WHO strategy for TB Research and innovation and its operationalisation at the Regional level (European TB Research initiatives)

Dr Andrei DADU
DaduA@who.int

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Outline

1. Global Strategy for TB Research
2. ERI Network and European TB Research Agenda
3. SORT-TB (about 50 studies)
4. IR 4 DTB
5. Flagship multi-countries research: mSTR, MDR-TB-HCV, MDR-TPT, CAT-TB, VST-TB
6. Small grants stream at TDR (2 series)
7. ERI-TB virtual workspace

What is our plan

GLOBAL STRATEGY FOR TB RESEARCH

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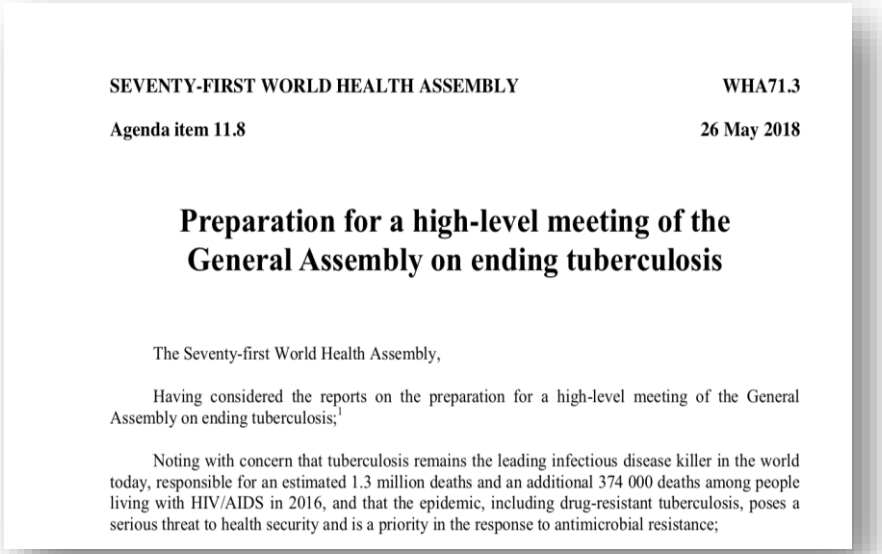
Development of a Global Strategy for TB Research

71st World Health Assembly:

- to develop a **global strategy for tuberculosis research** and innovation, taking into consideration both ongoing and new efforts, and to make further progress in enhancing cooperation and coordination in respect of tuberculosis research and development, considering where possible drawing on relevant existing research networks and global initiatives;



SEVENTY-FIRST WORLD HEALTH ASSEMBLY WHA71.3

Agenda item 11.8 26 May 2018

Preparation for a high-level meeting of the General Assembly on ending tuberculosis

The Seventy-first World Health Assembly,

Having considered the reports on the preparation for a high-level meeting of the General Assembly on ending tuberculosis;[1]

Noting with concern that tuberculosis remains the leading infectious disease killer in the world today, responsible for an estimated 1.3 million deaths and an additional 374 000 deaths among people living with HIV/AIDS in 2016, and that the epidemic, including drug-resistant tuberculosis, poses a serious threat to health security and is a priority in the response to antimicrobial resistance;

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A strategy that advances goals and targets of the End TB strategy and the SDGs

Main goal:
The aim of this strategy is to provide, for all Member States, a framework of interventions to remove barriers in TB research and innovation process to help achieve the goals and targets of the **End TB** Strategy

Strategy goals
(short, medium and long term)

Create an enabling environment for TB innovation

Increase financial investments in TB research and innovation

Ensure equitable access to the benefits of research

Promote and improve approaches to data sharing

THE END TB STRATEGY

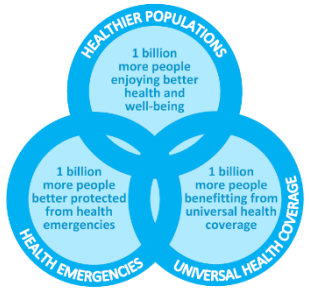
Introduce new tools: a vaccine, new drugs & treatment regimens for treatment of active TB disease and latent TB infection, and a point-of care Test by 2025

Optimize use of current & new tools emerging from pipeline, pursue universal health coverage and social Protection

No TB affected families facing catastrophic cost …95% reduction in TB deaths… 90% reduction in TB incidence rate

SUSTAINABLE DEVELOPMENT GOALS

SDG 3 "Ensure healthy lives and promote wellbeing for all at all ages" SDG 3.B Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.



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What to research

Tuberculosis

https://www.who.int/health-topics/tuberculosis#tab=tab_1

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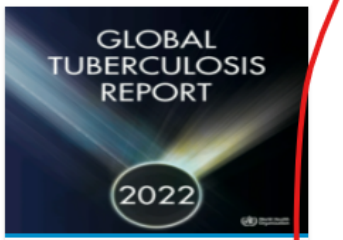
TB & COVID-19

Global Tuberculosis Programme and the COVID-19 Pandemic Response

Questions and answers

Coronavirus disease (COVID-19...

Global TB report



Access TB report →

Knowledge Sharing

WHO TB Knowledge Sharing Platform

GET IT ON Google Play Download →

Download on the App Store Download →

OpenWHO Course

End TB Courses →

Training courses dedicated to several aspects of Tuberculosis are available in multiple languages on the Open WHO platform. An End TB channel has been established to facilitate their retrieval.

News

All →

https://tbksp.org/ru

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Russian

World Health Organization

Сводное руководство | Прикладные пособия | Учебный каталог | Быстрый поиск | Рекомендации | Войти

Платформа ВОЗ по обмену знаниями о ТБ

Доступ к модульному руководству ВОЗ по туберкулезу с соответствующими пособиями и учебными материалами.

