World Health Organization

REGIONAL OFFICE FOR Europe

Quick guide to video-supported treatment of tuberculosis

ABSTRACT

Despite being a curable and preventable disease, tuberculosis (TB) remains as one of the major challenges for health systems, globally. Every year, TB affects more than 10 million people and kills more than 1.4 million people. WHO's Digital Health for the End TB Strategy – an Agenda for Action outlines a conceptual framework in which advantageously positioned digital health solutions are matched to the most urgent needs of TB programmes. Video-supported treatment is a component of one of the four core functions of this framework, the Patient Care domain, and primarily supports the first pillar of the End TB Strategy. This quick guide provides information on the solutions available for asynchronous modes of video communication and how these can be of use to TB programmes.

Keywords

DIGITAL HEALTH – tuberculosis
TUBERCULOSIS – prevention and control
EUROPE
HEALTH SYSTEM STRENGTHENING

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Contents

Abbreviations

DAT	digital adherence technologies
DOT	directly observed treatment
DR-TB	drug-resistant tuberculosis
EECA	eastern Europe and central Asia
GPW	general programme of work
HMIS	Health Management Information System
ICT	information and communication technologies
M&E	monitoring and evaluation
SMS	short message service
TB	tuberculosis
VOT	video-observed therapy
VST	video-supported treatment

Acknowledgements

This guide was developed by Alexander Asatiani (consultant)[1] and Giorgi Kuchukhidze,[1] and reviewed by Masoud Dara,[1] Askar Yedilbayev,[1] Ogtay Gozalov,[1] Andrei Dadu,[1] Dennis Falzon[2] and Sevim Ahmedov.[3]

1. Joint TB, HIV and Viral Hepatitis Programme (JTH), WHO Regional Office for Europe, Copenhagen
2. Global TB Programme, WHO, Geneva
3. United States Agency for International Development

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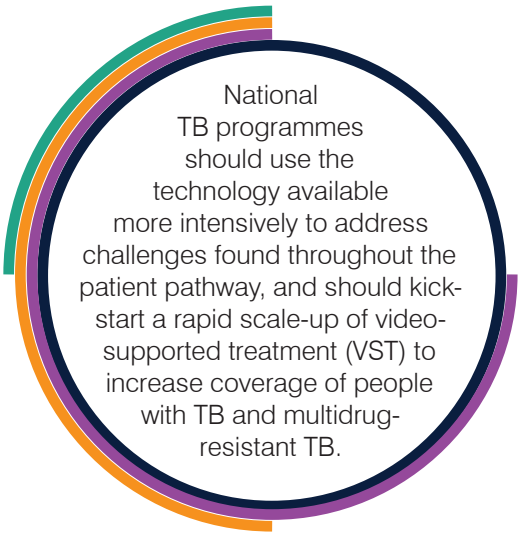
Preamble

Rapidly evolving information and communication technologies (ICT) build opportunities to catalyse the impact of digital health solutions on accessibility to essential health services and help to achieve higher standards of health. The growth rate, broad potential and diversity of digital health solutions can accelerate progress towards the global health targets articulated in the thirteenth General Programme of Work (GPW13) *(1)* and the Sustainable Development Goals *(2)*. Digital health is among four flagship initiatives of the European Programme of Work, which supports the GPW and sets out a vision for how the WHO Regional Office for Europe can better support countries to meet citizens' expectations on health in the future *(3)*.

The broad array of domains in which digital health concepts can be applied covers major disease programmes, including tuberculosis (TB) treatment and care. Digital health solutions have the potential to convert conventional service delivery modalities into more accessible and people-centred ones, while maintaining the same, or even greater, levels of effectiveness and efficiency. Digital health solutions are becoming more relevant in resource-limited conditions, during health emergencies and in other settings in which physical encounters with care providers are associated with challenges and constraints.



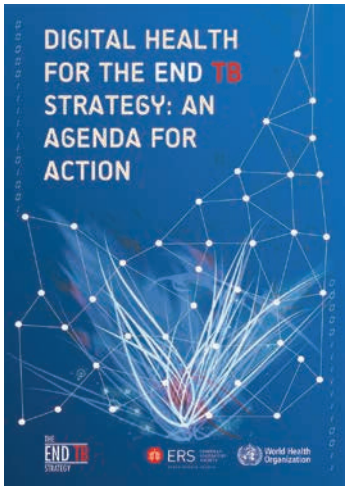
With the introduction of new TB medicines and the rapid transition towards the implementation of fully oral shorter and longer treatment regimens for drug-resistant TB (DR-TB), and considering the challenges during health emergencies, the need for implementation and scale-up of the digital health solutions is indisputable.

What are digital health solutions for VST of TB?

Despite being a curable and preventable disease, TB remains as one of the major challenges for health systems, globally. Every year, TB affects more than 10 million people and kills more than 1.4 million people. As technology advances, innovative approaches to TB care and prevention should be applied with greater consistency to overcome existing barriers, catalyse the effectiveness (and efficiency) of interventions and attain desired outcomes.

In-person observation of treatment can pose challenges for both patients and caregivers. The daily, or weekly, commute to the health setting involves transportation costs, takes time for both patients and health providers, is associated with logistic issues and possible loss of income, carries the risk of stigma if frequent visits to a TB facility are noticed, and increases the risk of disease transmission. In addition, requiring health care providers to carry out in-person observations entails a heavy workload that is not needed for all patient groups.

Video-observed therapy (VOT) is a technological alternative to conventional directly observed treatment (DOT). VOT is a recorded or live-streamed remote interaction between patient and care provider via Internet-enabled smartphones, tablets or computers. Leveraging current ICT for use for health, VOT is a solution that addresses the challenges posed by DOT to professionals and affected communities. In comparison with other types of digital adherence technologies (DAT), such as text messaging platforms (short message service (SMS)) and event monitoring devices for medication support (smart pill boxes and sleeves), the unique nature of the VOT interaction makes it best positioned to support remote management and observation of TB treatment.[1]



WHO's Digital Health for the End TB Strategy – an Agenda for Action outlines a conceptual framework in which advantageously positioned digital health solutions are matched to the most urgent needs of TB programmes *(4)*. e-DOT, or VST, is an important component of the Patient Care domain of the framework, and primarily supports the first pillar of the End TB Strategy *(5)*. VOT was included in the initial set of target product profiles *(6)* that defined key features of priority d-Health concepts and these concepts have been translated into actual technological solutions in some WHO European Region countries.

VST as part of the concept of people-centred holistic approach to care and treatment

Whereas the ability to remotely observe treatment laid the foundations for VOT, evolving ICT has created new and exciting opportunities for TB control and has broadened the potential of technological solutions beyond observation alone. Management of adverse events, support for associated health conditions and lifestyle risks, information, education and communication are a few areas that affect treatment outcomes and can be backed by technological solutions.

Using technologies for more than observation, facilitates continued engagement in care and strengthens rapport-building with patients. Building upon the increasing evidence that VOT can achieve outcomes comparable to in-person observation of treatment *(7–12)*, VOT also enhances tailored, people-centred support systems to improve TB treatment outcomes. To reflect this, this publication refers to VOT as comprehensive VST.

1 Further reading: WHO. Handbook of the use of digital technologies to support TB medication adherence. Geneva: World Health Organization; 2018 (https://www.who.int/tb/publications/2018/TB_medication_adherence_handbook_2018, accessed 11 July 2020).

VST interaction types

The two main categories of VST are based on the type of interaction between the patient and health care provider.

- **Synchronous VST** uses real-time (live) video communication modes between the patient and health care provider. Using videoconferencing-enabled software, the health care worker remotely observes the patient's ingestion of medications in front of the Internet-enabled smartphone, tablet or computer and then documents the interaction on the patient's adherence record. This approach enables care providers to verify the medication intake at the exact time it is taken, and care providers can personally collect information on adverse events and promote treatment engagement. However, a set of conditions has to be met in order to successfully establish this type of communication: firstly, providers and patients have to agree on and schedule the videoconference time; secondly, an uninterrupted and adequate Internet connection has to be available for the session. While the benefits of synchronous communication are obvious, meeting the requirements for implementation can be challenging for both providers and patients, especially in resource-limited settings.

- **Asynchronous VST** also uses Internet-enabled smartphones, tablets or computers and allows patients to submit video recordings of medication intake to treatment providers via a specialized mobile application or a dedicated web-based platform. This approach removes the requirement for concurrent ingestion and observation, and thus increases flexibility and convenience for both patients and providers. Moreover, in most cases asynchronous VST can usually be managed when Internet connectivity is erratic. Video recordings sent to the destination server can be reviewed by appointed care providers at any time – either immediately upon upload or at the earliest opportunity. This is especially convenient for doses taken during evenings, weekends and national holidays. Asynchronous VST may also be continued when patients travel away from the treatment centre, or even go abroad.

