics covered in this book were selected by Guest Editors Giovanni Battista Migliori, Graham Bothamley, Raquel Duarte and Adrian Rendon. They worked to bring together expert authors in the field and in doing so, have successfully integrated different views on various aspects of TB. They have produced a *Monograph* that will not only be useful in the clinical practice of a broad range of respiratory physicians, but will be a trusted resource for many years to come.



Guest Editors

Giovanni Battista Migliori



Giovanni Battista Migliori is a specialist in respiratory medicine and medical statistics, and an auditor of quality systems. He has over 20 years of experience in design, implementation, and monitoring and evaluation of TB and TB/HIV control programmes globally.

Giovanni Battista Migliori is Head of Clinical Epidemiology of the Respiratory Diseases Service and Director of the WHO Collaborating Centre for TB and Lung Diseases at Maugeri Care and Research Institute (Tradate, Italy).

Giovanni Battista Migliori is active in TB control, training and research activities at a global level. In 2012, he was elected a Fellow of the Royal College of Physicians, (London, UK) (honorary nomination, by-law 39b); and in 2014, he was elected Foundation Fellow of the European Respiratory Society (ERS).

Giovanni Battista Migliori has published more than 400 peer-reviewed papers on COPD, asthma, pulmonary rehabilitation and TB (h-index: 59). He was: one of the authors of the first ERS TB guidelines in 1999; an author/coordinator of several guidelines supporting ECDC/WHO development of a European Union TB control policy; an author on all of the guidelines belonging to the Wolfheze series (the European WHO/International Union Against Tuberculosis and Lung Disease (IUATLD)/ECDC Consensus); a coordinator of the European Standards for Tuberculosis Care (ESTC); a promoter of the newly created Kosovo national TB Programme, in collaboration with the United States Agency for International Development (USAID), and of the implementation of TB control in countries experiencing war or mass migration; a coordinator of DST external quality assessment studies and drug-resistance surveys in several countries (Italy, Mozambique, Burkina, Kosovo, Russia and the Ukraine); a pioneer of the TB under-reporting evaluation with a series of important studies in different journals, which have been used by WHO to implement better surveillance

guidance; a promoter of treatment-outcome evaluation as a surveillance and research tool; and an author on the 2013 WHO educational package supporting countries to develop national strategic plans and to apply to the Global Fund for funding. He demonstrated with experimental data the adequacy of the XDR-TB definition, the impossibility of using the TDR definition and the need to stratify outcomes beyond XDR-TB. He coordinated the USAID-funded project, which developed a tool that supported countries in the identification of gaps and in the proposal of solutions to prevent and manage MDR- and XDR-TB. This has become the standard tool used by the WHO Green Light Committee. He is the coordinator of the European TB Elimination movement, which involves the conceptualisation of TB elimination, the development of the first framework, creation of a feasibility white paper within the ERS Forum initiative, a European survey on preparedness and finalisation of the WHO framework resulting from the ERS/WHO event in Rome, Italy (2014).

Giovanni Battista Migliori has created and directed over 100 WHO training courses for consultants/managers of: TB and TB/HIV, the public-private mix, the laboratory, infection control and the Global Fund to Fight AIDS.

He is currently an Associate Editor of the *European Respiratory Journal* and the *International Journal of Tuberculosis and Lung Disease*. He was previously Secretary General of ERS.

Graham Bothamley

Graham Bothamley has been a respiratory physician for 35 years and has looked after >4000 patients with TB. He gained a PhD with the Medical Research Council (MRC) and Royal Postgraduate Medical School, Hammersmith Hospital (London, UK) in TB monoclonal antibodies, diagnostics and pathogenesis. He is currently a member of the TB Centre and Immunology and Infections Department at the London School of Hygiene and Tropical Medicine (London, UK) and at the Blizard Institute (Queen Mary University of London, London, UK).



Graham Bothamley leads the British Thoracic Society (BTS) TB advisory group, is Head of the Respiratory Infections Assembly at the European Respiratory Society and is on the steering committee of TBnet as Past Chair.

