

DIGITAL HEALTH FOR THE END **TB** STRATEGY: AN AGENDA FOR ACTION

THE
END TB
STRATEGY



ERS EUROPEAN
RESPIRATORY
SOCIETY
every breath counts



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Organization**

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DIGITAL HEALTH FOR THE END TB STRATEGY: AN AGENDA FOR ACTION

“Digital health will be critical in helping us reach our new global targets to end the TB epidemic.”

Dr Mario Raviglione, Director, WHO Global TB Programme

“We remain committed to supporting the use of information and communication technology to save lives.”

Professor Elisabeth Bel, President, European Respiratory Society

KEY DEFINITIONS & ACRONYMS

Crowdsourcing: services, ideas or content obtained through the contribution of a large group of people, and especially from an online community.

Digital health: a collective term for eHealth and mHealth technologies.

eHealth (electronic health): the cost-effective and secure use of information and communication technology (ICT) for health and health-related fields.

eLearning: the use of electronic technology in learning and teaching.

Gamification: the application of game techniques to education.

Information and communication technology (ICT): the means employed to provide access to information through internet, wireless networks, mobile phones and other communication or media channels.

mHealth (mobile health): a component of eHealth involving the provision of health services and information via mobile technologies such as mobile phones, tablet computers and personal digital assistants (PDAs).

Scalability: the ability of a system, network or process to handle a growing amount of work in a capable manner or its ability to be enlarged to accommodate that growth.

SMS: short messaging service for sending text via mobile phones.

VOT: video (or virtually) observed therapy with the possibility of medical care or social support.

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DIGITAL HEALTH FOR THE END TB STRATEGY: AN AGENDA FOR ACTION

Scaling up the TB response in the post-2015 era through information and communication technologies

Tuberculosis (TB) remains an urgent global public health threat (1). Information and communication technology (ICT) presents opportunities to address this challenge on different fronts. Various innovative eHealth (electronic health)

and mHealth (mobile health) projects have been initiated by TB programmes and technical partners worldwide in support of their efforts to improve TB treatment and prevention. The rate

THERE ARE NOW OVER 7.5 BILLION MOBILE PHONE CONNECTIONS GLOBALLY, AND ABOUT 40% OF THE WORLD'S POPULATION IS USING THE INTERNET

by which ICT has developed and diversified in recent years can only be described as revolutionary and the consequent opportunities are huge. By mid-2015 there were over 7.5 billion mobile phone connections globally, and about 40% of the world's population had

an internet connection (Figure 1). Smartphones are progressively replacing less sophisticated mobile phones all over the world.

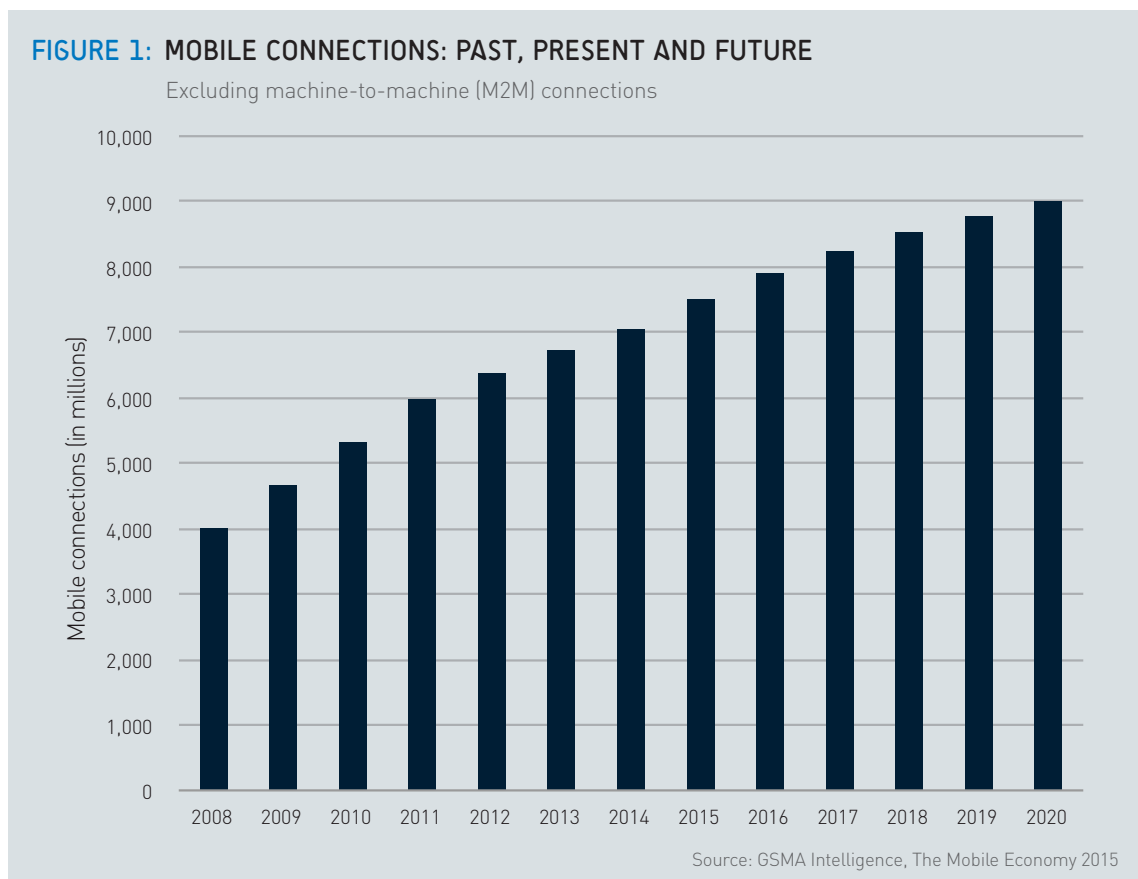


FIGURE 2: END TB STRATEGY – PILLARS AND PRINCIPLES



Why an agenda for action?

This agenda outlines the strategic direction that the Global TB Programme of the World Health Organization (WHO) is mapping out to promote the integration of digital health concepts into TB prevention and care activities. The document is primarily intended to inform TB decision-makers at national and international levels. Its alignment to the principles and the three pillars underpinning WHO's new *End TB Strategy* (2,3) (Figure 2) will help them coordinate their various efforts in one common direction in the coming years.

The products and critical activities discussed in this agenda are premised upon the pressing needs and realities of TB programmes, of which three are particularly important:

- The current difficulties faced by managers and other decision-makers to match needs in TB prevention and care to the most appropriate digital health solutions. This is a result of the limited evidence base for the

effectiveness of many digital health interventions for TB and the rapid advances in technologies of which potential users may be unaware.

- The need for an articulated and step-wise approach to develop comprehensive digital health solutions to support the *End TB Strategy*, in particular to limit fragmentation of efforts, leading for instance to multiple systems, redundancy and resource wastage.
- The opportunity to build upon, seek related synergies and align with promising ICT initiatives, both within health care and beyond, so as to increase the efficiency, scalability and sustainability of efforts.^a


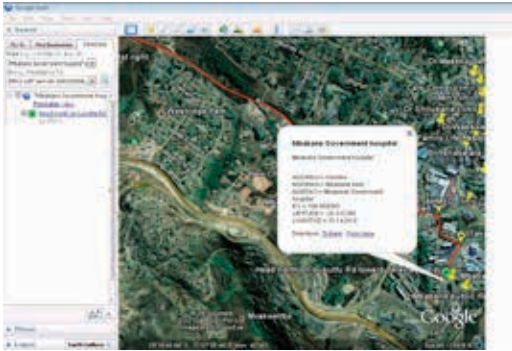
WHO will support the continued collation of the evidence and best practices for various digital health endeavours in TB prevention and care. This will make a stronger 'investment case' for innovative development and the essential implementation of digital health initiatives at scale.