Mobile software applications and VST management platforms

There are three options for VST implementation[2] based on the type of technological solution employed:

- third-party video communication platforms;
- proprietary, licensed, VST applications;
- a customized VST application created by a local provider.

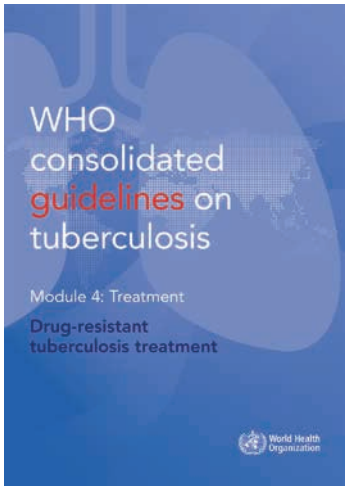
While synchronous VST can be implemented via both third-party video communication platforms and specialized applications,[3] asynchronous VST requires a dedicated system that ensures secure storage and transmission of recorded videos and compliance to relevant international and national data privacy and protection regulations.

2 Further reading: WHO. Annex IV – Comparison of different VOT options. In: Handbook of the use of digital technologies to support TB medication adherence. Geneva: World Health Organization; 2018 (https://www.who.int/tb/publications/2018/TB_medication_adherence_handbook_2018, accessed 11 July 2020).

3 NB. This is possible if the software supports live interaction features.

Software applications (either proprietary or customized) are installed onto smartphones or tablet computers and ensure submission of video recordings and access to application-level patient data through authentication mechanisms (passwords and pin codes, biometrics, etc.). To review and manage patients' submissions, mobile software applications are typically backed-up by VST management platforms that enable authorized access to a patient's data at the provider-level, and streamline the management of electronic adherence records.

Can VST replace DOT?



The 2020 WHO consolidated guidelines on tuberculosis includes a comprehensive set of recommendations for the treatment and care of DR-TB. VST is one of the treatment options outlined in the document, along with DOT delivered via community and facility settings. VST may replace DOT when video communication technology is available and when it can be appropriately organized and operated by health care providers and patients *(13)*.

There is increasing evidence *(7–12)* to suggest that VST is a solution able to achieve treatment outcomes which are at least as effective as conventional DOT *(14)*. This evidence will help VST gain a foothold in treatment options around the world.

How can VST solutions be used by national TB programmes?

The advantages of VST are the great convenience and flexibility it provides for both patients and care providers *(7)*. VST solves some of the limitations of conventional DOT programmes, including higher system costs and inefficient allocation of resources. VST can also allay patients' worries about aspects of treatment, such as limitations of autonomy and privacy, and loss of time and income, which can lead to underperformance of even well-functioning DOT programmes. The evidence suggests that, regardless of the type of interaction (synchronous or asynchronous), VST gets high approval ratings from both patients and providers, conserves resources for both parties and thus improves programme efficiency *(7–12)*.

The areas in which VST can be applied to TB programmes are described below.

Primary areas

Follow-up on medication intake

Remote observation of medication intake, either through live video communication or recorded sessions, is the basis of VST. Synchronous communication enables health workers to guide patients on the proper

administration of medicines and provide feedback in real-time, therefore increasing engagement and strengthening rapport, and mobile software applications enabling secure submission of recorded videos can offer technological solutions to address these needs. Mobile applications can integrate visual aids and user-friendly manuals to facilitate proper ingestion of medicines, and document these with quality video recordings. Video recordings can be enhanced with additional features such as a warning for low light conditions and/or by positioning a guiding lines overlay on the recording screen.

Asynchronous mode enables patients to take medications at the time that suits them best, and for providers to observe this intake at their convenience, giving a clear advantage over real-time observation. Applications are able to support submission of multiple recordings through the day, thus enabling patients who use split-dosing to use this recording method and enabling providers to track evening doses. Integration of the to-be-taken pill counts feature can enable health workers to easily track expected doses, while patients can benefit from single-click information on their prescription, including medication names, doses, the visual appearance of pills and even possible adverse events.

Most mobile applications support notification features that remind patients to take their pills, and refill and appointment dates. Patients can access the approval statuses of their submissions, which can be listed by date. Some applications even support video feedback from the provider, enabling two-sided communication.

The offline capabilities of the mobile applications ensure that all medications recorded are delivered to the care provider, even in limited Internet connectivity settings. This is achieved through an upload backlogging feature that applies repeated upload attempts until each date- and time-stamped video reaches its destination. Applications usually automate this process, requiring little effort from patients and ensuring the fidelity of videos.

Adverse events monitoring

The collection of adverse events data in a way that allows timely response and management is an integral feature of VST. While adverse events can be reported narratively during real-time video communication, or voice recorded as a part of the video in the case of asynchronous communication (if supported by the application), mobile applications can integrate dedicated features for documenting adverse events in a structured and traceable manner. Some applications ask the patient to report on possible adverse events every time a video is submitted, while others let patients decide when to report adverse events using a dedicated interface. In both cases, the list of adverse events can be standardized, often allowing an indication of severity and additional comments to be posted. Furthermore, if supported by the interaction model, certain visually apparent adverse events (e.g. skin rashes) can be directly identified by care providers.

Connectivity to treatment and care providers

While remote communication brings greater convenience, flexibility and privacy to patients, some patients might experience a sense of isolation and lack of person-to-person support. In particular, this might be the case with asynchronous communication; therefore, autonomy should be balanced against reduced patient–provider interaction. As well as patient–provider interactions through scheduled appointments, mobile applications can include single-click access to connect a patient with their caregiver. This is typically achieved via the integration of a connectivity interface, in the form of quick call and text buttons to a list of assigned care providers, such as nurses, doctors, social workers and psychologists. Embedding contacts of available support hotlines and a list of the nearest service delivery points for TB and other conditions is a way of allaying a patient's sense of isolation; however, these should not be considered to be substitutes for all face-to-face interactions with health professionals.

Information, education and communication

Apart from the convenience and flexibility of medication intake schedules, patients can benefit from digitally delivered information that is instantly and always accessible, concise and easy to grasp. While similar to in-person support, digital delivery of information, education and communication materials is not a replacement for provider-led interventions; it brings added value in enhancing patent awareness and engagement.

VST management systems

Digital solutions for VST are typically backed-up with management platforms (VST management systems) that allow providers to digitally manage their workflows. The management system enables secure access and organization of patient records, reviews of video recordings and reported adverse events, along with analytical capabilities in the form of dashboards and standard reporting formats. The majority of systems are equipped with interoperability features that enable their integration into the e-health ecosystem of the country and allow bidirectional data exchange with existing digital health solutions (e.g. transferring data to the TB patient's electronic health record). VST management systems are typically web-based and accessed via desktop computers. Some platforms can be accessed via mobile web browsers and even have dedicated mobile application interfaces.

Further areas

Support for associated health conditions and lifestyle risks

VST can also make use of the diverse and scalable nature of technology by encompassing the provision of support for associated health conditions and lifestyle risks that directly or indirectly affect treatment outcomes. Management of concomitant conditions that require integrated approaches can be accommodated either through the dedicated application interfaces or integrated into existing workflows, such as video observation of treatment, remote counselling, delivery of targeted information, education and communication materials. HIV, viral hepatitis, pre-exposure prophylaxis, opioid substitution therapy, smoking cessation, maternal and child health and mental health are priority domains to consider for integration.

Data collection through surveys

Dedicated mobile software applications can include patient feedback collection features in the form of mini-surveys and integrated questionnaires. Questionnaires can be delivered to the entire patient cohort or to certain groups of patients and can be designed for various purposes including, but not limited to, satisfaction studies, recording information on adverse events experienced in addition to the usual ones reported, factors affecting adherence, etc. The survey component is typically managed via the provider's web portal, allowing the provider to define the questions and types of answers. Some systems require limited or no effort from technical personnel to set up surveys and can be administered by health workers.

Community engagement

Mobile software applications can include features that facilitate community empowerment and engagement. These features could include integrated community messaging modules with posting boards and chat functions. Some applications integrate dedicated interfaces aimed at providing community feedback on service quality, treatment accessibility, reporting on ill treatment, stigma and discrimination and the challenges interfering with patients' abilities to complete TB treatment.

E-learning

In addition to the digital delivery of information, education and communication materials, e-learning encompasses more complex and sequential approaches to education and can be targeted at various audiences. Primarily focusing on patients, peer educators and community leaders, e-learning can benefit treatment supporters and health care providers if supported by mobile application interfaces.

Options available in eastern Europe and central Asia

In recent years, both patients and care providers have taken advantage of evolving digital health technologies. Several countries in the WHO European Region already have a track record of employing VST as a part of TB control interventions.

In April 2020, the WHO Regional Office for Europe commissioned the assessment of the application of VST systems in six selected eastern Europe and central Asia (EECA) countries (Armenia, Azerbaijan, Belarus, Georgia, the Republic of Moldova and Ukraine).

