Digital innovations, TB and implementation research

7 February 2020
Geneva, Switzerland

Report of a joint meeting organised by
the World Health Organization and
the European Respiratory Society

Acknowledgements

The World Health Organisation (WHO) acknowledges with gratitude the contribution of participants of this consultation and administrative personnel who made this meeting possible and productive. The WHO Global TB Programme organised the meeting with funds made available by the European Respiratory Society (ERS). We wish to thank particularly Dr. Vitalii Poberezhets (ERS) and Dr. Zelalem Temesgen (Mayo Clinic) for co-chairing the meeting. This meeting report was drafted by the WHO secretariat and circulated to meeting participants for review ahead of finalization.

FRONT ROW **from left:** Nebiat GEBRESELASSIE, Nontobeko NDLOVU, Evan SPARK-DE PAS, Dennis FALZON, Sudarshan MANDAL, Alena SKRAHINA , Hazim TIMIMI
BACK **ROW from left**: Yohannes MOLLA, Katya GAMAZINA, Saskia DEN BOON, Baraka ONJARE, Vanessa VERONESE , Andre VILLANEUVA, Richard LESTER, Donna Mae GEOCANIGA-GAVIOLA, Mohammed Aamir KHAN, Kristian van KALMTHOUT, Ficard NDAYIMIRIJE, Nnamdi NWANERI, Thomas Dale HIATT, Richard GARFEIN, Werner BILL, Achilles KATAMBA, Zelalem TEMESGEN, Vitalii POBEREZHETS, Chris ISAACS
(see annex for full list of participants)

Background

Research and innovation constitute one of the three pillars of WHO's End TB Strategy. This encompasses both the discovery and development of new tools as well as study on how to optimize their impact through implementation. WHO has promoted implementation research for several years, as a way to study and improve health care delivery. In December 2018, the Global Tuberculosis (TB) Programme of the World Health Organization (WHO/GTB) and the European Respiratory Society (ERS) convened a first technical consultation on "Digital innovations, TB and implementation research". The meeting discussed experiences and perspectives in implementation science methods to help scale up digital innovations in support of different efforts against TB in the BRICS countries. Following this consultation, WHO/GTB and the Special Programme for Research and Training in Tropical Diseases (TDR) worked on an implementation research toolkit to help national programmes worldwide integrate digital technologies more effectively and study their performance while putting them in place. This second meeting follows on the same theme and comes at a critical juncture when many countries are updating their national TB strategic plans and preparing funding proposals for submission to the Global Fund to Fight AIDS, TB and Malaria (Global Fund). The introduction of digital innovations to support TB efforts along different critical points in the patient pathway will be important and needs to be accompanied by evidence gathering at every stage to enrich the knowledge base on what works and what doesn't and how to overcome common barriers to implementation in different settings. While some randomised controlled trials and implementation research is already ongoing for technologies employed to support TB medication adherence, there is a dearth of knowledge on how to evaluate systematically other technologies applied for other common "use cases" or scenarios in the context of TB care and prevention. **Figure 1** below presents a framework with 4 functions into which the application of digital technologies for TB can be classified : patient care, programme management, surveillance and monitoring and eLearning.