^a Subscribing to general healthy approaches in digital development (see also digitalprinciples.org).

FRAMEWORK FOR DIGITAL HEALTH IN THE END TB STRATEGY

In recent years, the WHO Global TB Programme has been following the development and uptake of various digital health products by TB programmes. The conceptual framework shown below classifies these initiatives into four basic functions. The utility of some of these interven-

tions for health conditions and risks beyond the immediate purpose of TB programmes – such as diabetes and tobacco control – is part of the holistic approach at heart of the 2nd pillar of the *End TB Strategy* and the United Nation’s Sustainable Development Goals (4).

FUNCTIONS	POTENTIAL APPLICATIONS	SOME INNOVATIVE EXAMPLES
Patient care and “eDOT”	<p>Video (virtually) observed treatment (VOT) [Box 1]</p> <hr/> <p>Drug administration monitoring devices [Box 2]</p> <hr/> <p>SMS communication for treatment and follow-up</p> <hr/> <p>Telephone or web-based interventions, for smoking cessation among TB patients</p> <hr/> <p>Enablers or incentives for adherence to TB treatment (e.g. cash transfers, free airtime)</p>	<p>Kenya – Cash transfers through mobile banking to people with multidrug-resistant (MDR-TB): Kenya’s extensive mobile communications network and widespread use of cellular phones enable cash transfers through mobile banking to MDR-TB patients to support their treatment.</p> 
Surveillance and Monitoring	<p>Notification of TB episodes to existing electronic surveillance systems [Box 3]</p> <hr/> <p>Reporting drug safety concerns</p> <hr/> <p>Mapping of patient location</p> <hr/> <p>Feedback from service users</p> <hr/> <p>Operational research on transactions between community health workers, patients and facilities</p>	<p>Swaziland – Matching MDR-TB patients’ residence to treatment supporters. In Swaziland, health managers can see maps of treatment facilities and how they relate to the location of MDR-TB patients and treatment supporters’ homes (as captured on GPS-enabled phones).</p> 

FUNCTIONS	POTENTIAL APPLICATIONS	SOME INNOVATIVE EXAMPLES
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Programmatic management

Stock levels of equipment, medicines and other consumables

Management and coordination of logistics

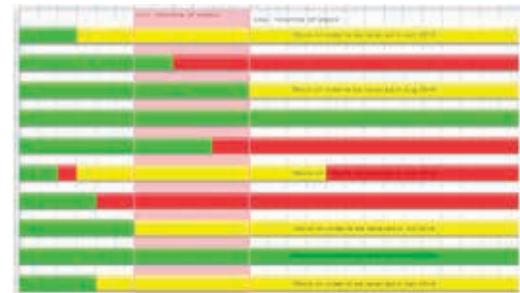
Drug ordering and management systems

Mobile access to patient medical records

Communication of test results on TB and comorbidities (e.g. HIV, diabetes)

Drug forecasting – Avoiding drug stock outs using software:

To make sure no patient’s treatment is interrupted due to lack of medicines, the QuanTB programme creates a dashboard for managers to see how long current drug stocks are forecast to last and when new drug orders should be placed [Box 4].



eLearning

Self-teaching tools for patients and health care providers on healthy lifestyles (e.g. smoking cessation, diabetes management)

‘Apps’ containing guidelines and diagnostic aids

Social networking forums and other tools for civil society engagement

Health professional education – Online platforms on clinical and public health topics including TB [Box 5]



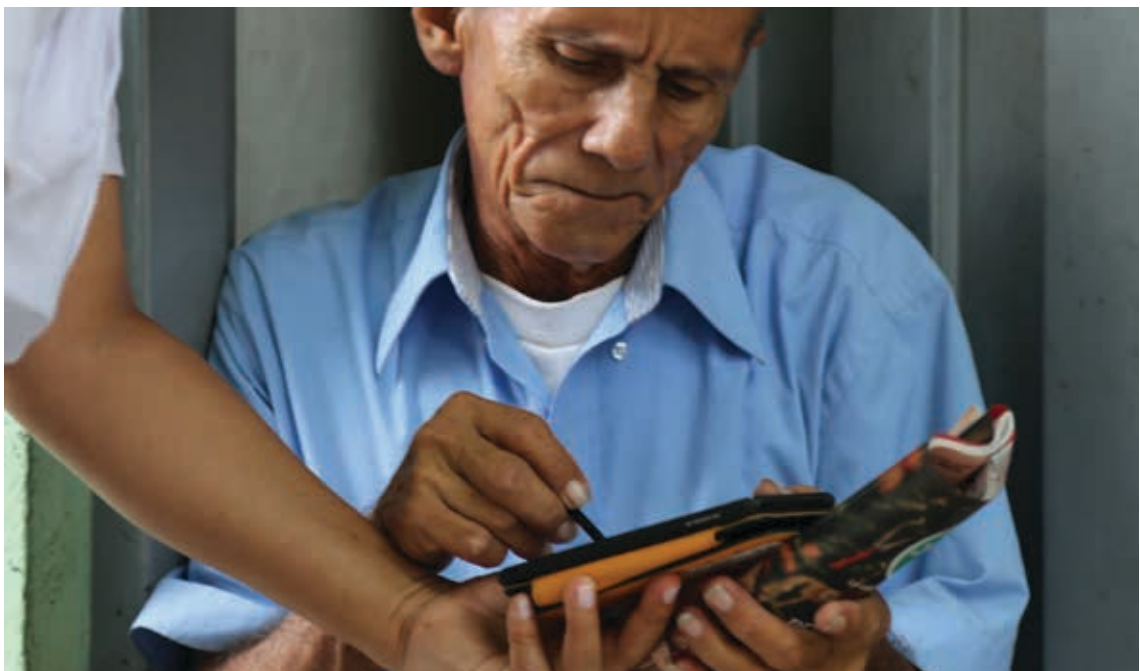
EVIDENCE, DIGITAL HEALTH AND TUBERCULOSIS

Strengthening the knowledge base where there is uncertainty and investing in what we know works

Field experience with digital health interventions for TB and other health conditions is growing. However, there is a need for better quality evidence of more relevance to programme implementation. One important question is: what type of evidence is required to support the operationalization of digital health in TB programmes? Several digital health approaches need to be validated under a more diverse set of conditions, including geographical spread, different levels of decentralization and models of care, and in a larger cross-section of patient sub-groups. Certain interventions – such as SMS reminders, medication monitors and video (virtually) observed therapy (VOT) to support patient adherence – have been studied more frequently under

randomized controlled trial conditions than other more complex interventions, such as eLearning for patients or professionals, or laboratory information systems. This is largely because classical study design lends itself better to interventions that are relatively discrete and well standardized; for which the collection of quantitative data on both the intervention and the outcome is straightforward; allowing randomization and comparison groups; and where large numbers of study participants can be recruited. A number of trials are under way for such interventions [Boxes 1 and 2]. Moreover, certain mHealth activities are implemented on the basis of evidence for the treatment of conditions other than TB (such as HIV), meaning that inferences may not always be direct.