Сводное руководство

Руководства ВОЗ содержат последние научно обоснованные рекомендации по профилактике и лечению ТБ, призванные помочь странам в достижении Целей в области устойчивого развития (ЦУР) и задач стратегии по ликвидации ТБ.

Узнать больше →

Прикладные пособия

Прикладные пособия ВОЗ по туберкулезу предоставляют пользователям практические рекомендации с подробным описанием шагов, необходимых для надлежащей реализации соответствующего руководства ВОЗ.

Узнать больше →

Учебный каталог

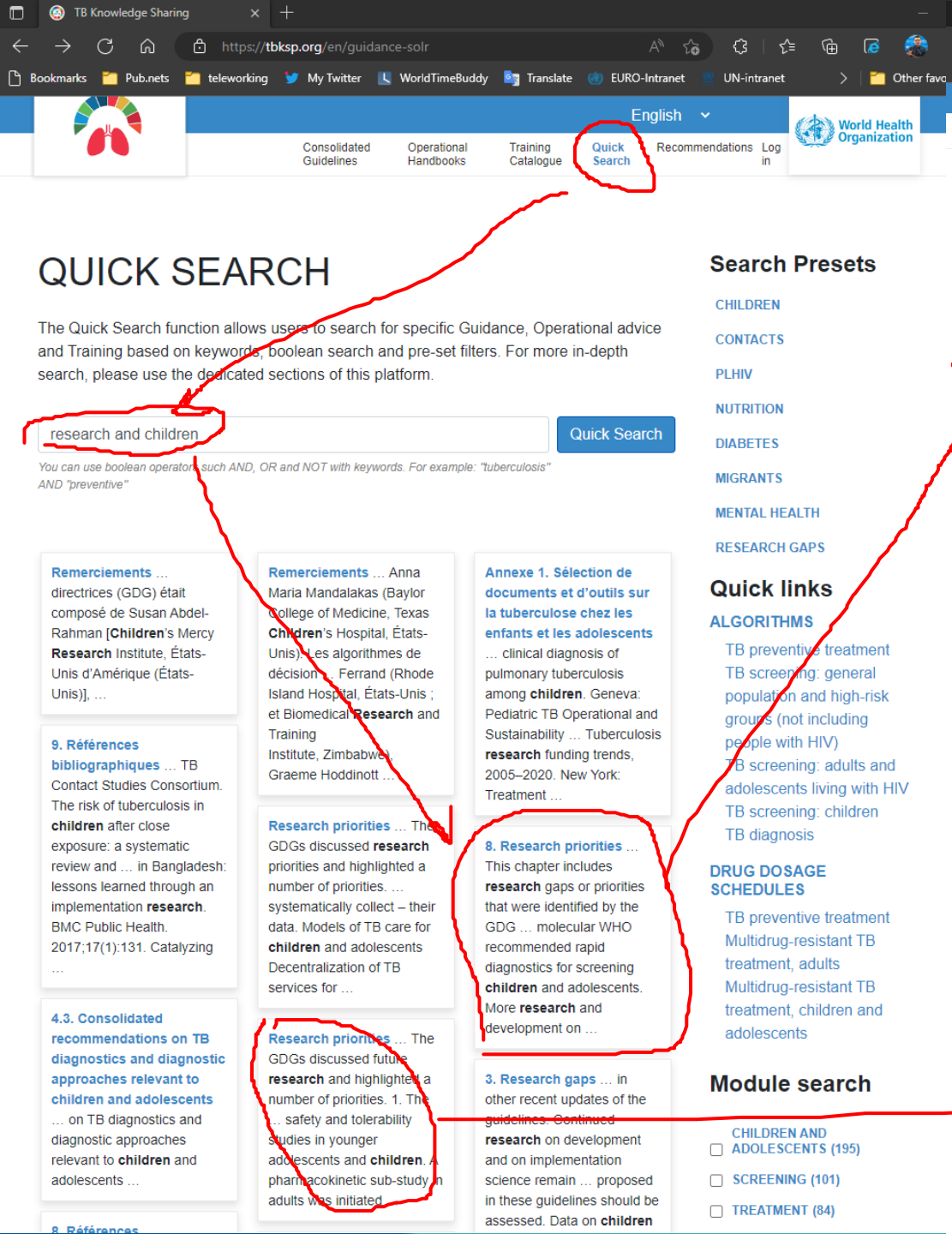
Учебный каталог ВОЗ по туберкулезу состоит из онлайн-курсов электронного обучения и других учебных материалов, помогающих пользователям применять соответствующее руководство ВОЗ.

Узнать больше →

О нас

Глобальная программа ВОЗ по туберкулезу стремится к достижению цели - мира, свободного от туберкулеза, с нулевым уровнем смертностью, заболеваемости и страданий, вызванными этим заболеванием. Миссия команды заключается в том, чтобы возглавить и направить глобальные усилия по прекращению эпидемии ТБ путем обеспечения всеобщего доступа к профилактике и лечению, ориентированным на потребности человека, многосекторальных действий и инноваций. В рамках своих основных функций Глобальная программа по туберкулезу разрабатывает варианты стратегии, нормы и стандарты по профилактике и лечению ТБ и содействует их реализации.