The assessment aimed to provide a definition of the generic functional and technical properties of the systems in use, the special features and the potential of replication and scalability. For the sake of comparability across systems, an assessment tool was developed that focused on a set of 16 standard functional features with their respective technical attributes and employed demand grading for features that were not available or were subject to adjustment; the latter were translated into areas of expansion and further upgrades for a particular system.

The assessment found that three countries have applied the VST concept by employing customized, locally developed dedicated systems (Belarus, Georgia and the Republic of Moldova), all of which support asynchronous interaction. And while three countries (Armenia, Georgia and Ukraine) have been using third-party video communication platforms for real-time VST, only one (Azerbaijan) has not yet used the VST concept. Despite regulatory enablement and the availability of documented procedures, countries practising synchronous VST through third-party video communication platforms reported scheduling arrangements, caseloads similar to DOT, absence of streamlined linkage between video interaction and available patient record management systems, along with technical issues as key impediments to scaling-up the VST concept. These results highlight the clear advantages of using dedicated systems for asynchronous VST.

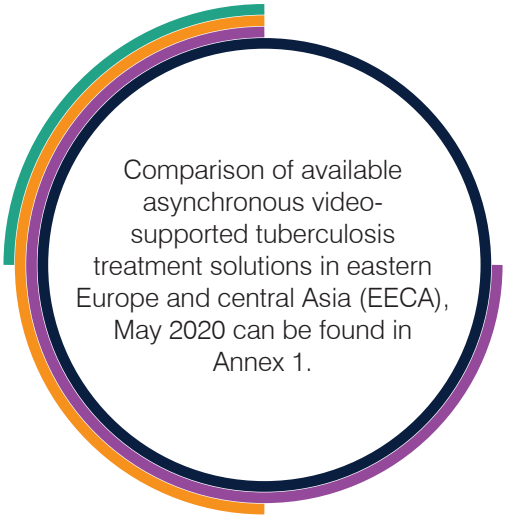
In **Belarus** VST is an integral part of the national TB registry under the hood of the Republican Health Management Information System (HMIS), rather than a standalone technological solution.

Integration into the national e-health ecosystem brings significant gains in efficiency and realization of the people-centred holistic approach to care and treatment. Native linkage to the TB registry, and therefore the HMIS common health record, provides streamlined access to health data and enables complex management of associated and non-associated health conditions.

Ukraine is part of the Unitaid-funded ASCENT *(12)* project led by the KNCV Tuberculosis Foundation that aims to operationalize an integrated approach to DATs and generate evidence for optimal use and scale. Adherence data collected through multiple DATs, such as medication sleeves (99DOTS), smart pill boxes (evriMED) and the proprietary, licensed VST application (SureAdhere), will be fed into the centralized adherence platform (Everwell Hub). The ASCENT project is currently in the implementation stage (until December 2022).

The **Republic of Moldova** has recently rolled out its VST system as a part of national measures against the spread of coronavirus disease.

The system allows patients to record and submit videos via handheld devices and also though a dedicated web platform. The mobile application features integrated guidance for each recording session that improves ease of use and has a streamlined adverse events reporting interface that checks on the patient's condition every time the video recording is submitted.



Georgia has been using its VST system since 2017 and the system has undergone several updates based on lessons learned and practical experience. The system features robust management platform powered with visual aids to streamline reviews of reported cases, additional controls over prescription management, such as "pausing" particular medication, or enabling an "inpatient mode" that does not categorize the unavailability of video recordings as missed doses until this mode is disabled.

Complex search and reporting features enable managers to be up-to-date on programme implementation status. The patient survey module does not require experience with information technology to set up and manage the questionnaires and can therefore be easily administered by care providers.

The system is currently being replicated in Kazakhstan and will be rolled out in June 2020.

What resources are needed?

VST system

Once a national TB programme decides to implement VST concept as a part of the national TB response, the technological solutions available, the options for replication and the need for fresh development have to be evaluated thoroughly. New VST developments might be time intensive, associated with higher costs and challenges associated with the selection of a system developer; the adjustment of an existing system conserves development costs and proof-testing time as it builds upon the existing platform. The key factors

to consider are data privacy and the security features necessary to comply with the relevant national or international requirements.

Post-deployment support for minor bug-fixing and adjustments is another important aspect for consideration in both cases. This is typically outsourced to the application vendor for a defined time or provided by trained in-house personnel.

Hosting options

Patients data collected through the VST application has to be stored in a manner that ensures security and uninterrupted access to records by authorized personnel. There are two options for hosting the data.

- Direct hosting is when the server is located locally, in-country and designated agencies (health ministry, National Tuberculosis Programme, etc.) have control over the stored data. This option requires the availability of adequate recourses: such as technological infrastructure, human resources for maintenance and support of the server, licensing of server management software, back-up and failover policies and storage upgrades as collected information grows. As with the mobile application, the data storage system has to comply with national or international data privacy regulations. However, unlike with the replication of existing mobile software solutions when those requirements might already be met by the application vendor, the country must ensure conformity with regulations on data storage and access levels independently.

- Cloud hosting solutions are also referred to as server on-demand hosting; cloud server hosting is a good option if a country lacks the information technology capacity for setting up local infrastructure. Cloud hosting is advantageously positioned due to its high levels of security, failover prevention, scalability, its user maintenance-free concept and pricing options (monthly, annual and usually cheaper than in-country solutions). The key factor to consider is whether national regulations on personal data protection permit storage of patient records outside the country.

A data usage and ownership agreement is essential in all cases when data are stored on a third-party provider's infrastructure, whether it is a cloud hosting solution, or an outsourced in-country hosting provider.

Handheld devices, Internet connectivity and supporting tools

TB programmes should consider uptake levels of mobile technology and handheld devices in the target population as well as the prevalence of particular mobile operating systems. If the latter matches the VST-supported platform, there might be fewer patients requiring smartphones to be provided. When, and if, a TB programme plans procurement of handled devices, application developers should be consulted to ensure that the minimum technical requirements for the selected VST solution are met.

As Internet connectivity is pivotal for VST, it is important that patients and health workers are both provided with a good quality and sufficient Internet connection. Internet data plans can be prepaid – i.e. purchased in advance – and postpaid – covered monthly based on a contract with network provider. Provision of free

Internet connectivity to patients along with the smartphone (if required) can be regarded as an enabler to treatment adherence on a set of other targeted interventions.

Distribution of supporting tools, such as tablet dividers, daily packaging of pills and transparent glasses for video documentation of medication intake, can facilitate a streamlined implementation of asynchronous VST.

Human resources

Allocation of human resources to particular areas of the implementation of VST is required prior to the rollout of solution. There are direct and indirect personnel requirements for the operationalization of the VST concept.

Direct personnel needs

Individuals directly engaged in service delivery include:

- nurses;
- doctors;
- community health workers;
- social workers (varies by programme);
- psychologists (varies by programme).

Since the adoption of VST may involve enrolling new patients rather than switching existing cases to this mode of treatment, or in situations where there are capacity limitations, the programme might need to hire new staff. The number of assigned patients per caregiver needs to be considered during the resource planning stage.

Indirect personnel needs

Personnel mandated to manage and support the implementation of VST include:

- programme management;
- monitoring and evaluation (M&E) staff;
- ICT/network support staff.

In most cases, programme management and M&E requirements can be accommodated using existing resources and the technical support of the system can be outsourced and be part of post-deployment support agreement with developers. In-country hosting arrangement will still require ICT support.

Relevant training of existing and new personnel is essential to ensure proper set up and management of VST programme.

Regulations and policies

VST has to be part of the national digital health agenda and reflected in national strategies and policies. Set of guiding and regulating norms has to be in place in order to legitimate the concept and allow further scale-up.

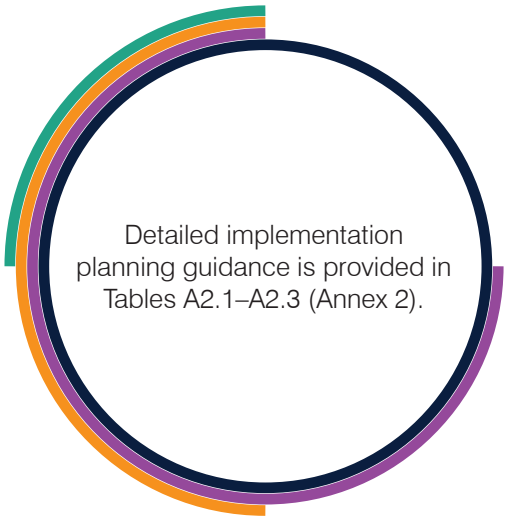
Along with the integration in guidelines and the development of dedicated protocols, the employment of standard operation procedures and instructions for both care providers and patients is an essential step in setting up VST programmes. Applications and system specific privacy policies have to be in place to ensure the protection of patients and providers. Some countries might require clearance from national agencies working in the area of data privacy and protection.