**MONITORING AND EVALUATION
NEED TO ACCOMPANY THE
OPERATIONALIZATION OF DIGITAL
HEALTH PRODUCTS FOR TB**



The increased deployment of cutting-edge digital health concepts will bring greater power, speed, flexibility and diversity to the same computerized processes that have been helping public health practitioners, managers and clinicians to deliver better TB care to populations and patients for several decades. Thus, for instance, the gradual transition in the management of medical records and surveillance systems – from paper-based methods, through electronic systems installed on isolated computer terminals to systems on local area networks and internet-accessible databases – is an evolution over a continuum that happened in the space of a few decades. Such processes are not easy to evaluate with efficacy trials and users would benefit from the description of best practices and lessons learnt narratives [see [Boxes 3 and 4](#)]. It would be a missed opportunity if the adoption and large-scale roll out of such technological advances is put on hold until suitable studies have been devised and completed. Nonetheless, basic principles which apply to analogous interventions – such as how to protect patient confidentiality and ensure that data are valid, safely stored and not corrupted – must be followed when implementing digital health interventions.

Just as monitoring and evaluation have become integral to many TB programme activities, they should also apply to digital health at the local level. Improving this knowledge base could increase opportunities for more of the successes and failures to be fed into a cycle of continuous quality improvement. There are various options for achieving this aim, ranging from automating error logs and crash reports (e.g. for electronic surveillance systems), building in user feedback modules (e.g. in eLearning packages) and also holding regular audit reviews with system users to analyse critical episodes. Implementation research to document gaps, bottlenecks and good practices will be important for continued advancement.

Evidence for SMS reminders and VOT

The potential for mHealth to improve patient outcomes is attracting increasing interest. The knowledge base for treatment adherence in TB is largely limited to observational studies and focus group discussions. However, this is set to change as the results from randomized controlled trials employing mobile phones in very contrasting settings will be released in a near future. The video function on smartphones has the potential to save resources when used to observe treatment and support patients. VOT is becoming more feasible as internet-enabled phones increasingly dominate the mobile phone markets in both rich and poor settings [[Figure 3](#)]. Randomized controlled trials are looking at the efficacy of smartphone VOT among TB patients. Mobile phone interventions can also help people to stop smoking, by providing motivation, support and tips to smokers on how to quit.

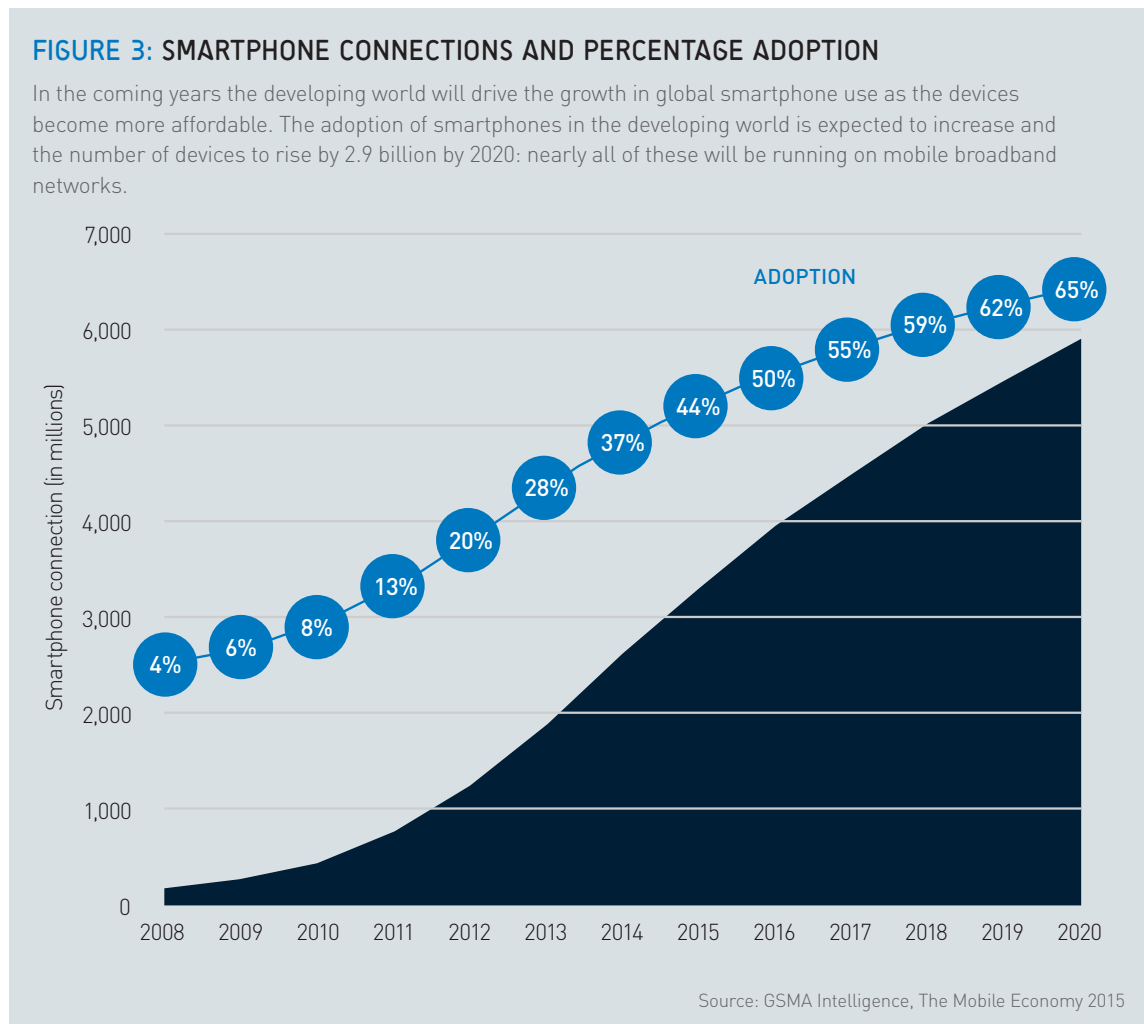
eLearning: approaches, rationale and evidence

Electronic media and devices are now being used in many teaching and learning activities, including those related to health care. eLearning is employed on a continuum moving from limited support of conventional textbook and classroom learning ('blended' approach) to approaches that are delivered entirely online. Both health care workers (formal or lay) and patients can benefit from eLearning. eLearning has the makings of a transformative intervention, by virtue of its potential to reach huge number of users across geographical space, diversity, and resource-availability, offering great promise for rapid and efficient scale-up. It is also likely to reduce costs, improve speed by which training and refresher courses are delivered, and permit access to a vaster spread of experts, peers and novel curricula. eLearning has the added advantage that it provides both the learner and the experts with greater flexibility, allowing learners to work at their own pace and to adapt their learning paths to

their personal needs and preferences. Innovative approaches such as the application of game techniques to education, and technologies like augmented reality and 3-D learning environments are more conducive to 'immersive learning'. One of the risks of eLearning is the tendency for the depersonalization of teaching and training. There is also a significant need for the maintenance and updating of eLearning course material, which is often neglected. Greater interaction between eLearning participants may allay student feelings of isolation, another risk of online learning which has been associated with considerable student dropout rates. eLearning resources are still frequently text-heavy and not always appropriately customized for the virtual environment and for mobile devices (smartphones or tablets) in

particular. Programmes also tend to focus on one particular disease and to lack balance in relevant background subject matter (e.g. too much focus on TB and less on other pulmonary conditions or health risks such as smoking).

There is as yet limited research published comparing the outcomes of eLearning with more traditional methods of acquisition of knowledge in the fields of medical education and health care. However there is a growing literature which supports the benefits of web-based training and use of multimedia techniques. In addition, online tobacco cessation courses have been shown to improve the self-reported acquisition of skills to counsel patients on tobacco cessation.