Глобальная программа борьбы с туберкулезом | Официальное уведомление о конфиденциальности | Обратная связь | © 2021 WHO


TB Knowledge Sharing
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QUICK SEARCH
The Quick Search function allows users to search for specific Guidance, Operational advice and Training based on keywords, boolean search and pre-set filters. For more in-depth search, please use the dedicated sections of this platform.
research and children
Quick Search
You can use boolean operators such AND, OR and NOT with keywords. For example: "tuberculosis" AND "preventive"
Remerciements … directrices (GDG) était composé de Susan Abdel-Rahman [Children's Mercy Research Institute, États-Unis d'Amérique (États-Unis)], …
Remerciements … Anna Maria Mandalakas (Baylor College of Medicine, Texas Children's Hospital, États-Unis) ; Les algorithmes de décision … Ferrand (Rhode Island Hospital, États-Unis ; et Biomedical Research and Training Institute, Zimbabwe) Graeme Hoddinott …
Annexe 1. Sélection de documents et d'outils sur la tuberculose chez les enfants et les adolescents … clinical diagnosis of pulmonary tuberculosis among children. Geneva: Pediatric TB Operational and Sustainability … Tuberculosis research funding trends, 2005–2020. New York: Treatment …
9. Références bibliographiques … TB Contact Studies Consortium. The risk of tuberculosis in children after close exposure: a systematic review and … in Bangladesh: lessons learned through an implementation research. BMC Public Health. 2017;17(1):131. Catalyzing …
Research priorities … The GDGs discussed research priorities and highlighted a number of priorities. … systematically collect – their data. Models of TB care for children and adolescents Decentralization of TB services for …
8. Research priorities … This chapter includes research gaps or priorities that were identified by the GDG … molecular WHO recommended rapid diagnostics for screening children and adolescents. More research and development on …
4.3. Consolidated recommendations on TB diagnostics and diagnostic approaches relevant to children and adolescents … on TB diagnostics and diagnostic approaches relevant to children and adolescents …
Research priorities … The GDGs discussed future research and highlighted a number of priorities. 1. The … safety and tolerability studies in younger adolescents and children. A pharmacokinetic sub-study in adults was initiated.
3. Research gaps … in other recent updates of the guidelines. Continued research on development and on implementation science remain … proposed in these guidelines should be assessed. Data on children
Search Presets
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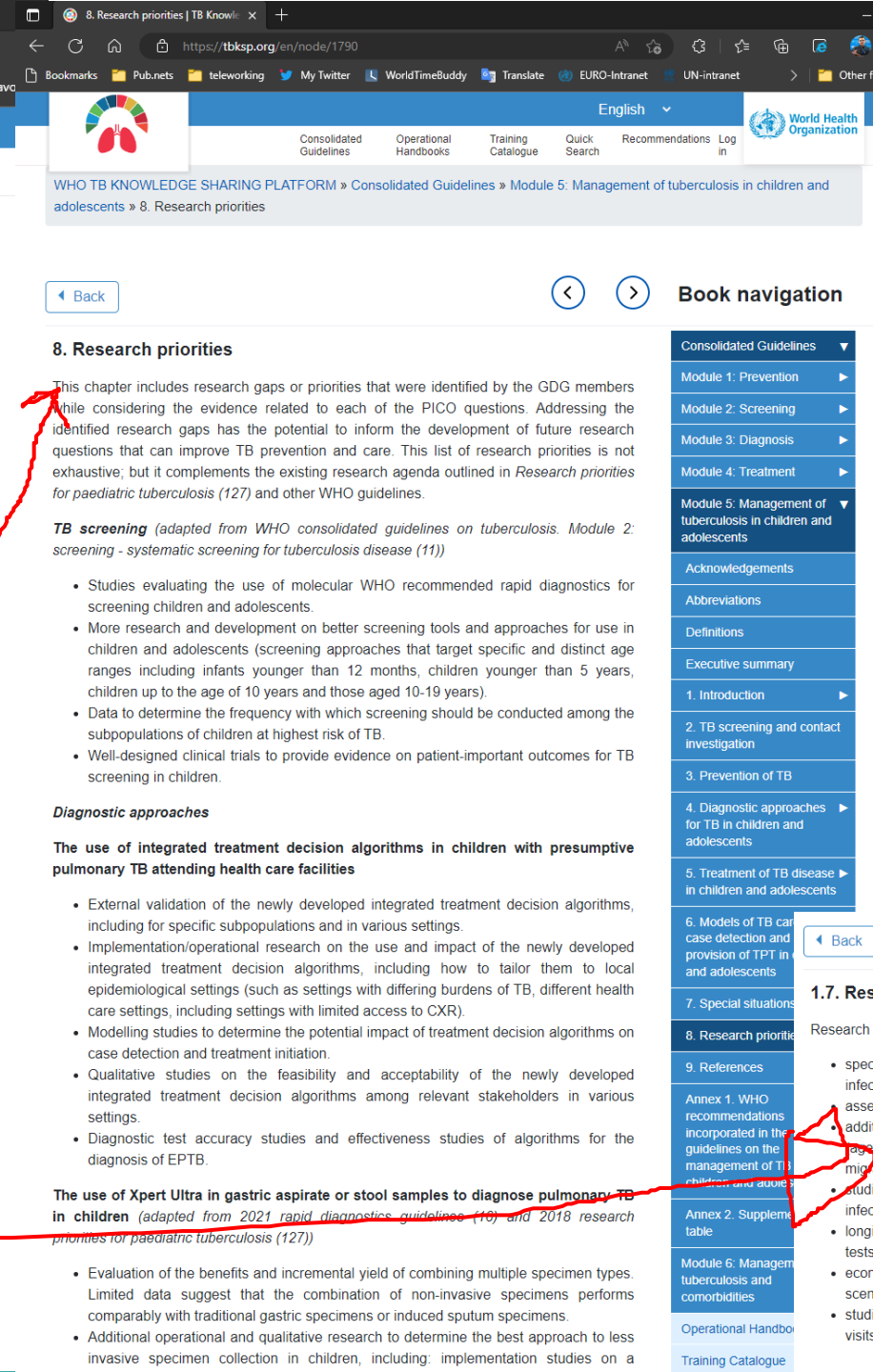
Quick links
ALGORITHMS
TB preventive treatment
TB screening: general population and high-risk groups (not including people with HIV)
TB screening: adults and adolescents living with HIV
TB screening: children
TB diagnosis
DRUG DOSAGE SCHEDULES
TB preventive treatment
Multidrug-resistant TB treatment, adults
Multidrug-resistant TB treatment, children and adolescents
Module search
CHILDREN AND ADOLESCENTS (195)
SCREENING (101)
TREATMENT (84)