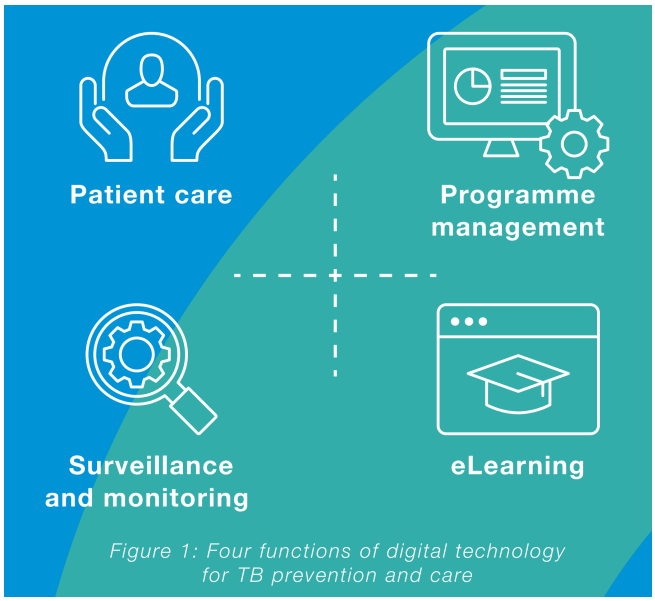

Figure 1: Four functions of digital technology for TB prevention and care

In this context, the two objectives of the meeting were to discuss

- progress in the development of the implementation research toolkit, and;
- future perspectives relevant to the use and study of digital innovations to improve efforts against TB.

The report of the meeting is organized according to the order of the presentations, and includes a short summary with hyperlinked slide access. The agenda and list of participants are annexed to this report (see end of this document). Some of the participants joined the discussion via webinar. This present meeting followed another consultation held at the same venue on 6 February which was focused on the new ASCENT project: the discussions and next steps from the ASCENT meeting will be summarised in a separate report.

Introduction

After a welcome by Dr. Dennis Falzon (Team Lead, Prevention, Research and Innovations, WHO/GTB), Dr. Tereza Kasaeva (Director, WHO/GTB) opened the meeting at 9:00 AM February 7, 2020. The participants then introduced themselves.

WHO/ERS activities on digital technologies for TB and meeting objectives

Dr Dennis Falzon, Global TB Programme, WHO

Dr. Falzon presented the potential cross cutting application of digital technologies across the three pillars of WHO's End TB Strategy, as well as the broader context that digital technologies are envisioned to contribute to achieving Sustainable Development Goal (SDG) targets. WHO/GTB's efforts to support national tuberculosis programmes (NTPs) and other relevant stakeholders utilize and integrate digital technologies through the development of supportive documents (Digital Health for the End TB Strategy-an agenda for action, Handbook for the use of digital technologies to support tuberculosis medication adherence); guidelines; technical advisory groups (Global Task Force on Digital Health for TB 2015 to 2019); and, organization of several scientific fora for knowledge exchange. Dr. Falzon summarized the outcomes of the most recent WHO/ERS meeting on digital health (2018), focusing on how high TB burden countries are utilizing implementation research (IR) to optimize and scale up digital technologies for TB. He concluded his presentation by introducing the objectives and the agenda of this 1-day meeting. **Slide access**

Implementation research toolkit for digital technologies and TB

Dr. Cecily Miller, Global TB Programme, WHO

Dr. Miller started her presentation by reiterating the importance of digital technology applications in improving TB care delivery, and the role that IR can play in generating evidence for its successful and sustainable deployment under programmatic setting. In this context, the RE-AIM framework was presented as an example of a practical approach to implementation research. The five domains of the RE-AIM framework that can help build evidence in relation to their potential role in addressing implementation questions of digital technologies under programmatic setting were presented. An overview was presented showing how implementation research could be run alongside the roll-out of digital technologies for TB care. Examples of IR studies conducted in alignment with the RE-AIM approach to optimize digital technology use by BRICS countries, at the 2019 ERS/WHO meeting was summarized. After the presentation, participants discussed the potential for stepwise IR to serve as complementary and/or alternative option (at times) to traditional randomized clinical trials, which are often expensive, long, and inflexible. Participants also reflected the need to encourage new trial designs that allow adjustments to changing contextual factors or data, as needed. **Slide access**

Updates from countries, TB-REACH and ASCENT projects

TB REACH and ASCENT projects on digital adherence technologies

Ms. Amera Khan presented ongoing TB REACH funded digital adherence technology (DAT) projects and their progress in various countries across four continents. IR is being implemented in these countries with support from TB REACH, McGill University, KNCV, M&E experts, and, using an IR framework as defined by Proctor et al and Peters et al, to monitor impact and generate data for optimizing and improving use of digital technologies. Philippines and Tanzania project leads shared progress updates, as country examples.