MATCHING TB NEEDS WITH DIGITAL HEALTH SOLUTIONS

Using target product profiles to focus discussion on the most promising avenues for priority action

The operationalization of the *End TB Strategy* requires that TB programmes, other national authorities and all stakeholders re-examine how their respective objectives must evolve in order to align with the post-2015 trajectory. Digital health products are destined to play a pivotal role in this process, given that ICT is indispensable to implementing most if not all interventions, be they old or new, and whether they relate to patient care, surveillance, programme management, staff development or the engagement of communities.

Since the end of 2014, the WHO Global TB Programme and the European Respiratory Society have jointly led a consultation among a broad cross-section of stakeholders to identify eHealth and mHealth concepts that are advantageously positioned with respect to the priority needs of TB programmes. In this process, a set of target product profiles (TPPs) have been elaborated as a way of matching these pressing needs to existing digital health solutions. By identifying these products the discussants considered also their potential to be applied at a scale large enough to have a substantial impact at country and global level. These TPPs will define the features of the desired solutions and thus characterize the particular need in sufficient detail and transparency to stimulate more interest from potential developers. TPPs are dynamic discussion tools that are revised in the development process, particularly in this case, where a rapidly-evolving technology is expected to constantly present novel solutions to a new global strategy that

requires fundamental changes to the way that TB strategies have been approached until now.

The TPPs will eventually need to evolve into more detailed technical specifications for the design of concrete products. They will not by themselves cover all the issues needed for the successful implementation of the products, such as the associated human resource development and regulatory changes. Several concepts and products that are also deserving of consideration may not have been captured by the TPPs included in this document: these include electronic monitoring of the use of medication containers, drug procurement tools, many telemedicine initiatives, as well as add-on hardware that convert smartphones into instruments for clinical measurement. Some examples of these are illustrated in [Boxes 2 and 4](#). Future initiatives by technical or funding agencies to take forward TPPs additional to the ones in this agenda would be an encouraging development.

The introduction of new technologies into a setting needs to be coordinated to minimize piecemeal approaches, and to ensure alignment with eHealth strategies that countries already have. They need to be consistent with other technologies and approaches that are already in place (5,6). Finally, it is expected that the process for designing, building and rolling out a digital application embraces a broad cross-section of representative users and policy-makers, one that engages with them and that supports their efforts.



Patient care

Video treatment support (VOT) for TB patients via mobiles

The long duration of TB treatment requires sustained commitment by both patients and health providers to ensure a successful result. Communication with the caregiver via internet-based video (video (or virtually) observed therapy; VOT) can help support patients to complete their treatments. The observation of patients taking their medication remotely can still allow useful discussion while cutting down on time lost and travel costs.

Key features for a VOT product that could make it effective at a large scale include:

- The video communication is transmitted live or self-recorded over a secure internet connection, allowing confidential on-line chat between the patient and the health care provider. It would typically employ affordable smartphones or tablet computers provided to the patient, along with a data plan for the communication.
- Apart from supporting the administration of TB medication, VOT may address associated health and social issues that patients have, especially when visual contact between care provider and patient is important. This could apply for instance to tobacco cessation, concurrent antiretroviral medication or drug-replacement therapy.
- The application can interoperate with patient electronic medical records and other existing digital products.
- The software generates a log that can be used for the provision of enablers to patients, in the form of cash transfers or mobile credit, as well as for implementation research.

eHealth portal to improve TB and tobacco care

One single web address will allow the TB patient and health care provider to locate the different health services available. This will help promote choice and diversity of care for both TB and other health conditions, or risks relevant to the individual patient, such as tobacco smoking and diabetes. Using a mobile device or a desktop connected to internet, the one-stop hub will allow the user to navigate easily towards resources such as information on clinic access, on treatment and healthy lifestyles, on helplines and quit-lines, on mobile phone apps to support adherence, and on social networks for peer-group and professional support.

The portal will function closely with other web-products focused mainly on educating patients, caregivers, public and professionals (see under eLearning below). Some of the key features the product needs to demonstrate include impact at large scale and sustainability:

- Uses intuitive and graphical approaches with easy-to-follow instructions.
- Provides complementarity to the human interaction between patient and carer, and upholds the principles of patient-centred care.
- Conforms to the national eHealth strategy and is integrated with other existing digital utilities for public services.
- Organized and updated by a clearly-identified mechanism with sustainable resources allocated for the purpose.
- Allows access through full range of internet browsers and screen sizes.



BOX 1: USING VIDEO-ENABLED MOBILE DEVICES TO SUPPORT TB PATIENTS WHEREVER THEY ARE

The DOTS strategy – which was launched in the early 1990s when the global TB emergency was declared – included direct observation of treatment as one of its five core components. The concerns around close, regular support to patients remain ever as topical today, as increasing numbers embark on TB treatment lasting at times two years or more. Many patients now also need support for associated health conditions and lifestyle risks that may influence their outcomes. Over time, a number of innovations have been proposed, designed, tested and implemented to minimize the inconvenience and expense for patients to travel daily to and from clinics for treatment observation. One of the most recent and promising of these has been live or recorded video conferencing via telephone. Early work from Mexico and the United States employing mobile phones attests to the potential for video (or virtually) observed therapy (VOT) to save resources and improve engagement when used to observe TB treatment and support patients remotely. In the United Kingdom, a multi-centre clinical trial, in partnership with the Find & Treat service, is now providing patients with free smartphones and data subscription to facilitate VOT. Two randomized controlled trials have now started in the Republic of Moldova and the UK to investigate the effectiveness of VOT for TB. It is likely that TB programmes in low- and middle-income countries will increasingly consider VOT to improve communication between caregivers and patients as

the availability of broadband internet and affordable smartphones increases.

VOT subscribes to the principles of patient-centred care, respecting the patient's autonomy and individual preferences, and promoting a more holistic approach to the care of patients with multiple diseases or health risks. The intervention is expected to make savings for the patients in time, cost and physical exertion associated with regular travel to health care facilities; it is also likely to reduce stigma for patients visiting clinics or having a nurse coming to their homes every day. As with other e/mHealth products, VOT is not a 'magic bullet' intervention destined to substitute all face-to-face interaction with health professionals. Neither will it address all the dimensions required for case management. But it has the makings of a valuable addition to the future package of approaches available for care. It also provides the possibility to explore synergies between different ways of helping TB patients, including others that are mobile-phone mediated (e.g. interaction with SMS communication and electronic medication monitors (see Box 2)). The objective for VOT in TB is to reduce patient and provider burden without sacrificing any of the benefits of traditional methods of monitoring TB medication adherence. VOT needs to be rigorously evaluated in a range of settings and show real advantages over other interventions intended to improve patient adherence to TB treatment.