8. Research priorities | TB Knowle
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WHO TB KNOWLEDGE SHARING PLATFORM » Consolidated Guidelines » Module 5: Management of tuberculosis in children and adolescents » 8. Research priorities
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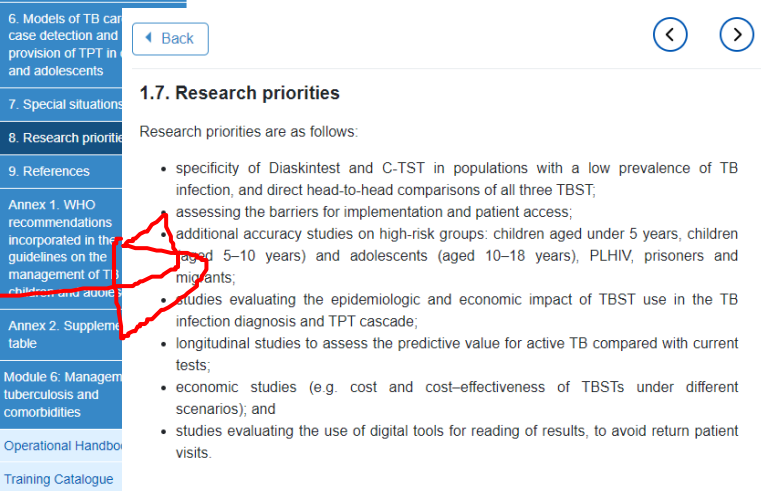
Book navigation
8. Research priorities
This chapter includes research gaps or priorities that were identified by the GDG members while considering the evidence related to each of the PICO questions. Addressing the identified research gaps has the potential to inform the development of future research questions that can improve TB prevention and care. This list of research priorities is not exhaustive; but it complements the existing research agenda outlined in Research priorities for paediatric tuberculosis (127) and other WHO guidelines.
TB screening (adapted from WHO consolidated guidelines on tuberculosis. Module 2: screening - systematic screening for tuberculosis disease (11))
Studies evaluating the use of molecular WHO recommended rapid diagnostics for screening children and adolescents.
More research and development on better screening tools and approaches for use in children and adolescents (screening approaches that target specific and distinct age ranges including infants younger than 12 months, children younger than 5 years, children up to the age of 10 years and those aged 10-19 years).
Data to determine the frequency with which screening should be conducted among the subpopulations of children at highest risk of TB.
Well-designed clinical trials to provide evidence on patient-important outcomes for TB screening in children.
Diagnostic approaches
The use of integrated treatment decision algorithms in children with presumptive pulmonary TB attending health care facilities
External validation of the newly developed integrated treatment decision algorithms, including for specific subpopulations and in various settings.
Implementation/operational research on the use and impact of the newly developed integrated treatment decision algorithms, including how to tailor them to local epidemiological settings (such as settings with differing burdens of TB, different health care settings, including settings with limited access to CXR).
Modelling studies to determine the potential impact of treatment decision algorithms on case detection and treatment initiation.
Qualitative studies on the feasibility and acceptability of the newly developed integrated treatment decision algorithms among relevant stakeholders in various settings.
Diagnostic test accuracy studies and effectiveness studies of algorithms for the diagnosis of EPTB.
The use of Xpert Ultra in gastric aspirate or stool samples to diagnose pulmonary TB in children (adapted from 2021 rapid diagnostics guidelines (16) and 2018 research priorities for paediatric tuberculosis (127))
Evaluation of the benefits and incremental yield of combining multiple specimen types. Limited data suggest that the combination of non-invasive specimens performs comparably with traditional gastric specimens or induced sputum specimens.
Additional operational and qualitative research to determine the best approach to less invasive specimen collection in children, including: implementation studies on a
Consolidated Guidelines
Module 1: Prevention
Module 2: Screening
Module 3: Diagnosis
Module 4: Treatment
Module 5: Management of tuberculosis in children and adolescents
Acknowledgements
Abbreviations
Definitions
Executive summary
1. Introduction
2. TB screening and contact investigation
3. Prevention of TB
4. Diagnostic approaches for TB in children and adolescents
5. Treatment of TB disease in children and adolescents
6. Models of TB care
case detection and
provision of TPT in
and adolescents
7. Special situations
8. Research priorities
9. References
Annex 1. WHO recommendations incorporated in the guidelines on the management of TB
Annex 2. Supplemental table
Module 6: Management tuberculosis and comorbidities
Operational Handbo
Training Catalogue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1.7. Research priorities
Research priorities are as follows:
specificity of Diaskintest and C-TST in populations with a low prevalence of TB infection, and direct head-to-head comparisons of all three TBST;
assessing the barriers for implementation and patient access;
additional accuracy studies on high-risk groups: children aged under 5 years, children aged 5–10 years) and adolescents (aged 10–18 years), PLHIV, prisoners and migrants;
studies evaluating the epidemiologic and economic impact of TBST use in the TB infection diagnosis and TPT cascade;
longitudinal studies to assess the predictive value for active TB compared with current tests;
economic studies (e.g. cost and cost–effectiveness of TBSTs under different scenarios); and
studies evaluating the use of digital tools for reading of results, to avoid return patient visits.