While some of these issues can be dealt with by making adjustments to existing regulations, programmes might need to develop operational procedures and protocols from the ground up, in which case technical assistance will be required.

Implementation considerations

Implementation of VST should be an iterative and consultative process following rapid developments in technology, generated evidence and community feedback. The adoption of the concept works best when a step-wise approach is employed, engaging stakeholders and relevant decision-makers. Below are three key stages required for rollout and operationalization.

- **Plan:** selection of VST solution, resource planning and allocation, estimation of needs and costs fall in to this phase. Regulatory amendment needs and needs for new developments is part of the planning stage.
- **Set up:** this stage includes either the development of new system from scratch, or the adjustment and replication of existing solution. The relevant regulatory arrangements along with the procurement of hardware fall in this phase.
- **Rollout and support:** this stage typically includes beta testing of the system, launch and post-deployment support.



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Annex 1. Comparison of available asynchronous video-supported tuberculosis treatment solutions in eastern Europe and central Asia (EECA), May 2020

Table A1.1. Asynchronous VST solutions, May 2020

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
General information			
Product initiator	**Republic of Moldova** The Centre for Health Policies and Studies (PAS Centre), Act For Involvement (AFI); National Programme for Control of Tuberculosis and the Institute of Phthisiopneumology "Chiril Draganiuc"	**Georgia** National Centre for Disease Control and Public Health (NCDC), National Centre for Tuberculosis and Lung Disease (NCTBLD)	**Republic of Belarus** The Republican Scientific and Practical Centre of Medical Technologies, Informatization, Management and Economics of Public Health (RSPC MT)
Development funder	TB REACH (Stop TB Partnership)	Global Fund to Fight AIDS, Tuberculosis and Malaria	Global Fund to Fight AIDS, Tuberculosis and Malaria
Product developer	"Qsystems" S.R.L. //www.qsystems.md/ Email: office@qsystems.md	"Leavingstone" //www.leavingstone.com/ Email: info@leavingstone.com	"Computer Information Systems" //www.cis.by/ Email: post@cis.by; user001@cis.by
Status	Available for replication	Available for replication	Subject to adjustments prior replication Replication is subject to modifications, as "VOT module" is integral part of the national TB registry under the hood of the integrated Health Management Information System (HMIS "Lekar") operating countrywide.
Lead contact person(s) and email address	Cristina Celan Project Manager Centre for Health Policies and Studies (PAS Centre) cristina.celan@pas.md	Irakli Gabisonia TB Programme Specialist The Global Funds Projects Implementation Unit, NCDC i.gabisonia@ncdc.ge	Dzmitry Klimuk Head of Monitoring and Evaluation Unit Republican Scientific and Practical Centre for Pulmonology and Tuberculosis dzklm99@yahoo.com
Ownership status	Public since April 2020 (NTP)	Private – until Dec 2021, then the rights on source code transfers to NCDC	Public – Operated by Republican Scientific and Practical Centre of Pulmonology and Tuberculosis
Product launch date	April 2020	December 2017	January 2016
Number of updates	4	4	No major updates to the interface and workflow reported

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General information			
Countries using this system	Republic of Moldova	Georgia; Kazakhstan (Planned rollout in early June 2020)	Belarus
Number of patients enrolled in the system (total)	18 (as of 25 May 2020)	769 (as of 25 May 2020)	1 273 (as of 1 May 2020)
Supported mobile operating system(s)	Android™	Android™	Android™
Application interface users	**Patients** Primary and the only users of mobile application interface are patients. Patient management is handled via the provider web portal – i.e. the mobile application does not support a dedicated interface for treatment providers. However, the provider's web portal can be accessed via the mobile device's web browser.	**Patients** Primary and the only users of mobile application interface are patients. Patient management is handled via the provider web portal – i.e. the mobile application does not support a dedicated interface for treatment providers. However, the provider's web portal can be accessed via the mobile device's web browser.	**Patients** Primary and the only users of mobile application interface are patients. Patient management is handled via the VOT module of the TB registry under the hood of the integrated HMIS web portal – i.e. mobile application does not support dedicated interface for treatment providers. However, the provider's web portal can be accessed via mobile device's web browser.
Brief description of application interface	Application interface includes an expandable side panel for user profile management and settings. Bottom level horizontal tabs – "Homepage", "History" and "Messages". Four home screen sections and "Always on-top video recording" button. Home screen sections are described in respective block and are as follows: 1) information materials; 2) community feedback; 3) success stories; 4) service delivery points.	Application interface includes three top level tabs – "Medication", "History" and "Help" sections. Expandable side panel for user account management, pin code activation and language switching and other settings. The "Medication" tab is selected by default and displays two controls: 1) "Take Medicines" 2) "Today's Medicines"	Mobile application interface displays two home screen controls as follows: 1) "Getting Ready" – for initiating the video recording; 2) "Archive" – lists date specific submissions with relevant statuses and controls.
Patient registration and credentials management			
Patient-led registration via dedicated interface	Patient has to register user account via web interface. Upon registration, account activation key is delivered to the registration email, providing further instructions for authentication.	N/A	N/A
Registration of patients via provider's portal	Treatment provider completes patient profile by filling in relevant information – such as treatment facility, care provider information and treatment data.	Patients are pre-registered by NTP, a one-time password is provided that is subject to change upon the first login to the application.	Citizens registered in the centralized HMIS are assigned unique global and local identification numbers.

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Patient registration and credentials management			
			(cont'd). While the global identification number represents the ID for the patient's master health record in the system, the TB registry identification number is disease specific and used for patient identification in both the TB registry and the VOT module. Once patient is listed in the TB registry, creation of the VOT account links profile with both the global and local identification numbers, master health record and TB registry respectively.
Login credentials	**Email address** Login credentials are registration email address and password.	**Telephone number** Login credentials are patient's telephone number and password.	**TB registry ID** Login credentials are TB registry ID number and passcode.
Credentials management	Password can be changed via the in-app interface. Registration email address is used for password recovery, the latter can be initiated by user via the application or by the system administrator upon request.	Password can be changed via the in-app interface. Password recovery is handled by the nurse or system administrator via provider web portal. One-time password generation feature is built in to the patient's profile (medical record).	Upon patient's registration in the TB registry, the system automatically generates registry specific ID number and passcode for VOT application authentication. Application does not use a user-level login interface and credentials management feature and is pre-configured by treatment provider individually at the time of enrollment. Authentication and connection parameters are entered into the application configuration screen accessible to provider only. Once patent's configuration details are entered into the application settings, user remains authenticated.
Accessibility features			
Multilanguage support	**Yes** Language switching option available as an application menu item.	**Yes** Language switching option available as an application menu item.	**No** Currently supports Russian language, though capable of localization services.

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Accessibility features			
User guide	**Yes** Step-by-step user guide is displayed every time, prior to recording session. User guide is presented as a horizontal swipeable gallery and depicts each step of video submission (12 in total). NB: Swiping through all steps is not required to initiate recording session.	**Yes** Video submission and general user guides are integrated into the help section of the application interface. User guides provide illustrated tips for each step of mediation intake and application controls.	**No** Available as handout, though not integrated into the application interface.
Access to prescription information			
Access to prescription information as a part of video documentation of treatment	**No** Prescription information, including medication names, doses, pill counts, possible adverse events is not integrated into the application interface.	**Yes** Prescription information is accessed via the "Today's Medicines" section on the home screen and includes information on prescribed medication names, doses, pill counts, possible adverse events. Information for each medication is managed through the provider's web portal.	**No** Prescription information, including medication names, doses, pill counts, possible adverse events is not integrated into the application interface.
Video documentation features			
Video recording	Video recording button is constantly available on the home screen – providing instant access to documentation of medication intake. Pushing the video recording icon brings up illustrated stepwise guide and "Record" button. During the recording process following interface controls are displayed: Stop; Save; Cancel. Estimated time of recording and/or recording duration is not displayed.	Video recording is initiated through the dedicated "Take Medicines" button on the home screen. In order to initiate recording, pill counts have to be selected (see below). Recording screen displays "Start" and "Stop" controls along with the recording runtime. Upon completion of the recording, the patient has the option to record another video as a part of the current session or finish the session. The "Take Medicines" function is locked after patient reports intake of all medications (total pill counts) for that day.	Video recording is initiated through the "Getting Ready" button on the home screen that brings up recording screen with following controls: • "Start"; • "Stop"; • "Review" – previews recorded video; • "Confirm" – confirms recording and automatically initiates submission; • "Cancel" – deletes recorded file.