BOX 2: ELECTRONIC MEDICATION MONITORS FOR TB PATIENTS IN LOW-RESOURCE SETTINGS: HISTORY, EVIDENCE AND FUTURE PERSPECTIVES

Poor medication adherence is a significant barrier to realizing the full benefits of long-term therapy for conditions such as TB. In many settings, TB patients are constrained to self-administer their medication with little support from formal health care workers in the course of their long regimen. Under these circumstances, new approaches to adherence monitoring are urgently needed that are affordable, scalable and of proven effectiveness. Aids to remind patients to take medication regularly have included appliances to monitor the opening of pill boxes, which have a long history in the field of TB care. As technology advanced over recent decades, these medication monitors have also come of age. Electronic medication event monitors can now be equipped with reminding features to provide dosing and refill reminders to patients, and to collect and transmit detailed, patient-specific dosing histories. These details provide insight into discontinuation behaviour, and adherence patterns – feedback that is useful to improve adherence. TB-customized reminder-monitors were recently evaluated in a

13-month, 4200 patient cluster-randomized trial in China, in which TB medication implementation and persistence were supported using various mobile phone and monitor-based interventions. In this trial, reminder-monitors were more effective than mobile phone interventions in reducing treatment interruption; the combination of SMS reminders and monitor-based counselling yielded an approximate 45% improvement in patient medication adherence. Monitors were also found to be highly acceptable to both patients and providers. A second cluster randomized trial, designed to evaluate the impact of reminding-monitoring on both TB medication adherence and on health outcomes is planned to start in early 2016. To use today's health system resources more effectively in reducing TB morbidity and mortality, and forestall the development of drug-resistance, it is important for TB patients to have more effective help with medication to avert disruptions. Recent improvements in the function, affordability and scalability of electronic monitoring create exciting opportunities to achieve this goal.



Surveillance and monitoring

Digital dashboard for TB indicators and epidemiological trends

In order to improve the understanding and use of surveillance data, decision-makers need ready access to key summary indicators on TB, associated conditions and health risks, such as diabetes, HIV and tobacco use. The digital dashboard will provide snapshots and graphical displays through which health care providers and public health officials can interact when they wish to know about the impact of TB programme efforts and the background epidemiological trends, such as the clustering of cases.

A number of examples of such products exist linked to TB surveillance systems as well as patient databases, allowing efficient summarization across different administrative divisions of a country (for some examples see (7) and (8) and [Boxes 3 and 4](#)). A meaningful and large-scale implementation of such a product would require that:

- Software developers are closely informed of what users at local, regional and national levels need in order to facilitate their work. To create utilities that add value developers also need to understand how to derive and stratify indicators, what software options could serve the users best and to give users the possibility to customise outputs to their needs
- The tool is user-friendly and has the agility to interact with the main electronic registers in the country and derive basic graphs, tables and shaded maps, as well as more advanced cartography of the distribution of cases over space and time. The possibility to download outputs as images or publish them online are important features.

Digital notification of TB cases

Under-notification of TB to the public health surveillance system is common in both low- and high-resource settings. As a result, opportunities for timely patient care and public health preventive action are often missed and the accuracy of national statistics – on which disease control planning depends – often suffers. This product will provide front-line public and private health care providers with a portable application to report basic information on notifiable episodes of TB, thus removing the need for the workers to complete and send paper forms, a cumbersome process that often impedes the completeness of reporting.

For the product to serve its purpose and to promote broad scale use in a country, the following key characteristics will be required:

- In order to promote standardized notification, parameters for reporting must adhere to the local legal requirements and to WHO case definitions. The number of data elements are kept to the minimum needed for public health action.
- The system can either accommodate additional information needed for the follow-up of the patient (e.g. bacteriology results, record of treatment adherence and outcome, adverse events) or can interoperate with a separate database used for this purpose.
- It facilitates the collection of data through the use of menu-driven entry to limit errors and missing information.
- Promotes the use of unique patient identifiers to enable the linking of data to existing surveillance systems (including laboratory and drug safety) and easier removal of repeat notifications for the same individual.
- Allows case notifiers to request additional services as needed for the management of care, such as social services to the patients and close contacts.

BOX 3: ELECTRONIC TB SURVEILLANCE ON A LARGE SCALE IN CHINA

In China, tuberculosis surveillance is organized through a nationwide network of about 3200 disease control centres or TB dispensaries. In 2005, an electronic Tuberculosis Information Management System (TBIMS) started to be phased in nationwide to replace paper recording. Since then the TBIMS has become more elaborated and collects key information on TB cases notified (confirmed or under evaluation) in TB care facilities. Data are exchanged in real time with the Infectious Disease Reporting System, which covers the country's 37 notifiable diseases.

By 2009, the TBIMS achieved countywide coverage. A paper-based surveillance system ran in parallel with the TBIMS from 2005 to 2008 and was discontinued in 2009, by when the difference between TB cases captured on the two systems had diminished and the TBIMS was able to capture almost all TB cases notified in the TB dispensaries. Based on WHO estimates for China in 2011, notifications for new and relapses on the TBIMS represent about 90% of incident TB cases. Completeness of data on patient bacteriological endpoints has improved over time. Data on approximately 2700 persons under evaluation for TB or with confirmed disease are notified and entered into TBIMS every day. Since 2005, the numbers of active TB cases

registered on the TBIMS have averaged to about one million annually.

The Chinese Center for Disease Control and Prevention (China CDC) analyses surveillance data from TBIMS every quarter and publishes quarterly and annual reports summarising key indicators. The TBIMS is accessible to authorized users at every level of the TB network through a password-protected website. Health personnel from provincial and prefectural TB health facilities were trained when the system was introduced; these staff in turn trained other workers at county level through a cascade system. Annual surveillance workshops provide an opportunity to discuss any problems arising with the use of TBIMS and how to improve its use. At present, there are about 20,000 users in the TB health facilities across the whole country using the TBIMS. Over the coming years, municipalities are expected to incorporate TB into the local health care surveillance system and the vision is to have this information transmitted directly to the TBIMS.

The sheer scale of the data handling and the intricate functions that the China TBIMS performs makes it stand apart from the electronic information systems for TB adopted in other countries.

Digital application for active anti-TB drug safety monitoring

Recent years have seen new drugs and regimens being introduced in the care of TB patients with TB, especially those with drug-resistant forms. As these innovations are destined to increase, national programmes will need to bolster their data systems to allow adequate monitoring of both effectiveness and patient safety. A digital application to support health care workers register drug-safety data for TB patients on treatment is therefore increasingly needed. The information provided will also facilitate timely action in case of serious adverse events and signals.

The product is envisaged to operate at large scale and have the following features:

- It provides the data needs for patients being actively monitored in a given cohort. This requires a standardized collection of data on adverse events elicited through questions as well as clinical and laboratory testing. This will complement the information from existing and ongoing trials, and will provide a more complete understanding of drug-drug interactions, for example.
- Assessment of patient status at baseline, while on treatment and after it ends.



- The product will follow the minimum data elements list for TB drug-safety surveillance (9).
- A unique patient identifier is used to facilitate the follow-up of a patient and proper assignment of outcomes.
- The adverse events observed in association with anti-TB therapy are recorded in the system and used to generate summary indicators and for causality assessment.
- Depending on the association between the event and the exposure, the programme will alert the corresponding clinicians as well as the national authorities responsible for drug-safety, and initiate appropriate preventive and curative action on affected patients and other exposed individuals.

BOX 4: E-TB MANAGER AND QUANTB: COMBINING TB PATIENT CARE WITH PROGRAMME MANAGEMENT THROUGH ELECTRONIC PATIENT REGISTERS

Treating patients with multidrug- and extensively drug-resistant TB poses a major challenge worldwide given the complicated and long-lasting nature of the regimens involved. Under such circumstances reliable information is central to the quality of patient-centred care and TB programme management. It ensures, for instance, that clinicians have all the necessary details on medication, adverse reactions, and results of testing in one place when making decisions on individual patient care. It also helps the efficient management of medicines, laboratory materials and other programme components. Electronic systems are now making this increasingly feasible and providing an important backing to different components of Pillars 1 and 2 of the End TB Strategy (3; [Figure 2](#)).