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EDITORIAL

Bridging the gap: key evidence needed to strengthen global policies to end TB

Преодоление разрыва: ключевые фактические данные, необходимые для укрепления глобальной политики по ликвидации туберкулеза

The way forward

Obstacles to the development and uptake of safer, effective, affordable, people-centred tools for screening, preventing, diagnosing and treating TB are considerable, but the greatest challenge remains inadequate funding.[22,23] The Global Strategy for TB research and innovation[24] also underscores that collaboration, data sharing and equitable use of the benefits of research are critical for bridging the research to policy and practice gap. During the 2023 United Nations high-level meeting on TB, Member States have the opportunity to boost efforts to get the world back on track to end TB, including through increased investment in research and innovation.

N. Gebreselassie
D. Falzon
M. Zignol
K. Viney
N. Ismail
F. Mirzayev
F. Mavhunga

Препятствия на пути разработки и внедрения более безопасных, эффективных, доступных, ориентированных на нужды людей инструментов для скрининга, профилактики, диагностики и лечения туберкулеза значительны, но самой большой проблемой **остается недостаточное финансирование**. В Глобальной стратегии исследований и инноваций в области туберкулеза также подчеркивается, что сотрудничество, обмен данными и справедливое использование преимуществ исследований имеют решающее значение для преодоления пробелов в политике и практике.

В ходе совещания высокого уровня Организации Объединенных Наций по туберкулезу в 2023 году государства-члены имеют возможность активизировать усилия по возвращению мира на путь ликвидации туберкулеза, в том числе путем увеличения инвестиций в научные исследования и инновации.

What EURO does to support it

EUROPEAN TB RESEARCH AGENDA AND ERI-TB NETWORK

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Objectives

Policies Definition and Advocacy:	1. to ***map ongoing*** and planned TB-related research activities in the Region and review and ***update research priority agenda*** on a regular basis 2. to document the funding gaps in research and ***advocate with potential funding*** agencies, bilateral and multilateral organizations
Capacity Building and Mentorship	3. to ***strengthen research capacity*** of national programs and other TB actors at country level 4. to provide ***guidance and mentorship for researchers*** and institutions aiming to implement research in the area of tuberculosis 5. to facilitate ***dissemination of the results*** of research and their translation to evidence-based policies and programmatic implementation via relevant fora and mechanisms
Networking and Implementation	6. to facilitate ***collaboration and networking*** between individual researchers, research institutions and key state and non-state research stakeholders, and identity and promote areas for further cooperation 7. to ***promote and support intercountry research*** and enhance intercountry collaboration in the area of TB research

E = European

R = Research

I = Initiative

-

TB = Tuberculosis

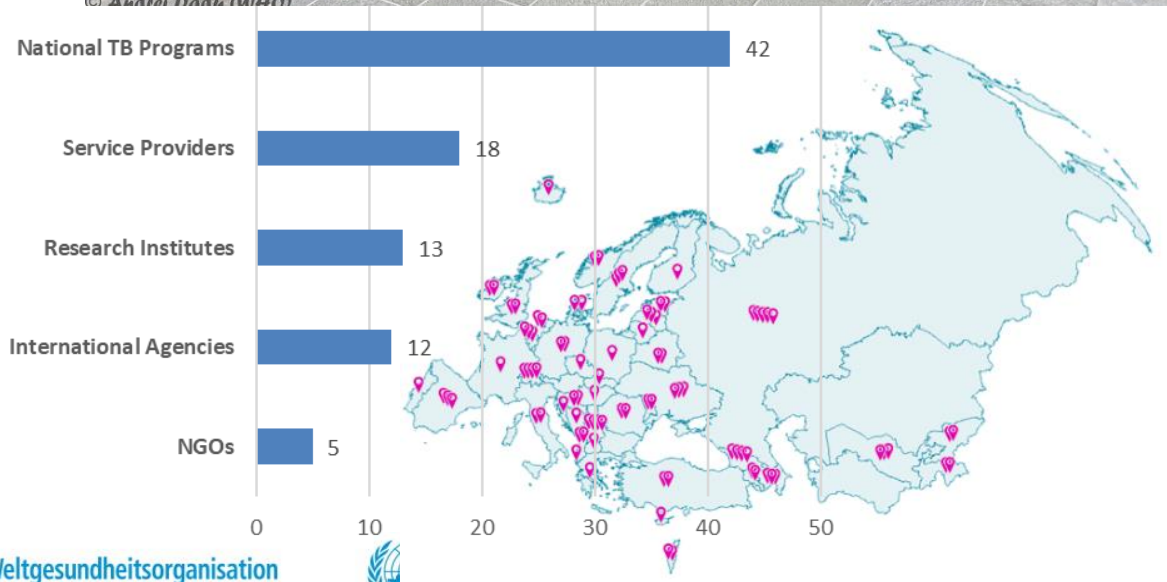
Secretariat @EURO-TB

Advisory board (CSO + area experts)

Research mentors roaster

Network (more then 300 members across entire Region)

SORT-IT/TB (European alumni)



