

European Tuberculosis Research Initiative

The fifth meeting of the core group
11 March 2020, Copenhagen, Denmark

Abstract

The European Tuberculosis Research Initiative (ERI-TB) was launched by the WHO Regional Office for Europe in 2016 to advance tuberculosis (TB) research in the WHO European Region. It was intended as a platform to build the capacity Member States of the WHO European Region to implement operational research, which is considered an important source for evidence-informed TB programme management and relevant policy decision-making. ERI-TB's activities are prioritized and overseen by its core group, while the ERI-TB Secretariat (located at the Regional Office) is responsible for their primary implementation. During its first three years, ERI-TB made good progress in setting Regional TB research priorities and building Member States' capacity to implement operational research. In November–December 2019 the ERI-TB Secretariat organized the selection of 15 new core group members to succeed the outgoing members, whose mandate had come to an end. This report summarizes the discussions and actions from the fifth meeting of the ERI-TB core group, held on 11 March 2020, including the introduction of new ERI-TB core group members, the presentation ERI-TB's achievements during 2016–2019, and discussions on the revision of ERI-TB's terms of reference and the prioritization of ERI-TB activities for 2020–2022.

Keywords

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Acknowledgements

This meeting report was prepared by Mr Oleksandr Korotych and Dr Andrei Dadu of the WHO Regional Office for Europe. We are grateful to ERI-TB core group members (new and outgoing) and the ERI-TB Secretariat (Dr Andrei Dadu, Dr Masoud Dara, Mr Oleksandr Korotych, Dr Giorgi Kuchukhidze and Dr Askar Yedilbayev) for their input to the report.

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Abbreviations

DR-TB	drug-resistant tuberculosis
ERA-TB	European Tuberculosis Research Agenda (of the European Tuberculosis Research Initiative)
ERI-TB	European Tuberculosis Research Initiative
MDR-TB	multidrug-resistant tuberculosis
NTP	national tuberculosis programme
OR	operational research
SORT-TB	Structured Operational Research Training (of the European Tuberculosis Research Initiative)
TB	tuberculosis

Background

The WHO European Region incorporates 53 Member States and with a reported incidence of tuberculosis (TB) that ranges from near eradication to rates exceeding 100 per 100 000 population. The Region includes 18 high-priority countries to end TB, nine of which are included in the global list of countries with the highest burden of multidrug-resistant TB (MDR-TB) (1).

The target of Strategic Development Goal 3 for TB is to end the epidemic by 2030 (2), and the Sixty-seventh World Health Assembly adopted the End TB Strategy, with its high-reaching targets of ending the TB epidemic by (i) eliminating catastrophic expenses for TB patients and achieving (ii) a 90% reduction in TB deaths and (iii) an 80% reduction in TB incidence by 2030 compared with 2015 (3). The third pillar of the End TB Strategy – research and innovation – pursues operational research (OR) for the design, implementation and scaling up of innovations and calls for an urgent boost in research investments so that new tools can be rapidly developed and made available and widely accessible in the next decade.

Acting in accordance with the Roadmap to implement the Tuberculosis Action Plan for the WHO European Region 2016–2020: towards ending tuberculosis and multidrug-resistant tuberculosis (4), which was developed to operationalize the global End TB Strategy across the Region, the WHO Regional Office for Europe launched the European Tuberculosis Research Initiative (ERI-TB) in 2017 to support the scaling up of TB research in the Region (4,5). The primary aims of ERI-TB are to (i) define priority research areas and research questions for countries in the Region, (ii) catalyse capacity-building at country level, and (iii) facilitate and promote collaboration between research institutions and relevant stakeholders (6,7).

ERI-TB's activities are prioritized and overseen by its core group, while the ERI-TB Secretariat located within Regional Office is responsible their primary implementation. During its first three years, ERI-TB made a lot of progress in setting Regional TB research priorities and building Member States' capacity to implement OR. In November–December 2019 the ERI-TB Secretariat organized the selection of 15 new core group members to succeed the outgoing members, whose mandate had come to an end. On 11 March 2020 the fifth ERI-TB meeting took place, covering the introduction of new ERI-TB core group members, the presentation of ERI-TB's achievements during 2016–2019, and discussions on the revision of ERI-TB's terms of reference and the prioritization of ERI-TB activities for 2020–2022.