One digital solution to support TB efforts – e-TB Manager – was created by Management Sciences for Health (MSH) through a USAID-funded programme, Systems for Improved Access to Pharmaceuticals and Services (SIAPS). e-TB Manager was conceived as a web-based system to centralize information on diagnosis, treatment, medicines and laboratory use. It can generate indicators based on these activity data. By mid-2015, MSH had supported the deployment of e-TB Manager in over 2500 sites located in 10 countries in Africa, Asia, Latin America and Eastern Europe. Close

to 400 000 patient records are stored in individual format in all sites combined. As is the case for any information system, electronic registers require regular and careful updating of data to serve their clients' needs. However, experience with the use of e-TB Manager has shown that this investment bears substantial gains, such as reducing the time that supervisors need to spend to collect data on-site, thus freeing more time for them to devote to other aspects of programme monitoring.

Another electronic resource developed more recently by SIAPS is QuanTB. This tool supports the procurement, ordering and planning for TB medication and consumables. Avoiding interruptions in access and the over-stocking of drugs requires complicated quantification and projections by TB programme staff. On the basis of data on regimens and patient recruitment, QuanTB calculates and forecasts drug needs and can provide early warning alerts for stockouts. Substantial reductions in stockouts of first-line and second-line TB medicines were reported by countries using the tool. By July 2015, QuanTB was being used in Bangladesh, DR Congo, Kenya, Mozambique, Myanmar, Nigeria, Philippines, South Sudan, Tajikistan, United Republic of Tanzania, Uganda, Uzbekistan, Zambia and Zimbabwe. QuanTB can be downloaded and installed free of charge.

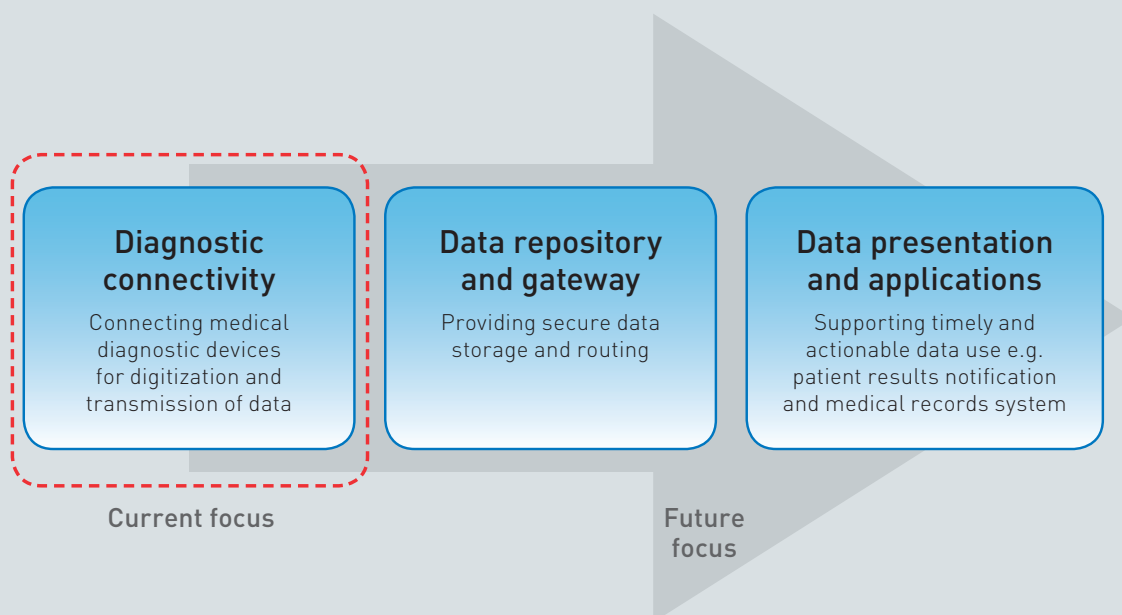
Diagnostic device connectivity for TB

In recent years, many diagnostic services in low-resource settings have started to introduce state-of-the-art rapid diagnostic tools for tuberculosis patients. While new technologies may offer faster and more accurate testing, much of this potential is jeopardized by the remaining bottlenecks in the handling of samples and results.

As with other priority products, diagnostic connectivity needs to operate at large scale in addition to smaller setups:

- Streamlining the flow of data between testing, storage and sending of results is a critical sequence of steps that must accompany the roll out of new tests (Figure 4). The first logical step in this chain – connecting different diagnostic devices together to allow them to share data in unison – is addressed by the digital health product for which the target profile is proposed.
- For diagnostic systems to make a measurable impact on patient care they should be able to communicate through a standardized digital interface, using technologies that are feasible regardless of the income level of the country or setting. The product will address the needs and constraints of laboratories and other diagnostic sites located in low-resource settings, in both centralized and decentralized situations.
- When all elements of the system are in place, the product is expected to integrate well with the surrounding laboratory information systems and other digital health systems that are relevant, including hospital information systems, patient electronic medical records and public health surveillance systems.

FIGURE 4: SCHEMATIC REPRESENTATION OF THE POSITION OF 'DIAGNOSTIC CONNECTIVITY' AS THE FIRST OF THREE COMPONENTS OF FUNCTIONAL LABORATORY INFORMATION SYSTEMS



eLearning

Information resources platform for patients on TB and smoking cessation

A diagnosis of TB often generates a demand for information from patients and their families. What is the disease? What are its implications on lifestyle? How should treatment be taken? What would be the support needed and who can provide it? eLearning can have a significant role in fulfilling such a demand. The proposed digital product aims to educate patients and their families about TB, TB care and other associated conditions – such as diabetes prevention and smoking cessation – which can also influence their care outcomes.

In order to have an appreciable impact on a larger scale, the product needs to fulfil a number of features, foremost among which are:

- Relevance of information to the demands of target users (patients and public) and complementary with other education received as part of the patient–carer interaction.
- Conformity of the information contained with WHO and European Respiratory Society (ERS) evidence-based guidelines and recommendations on TB and other conditions and health risks.
- Simplicity of access and interfacing for a broad cross-section of patients to be able to use it.

- Compatibility with browsers and operating systems most widely used on mobile phones and tablets, as well as desktop computers.
- Integration with other existing and related digital health programmes (e.g. mCes-sation) and conformity with any national strategy for eHealth and mEducation.
- Building upon established eLearning concepts including social forums for sharing of experiences from patients and caregivers, peer patient support, crowdsourcing, and state-of-the-art innovative approaches such as gamification for education.

Web-based training for health professionals on TB and smoking cessation

New interventions for TB prevention, diagnosis and treatment are expected in the coming years. These include the large-scale introduction of novel diagnostics and medicines, as well as new approaches addressing upstream determinants of TB in line with the *End TB Strategy*. Health care providers will need to acquire new knowledge and skills in order for these changes to be effectively implemented. eLearning is once again an important accessory to this end. Internet-based, self-directed learning tools on the care of TB and associated risks – particularly smoking cessation – addressing the needs of primary care providers are envisaged.



For the product to exert large-scale impact it would include, amongst others, the following critical features:

- A problem-oriented approach and evidence-based content focused on needs expected to be of topical interest to general practitioners, nurses and other primary health care staff. These include practical aids on how to design treatment regimens and manage adverse reactions.
- Alignment with other digital information resources on TB and smoking cessation available to the practitioner.
- Conformity of the information contained with WHO and ERS recommendations on TB and other conditions and health risks.
- Compatibility with browsers and operating systems most widely used on mobile phones and tablets, as well as desktop computers.
- The possibility for practitioners who complete the training to be appropriately credited through certification or continuing medical education points.