Mr. Kristian van Kalmthout presented the Adherence Support Coalition to end TB (ASCENT) project, currently funded by Unitaid to facilitate evidence-based country adoption and uptake of digital adherence technologies, together with the necessary global market and implementation plan to support scale up. In this context, the ASCENT project is supporting IR to build evidence needed for optimization and scale up of digital technologies, as per the framework presented by Ms. Khan in Philippines, Tanzania, South Africa, Ukraine and Ethiopia. Cluster randomized effectiveness evaluation is ongoing to assess broader impact of DAT on treatment outcomes (Philippines, Tanzania, South Africa, & Ukraine), using similar protocol across countries. The success and other outcomes of these technologies will be explored using data from 70,000 patients, for both drug-susceptible and drug-resistant TB, and to

catalyze similar initiatives on TB preventive treatment in project countries and beyond. (**Slide Access** for joint presentation on TB REACH and ASCENT)

China: After introducing national TB epidemic context, Dr. Hui Zhang introduced the medicine dispenser technology (Medication Event Reminder Monitor System or MERM) that is being implemented and scaled up in some provinces. MERM generates a detailed history of patient dosing to inform personalized care and follow up. The optimization and scale-up of MERM is being informed by IR using all five domains of the RE-AIM framework, with some results published and/or to be published in 2020. **Slide Access**

India: Dr. Sudarsan Mandal presented the vision of India to eliminate TB by 2025, and noted the role of digital technologies for accelerating efforts towards this goal. As part of this effort, progress on the implementation of Direct Benefit Transfer (DBT), which is geared towards four different types of beneficiaries in the TB cascade of care was presented. Challenges such as skills gap in using the technology, bridging the urban-rural digital divide to improve reach, the need for product optimization to improve user experience and accuracy of service provision were presented. DBT has been modified 4 times according to changing circumstances, and IR remains central to further improve its impact and reach. **Slide access**

South Africa: Dr. Nazir Ismael presented South Africa's achievements and progress in connecting digital information generated by diagnostic devices to health care providers and patient medical records, to facilitate notification and improve patient care, while facilitating overall M&E processes. The application of IR, RE-AIM framework in facilitating the optimization and scale-up of diagnostic connectivity through both qualitative and quantitative approaches was presented. **Slide access**

Philippines: Ms. Donna Mae Geocaniga-Gaviola opened her presentation by noting the importance of digital technologies in promoting connectivity in a country like the Philippines consisting of many islands over a huge geographical span. Care provision is through both public and private sectors, making it further diversified. Several initiatives of digital technology application, their implementation progress and challenges were presented, the most notable of which was lack of sustained resource to support optimization and scale up. **Slide access**

Belarus: Dr. Alena Skrahina presented Belarus's journey to a nationwide scaleup of case-based electronic patient (TB) records (eRR) from 2006-2010, to centralize information and improve M&E. Belarus views IR as key to investigate barriers to improved uptake of its eRR and further optimize reach, improve utilization, and quality of electronic recording. The national TB programme has experience in undertaking operational research for a number of innovations that have been rapidly scaled up nationwide, such as new treatment regimens for drug-resistant TB and video-supported treatment for TB. Financing remains the single most important barrier to conducting IR for innovations such as eRR. **Slide access**

Brazil: Ms. Patricia Bartholomay Oliviera opened her presentation by presenting Brazil's progress in reducing TB incidence and mortality. To further improve progress, free, self-paced, e-learning modules for healthcare professionals are being provided nationwide on various aspects of TB/HIV management in collaboration with academic institutions in the country. Currently, the modules have various degrees of use in different provinces. IR is important to optimize uptake and use of these modules across provinces. Based on the successful outcome of this eLearning initiative the programme is developing additional modules. **Slide access**