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Video documentation features			
To-be-taken pill count	**No** Pill count is not selected by the patient, this information is entered into the patient's profile via the provider web portal, based on observation of individual video sessions.	**Yes** Total pill count of medications to be video-reported is selected by the patient prior to the recording.	**No** Pill count is not selected by the patient as a part of the documentation procedure. This information is entered into the patient's VOT account via the provider web portal, based on observation of individual video sessions. Data entry is not standardized – entered as a free text in the comment section of particular submission.
Multiple recordings *(e.g. for twice-daily dosing)*	**Yes** Application allows multiple video submissions through the day.	**Yes** Application allows multiple video submissions through the day.	**No** Patient can submit only one video recording through the day.
Video recording runtime limitation	**No** Video recording duration is unlimited.	**Yes** The system defines video recording duration limit as number of pills selected by patient multiplied by time interval defined by system administrator.	**Yes** Video recording duration limit is individually set in the application settings during the provider preconfiguration stage.
Time and date signature	**Yes** Each video includes recording date and time stamp.	**Yes** Each video includes recording date and time stamp.	**Yes** Videos do not display recording date and time stamp, though the system logs submission date and time and displays this information in the provider web portal as a line item in the patient's submission list.
Video with audio	**Yes** Patient's narration is captured by default during the each video recording.	**No**	**Yes** Patient's narration is captured by default during the each video recording.
Features to support quality video recording	**No** Warning for low light conditions and/or position guiding lines overlay on the recording screen are not available.	**No** Warning for low light conditions and/or position guiding lines overlay on the recording screen are not available.	**No** Warning for low light conditions and/or position guiding lines overlay on the recording screen are not available.
Camera modes	Front camera only	Front and back cameras	Front camera only
Storage and upload			
Video storage	**Temporary** Video is stored on the device temporarily, until file upload is successfully completed.	**Temporary** Video is stored on the device, in application memory temporarily, until file upload is successfully completed. Patients cannot access and modify videos.	**User managed** Videos are stored in application directory unless deleted manually. Date specific video recordings are accessible through the "Archive" section of the application interface.

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Storage and upload			
Video submission	Video upload is triggered by dedicated "Submit" button that becomes active only after adverse event is reported (ref. Adverse events reporting steps). File upload is a background process – application can be closed as soon as the submission is initiated.	Finishing the recording session automatically submits video to the destination server. File upload is a background process – application can be closed as soon as the submission is initiated.	Pressing approval button following completion of the recording automatically attempts to submit the video to the destination server.
Offline capabilities and upload backlogging	**Yes** Recording is still possible when an Internet connection is not available, weak or intermittent. Repeated upload attempts are automatically initiated until the video is delivered to the destination server.	**Yes** Recording still possible when Internet connection is not available, weak or intermittent. Repeated upload attempts are automatically initiated until the video is delivered to the destination server.	**Manual** In the event of upload failure video is marked with the red warning icon in the "Archive" section of the interface. Date-specific list items in the archive have following controls: re-submit; delete selected video; delete all videos prior to the selection.
Reporting adverse events			
Reporting frequency	**Per video submission** Adverse events reporting interface is displayed every time after recording is completed, prior to the submission.	**At the patient's discretion** The adverse events reporting interface is nested under the "Help" section of the application's interface. Adverse events and clinical signs/symptoms can be reported any time at the patient's discretion.	**None** Adverse events reporting feature not present.
Adverse events standardization	**Yes** Adverse events feedback is provided through the standardized form.	**Yes** Adverse events feedback is provided through standardized form, with the option of additional entries from the patient. Each adverse event has a severity grading (mild, moderate, severe).	NA
Reporting steps	(1) Record video; (2) Rate condition; (3) Select symptom(s); (4) Submit video. Upon each completed recording the patient is required to rate his/her condition with three grade scale (bad–average–normal). While selection of the "Normal" option automatically activates the submission button, checking the side-effects from the standard list is required for the other two options, in order to activate the submission button.	Patient has to access the "Help" section/tab on the application interface and select the "Adverse events reporting" function.	NA

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Treatment progress tracking and adherence history			
Treatment progress tracking	**No** Dashboard/timeline displaying estimated date of treatment completion and current progress is not available within the application interface.	**No** Dashboard/timeline displaying estimated date of treatment completion and current progress is not available within the application interface.	**No** Dashboard/timeline displaying estimated date of treatment completion and current progress is not available within the application interface.
Medication history	**Yes** Date specific video recordings can be accessed via dedicated button. Files are accessed via network connection as they are deleted from the device upon upload and stored on the server for defined time.	**Yes** Medications taken for specific date along with the approval status is displayed under the "History" section/ tab of the application interface. Video recordings are not accessible to the patients from the point in time they are successfully submitted.	**No** The application does not have the features to display a medication-specific video submission history; therefore, approval status of submitted video recording cannot be displayed.
Approval status	**No** Approval status is not explicitly displayed in the history section. While provider feedback is available for each recording, it is not categorized as approval or rejection.	Per medication intake reported, green and red icons display approval or rejection status respectively. The "Quick connect with the nurse" button that dials phone number of assigned health worker is activated if the video is rejected.	NA
Integration of patient enabler features			
Progress towards milestones	**No** Features to track and display the progress towards defined milestones (days until the next incentive, weekly goals etc.) are not available.	**No** Features to track and display the progress towards defined milestones (days until the next incentive, weekly goals etc.) are not available.	**No** Features to track and display the progress towards defined milestones (days until the next incentive, weekly goals etc.) are not available.
Features to increase motivation and facilitate patient enablement (gamification of achievements, motivational quotes etc.)	**Yes** Uplifting messages from past and/or current patients is nested under the dedicated section ("Success stories") on the application home screen.	**No**	**No**
Connectivity features			
Quick connect with defined list of contacts (i.e. "Quick call" buttons to access nurse, doctor, social worker etc.)	**No** List of quick contacts is not available within the interface.	**Yes** Help section displays list of quick connect options that are defined and assigned by system manager.	**No** List of quick contacts is not available within the interface.
Call-back function	**No** Feature to request call-back from specified person (nurse, doctor, social worker etc.) is not present.	**No** Feature to request call-back from a specified person (nurse, doctor, social worker etc.) is not present.	**No** Feature to request call-back from specified person (nurse, doctor, social worker etc.) is not present.

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Connectivity features			
Features to facilitate access to TB and associated conditions care services	**Yes** Service delivery points map is integrated under the dedicated section on the application home screen.	**No** Service delivery points information is not part of the application interface	**No** Service delivery points information is not part of the application interface
Scheduling of health visits			
Health visits can be scheduled	**No**	**No**	**No**
Notifications and reminders			
Notification channels	Application push (notification via the application).	Application push (notification via the application).	**No** Application does not support notification and reminder features.
Notification events	Reminders to take medicine. Upload status notification.	Currently notifications are delivered for event of the survey request (ref. to Mini-survey/questionnaire integration feature).	
Integrations and add-ons as a part of patient-centred holistic approach to care and support			
Management of associated health conditions and lifestyle risks that may influence their outcomes *(e.g. HIV, PrEP, HCV, OST, smoking cessation, maternal and child health, mental health conditions)*	**No**	**No**	**No**
Education and awareness raising	**Yes** Application home screen includes dedicated info section, that allows electronic distribution of information and education materials, news and announcements.	**No**	**No**
Community engagement features	**Yes** Application home screen incorporates community feedback section that includes three categories: • quality of services; • access to medical services; • challenges during the treatment. Each category includes sub-categories relevant to the topic.	**No**	**No**

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Integrations and add-ons as a part of patient-centred holistic approach to care and support			
	(cont'd). Feedback provided through those channels is delivered to the provider web portal for the further follow-up. In the application interface, outgoing messages are categorized per solution status – active and archived.		
Application as resource for technical and research data collection			
Automated error logs and crash reports	**Yes**	**Yes**	**Yes**
Mini-survey/ questionnaire integration feature	**Yes** Currently available in generic form upon completion of the treatment. Though the feature can be employed during the course of the treatment and adjusted respectively.	**Yes** Mini-survey feature is built into the provider web portal. Survey panel has controls to add, edit and modify questions, define answer types and respective options. Survey can be sent out to all patient or certain groups (sensitive, MDR, XDR).	**No**
Patient management system			
Brief description of interface and features	Patient management system is accessed via provider web portal. Homepage header displays number of new videos as well as number of overdue submissions. Sidebar includes list of patients, list of overdue submissions, adverse events monitoring and reporting sections. For each submitted video, quality rating (i.e. 1) Quality video; 2) Not all drugs visible; 3) No drugs can be seen) by the health worker is mandatory. For each video reviewed, the health worker has to select the drugs (name and quantity) that were taken by the patient.	Patient management system is accessed via provider web portal. Controls are accessed via sidebar which includes following categories: • daily activity – displays list of reports per specific date; • patient list; • nurses – displays list of nurses and number of assigned patients; • personnel – displays list of caregivers (social worker, psychologist, etc.); • medicines – Registry of medicines, including descriptions that are furtherly displayed in the application interface ("Today's medicines" section). This panel has the option to post images (e.g. visual appearance of the packaging, pills); • medical facilities – lists providers engaged in VST;	The VOT module is an integral component of the TB registry – one of the building blocks of the integrated HMIS that is operating countrywide and includes a complex set of modules per disease area and facility management (up to 40 modules). HMIS has separate entry (authentication) points per each component via web-based platform, including TB. Assessment of the national TB registry and HMIS features was beyond the scope of the country consultation objectives, hence only interface components of the VOT module were reviewed. The VOT module interface displays a list of patients with two key controls per patient record and separate control to add a VOT record.