BOX 5: NEW APPROACHES TO HEALTH PROFESSIONAL LEARNING IN INDIA AS TB CARE GOES DIGITAL

Novel eLearning technologies and applications are empowering the public, patients and professionals alike to decide where, when, what and how they learn. Teaching efforts are harnessing the power of ICT thereby dramatically altering the educational landscape and the way we interact with each other and the world around us.

In India, eLearning is recognized as an important complement to formal medical education. The national Revised National TB Control Programme is also following this trend by leveraging the impressive ICT infrastructure of the country to improve its reach to a vast network of more than 600 000 health care providers involved in observing treatment and supporting TB patients. In Gujarat and elsewhere, eLearning tools in local languages are being used to improve knowledge on the roles and responsibilities of TB health care providers through interactive sessions. These tools are proving to have several advantages, by enabling the training of a large number of people simultaneously, ensuring that training is standardized and up-to-date, lowering costs for trainers and trainees, and facilitating repetition of sessions. Self-learning training toolkits, including CD-based modules to promote the

'Standard for TB care in India', are becoming popular because of the flexibility they offer and reduced demands on the physical availability of trainers. Knowledge acquisition is assessed using multiple-choice questions at the end of each module. Mobile applications with graphical messages and audio-visual clips are being used in rural and tribal areas to train rural health care providers and other workers to identify clinical manifestations of TB and facilitate referral for examination. Another mobile application under trial sends questions and answers via SMS to health care providers to increase knowledge on the diagnosis and treatment of TB. Training videos on Nikshay, the online case-based notification platform that India introduced to facilitate the mandatory notification of TB, have been rolled out and integrated within the application for learning and online reference for all data entry operators. Other digital health techniques are being used to complement eLearning efforts. For instance a toll-free helpline for patients, the general public and other stakeholders is helping to raise awareness and answer specific queries. India envisages that digital health will increasingly be integral to its implementation of the three pillars of the *End TB Strategy* in the coming years.



Clinical decision support systems for TB treatment and smoking cessation

TB is a disease that can present with different clinical manifestations and challenge the diagnostic skills of the primary care practitioner. For this reason TB may be missed or its diagnosis delayed. Prescribing the correct care plan in accordance with the latest consensus guidance may also prove difficult. The patient-centred approach envisaged by the *End TB Strategy* requires that interventions are tailored to the needs and values of the patient. A product that can assist practitioners to make clinical decisions based on the data of a particular episode could thus provide added value to other eLearning products targeting health care workers.

An application to support clinical decision-making could facilitate the daily work of many practitioners and help optimize the treatment of TB patients who may have other co-morbidities or health risks. For its successful roll-out, the product would need to feature a number of key characteristics, namely:

- A single interface will provide general practitioners, nurses and other health care workers with automated responses through inbuilt algorithms, based on clinical scenarios.
- Apart from the offline element, the application will also enable access to expert advice from TB and lung specialists for primary care providers to make informed decisions for their patients (such as via online networks like www.tbconsilium.org for the management of multidrug-resistant TB (MDR-TB)).
- The application will be compatible with browsers and operating systems most widely used on mobile phones and tablets, as well as desktop computers.
- Conformity of the information contained with WHO and ERS recommendations on TB, as well as other conditions and health risks.
- Agile software backed with a support structure to ensure adaptations (e.g. translation) and regular updates of content, fixing of bugs and response to user feedback.



DIGITAL HEALTH AND THE END TB STRATEGY

Entry points for different products within the components of the End TB Strategy

Ending the global TB epidemic will require a drastic reduction in TB incidence and mortality from the current levels [2]. Achievement of this goal by 2035 will require action within three pillars:

1. Expanding the scope and reach of interventions for TB care and prevention, with a focus on efficient, high-impact, and patient-centred approaches.

2. Maximizing the benefits of health and development policies and systems, by engaging a broader cross-section of actors across government, communities and the private sector.

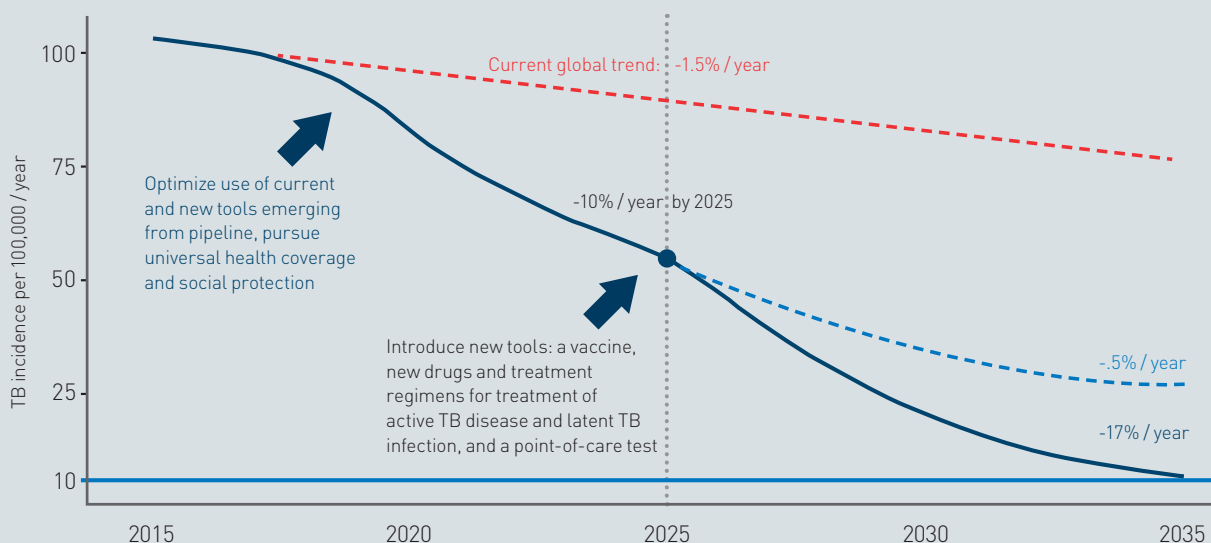
3. Pursuing new scientific knowledge and innovations that can dramatically change TB prevention and care.

Digital health interventions can contribute to all three pillars. They will be important to achieve the early targets envisaged by the *End TB Strategy*, when programmes will need to be creative to optimize the effectiveness of current

approaches to TB care and prevention (Figure 5). For instance ICT needs to be applied more consistently to improve patient care (e.g. support to adherence and registration of medical records), surveillance (e.g. improved notification and