Objectives and participants

The meeting objectives were as follows:

- introduction of new core group members
- election the core group chair
- review of recently accomplished and ongoing activities of the ERI-TB
- revision of the ERI-TB terms of reference
- discussion the next steps and plans.

The list of participants is shown in Annex 1. Three members of the core group (Sevim Ahmedov, Raquel Bessa de Melo and Alberto Matteelli) could not join the meeting due to prior commitments.

Welcome and introduction

Dr Masoud Dara, representing the ERI-TB Secretariat and acting on behalf of Dr Sevim Ahmedov, opened the meeting with a brief overview of ERI-TB. Since its launch in 2016, ERI-TB has made a lot of progress, specifically in setting regional research priorities and strengthening Member States' capacity to implement OR. Dr Dara thanked all participants who managed to join the tele-meeting during this difficult period of battling COVID-19. He also praised all of those boosting response to the virus.

Dr Dara announced that the key objectives of the meeting were to present new core group members and elect the chair and vice-chair of the ERI-TB core group. The chair, vice-chair and all members of the core group guide the WHO European Region in conducting good-quality research, introducing innovations and using data for evidence-informed policy-making in the fight against TB over the next three years.

All participants then introduced themselves and the meeting was carried out in accordance with the agenda.

Election of the core group chair

Dr Masoud Dara invited everyone to nominate candidates for the positions of the core group chair and vice-chair.

Dr Giovanni Battista Migliori indicated that he is disposed to serve and, if asked, was ready to chair the core group. Dr Migliori said that he views the wider ERI-TB network as a platform to support and involve more individuals and institutions in conducting high-quality research. He stressed that he considers the publication of research findings a key aspect of research capacity-building and he would like to devote his attention to this topic.

Dr Irina Vasilyeva, representing members of the outgoing ERI-TB core group, suggested that Dr Anastasia Samoilova should be nominated as chair. Since 2016 Dr Samoilova has been responsible for research at the Federal State Budgetary Institution "National Medical Research Center of Phthisiopulmonology and Infectious Diseases" under the Ministry of Health of the Russian Federation. With more than 100 published manuscripts and 10 patent-protected innovations, her research covers crucial areas of TB prevention and care such as treatment for MDR-TB and extensively drug-resistant TB, research into new treatment regimens, and drug-resistance mechanisms.

Dr Gunilla Källenius nominated Dr Daniela Cirillo, who has broad experience in health services research, for the position of the core group chair. However, Dr Cirillo withdrew her nomination and instead seconded the nomination of Dr Migliori. Dr Dominik Zenner and Dr Simon Tiberi also seconded Dr Migliori.

Since not every core group member was present at the meeting, Dr Dara proposed extending the nomination window for two days and then carrying out the elections via an online voting tool. The core group agreed to leave the nomination window open until Friday, 13 March 2020).

Recent accomplishments and ongoing activities

Dr Andrei Dadu then summarized ERI-TB's achievements during 2016–2019 and outlined its ongoing projects. The ERI-TB network was established in 2016 and the first meeting of the previous core group took place in November 2016. At that meeting, an initial set of research questions was drafted that aimed to fill the knowledge gaps in the area of TB prevention and care in the WHO European Region. Consultations using Delphi methodology, consultations with Member States were held in 2017 to prioritize research questions for the whole Region. The study report, now known as the European TB Research Agenda (ERA-TB), became available as a publication in the third quarter of 2019. The three pillars of ERA-TB are epidemiological research, basic research and OR. Since OR includes most of the high-priority research questions, ERI-TB has offered capacity-building initiatives to boost the implementation of OR.

In 2018 the ERI-TB's Structured Operational Research Training (SORT-TB) was introduced to serve as a platform to build the capacity of national TB programme (NTP) employees to implement OR at country level. In the first SORT-TB cohort, 12 young researchers from six eastern European countries (Armenia, Azerbaijan, Belarus, Georgia, Republic of Moldova and Ukraine) were taught to conduct, analyse and publish research. As the result, 12 manuscripts were published in the peer-reviewed journal. Public Health Panorama. The second cohort in 2019 had wider geographical coverage: researchers from Armenia, Belarus, Georgia and the Republic of Moldova were joined by participants from Lithuania, Romania and the Russian Federation. The ERI-TB Secretariat is currently preparing the third workshop on data analysis and manuscripts from the second cohort, which has been postponed from April 2020 to June–July 2020 due to the COVID-19 outbreak.