Raquel Duarte

Raquel Duarte is a Portuguese pulmonologist, with a Masters in Public Health and Health Economics and a PhD in Public



Health. She is the Coordinator of the National Reference Centre for MDR-TB, the Director of the National Programme for TB, and Associate Professor at the Medical School and at the Institute of Public Health of Porto University (Porto, Portugal).

In terms of international appointments, Raquel Duarte is Vice-President of the Europe Region Officers of the International Union Against Tuberculosis and Lung Disease, and Chair of the European Respiratory Society's Tuberculosis Group.

Raquel Duarte combines interests in public health with clinical, academic and research activities. Her main fields of interest are TB in vulnerable populations, the effects of social and economic determinants on TB incidence, LTBI, MDR-TB and XDR-TB, and NTM.

Adrian Rendon



Adrian Rendon is a specialist in internal medicine and pulmonary and critical care medicine. He is Professor of Medicine at the School of Medicine and the University Hospital of Monterrey of the Universidad Autonoma de Nuevo Leon (Mexico), where he has run a busy TB clinic since 1994.

Adrian Rendon was trained in both Mexico and the USA. He graduated with honours as the first of his class, and later became Chief Resident of Internal Medicine and Chief Fellow of Pulmonary Medicine at the University Hospital of Monterrey.

For the last 15 years, Adrian Rendon has lead a TB Research, Prevention and Care Center in Monterrey (Mexico) that has become a referral centre for the Nuevo Leon State TB Program. The centre was something of a pioneer in Mexico and Latin America, as it was the first to routinely perform DST in all new TB cases, and has been doing so since 1994. In 2013, the Nuevo Leon State Public Health Society officially recognised his work in TB.

Adrian Rendon is the leading clinician involved in the local TB consilium and a consultant for the Mexican TB Consilium. He also is a founding member of the international European Respiratory Society (ERS)/WHO Tuberculosis Consilium.

Adrian Rendon's research focuses on several fields: basic, clinical and epidemiological TB topics, COPD, asthma, coccidioidomycosis and pneumonia, among others. He has published more than 50 peer-reviewed papers (h-index: 15), has participated in several COPD and TB guidelines and has collaborated with several international journals as a

reviewer. He has also written several TB chapters in pulmonary medicine books.

Adrian Rendon is considered an opinion leader not only in Mexico but also in Latin America and has developed several collaborative projects with researchers and institutions in the USA and Europe. He is currently the Director of the TB Department of the Latin American Association of Thorax (ALAT) and the incoming President of the Mexican Society of Pulmonary Medicine and Thoracic Surgery (SMNYCT).



Introduction

Giovanni Battista Migliori¹, Graham Bothamley^{2,3,4}, Raquel Duarte^{5,6,7}
and Adrian Rendon⁸

 @ERSpublications

Physicians feel TB is either very easy to treat with standard regimens or is too complex. This book provides trainees with basic TB management knowledge; offers insight into addressing complexities in individual patients; is a useful resource for experts. <http://ow.ly/zroQ30mipoT>

On 26 September 2018, the United National General Assembly agreed to take concerted action on TB. With over 10 million new TB cases (90% in adults and 9% in HIV co-infected individuals) and 1.6 million deaths (300 000 in HIV coinfecting persons) in 2017, TB is a global health priority [1]. Of particular concern for both clinicians and national TB programmes is MDR-TB: in 2017, WHO were notified of 558 000 new rifampicin-resistant cases and 460 000 confirmed MDR-TB cases [1]. Heads of state and government agreed to mobilise US\$13 billion a year by 2022 in order to ensure that TB care is received by 40 million people and preventive treatment is given to 30 million people [2].

Although the “white plague” has historically been studied in an extensive manner (it was “the” respiratory disease in the pre-antibiotic era), there is still much to learn about its prevention, diagnosis and treatment. TB is therefore a hot topic in respiratory medicine, attracting an increasing amount of interest from clinicians, scientists, public health officers and the pharmaceutical industry, given that new drugs are finally available after more than 40 years of neglect. The High-Level Meeting on the Fight to End Tuberculosis also agreed to fund a US\$2-billion research agenda [2].