New perspectives in digital technologies for TB care

Dr. Zelalem Temesgen, Mayo Clinic

Dr. Temesgen presented several examples of novel future perspectives in digital technologies in TB prevention and care, including those being developed by the Mayo Clinic Center for Tuberculosis, a WHO Collaborating Centre on Digital Health And Precision Medicine For Tuberculosis since 2018. Among others, the presentation touched upon a project design for a clinical decision support system via a mobile app, and the Point-of-Care Continued Medical Education (POC CME) being coordinated by the Mayo Clinic as a consultative virtual learning platform for TB, HIV and associated conditions. The linkage of equipment and digital processes that exist around a patient can hasten the delivery of knowledge to the point of decision-making. Dr Temesgen described how precision medicine and public health - once considered at opposite ends of a spectrum - are now being reconciled as technologies that allow knowledge on critical individual patient characteristics (such as TB strain DST and comorbidity) to be assessed and shared easily have become widely available thanks to the digital revolution to a large degree. Other opportunities such as the ethical application of artificial intelligence; and legal and ethical questions around regulating digital health devices or softwares used for clinical decision making were discussed. WHO/GTB will evaluate computer aided detection (CAD) software as applied to chest radiography for TB screening in 2020. **Slide access**

Implementation research toolkit for digital technologies and TB

Dr. Vanessa Veronese

Dr. Veronese presented an overview of the IR toolkit for for the integration and scaling up of digital technologies under programmatic setting currently in development. The toolkit has six modules that can be used in a stepwise approach or as stand-alone support tools, as per the need of the user. The objectives and overview of each module (preparing for IR, developing an IR objective, research methods, data analyses & management, IR management, knowledge translation, and resource library) were presented, along with the intended outputs (a printable/PDF version and interactive website), the timeline for completion, and planned dissemination strategy. The toolkit incorporates case studies from different countries to reflect the real-life application of digital technology within TB programmes across the four digital functions articulated in the *Digital Health for the End TB Strategy: an agenda for action;* as well as tips for NTPs on how to incorporate IR proposals into concept notes for Global Fund request applications. The toolkit will be launched later in 2020 and a training workshop on its application is being planned for high TB burden countries (in addition to the generic Massive Open Online Course or MOOC that TDR has already prepared on implementation research). **Slide access**

After the presentation, a round table discussion was facilitated by the presenter to receive feedback and comments on the elements of the toolkit (summarized below).

- Content: To consider the breadth and extent of what the toolkit will cover in the context of the audience, their needs, and incentives available at country level
- Audience: To consider framing the toolkit to target broader audience beyond NTPs, e.g. partners or other relevant stakeholders that will likely support NTPs conduct this work, including TB survivors and civil society organizations.
- Optimization pre-launching: To consider hosting an interactive online workshop to provide an opportunity for more experts and partners to provide feedback
- Optimization post-launching: To consider hosting a central online platform to receive feedback, answer questions and to update the toolkit as needed
- Experience Sharing: To encourage more countries to use the toolkit by posting reports from countries that have conducted IR.
- Mentorship: To consider maintaining a virtual mentorship roaster to facilitate capacity building, collaboration and learning
- Packaging: To consider developing short videos for each module, to summarize its content and application

New WHO Department of Digital Health and Innovation

Dr. Sameer Pujari

In 2019, WHO established a new department of digital health and innovation under the chief scientist. The department's mission is to better harness and steer the power of digital technologies for health. Following the release of evidence based recommendations on digital interventions for health system strengthening – released in early 2019 –the department, upon the request of Member States, has developed a draft global strategy on digital health, for consideration at this year's Executive Board and World Health Assembly. Dr. Pujari shared the goals of the strategy, which are (i) to promote global collaboration, (ii) to advance transfer of knowledge and support the implementation of national digital health strategies; (iii) to strengthen governance for digital health, as well as (iv) to enhance people-centred care enabled by digital health. Dr Pujari also shared the structure of the new department, and introduced its Technical Advisory Group (established in 2019), and a roster of experts it plans to engage and work with post 2020. These experts will be called upon to advise WHO across a variety of aspects of digital health. Following questions from participants, Dr. Pujari announced ongoing work the new department is steering, in collaboration with ITU and Member States on principles and agreements for multi-country data sharing and storage, taking into context dimensions of interoperability, privacy, security and confidentiality. Ms. Jacqueline Huh, of the Stop TB Partnership, announced recent discussions to establish a task force on digital technologies within the partnership. **Slide access**