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Patient management system			
		(cont'd). • adverse events – displays 1) adverse events management panel, with options to edit, add, delete particular symptoms; 2) displays reported adverse events; • survey – survey management panel as described above; • reporting – dashboards and reports.	(cont'd). 1) View patient's submission history: Displays date specific list of submitted recordings with prescription info header, with the options to preview the recording, select the observation result based on three point grading (good, average, rejected) and a free text field for provider's comments. 2) Edit prescription: Displays interface with the options to edit and modify prescription information with the following fields: date of prescription, prescribed medicines (entered in a free text format); completion date; options to prolong or cancel prescription, cancel/call-off particular day in the medication schedule. Adding VOT patient record: The prerequisite for opening a VOT record is the presence of a master health record in both the HMIS and TB registry. Once those criteria have been met: 1) prescription starting date and duration (number of days) are entered; 2) prescription information (medications, doses) is filled manually in the free text field; and 3) control/checking time is indicated.
Patient's profile	Patients general profile data - demographics and treatment facility information is completed upon registration. Patient profile includes four sections/tabs: 1) Treatment section - includes information on diagnosis (intra-extrapulmonary) type of treatment (lines), and duration; 2) Scheme data and 3) Combination of treatment sections - include selection of medicines, dosing and pill counts;	Patient's profile is presented as a single non-tabbed page. Along with demographics and general information on treatment, profile includes information on: • VOT enrollment date; • categorization of drug-resistance profile; • scheme data – which includes start and end dates, administration schedule (week days) for each prescribed medication.	Demographics and disease characteristics are nested under the patient's common profile in the TB registry; therefore, the HMIS master health record, VOT module includes only listings of enrollees and prescription management features as described above.

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Patient management system			
	(cont'd). 4) Monitoring section - includes AFB, culture and weight measurements tracking.		
Search terms	**Yes** Two search fields – Patient's ID number and full name.	**Yes** List of patients includes six search fields, as follows: • name; • surname; • telephone number; • assigned nurse; • drug resistance profile; • status (on treatment, completed treatment). List of nurses can be filtered by name, surname and telephone number. List of medications can be filtered by name and type.	**Yes** The VOT module of the provider web portal includes an option to filter active and passive patients and single search field for "Name" and "Surname" (without an exact match requirement).
Reporting features	**Yes** Reporting section shows integrated view (sheet) of adherence records in the form of patient list (Y) by dates (X). Filtering is possible by time range, gender and age group. Additionally, there are three reporting sections in the sidebar that bring up templates by gender, region and treatment facility. NB: Each report has an export feature.	**Yes** Reporting section provides sample dashboards as follows: • patients currently on treatment by regions; • adherence dashboard; • current to completed treatment cases; • rejected to approved cases. Each dashboard can be filtered by drug resistance type, rejected to approved cases includes additional filter for medications, and treatment facilities. Reporting section has an option to download complete dataset.	**Yes** VOT module has two built-in reporting modes: 1) Listing of patients with overdue submissions: Line items of the patient list expanded to the information on prescription and respective dates without video submissions. 2) Quality rating of submissions: Following selection of reporting period, quality grading categories along with corresponding numbers is displayed. This can be expanded to the patient level listing individuals with video submissions that fall under particular quality categorization.
Access via mobile device	**Yes** Provider web portal can be accessed via the both, desktop and mobile web browsers.	**Yes** Provider web portal can be accessed via the both, desktop and mobile web browsers.	**Yes** Provider web portal can be accessed via the both, desktop and mobile web browsers.
Multilanguage support	**Yes**	**Yes**	**No** Currently supports Russian, though capable of localization services.
User manual	**No** User manuals are available in Romanian and Russian, though not integrated into the web portal interface.	**Yes** Integrated into the provider web portal interface.	**Yes** Web-based user manual is integrated into the system for each module, including the TB registry and VOT.

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
Data protection and privacy			
Privacy policy and Terms of use	**Yes** Privacy Policy and Terms of Use are available and signed upon user registration.	**Yes** Privacy Policy and Terms of Use are available and signed upon user registration.	**Yes** Privacy Policy and Terms of Use are available and signed upon user registration.
Data protection and privacy			
User access levels management	**Yes** The system has multilevel access management feature. Currently the following roles are enabled: Administrator, Doctor, Nurse, Patient, Support Service, Monitoring and Control, Editor.	**Yes** The system has multilevel access management feature. Currently the following roles are enabled: Super administrator (used by NTP and doctors), nurse, patient.	**Yes** HMIS is equipped with multilevel user access management features, that enables control of secured access to particular modules, components and subcomponents with defined levels to read, write and modify.
Application access management	**Yes** Passwords must meet complexity requirements policy. Additional authentication options such as pin code, biometrics, two factor authentication are not available.	**Yes** Passwords must meet complexity requirements policy. Additional authentication options such as pin code and biometrics authentication are available.	**No** One parent's configuration details are entered into the application settings, user remains authenticated.
Data encryption	**Planned update** As a part of the planned update by mid 2020, the system will employ application level encryption (RSA).	**No** Though recordings are not encrypted, application employs secure communication protocols for data transfer between the client and destination server (see below).	**Yes** As per application developer report, system supports following standards: Data Encryption Standard (DES); TripleDES; Advanced Encryption Standard (AES); Set of standards STB 34.101, GOST 28147
Connection security	HTTPS; SSL	HTTPS; SSL	HTTPS; IPsec; SSL; Set of standards STB 34.101
Can system be hosted in-country?	**Yes**	**Yes**	**Yes**
Can system be hosted in a private cloud?	**Yes**	**Yes**	**Yes**
Operations, Privacy policy and Terms of use compliant with the General Data Protection Regulations (GDPR) from the EU (based on the information reported during the assessment consultations)	**No** Conformity to GDPR regulations were not reported; however, the system complies to key concepts of GDPR such as: • Privacy by design: data protection and user privacy is considered as a basis for the application (Password protected access, multilevel user access management).	**Yes** Statement of client (application) conformity available from developers upon request.	**No** Conformity to GDPR regulations were not reported; however, the system shows potential to comply to key concepts of GDPR. The integrated HMIS has undergone certification by the national authority: Operations and Analysis Centre under the President of the Republic of Belarus (certificate available upon request).

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
Data protection and privacy			
	(cont'd). • Explicit consent: patients are required to sign informed consent prior to enrollment in VST. • Encryption and data storage: application uses HTTPS and SSL secure connection protocols for data transfer.		
Interoperability, special features and upgrade options			
Interoperability with external systems	Connecting with other systems and databases is possible through an API (RESTFUL).	Connecting with other systems and databases is possible through an API (RESTFUL).	Connecting with other systems and databases is possible through an API. Considering the integrity of HMIS, demand for linkage to external systems has been low. Currently, the HMIS is interoperable with the nation's Digital Prescription System, employing ATC Classification.
Special features	• Patients can submit video recordings via a web browser by logging in to the user account and using web camera. • The system provides patient's geolocation data at the time of the video recording. • For each video submitted by the patient, a nurse records a video response (currently mandatory). Response includes narration of approval status along with feedback and recommendations, and is displayed in the "history" section of the application interface.	• Daily activity section of the provider web portal offers visual aids to streamline the review of reported cases. It allows quick identification of the records that need to be reviewed or followed-up and those that are resolved. Each line representing the patient record is colour coded as follows: - red: video(s) is/are not yet submitted or either all or part of them are rejected; - yellow: video recording has been submitted and needs to be reviewed or not all videos are reviewed; - green: all videos has been reviewed and approved.	As the VOT module is not presented as a standalone ICT solution for VST, integration into the national e-health ecosystem brings significant gains in efficiency and realization of the patient-centred holistic approach to care and treatment. Native linkage to the TB registry, and therefore the HMIS common health record, provides streamlined access to health data and enables complex management of associated and non-associated health conditions. The entire HMIS builds on a modular approach, with up to 40 dedicated modules for health conditions and facility operations management (including dedicated modules for "Telemedicine" and "Patient's Personal Cabinet" that provides summary information on health record).