In 2019 another ERI-TB subgroup was established to help countries share their experiences in tackling drug-resistant TB (DR-TB) through research and to prioritize research questions for DR-TB. Four country-led webinars for experience exchange have been held so far and list of priority questions for DR-TB research has been published.

The ERI-TB network currently consist of over 200 members, as well as the ERI-TB Secretariat at the WHO Regional Office for Europe and the core group. At the moment, ERI-TB is running three SORT-TB courses: the second regional cohort and first country cohorts in Ukraine and Uzbekistan (the former is targeting vulnerable populations and civil society).

In 2019 an additional important workstream was introduced: intercountry OR on all-oral modified shorter treatment regimens for rifampicin-resistant TB and MDR-TB. Within this workstream, the Regional Office established a task force and prepared an OR package that includes a generic protocol, forms, a data collection instrument and patient educational materials. In December 2019 in Kyiv, Ukraine, all of these materials were presented to representatives from 11 eastern European and central Asian countries and task force members

were sent to the countries to help adapt the regional OR package to country-specific conditions. The objectives of this initiative are to facilitate the introduction of all-oral modified shorter treatment regimens for MDR-TB under OR; foster good clinical care for MDR-TB through OR; build and strengthen research capacity in countries; and contribute to global knowledge for the generation of new policy guidance for DR-TB. Country missions are currently being undertaken by task force members. Patient enrolment is planned to start in July 2020 after the necessary ethics approval is received. Once the research results are available, they will be presented for consideration to the WHO Treatment Guidelines Development Group.

ERI-TB also supports the scaling up of qualitative research in the Region. In 2019 an intercountry study on TB/HIV collaborations was launched. Primary data collection has already been carried out in Belarus and two additional countries will be enrolled to the study in 2020.

Dr Dadu thanked all outgoing ERI-TB core group members for their support in establishing and implementing these activities.

Dr Migliori requested the ERI-TB Secretariat to share the weblinks to relevant materials produced by ERI-TB. Dr Dadu confirmed that all materials will be shared later, along with the meeting report.

Dr Dadu stated that ERI-TB's work is supported by the United States Agency for International Development. A recent WHO internal audit described the ERI-TB network as one of the best examples of capacity-building for other programmes.

Review of the ERI-TB terms of reference

Dr Masoud Dara stated that the objectives of ERI-TB have not changed since 2016 and thus need thorough revision by the newly appointed core group. He noted that one possibility for the future may be to expand the ERI-TB network to cover HIV, hepatitis C and other infectious diseases. This does not mean that the focus of ERI-TB should immediately turn to those diseases but rather that research projects concerning comorbidities and coinfections should be encouraged. Dr Dara then presented the ERI-TB's current objectives, which are to:

- map ongoing and planned TB-related research activities in the WHO European Region;
- develop and regularly update the ERA-TB;
- facilitate collaboration between research institutions and key research stakeholders, and identify and promote areas for further cooperation;
- ensure the engagement of civil society organizations, ex-patients and patients, and other relevant non-state actors in TB research;
- facilitate the dissemination of research results, their translation into evidence-based policies and programmatic implementation of such policies via relevant forums and mechanisms; and
- document the existing funding gaps in research and share this information with potential funding agencies and with bilateral and multilateral organizations.

Dr Dara stated that although a much progress had been made across most objectives, mapping the ongoing and planned TB-related research activities in the Region has not yet been achieved and would require much more effort. Dr Dara asked the core group whether further time and effort should be invested to achieve this.

Dr Andrei Dadu then presented the activities prioritized by outgoing members at the fourth meeting of the ERI-TB core group for review by the new ERI-TB core group. The priority activities were:

1. creating a virtual (online) platform for researchers to share their research plans; establish partnerships with relevant NTP representatives, academia members and clinicians; and share research protocols, questionnaires and other instruments;
2. creating an online repository of manuscripts and publications related to implementation of ERA-TB;
3. conducting regional, subregional and country-level workshops on turning evidence into practice, accessing funding resources available for research, and initiating/accessing intercountry and interagency collaboration;
4. converting research evidence into practice through the development of guidelines for NTP managers and/or creation of a platform for exchanging experiences;
5. hosting a consultation with Member States on their research-related needs (e.g. research implementation, data sharing, capacity-building); and
6. creating an online version of the SORT-TB course for the whole Region.