New Global Fund grant development 2020 and digital technologies

Dr. Nnamdi Nwaneri

Dr. Nwaneri presented an overview of the Global Fund's 2020-22 allocation and strategy, and reiterated Global Fund's support for countries interested in scaling up and integrating evidence-based digital technologies to accelerate end TB efforts. Overall, the total allocation for TB has increased by 19% in the current cycle, allowing Global Fund to increase allocation to eligible countries. Dr. Nwaneri also presented potential opportunities for further investment by the Global Fund in appropriate digital technologies, innovations and operational research in countries. The Global Fund has already invested over US$170 milllionin TB operational research so far and encourages countries to invest in further relevant operational research. These include (i) as part of the regular grant funding application; (ii) the TB catalytic funding/investment, through which additional funding is made available to support innovative approaches to finding missing people with TB in the 20 eligible countries; and (iii) using portfolio optimization to fund prioritized interventions during the grant implementation cycle. **Slide access**

Conclusions and way forward

At the conclusion of the meeting, Dr. Falzon presented a brief summary of the day. He thanked experts who had served on the past *WHO global task force on digital health for TB* that ended its tenure in 2019 as we enter a new era with the creation of new expert groups by the WHO Department of Digital Health and Innovations, as well as with the establishment of the Stop TB Partnership task force targeting scale-up of digital technologies.

As a next step, WHO/GTB together with the Special Programme for Research and Training in Tropical Diseases is planning a multi-country workshop to pilot and receive inputs on the elements of the implementation research toolkit. Participants will receive drafts of the toolkits to comment upon ahead of its finalization in the coming weeks.

Prof. Thomas Geiser (treasurer of ERS) and Mr. Werner Bill (Executive Director, ERS), on behalf of ERS that funded the meeting, thanked the participants for their contributions during the day and in the past years. They announced that digital health will be one of the main themes of the ERS Congress in September 2021 in Barcelona and invited WHO/GTBto co-organise sessions on the theme and TB in the coming months.

Annex 1 – Programme

Venue: WHO Geneva, Switzerland - UNAIDS Building 4th floor: Room D46025
Date: 7 February 2020
Chairs: WHO (Dennis Falzon) / ERS (Vitalii Poberezhets) / WHO CC digital health for TB (Zelalem Temesgen)

Time	*Session*	*Speaker*
08:45-09:19	Registration	
09:10-09:25	Welcome and introductions	Tereza Kasaeva (WHO)
09:25-09:45	WHO / ERS activities on digital technologies for TB and meeting objectives	Dennis Falzon (WHO)
09:45-10:00	Implementation research, digital technologies and TB	Cecily Miller (WHO)
10:00-10:45	TB REACH and ASCENT projects on digital adherence technologies	Amera Khan (Stop TB Partnership) Kristian van Kalmthout (KNCV)
10:45-11:00	*Break*	
11:00-12:30	Updates on implementation research from countries undertaking innovations: progress, challenges, successes (China, India, S Africa, Philippines, Belarus)	National programme staff
12:00-13:00	New perspectives in digital technologies for TB care	WHO Collaborating Centre on Digital Health and precision medicine for TB (Mayo Clinic, US)
13:00-14:00	*Lunch*	
14:00-15:15	The implementation research toolkit for digital technologies & TB: introduction to purpose and features (as they apply to digital adherence technologies; electronic recording; connected diagnostics & eLearning)	Vanessa Veronese (TDR); presentations and moderated discussion
15:15-15:45	New WHO Department on Digital Health and Innovations (& its expert groups)	Sameer Pujari
15:45-16:15	*Break*	
16:15-16:45	New Global Fund grant development 2020 & digital technologies: forthcoming opportunities for innovation and operational research	Nnamdi Nwaneri & discussion
16:45-17:15	Views of technical and funding agencies on digital technologies for TB	All participants
17:15-17:45	Next steps until finalisation of toolkit and conclusions	WHO / ERS