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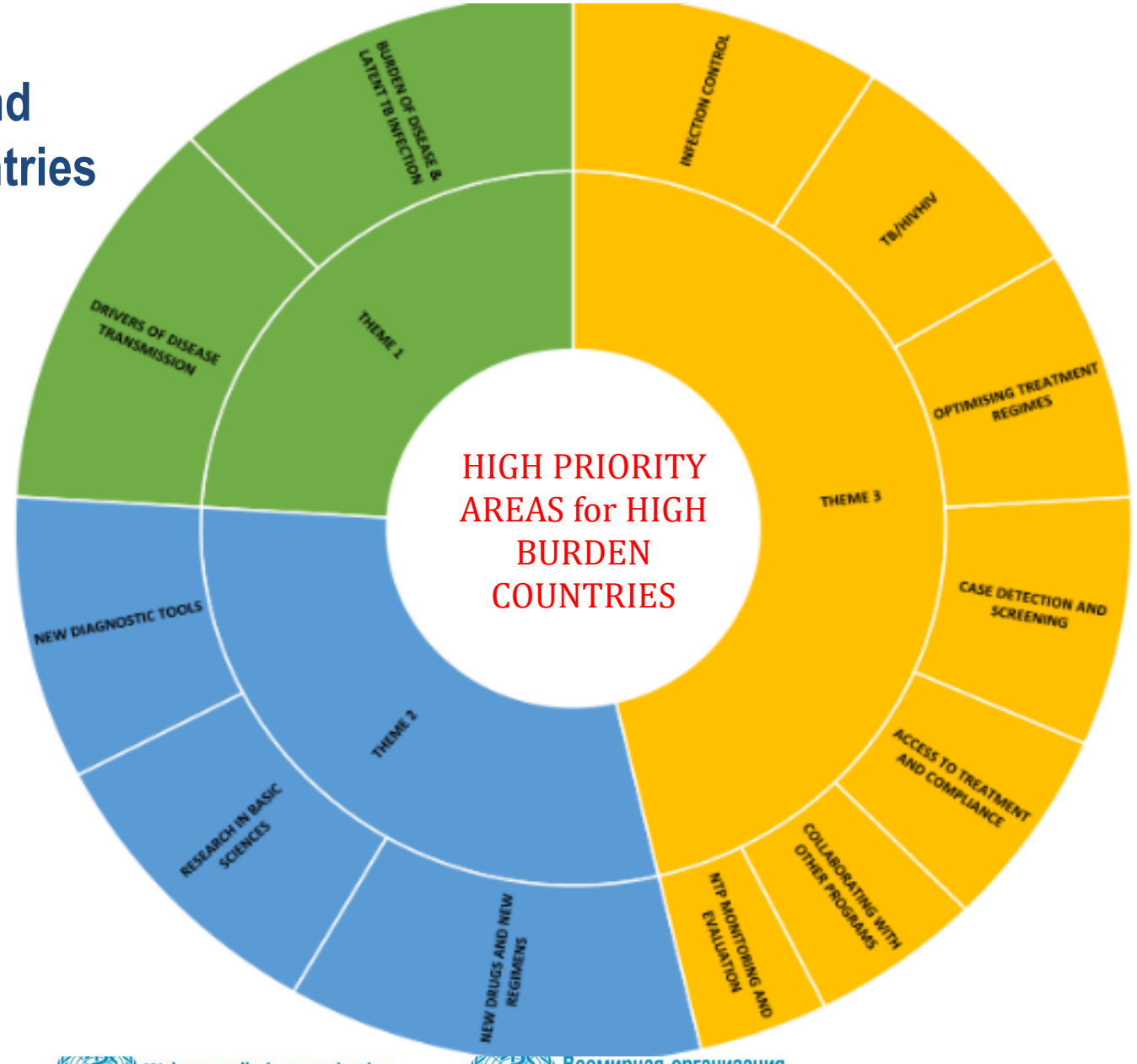
Structure TB research priorities for Region and distribution of those for the high burden countries

Theme 1 Epidemiological Research	1. BURDEN OF DISEASE, INCLUDING LATENT TB INFECTION 2. DYNAMICS AND DRIVERS OF DISEASE TRANSMISSION
Theme 2 Innovation & Fundamental Research	3. RESEARCH IN BASIC SCIENCES 4. NEW DIAGNOSTIC TOOLS 5. NEW DRUGS AND NEW REGIMENS 6. NEW VACCINES
Theme 3 Operational Research	7. CASE DETECTION AND SCREENING 8. ACCESS TO TREATMENT AND COMPLIANCE 9. OPTIMISING TREATMENT REGIMENS 10. HEALTH SYSTEMS AND PUBLIC PRIVATE MIX 11. COLLABORATION WITH HIV PROGRAMS 12. COLLABORATING WITH OTHER PROGRAMS 13. INFECTION CONTROL 14. NATIONAL TB PROGRAM MONITORING 15. COMMUNITY PARTICIPATION 16. SOCIAL DETERMINANTS OF TB 17. LINKING TB RESEARCH WITH OTHER DISCIPLINES



HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

Theme 1 Epidemiological Research	
1. Burden of disease, including latent TB infection	1. "What are the trends of drug- resistant TB among the countries in the Region with specific reference to resistance to the new (bedaquiline, delamanid) and repurposed TB drugs (including clofazimine, the fluoroquinolones, and linezolid)?" 2. "Which are the most cost-effective TB case- finding screening methods among high risk populations?"
2. Dynamics and drivers of disease transmission	3. "Which are the most cost-effective interventions to reduce the spread of drug-resistant TB in the Region?" 4. "What are the social and biological drivers of drug-resistant TB in the Region?"

HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

Theme 2 Innovation & Fundamental Research	
3. Research in basic sciences	5. "Which biomarkers are useful to determine the risk of progression from latent TB infection to active disease and to distinguish relapse from reinfection?" 6. What are the genetic mutations associated with resistance to new and repurposed medicines?" 7. "What are the candidate molecular targets for anti-TB drugs?"
4. New diagnostic tools	8. "What is the evidence that rapid molecular diagnostic techniques for the initial diagnosis of TB and resistant forms of TB (such as Xpert® and Whole Genome Sequencing) improve the diagnosis and treatment outcome, especially among children and people living with HIV?" 9. "How effective and cost-effective are the new diagnostic platforms (including most recent molecular drug sensitivity tests and Whole Genome Sequencing platforms)?"
5. New drugs and new regimens	10. "What are the observed efficacy, safety and tolerability of new and repurposed medicines (especially among children, adolescents, people living with HIV and the elderly)? Are there any interactions with antiretroviral (ARV) drugs?" 11. "What are the optimal doses of new and repurposed medicines in children?" 12. "What are the most effective and patient- friendly short-term regimens for MDR/ extensively drug-resistant (XDR)- TB (taking into account the pill burden, use of injectable drugs and duration of treatment) in the Region?"

HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

Theme 3 Operational Research	
6. Case detection and screening	13. "What is average time to TB diagnosis among the various risk groups and what are reasons for diagnostic delay?" 14. "What are the most effective approaches to the management of close contacts of MDR and XDR-TB index patients?"
7. Access to Rx and compliance	14. "What are the main reasons for patients to discontinue treatment in the Region?"
8. Optimising treatment regimes	15. "What is the optimal preventive regimen for tolerability, efficacy, safety and compliance for close contacts of isoniazid resistant, MDR and XDR-TB index patients?" 16. "What are the extent and impact of the short course MDR- TB regimen in National TB programmes in the Region?"
9. Collaboration with HIV programs	17. "What is the optimal screening algorithm for active TB and latent TB infection among people living with HIV" 18. "Integrating TB-HIV care: What are the best models for delivering TB-HIV treatment and monitoring?"
10. Infection control	19. "For how long do patients with drug-sensitive and drug-resistant TB remain infectious after starting treatment?"

How we do it

SORT-TB

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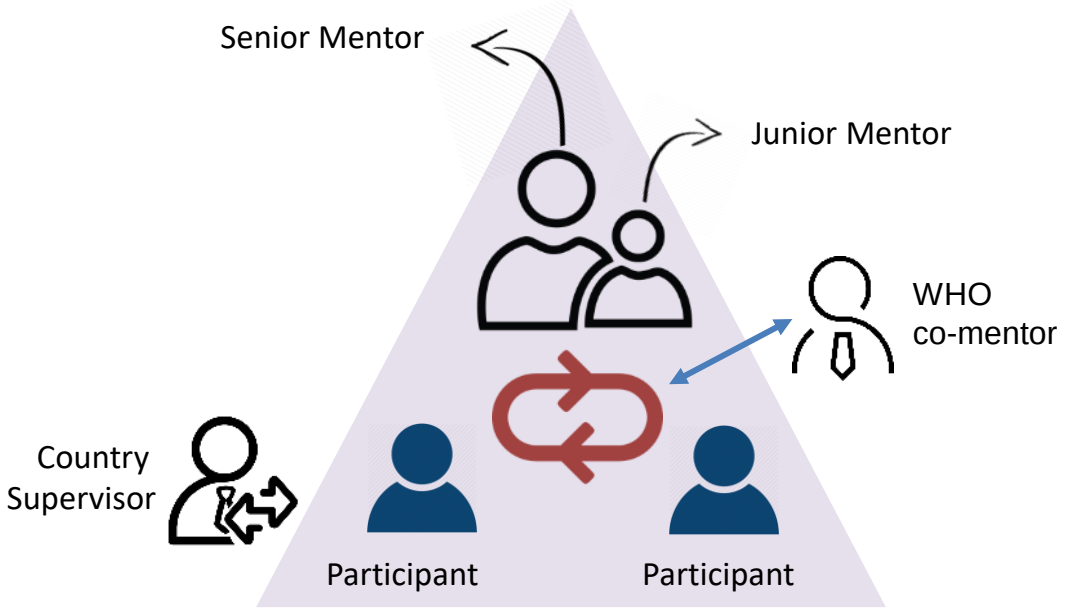
Mentorship Model and Study Process



2 senior-junior mentors + 2 participants

12 mentors + 12 participants

Pre-Course Mentoring
Products: Title and objectives

Module 1&2 (in person)
Products: Research protocol and data analysis plan

Research implementation (part 1)
Products: Ethics approvals from WHO ERC and local IRB, cleaned database

Research implementation (part 2)
Products: analysed data (key findings, tables, graphs, charts etc.)

Module 3 (in person)
Products: manuscript for publishing

Manuscript submission
Products: confirmation of publication from peer-reviewed journal

Findings dissemination:
Wolfheze Workshop and publications

Modus Operandi

Hands-on in modules

Progress tracking through milestones

Continuous support from mentors

Mentors are co-authors

SORT-IT faculty at ERI-TB

Linkage with NTP through supervisors

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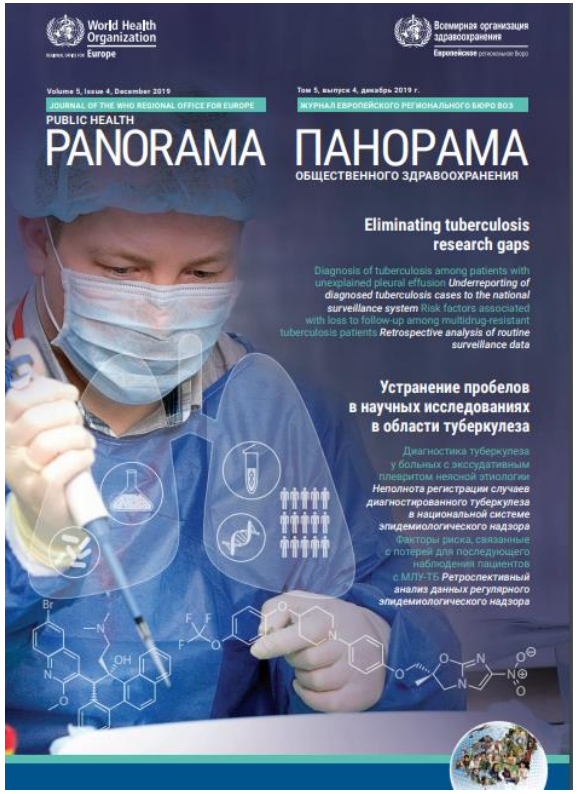
Eliminating TB research gaps