WITH ITS BROAD SCOPE, DIGITAL HEALTH HAS VARIOUS POTENTIAL ENTRY POINTS WITHIN ALL COMPONENTS OF THE END TB STRATEGY

FIGURE 5: PROJECTED DECLINE IN GLOBAL TUBERCULOSIS INCIDENCE IN 2015–2035 AS ENVISAGED BY THE END TB STRATEGY



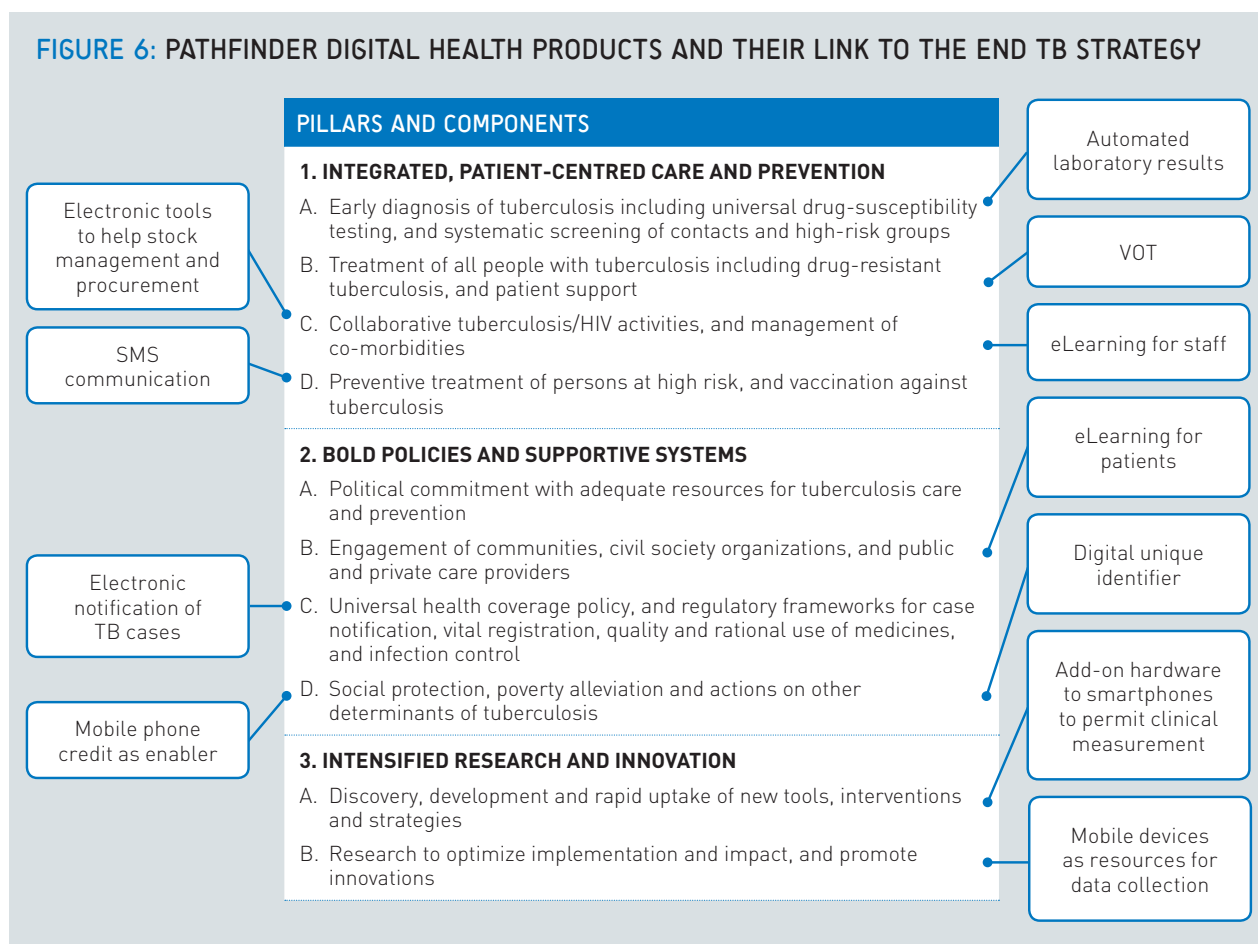
drug-safety monitoring), programme management (e.g. laboratory management and drug procurement), and eLearning for patient education and professional development (Figure 6).

Moreover, digital health has a far-reaching potential to help address more upstream determinants of TB, a principle underpinning the second pillar of the *End TB Strategy*. For instance, ICT is required for the reliable assignment and management of unique personal identifiers, a crucial element in the promotion of universal health care and in granting greater access to the social support to which people are entitled. Similarly, schemes to enable healthy behaviours can be mediated more readily when records and monetary transfers

are automated. And in the later phases of the strategy, ICT will remain an important factor for the large-scale roll-out of new diagnostics and novel measures to prevent TB and to improve TB patient outcomes.

Wider use of ICT needs to follow closely the rapidly advancing state-of-the-science of the methods employed, and to contribute to the knowledge about when and how they are best applied. The growing body of evidence and documented best practices on digital health will thus be an important resource for decision-makers and needs to be enriched by more experience gathered systematically from the field, in support of the third pillar of the strategy.

FIGURE 6: PATHFINDER DIGITAL HEALTH PRODUCTS AND THEIR LINK TO THE END TB STRATEGY



UNITING DIGITAL HEALTH EFFORTS TO ONE COMMON PURPOSE

Operationalization of priority products when countries implement the End TB Strategy

'Thinking digital' needs to be one of the recurring motifs when bringing national TB strategic plans, TB guidelines, budgets, grant proposals and other documents in line with the concepts of the *End TB Strategy*. This process should align to the fast pace with which ICT advances, so that solutions do not lose their edge between the time that they are conceived to when they are implemented. A sequence of key steps is proposed for decision-makers to follow when digital health is operationalized at country level:

- Champions within the TB programme who have the vision, knowledge, authority and drive will need to **steward** the necessary changes. They need to unify different concepts into a single vision. A group of key stakeholders – representing TB, public health, ICT, mobile and internet network providers, technical agencies, private caregivers, patients and donors – is needed to advise in different areas. Multidisciplinary 'consortia' of developers and designers, users and donors could be assigned to specific tasks and to develop particular concepts.
- **Pillar 2** components that lie beyond the span of control of the TB programme or even the Ministry of Health are a particular challenge. Nonetheless, digital health can provide opportunities to make significant inroads in this domain and can have a profound impact on many of the upstream determinants of TB. These include broader issues in lung health and noncommunicable disease prevention, poverty alleviation through conditional cash transfers, universal health care (e.g. unique digital identifiers), and health system strengthening;
- **Critical points** need to be identified on the pathway to the successful implementation of the *End TB Strategy* at country level. These can then be mapped to complementary digital health interventions to help facilitate the process. These interventions would need to be prioritized based on the dual considerations of knowledge of their effectiveness and programmatic circumstances, including feasibility, time to implementation, resource use, potential benefit, associated opportunities, support structure for particular technologies, and so on. The target product profiles described in this agenda document were identified through a similar process and could be a starting point for similar country-level discussions. The documents (e.g. national strategic plan) and any regulatory instruments (e.g. eHealth strategy) which need to be updated should be targeted for specific action.
- **Resources** will be needed for implementation. The interventions can be mapped to various potential sources of funding and donors to create sound 'investment cases' for specific interventions. Human resource development for the implementation of the *End TB Strategy* needs to factor in the additional requirements for the workforce of tomorrow to be conversant with ICT and its use. Looking for in-country expertise can stimulate innovation and cultivate partnerships that are more likely to be sustainable than those depending wholly on external support.
- A **realistic timeline** to implementation should be developed, new interventions tested and validated in the local setting ahead of scale-up. The notion of feasibility

at scale is an important consideration when prioritizing products: interventions should not remain stuck in the pilot stage.

- Operational **research and monitoring** should be planned in advance to measure the impact of the intervention and improve performance, including costs. It is also a

means to ensure adherence to good practice, for instance in data management and security during implementation (7). Lessons learnt would be fed back into a continuous improvement cycle. Communication of findings would be of interest to both local and international workers.



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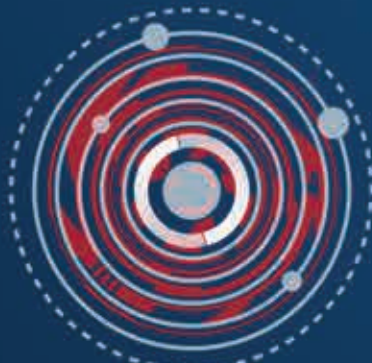
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