Annex 2 – Participants

Participants	Affiliation
Thomas GEISER	Treasurer, European Respiratory Society (ERS), Lausanne, Switzerland
Werner BILL	Executive Director, European Respiratory Society (ERS), Lausanne, Switzerland
Vitalii POBEREZHETS	ERS digital health group representative, National Pirogov Memorial Medical University, Vinnytsia, Ukraine
Yohannes MOLLA	ASCENT programme manager, Ethiopia
Andre VILLANEUVA	ASCENT programme manager, Philippines
Nontobeko NDLOVU	ASCENT programme manager, South Africa
Baraka ONJARE	ASCENT programme manager, Tanzania UR
Katya GAMAZINA	ASCENT programme manager, Ukraine
Alena SKRAHINA	Republican Centre on TB, Minsk, Belarus
Donna Mae GEOCANIGA-GAVIOLA	Project Coordinator (M&E), DOH-National TB Control Program (NTP) Management Office, Philippines
Richard LESTER	Assistant Professor, Division of Infectious Diseases, Department of Medicine, The University of British Columbia Vancouver, Canada
Richard GARFEIN	Professor, School of Medicine, Division of Global Public Health, UC San Diego Central Research, San Diego, USA
Achilles KATAMBA	Makerere University, Kampala, Uganda
Matthew QUAIFE	TB Centre, LSHTM, Keppel Street, London, UK
Salome CHARALAMBOUS	Aurum Institute for Health Research
Zelalem TEMESGEM	Executive Director, WHO Collaborating Centre for Digital health and precision medicine for TB, Mayo Clinic Center for Tuberculosis Division of Infectious diseases, Rochester, USA
Bruce THOMAS	Founder & Managing Director, The Arcady Group, Richmond, USA
Kristian van KALMTHOUT	Digital health officer, KNCV Tuberculosis Foundation, The Hague, Netherlands
Jens LEVY	KNCV Tuberculosis Foundation, The Hague, Netherlands
Chris ISAACS	Managing Director, Connected Diagnostics, Chiddingstone Hoath, Kent, United Kingdom
Jacqueline HUH	Strategic Initiatives & Innovative Financing Team, Stop TB Partnership, Geneva, Switzerland
Amera KHAN	Innovation & Grants Team, Stop TB Partnership, Geneva, Switzerland
Draurio BARREIRA CRAVO NETO	Senior Technical Manager, UNITAID, Geneva, Switzerland
Nnamdi NWANERI	Global Fund to Fight AIDS TB and Malaria, Geneva, Switzerland
Sudarshan MANDAL	Additional DDG, Central TB Division, Ministry of Health and Family Welfare, New Delhi, India
Vadim TESTOV	Acting Director, Ural Research Institute for Phthisiopulmonology, Yekaterinburg, Russian Federation
Nazir ISMAIL	Centre Head, Centre for Tuberculosis, National Institute for Communicable Diseases Johannesburg, South Africa
Yinyin XIA	National Center of TB Control and Prevention, China CDC, Beijing, China (People's Republic of)

Participants	Affiliation
Muhammad Amir KHAN	Pakistan
Ficard NDAYIMIRIJE	Burundi
Tereza KASAEVA	WHO UCN GTB
Matteo ZIGNOL	WHO UCN GTB
Dennis FALZON	WHO UCN GTB
Nebiat GEBRESELASSIE	WHO UCN GTB
Cecily MILLER	WHO UCN GTB
Saskia DEN BOON	WHO UCN GTB
Hazim TIMIMI	WHO UCN GTB
Tomas MATAS	WHO UCN GTB
Sameer PUJARI	WHO SCI DHI
Thomas Dale HIATT	Technical Officer (Tuberculosis), WHO Philippines
Olumide OGUNDAHUNSI	Scientist, RCS, TDR, Geneva, Switzerland
Vanessa VERONESE	Consultant, IIR, TDR, Geneva, Switzerland
Edward Mberu KAMAU	Technical Officer (Research), HQ/TDR/RCS, TDR, Geneva, Switzerland