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
Interoperability, special features and upgrade options			
		(cont'd) • Any medication intake schedule can be "Paused" by a health worker the using dedicated interface control in the patient's profile section of the provider's web portal. Reasons for pausing the schedules vary, and might be due to adverse events or in-person observed intake for specific day(s). Pausing a particular medication intake schedule is not reflected as a missed dose due to unavailability of the video recording and so does not affect the patient's adherence record. • Patient profile has a dedicated control to switch on "Inpatient mode" when the patient is transferred to an inpatient facility. Switching on this function does not categorize unavailability of video recordings as missed doses and, hence, does not affect the patient's adherence record. • The Administrator account has full access to add, edit and change patients records, manage personnel and health facility records, add and modify surveys, edit adverse event lists and gradings, and export the full dataset without involvement of ICT support.	(cont'd). And as the VOT module is currently not a ready-made individual solution, but rather a systemic component tied to a custom mobile application, replication of the country's practice would involve selection, extraction and adjustment of the respective HMIS modules (i.e. TB registry – hence, VOT integration, more broadly, infectious disease management, telemedicine modules etc.). Review of the complete feature set of the integrated HMIS was beyond the scope of the current assessment, consequently a key consideration for replication efforts should be an exploration of the features and capabilities of the system or selected set of modules in greater detail.
Areas of improvement / upgrade options *(based on country communication and review of application features)*	• Integration of communication APIs, particularly SMS engine, can streamline user registration, credentials management and notification features.	• Integration of communication APIs, particularly SMS engine, can streamline user registration, credentials management (i.e. for password recovery) and notification features. Since a one-time password generation feature is already present, binding this feature with the SMS engine	• In the event of weak, intermittent or absent Internet connection, a backlogging feature with automatic repeated submission attempts can remove the need for manual re-submissions by patient and prevent upload failures.

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
Interoperability, special features and upgrade options			
	(cont'd) • Quick connect controls, which would provide instant access to the predefined numbers, can streamline communication with treatment and care providers for those in need. A call-back feature would enhance connectivity feature as well. • Switching to phone number as login parameter and utilizing SMS for password reset and recovery can streamline credentials management. • Setting runtime limits per video can streamline the recording process and save hardware resources. Remaining recording time has to be displayed during the recording in order to support operationalization of this feature. • The recording screen has a cancel button; however, in order to avoid deleting unsubmitted video files the "Are you sure?" pop-up can be useful feature. • Application users can benefit from integrated and easily accessible prescription information (e.g. medication names, doses, pill counts, possible adverse events). • Explicit display of provider approval status in the submission history section. • Reporting capabilities can be further enhanced by introduction of additional filters for drug-resistance profiles for each reporting category (including adverse events) and/or as a separate report. The care provider (nurse, doctor) search function can be useful addition to the search features set.	(cont'd) can save human resource efforts and streamline the user management process – patients will be able to recover the lost password without involvement of the support team. • Provider led, frequent checking for adverse events via the application interface can enhance collected data quality and facilitate the data collection process. As opposed to passive collection, where the patient has to navigate to a specific section, surveying for presence of adverse events for each recording session will involve fewer reporting steps, allay any sense of isolation and amplify the patient-centred approach concept. • Since the application already has notification features for incoming survey requests, delivering notifications for reminders to take medicines and successful uploads can make the application more interactive and engaging. • Adding a toggle switch to display only records with unsubmitted videos (those marked with red) can further upgrade the patient recording review process. • Integration of education and awareness raising features in the form of a dynamic information, education and communication materials section will upgrade the application feature set and, in addition to the core designation, will bring greater engagement from patients.	(cont'd) • Display of provider approval status along with the video submission listing. • Allowing multiple submissions through the day will facilitate tracking of patients who receive twice-daily doses. • Notification features can be considered as additional preventive measure for skipped doses and increased engagement from patients. • Standardization of prescription information in the VOT module of the TB registry that would use a selection of medications, doses and pill counts instead of manual entry, can streamline patient management. The latter will enable introduction of additional features to the mobile application interface – such as information on prescribed medications, and selection of total pill counts prior to the recording, that would enhance skipped dose tracking measures. • Quick connect controls, providing instant access to the predefined numbers, can streamline communication with treatment and care providers for those in need. A call-back feature would also enhance connectivity features. • Reporting capabilities can be further enhanced by the introduction of additional categories and filters for drug-resistance profiles, for each reporting set. The care provider (nurse, doctor and facility) search function can be a useful addition to the search features set.

Product name	TBVOT.MD	Adhere2Tx-TB	Lekar
Interoperability, special features and upgrade options			
	(cont'd) • Streamline quick access to user manuals by integrating them into the provider web portal. • iOS™ support. • Reviewing existing procedures and policies against General Data Protection Regulation (GDPR) requirements and taking relevant measures to adjust will allow for the declaration of conformity.	(cont'd) • Adding a second layer of verification (specific controls and checkmarks) of nurse approvals for monitoring and supervision purposes can streamline overall management of the system. • iOS™ support.	(cont'd) • Adding a second layer of verification (specific controls and checkmarks) of nurse approvals for monitoring and supervision purposes can streamline the overall management of the system. • While an adverse events reporting feature was deliberately not integrated into the application interface, based on possible under- and over-reporting concerns, this feature remains a key aspect of VST and should be considered if replication is decided on. • Integration of a mini-survey feature can support treatment providers in patient feedback collection and research efforts. • Reviewing existing procedures and policies against General Data Protection Regulation (GDPR) requirements, and taking the relevant measures to adjust, will allow for the declaration of conformity. Moreover, considering the authentication characteristics of the system, restricting access to recorded videos and deleting recordings upon successful submission will enhance patient privacy.

ACT: Anatomical Therapeutic Chemical; API: application program interface; HCV: hepatitis C virus; HMIS: Health Management Information System; ICT: information and communication technologies; ID: identification; MDR: multidrug-resistant; NA: not applicable; NTP: National Tuberculosis Programme; OST: opioid substitution therapy; PrEP: pre-exposure prophylaxis; SMS: short message service; TB: tuberculosis; VOT: video-observed therapy; VST: video-supported treatment; XDR: Extensively drug-resistant.

Annex 2. Planning the implementation of VST of TB

Tables A2.1–A2.3 expand on the implementation requirements for VST and provide concrete action points along with planning considerations for each domain. A phased approach to VST implementation builds upon a three-step concept [Plan→Set-up→Rollout & support].

Table A2.1. Phase I. Planning and resource estimation

Phase I. Planning and resource estimation		
Requirement	Action point	Financial aspects
VST (Mobile application backed-up with the management platform)		
Once a TB programme decides to implement VST as a part of the national TB response, the options available for technological solutions, the possibility of replication and the need for fresh development have to be evaluated thoroughly. While new developments might be time intensive and associated with higher costs and challenges associated with the selection of a system developer, the adjustment of an existing system conserves development costs and proof-testing time as it builds upon the existing platform.	→ Establish a working group (WG) to review the technological solutions available for replication and define needs for new developments (if any). → Check if the capabilities of the system under review correspond to NTP needs and identify areas for possible adjustment. Engage all relevant stakeholders, with the primary focus on the ones to be directly involved in implementation – communities and care providers. → Make sure that VST system under consideration meets national and relevant international data privacy and security requirements. → Based on the extensive consultative review, agree on the VST system to be adopted and any required adjustments. → Agree on the conditions and period of post-deployment support. The latter can be provided by the system developer or trained in-house personnel.	→ Estimate system replication and adjustment costs (such as localization – i.e. translation; programme specific modifications, additional logics and validations). → Estimate post-deployment support costs based on duration and service conditions.
DATA HOSTING		
Patient data collected through the VST application has to be stored in a manner that ensures security and uninterrupted access to records by authorized personnel. There are two options for hosting the data:	→ Agree on the hosting option most suited to the implementation arrangements. The key factor to consider in the case of cloud hosting is whether the national regulations on personal data protection permit storage of patient records outside the country/via a third-party provider.	→ Estimate costs related to the relevant hosting options outlined below including: • modification/upgrade of existing infrastructure; • procurement of servers;

Phase I. Planning and resource estimation		
1) Direct hosting – server is located locally; in-country and designated agencies (Ministry of Health, NTP, etc.) have physical control over the infrastructure where data are stored. 2) Cloud hosting – also referred to as server on-demand hosting or third-party hosting. This does not require set-up of local infrastructure and is generally cheaper than direct hosting.	→ Define hosting requirements and server specifications relevant to the VST system of choice. Engage VST system developers to ensure that server capabilities match the VST system requirements. → Check if the country already has hosting infrastructure capable of accommodating the requirements and, where available, check for upgrade and modification requirements. → Make sure that the hosting option of choice meets national and relevant international data privacy and security requirements.	• contracting third-party provider for in-country or cloud hosting; consider payment schemes; (monthly, quarterly, annually); • additional costs related to achieving conformity with national and relevant international data privacy and security requirements. → Estimate server maintenance costs related to server software licensing, capacity upgrades, hardware maintenance, etc.
HANDHELD DEVICES, INTERNET CONNECTIVITY AND SUPPORTING TOOLS		
Uptake levels of mobile technology and handheld devices in target population settings as well as market shares of different mobile operating systems should be considered. If the latter matches the VST supported platform, there might be fewer patients requiring the provision of a smartphone. As Internet connectivity is pivotal for VST, it is important that patients and health workers are provided with quality and sufficient Internet connection. Distribution of supporting tools, can facilitate streamlined implementation of VST.	→ Set the target number of patients to be enrolled in VST and estimate the proportion of individuals who will need to be provided with mobile devices. → When, and if, the TB programme plans procurement of handheld devices, application developers must be consulted to ensure that the mobile devices meet the minimum technical requirements for the selected VST solution (operating system, storage capacity, camera specifications, etc.). → Consult with VST system developers on Internet connectivity requirements (speed and volume) for running the mobile applications and agree on the payment model for data plans (prepaid – purchased in advance; postpaid – covered monthly based on the contract with network provider) → Check if care providers (especially those located in remote areas) require Internet connectivity support and define data plan needs.	→ Estimate smartphone procurement costs based on the specifications developed and quantity defined. → Estimate data plan costs based on the target number of individuals to be enrolled and care provider requirements. → Estimate costs of supporting tools based on the chosen type and required quantity for the target number of patients.