Implementing research and transforming it into evidence for improvement of programmatic management of TB

Structured Operational Research Training of ERI-TB (SORT-TB) resulted in 12 publication in a peer-reviewed journal



https://apps.who.int/iris/handle/10665/326578

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How we do it

IR 4 DTB

Implementation Research toolkit for digital technologies and TB (IR4DTB)

Digital toolkit developed by TDR and GTB to guide NTPs to develop and conduct of IR projects related to digital technologies under programmatic settings

Aims:

- Provide guidance to countries on how to develop an IR study for use of digital innovations within TB programmes
- Support strengthening of evidence based regarding optimal implementation of digital innovations for TB

Output:

- Comprehensive IR study proposal to support fundraising efforts

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RESEARCH FLAGSHIP STREAMS

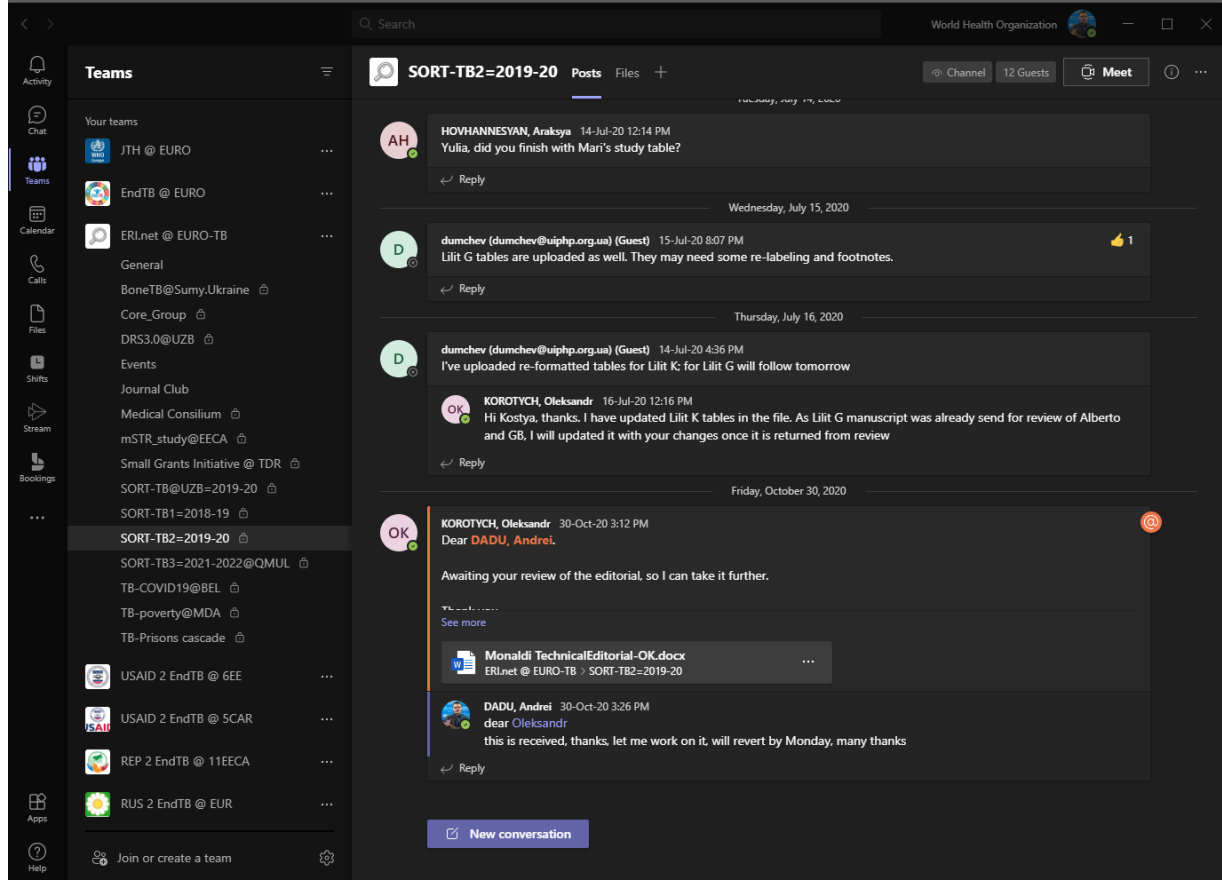
Implementation: Research flagship streams

1. Stream: mSTR-DR-TB: implemented
2. Stream: HCV/DR-TB coinfection: implementation ongoing
3. Stream: PASS to End TB:
   - PTOR-DR-TB: (protocol developed)
   - PASS-barriers (Georgia and Moldova)
4. Stream: IR4TDB: implementation ongoing
5. Stream: epidemiological research
   - DRS 3.0 @ Uzbekistan (link)
   - Epimodeling @ Ukraine for the NSP: scenario calibration
   - Epimodeling @ Europe = the impact of the war at regional level: model development

Join ERI-TB

eurotbri@who.int

www.euro.who.int/tb



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