Dr Giovanni Battista Migliori expressed his opinion that the mapping objective should not be dropped. He gave examples from his professional career of occasions when he had had to present aggregated retrospective data on new drugs and regimens that would not have brought much attention or influenced policy if presented individually. Thus, mapping is needed to unite the efforts of different researchers. Additionally, the willingness of different researchers to share data can be explored. However, Dr Migliori said he does not see much value in creating an online repository of manuscripts because most articles can be easily accessed through PubMed.

In response to Dr Migliori, Dr Daniella Cirillo mentioned that in low-resource settings access to licenced publications is limited and that an additional repository providing important full-text manuscripts for free may be needed. Dr Cirillo also added that the aggregation and provision of clean, standardized data for implementing OR could also become one of ERI-TB's objectives.

Dr Vladyslav Nikolayevskyy supported Dr Cirillo's statement about limited access to full-text publication in former Soviet Union countries but said that copyright should be respected and a means to share publications without breaching copyright should be explored. Dr Nikolayevskyy supported Dr Cirillo's idea of not sharing research plans as such, but rather to share high-quality data generated through routine practice and OR in order to save time and money and not duplicate efforts.

Dr Dominik Zenner also stated that he still considers the mapping of observational research projects to be an important topic because there is a lot of duplication, unlike in clinical trials, where projects must be registered. Mapping would enable such duplications to be merged within partnerships to produce more benefits.

Dr Dara said that potential focus areas should include latent TB infection and MDR-TB. In addition, collaboration with the WHO geographically dispersed office on noncommunicable diseases in Moscow could be considered on topics such as nutrition and TB and diabetes and TB. Core group members were encouraged to volunteer to help shape research questions around those topics.

Dr Nebiat Gebreselassie said that promising candidate TB vaccines in development and that the WHO Regional Office for Europe may want to explore related research questions, specifically on safety in the context of the drug-resistance profiles of TB strains prevalent in Region.

Dr Gunilla Källenius suggested mapping the TB research projects currently running through identifying country focal points who have a broad overview of research being implemented at country level. Information on current research projects could be obtained through those focal points.

Dr Dara proposed sharing questions related to revising the ERI-TB terms of reference and the list of prioritized ERI-TB activities by email. He suggested that dividing the core group into subgroups to work on specific topics might be necessary and has proven efficient in other initiatives.

Action points

Action points were to:

1. carry out elections of chair and vice-chair via an online tool;
2. initiate an email thread on revision of the ERI-TB terms of reference and prioritization of activities for 2020–2022, including expanding to include comorbidities; and
3. explore the possibility of establishing subgroups of the ERI-TB core group.

The ERI-TB Secretariat will circulate questions for updating the ERI-TB's terms of reference to core group members. The ERI-TB Secretariat will share the results of the elections by 25 March 2020.

Supporting documents

The following documents were sent to all ERI-TB core group members:

- *Defining the tuberculosis research agenda for the WHO European Region: a study report of the European TB Research Initiative (6)*;
- *Structured Operational Research Training of the European Tuberculosis Research Initiative. ERI-TB SORT-TB Course 1: 2018–2019 curriculum (8)*; and
- a draft progress report on the Roadmap to implement the Tuberculosis Action Plan for the WHO European Region 2016–2020.

Follow-up actions

Elections were held online, with two candidates (Dr Giovanni Battista Migliori and Dr Anastasia Samoiloa) and an option to submit an alternative vote. In all, 14 out of the 15 ERI-TB core group members voted. The results were as follows:

- Dr Migliori – 11 votes
- Dr Samoiloa – 3 votes
- other candidates – 0 votes.

Dr Migliori was therefore appointed Chair of the ERI-TB core group and Dr Samoiloa as Vice-Chair.

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Annex 1. Participants

Previous member of the ERI-TB core group

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New members of the ERI-TB core group

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Dr José María García

Expert; previously, Clinician at University Hospital San Agustín, Spain

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