Phase I. Planning and resource estimation		
	→ Agree on additional supporting tools to streamline implementation of VST, such as tablet dividers, daily packaging of pills and transparent glasses for video documentation of medication intake. Estimate the quantity required with respect to the target number of individuals to be enrolled.	
REGULATIONS AND POLICIES		
If the country decides to introduce VST, it should become a part of the national digital health agenda and be reflected in national strategies and policies. A set of guiding and regulating norms should be in place to authorize the concept and allow further scale-up.	→ Convene a WG meeting to develop a checklist of regulatory documents required to authorize and institutionalize VST; the regulatory checklist can include, but not be limited to: ☑ National Strategic Plan; ☑ State TB Programme; ☑ TB Treatment Guidelines and protocols (the latter can be developed separately for VST); ☑ Standard operation procedures (including informed consent procedures); ☑ M&E framework; ☑ User manuals for patients and care providers; ☑ Terms of use and privacy policy; ☑ Data usage and ownership agreements in case data are stored on a third-party provider's infrastructure (whether it is a cloud hosting solution, or an outsourced in-country hosting provider). → While some of documents on the list might involve adjustments of existing documents, others might require development from the ground up; hence, it is recommended to define which of those regulations require updating and which need to be developed. → Assign status, type of development and responsible party for each document on the checklist.	→ Estimate costs for technical assistance for the development of regulatory package for VST implementation. Consider areas where in-house resources can be utilized, and the need for external technical assistance.

Phase I. Planning and resource estimation		
HUMAN RESOURCES		
Allocation of human resources for particular areas of implementation of VST is required prior to rollout of the solution. There are direct and indirect personnel requirements for the operationalization of VST. Since the adoption of VST may involve enrolling new patients rather than switching existing cases, or where there are existing capacity limitations, the programme might need to hire new staff. In most cases, programme management and M&E requirements can be accommodated using existing resources. The technical support of the system can be outsourced and be part of the post-deployment support agreement with developers; however, the in-country hosting arrangement will still require ICT support.	→ Define direct personnel needed for VST implementation. Typically, this includes: • nurses; • doctors; • community health workers; • social workers (varies by programme); • psychologists (varies by programme). → Agree on the number of assigned patients per position and define the number of required personnel per position. → Take into consideration the available human resources, their current workload, and the target number of individuals to be enrolled to define needs for additional human resources → Define indirect personnel needs and check for availability with consideration of the workload and the implementation arrangements. Indirect personnel typically include: • programme management; • M&E staff; • ICT/network support staff.	→ Estimate direct and indirect personnel costs.
TRAINING		
Relevant training of existing and new personnel is essential to ensure proper set-up and management of the VST programme.	→ Develop a package of training materials that will include: • resources for application and system usage; • training material on regulations and operating procedures.	→ Estimate the cost for the development of the training package. → Estimate training costs based on the number of individuals to be trained (new and existing personnel).
BUDGETING AND FUNDING LANDSCAPE ASSESSMENT		
As soon as VST requirements, actions, financial aspects and cost estimations become available, it is important to document everything in a detailed action plan and reflect details in respective budget file.	→ Develop a quick action plan listing tasks, agencies and individuals in charge, and implementation time frames. → Develop a budget file reflecting all cost estimations as described above and time frames defined in the quick action plan.	NA

Phase I. Planning and resource estimation		
	→ Consult with relevant stakeholders on availability of domestic and donor resources within existing or upcoming (committed) funding; based on this consultation, estimate the financial gap for rolling out VST. → It is recommended to indicate the funding source in the budget file as well as quick action plan.	

NA: not applicable; NTP: National Tuberculosis Programme

Table A2.1.2. Task dependencies for Phase I

Task dependencies for Phase I	
Choosing VST solution	Initial step
Choosing hosting solution	Agreement on type of solution is nonsequential task, though developers shall be consulted on capabilities and specification of server
Handheld devices, Internet connectivity and supporting tools	Nonsequential, this step can be planned as long as a VST solution has been selected
Regulatory checklist	Nonsequential, this step can be planned as long as a VST solution has been selected
Human resource planning	Nonsequential, the number of the workforce required can be estimated as soon as the country decides to adopt VST
Training planning	While training costs are estimated at the initial stage, training materials can be developed as soon as major modifications to the system are applied and draft regulations are available
Budgeting and funding landscape assessment	Quick action plan and budget file development start at the initial stages, the details are updated incrementally and finalized when all estimations are completed

Table A2.2. Phase II. Set-up

Phase II. Set-up		
Requirement	Action point	Task dependency
ADJUSTMENTS TO THE MOBILE APPLICATION AND VST SYSTEM	→ VST developers to adjust the system based on the requirements defined on the planning stage and documented terms of agreement. → Engage “testers” of the system for each major adjustment and ensure an effective feedback loop with system developers.	Nonsequential, can be carried out in parallel with other tasks.

Phase II. Set-up		
REGULATORY ARRANGEMENTS	→ Update existing regulatory and policy documents as defined during the planning stage. → Develop system and concept specific set of regulatory documents. → If required, initiate procedures to obtain clearance from national agencies working in the area of data privacy and protection.	Nonsequential, can be carried out in parallel with other tasks.
HOSTING INFRASTRUCTURE PROCUREMENT AND SET-UP	→ Procurement of server infrastructure for data hosting based on specifications developed during the initial phase. → Procurement of server software and relevant licenses as required. → Set-up hosting infrastructure in accordance with VST system compatibility requirements and national and relevant international data privacy and security requirements.	Nonsequential, can be carried out in parallel with other tasks.
PROCUREMENT OF HANDHELD DEVICES AND DATA PLANS	→ Procurement of handheld devices based on quantity and specification defined in the planning stage. Agreement with the supplier shall include warranty terms and conditions in the event of faulty units and well as terms and conditions of repair and technical service. → Agreement with Internet network provider based on the requirements (data transfer speed and volume) defined on the planning stage. Agreement should explicitly define payment model (prepaid / postpaid). → Check if data plans will be enabled on existing personal SIM cards, or procurement of new ones is required.	Nonsequential, can be carried out in parallel with other tasks.
SUPPORTING TOOLS TO STREAMLINE VIDEO DOCUMENTATION OF MEDICATION INTAKE	→ Procurement of selected tools (e.g. tablet dividers, daily packaging of pills, transparent glasses) based on the quantity and specifications defined during the planning stage. If arrangements permit, samples should be provided to patients, to ensure that tools are acceptable and convenient.	Nonsequential, can be carried out in parallel with other tasks.

Phase II. Set-up		
TRAINING	→ Training of care providers. → Training of ICT and administrative personnel.	Training materials can be developed as soon as major modifications to the system are applied. Trainings should be conducted upon completion of adjustments and relevant regulatory documents.

Table A2.3. Phase III. Rollout and support

Phase III. Rollout and support		
Requirement	Action point	Task dependency
BETA TESTING	→ Ensure that the system runs without errors and disruptions; engage "testers" to ensure that the system is ready for operation.	Prior to launch.
M&E	→ Continuously monitor data consistency and conduct data verification on a regular basis. → Collect patient feedback either through application or through focus group discussions.	Continuous.
POST-DEPLOYMENT SUPPORT	→ Post-deployment support provided either under the scope of agreement with the system developers, or by the trained in-house ICT staff. This task is aimed at provision of continuous technical support after the system launch that is responsive to occurring needs (e.g. minor improvements, adaptations to changing conditions, etc.).	Continuous.[a]

[a] through the defined period is set by agreement with the system developers; continued by trained in-house ICT staff or an agreement extension.

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