With this *Monograph*, our aim is to provide an accessible resource that will help the young physician in training to recognise and treat TB in all its manifestations, as well as address a need for help with other mycobacterial diseases which might become apparent during the diagnostic process. Primarily providing clinical support, this book will also act as a reference resource for difficult TB. It will introduce topics of interest and scientific advances in TB that can be investigated by the interested reader at their leisure. Many of the chapters also indicate where TB management is going.

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This *Monograph* will discuss the main issues related to TB, with an innovative approach, beginning with a patient's perspective [3]. The role of patients is very important, given the burden of the disease on healthcare systems globally.

A chapter on the history of TB discusses recent advances in human and TB genetics and presents historical vignettes that are relevant to the current introduction of new treatments [4]. Social determinants are included in the chapter on epidemiology, so that the measures to control and eventually eliminate TB are more holistic [5]. Molecular biology has made significant advances since the last *ERS Monograph* on TB was published in 2012 [6], and clinically relevant material has been included in a number of chapters [4, 7–12]. The diagnostic aspects (clinical diagnosis, laboratory diagnosis, imaging, bronchoscopy and other invasive procedures) are reiterated and updated so that they are accessible to the physician in training [5, 9, 13, 14]. The treatment of drug-susceptible and drug-resistant cases, new and repurposed drugs, adverse events and the role of surgery are discussed, together with broad principles, so that physicians can apply these to the likely rapid changes in this area [15–18]. Specific patient groups (children, pregnant women and the elderly) are addressed [19]. Comorbidities have become an increasing problem in the management of TB, and diabetes, chronic renal impairment, liver disease and transplantation are addressed, in addition to coinfection with HIV [20]. The modern TB physician has to work with a team to manage homelessness, alcohol and opiate addictions, poverty and malnutrition and the disruptions caused by migration and fleeing war zones and persecutions [21].

A later chapter includes both treatment and therapeutic drug monitoring, noting that the latter will become increasingly important in personalised treatments regimens [22]. Rehabilitation after TB has become an important topic and receives its own chapter [23]. NTM have been included, as they are frequently diagnosed when TB is considered their increasing importance may merit an entire *Monograph* in the not-too-distant future [24]! Preventive issues have come to the fore, especially with the End TB Strategy and there are chapters on vaccines [10], infection control [25] and latent TB infection management [11]. Looking to the future, there is a chapter on research priorities [12], and one addressing the needs of the physician training [26].

Lastly, to emphasise the realities of managing TB, there are some clinical cases drawn from the experience of early career members with expertise in managing MDR-TB [27].

The developments and challenges over the last 6 years, since the publication of the first TB *Monograph* [6], have exceeded our expectations. We expect the recent pledges of world leaders to defeat TB will be met by a mixture of attention to patients' needs and scientific advances, in addition to those we have outlined in this *Monograph*. We hope the *Monograph* will encourage TB physicians and basic scientists to see the gaps and fill these with their own excellent research for the next TB *Monograph*.

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Disclosures: None declared.

List of abbreviations

ART	antiretroviral therapy
BCG	bacille Calmette–Guérin
CDC	Centers for Disease Control and Prevention
COPD	chronic obstructive pulmonary disease
DILI	drug-induced liver injury
DM	diabetes mellitus
DOTS	directly observed therapy, short course
DR-TB	drug-resistant tuberculosis
DST	drug-susceptibility testing
EPTB	extrapulmonary tuberculosis
ETT	extrathoracic tuberculosis
IFN	interferon
IGRA	interferon- γ release assay
IUATLD	International Union Against Tuberculosis and Lung Disease
LFT	liver function tests
LTBI	latent tuberculosis infection
MDR-TB	multidrug-resistant tuberculosis
MIC	minimum inhibitory concentration
MTBC	<i>Mycobacterium tuberculosis</i> complex
NGO	nongovernmental organisation
NTM	nontuberculous mycobacteria
PAS	para-aminosalicylic acid
PTB	pulmonary tuberculosis
RCT	randomised controlled clinical trial
RR-TB	rifampicin-resistant tuberculosis
SDGs	sustainable development goals
SLIDs	second-line injectable drugs
TB	tuberculosis
TDM	therapeutic drug monitoring
TST	tuberculin skin test
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis