Online Supplement[1]

Target Product Profiles for digital health products for the End TB Strategy

1. Patient care

1.1 Video treatment support (VOT) for TB patients via mobiles

1.1.1 Goals, scope and description

The end product will exploit video communication between patient and health care professional, transmitted live or self-recorded over a secure internet connection, to promote treatment continuity and adherence and to help TB patients improve their treatment outcomes. It is envisaged that the communication will be mediated in most settings through smartphones or tablet computers. This allows the caregiver to confirm remotely the self-administration of daily medication by the patient. The VOT interaction will not be limited to observing the act of ingesting TB drugs but also create opportunities to interact on associated problems, especially adverse drug reactions, comorbidities - particularly diabetes care for which there is trial-based higher-quality evidence for the effectiveness of mobile phone interventions(1) - and health promotion for risky behaviours (e.g. smoking cessation and substance use). VOT may help cut down on patient attendance to the clinic or on home visits. The mobile device used for VOT may also be used to communicate and provide enablers to the patient in order to increase adherence, in addition to documenting self-administration. The development of the intervention will be informed by the evolving evidence on its effectiveness and use, based on both observational studies as well as trials(2),(3),(4). The intervention itself will contribute to the expansion of this knowledge base, including aspects pertaining to the quality of care, patient experience and implementation practicalities.

1.1.2 Target end-users

There are two immediate end-users of the product:
1) the TB patient on treatment
2) the health-care provider (formal/informal)

[1] For abbreviations and acronyms please see the Glossary at the end

1.1.3 Value to the target end-user and other beneficiaries

VOT espouses the principles of patient-centred care, being adaptable to individual patient needs and preferences and promoting integrated care for patients with multiple diseases or health risks. The intervention is expected to make savings for the patients in time, cost and physical exertion associated with repeated travel to health care facilities. It is also meant to reduce TB-related stigma which may result when daily visits by the patient to the clinic or by a nurse to the patient's home results in disclosure of diagnosis. As for other digital health products, the intention is not that VOT replaces the health care workers, or that it will address all possible dimensions required for the proper management of a particular problem. VOT needs to be approached within a broader package of interventions and opportunities which can improve patient care and case management rather than a single "magic bullet". It also provides the possibility to explore synergies between different approaches, some of which may also be mobile-phone mediated (e.g. SMS communications). The data from VOT could be captured on the patient electronic register. VOT needs to offer clear advantages over similar products which exist or are coming up on the market or other options for patient care (such as a helpline).

1.1.4 Strategic fit

This product will build upon existing mHealth concepts which have been employed for TB treatment, support to mCessation or other comparable situations, especially SMS. Field experience and available evidence will guide the future direction of the key products proposed. The increasing access of health care professionals - as well as patients – to smartphones opens up new opportunities; this potential could broaden if better evidence is generated on the different application of smartphones for adherence in TB and tobacco care.

VOT has been successfully implemented using smartphones installed with basic, solid software incorporating an interface appropriate for different users. Apart from TB, VOT is destined to have broader application in health and social care, in situations where visual contact between the carer and the patient is important, ranging from the elderly person living alone who needs help with medication, persons who travel frequently, and individuals on methadone replacement therapy.

1.1.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current landscape are that:

- professional support for patients who take TB medicines daily is often needed but is resource intensive: bridging this gap through remote connection could address a number of needs for observed therapy
- in addition to TB, VOT may support patients with associated comorbidities (e.g. diabetes) and health risks (e.g. smoking, substance use) which likewise require support over a long duration to attain the desired outcomes
- there is now experience with VOT in different settings – including resource-limited countries and marginalized populations - and trials have been initiated to measure their effectiveness. Interest in these interventions is on the increase
- smartphone technology and broadband internet connectivity are currently low in many TB endemic settings but penetration is steadily increasing at a pace that by the time that this TPP matures VOT could become feasible in more settings. Clinicians may also be attracted to the added potential that digital connectivity offers for other work directly linked to patient care (e.g. electronic medical records, add-on clinical measurement technologies like pulse oximetry), as well as eLearning and surveillance (e.g. active TB drug-safety monitoring and management, or aDSM(5))
- development of products according to agreed parameters would be hugely reassuring to potential users and system developers who are often uncertain on how to approach an intervention for which the evidence is still incomplete.

1.1.6 Optimal requirements

The final product should achieve <u>most</u> of these criteria

- the possibility to protect patient identity by, among others, registering the patient anonymously or with minimal data on personal identifiers, ensuring data encryption and not storing image or video files
- allows online chat and/or other interactive functions
- generates a log which can be used for monitoring the patient/health care professional usage and the provision of incentives/enablers (e.g. as cash transfers or mobile credit)

- combining care functions with monitoring (across different functions)
- no license rights
- interoperable with existing digital records (especially patient electronic medical records)
- complies with other requirements (e.g. national treatment policies; training and eLearning developments)
- complies with recognised ICT standards as relevant;
- adaptable to different settings and devices, as well as to other specifics (e.g. twice-daily dosing)
- functional even when internet or cellular connectivity is weak or intermittent

1.1.7 Minimal requirements

The final product should achieve all of these criteria

- compatible with widely-used smartphone operating systems (e.g. Android, iOS, Windows, BlackBerry) or tablet computers and Internet browsers
- simple to download, install and use
- modest broadband requirements to function
- locally affordable or without license fees for software
- operates under secure connectivity which meets the data protection and privacy laws and regulations of individual countries
- inbuilt means to capture data on use, effectiveness, bugs and other feedback from the target population
- inbuilt mechanism to evaluate the downloading and other utilization and performance characteristics of the software package

1.1.8 Factors for success

The sustainability of this product will depend on favourable factors for its implementation and a number of other determinants:

- Achieves equivalent or better clinical outcomes when compared with existing local arrangements devised for the same purpose
- Achieves levels of adherence equivalent to or better than existing optimal local arrangements to support treatment continuity (clinic or community-based DOT, self-administered treatment)
- Can effectively address comorbidities and health risks additional to TB (e.g. diabetes, NCDs, smoking)

- Achieves better reporting and management of adverse drug reactions
- Is assessed to be highly accessible, acceptable and practically usable to a diverse and representative community of patients (equitable) among other quality indicators
- Reduces costs to both patients and providers when evaluated under standard cost utility analyses
- The number of different products that are derived based on the specifications of this TPP

1.1.9 Key risks (threats) for its development

The successful implementation of the project may be limited by the following factors:

- The local hardware, software and connectivity requirements prove not to be feasible for most settings rendering smartphone/broadband connectivity unreachable for many patients who could benefit most: overall impact on programme outcomes would therefore remain modest
- The evidence for VOT from ongoing trials fails to show efficacy
- The quality/quantity of the data do not allow an understanding of the effectiveness of the intervention
- Despite the availability of technology, patients are not offered a package which covers for the cost of the mobile, the software, the data plan and other necessary network subscription (i.e. not financially viable for the end users)
- Digital technology typically moves at much faster pace than the health care system and thus the VOT product may be outrun by other technologies that can do the same job by the time the intended product reaches the market
- Unrealistic expectations from the implementers, especially that the product will replace all human input
- Inadequate user skills to operate the VOT device or software
- There are breaches in the data protection or misuse of data
- The integration of services for associated comorbidities or health risks is not feasible when VOT is used to monitor TB treatment

1.2 eHealth portal to improve TB and tobacco care

1.2.1 Goals, scope and description

Online services to the TB patient simplified via a single internet hub accessible via smartphones and desktop computers. The TPP will specify the different functionalities which can be brought together in one internet site in order to improve continuity of care, facilitate patient adherence to TB treatment and increase the reach of smoking cessation efforts.

The product will consist of a common interface for "multichannel" access to a selection of digital tools which can provide, among others, support for adherence to TB and tobacco control measures [an example from the Republic of Moldova was used as a prototype for discussion(6)]. These could represent a range of items including electronic medical records, aids for adherence, information on health services and bidirectional communication. The tools need to be applicable within a range of field conditions, resource availability and patient/carer sub-groups.

The end-product is not intended to replace health care workers but to help them relate better to their patients. Using intuitive and graphical approaches with easy-to-follow instructions, it could affect the triage. It is envisaged to increase peer-group networking and other social media functions and help bridge the isolation of both patients and their health carers. It would need to bridge over seamlessly to other eHealth functions, such as eLearning for patients and health professionals. The product must have a patient-centred perspective and allow multiple health conditions to be addressed simultaneously. It takes cognizance of the fact that health-seeking behaviour differs not only between patients but also by the health condition. It will enable evidence gathering on uptake of the services, use and effectiveness, including those quality aspects of care which are commonly neglected. This product bears similarities with Target Product Profile 4.1 (see below) which is however more focused on the *education* of patients and public on TB and tobacco rather than *accessing information*.

1.2.2 Target end-users

There are two immediate end-users of the product:
1) the patient

2) the health care provider

1.2.3 Value to the target end-user and other beneficiaries

The patient and carer are provided with a set of products to choose from and can choose the technology which best suits them. The tool needs to provide a range of options to support TB treatment and/or tobacco smoking cessation. These would prioritise interventions for which there is an evidence base or sound experience, such as toll-free helplines and quitlines, mCessation programmes and referral to existing face-to-face tobacco cessation services. It also needs to offer clear advantages over similar products which exist or which are expected to become available shortly on the market.

1.2.4 Strategic fit

This product will build upon existing concepts which have been employed successfully for TB, smoking cessation or other comparable situations. The product should complement the national eHealth strategy and enrich other utilities devoted to public services if these already exist. These include electronic medical records and aids to adherence. Field experience and available evidence will be tapped into to determine the future direction of the key products proposed. The increasing access of health care professionals - as well as patients – to smartphones opens up new opportunities; this potential could broaden if better evidence is generated on the different application of smartphones for adherence in TB and tobacco care.

The portal will promote the concept of electronic health and services. The example from the Republic of Moldova shows the feasibility of the concept to create and use in lower middle-income settings. It is expected that such a system could contribute to improve the uptake of existing services as well as to increase the demand for others which can be created (e.g. instructions on accessing a particular health service or for TB adherence aids).

1.2.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current landscape are that:

- advancing technology is providing new opportunities but the users are often bewildered by how to make the best choice: having best-

practise examples - short of a solid base of high-quality evidence - to guide them would be hugely reassuring
- internet and smartphones are becoming more widespread and provide the clinician with aids to monitor adherence and, in a near future, to undertake clinical measurement (e.g. add-on technologies for pulse oximetry and monitoring of CO in breath)
- they promise to articulate better with different dimensions of care (e.g. surveillance or eLearning)
- could provide an array of flexible options for the users to choose from (e.g. same system allowing for SMS, video and also voice in case of emergency)

1.2.6 Optimal requirements

The final product should achieve most of these criteria
- operates using open-source software or socially-responsible licensing
- has a complementary application for use on mobile phones (e.g. HTML5)
- complies with other requirements (e.g. national treatment policies; training and eLearning developments)
- combining care functions with monitoring

1.2.7 Minimal requirements

The final product should achieve all of these criteria
- compatible with widely-used smartphone operating systems (e.g. Android, iOS, Windows, BlackBerry) and Internet browsers
- users find it easy to navigate
- customisable to the field (e.g. translation, modification of lists of options)
- locally affordable or no license fees
- inbuilt means to capture data on use, effectiveness, “bugs” and other feedback from the target population
- inbuilt mechanism to evaluate the performance of the tool
- complies with recognised standards (where relevant)

1.2.8 Factors for success

The long term success for this product will be determined by:
- The users finding added benefit from the tool, such as improving the quality of services

- A real reduction in costs to the patient (e.g. avoid extra travel) and to the services
- Accessibility to poorer users (inequality)

1.2.9 Key risks (threats) for its development

The successful implementation of the project may be limited by the following factors:

- The technological requirements prove to be insurmountable
- The expectation on the tool to reduce labour costs are unrealistic
- Patients access services through other routes
- ICT typically moves at much faster pace than the health care system
- Infrastructural challenges (e.g. connectivity, devices)
- Inadequate eLiteracy of the users
- Data protection (software which can register the unique gesture of an individual patient ingesting a specific pill (e.g. (7)) may in future obviate the need to send video recordings over the web)
- Misuse of data
- Clinical quality of the data

2. Surveillance and monitoring

2.1 Digital dashboard for TB indicators and epidemiological trends

2.1.1 Goals, scope and description

In order to improve the understanding and use of surveillance data, health care workers and public health officials should have access to a user-friendly and interactive digital dashboard that displays up-to-date epidemiological trends in TB diagnosis and treatment and service delivery for tobacco control for any area in the country.

The product will consist of a dashboard visual display of programme and epidemiological data for use in public health decision-making on control of TB and other associated conditions (e.g. tobacco use) at local, regional and national levels.

It will include information on key risk factors, such as non-communicable diseases (e.g. tobacco and alcohol use). The dashboard can form part of an “early-warning system” to alert the programme management about particular action needed.

The product will have the following features:

- The digital dashboard provides a snapshot of key TB indicators necessary for public health decision making
- The TB information is presented through various graphical forms which are easy-to-interpret, customize, and download, including graphs, charts, tables and maps (geographical information system), as described elsewhere by WHO(8)
- These data originate from the national TB surveillance database and are converted into a user-friendly display which can be customized to the need of public health officials and front-line health care workers
- Data can be examined at different levels (local, regional, national):
    - **Facility level**: focus on patient care activities (e.g. cases registered, cases put on treatment, numbers cured, patient visits, numbers currently on treatment, number of adverse events, numbers lost to follow-up, data on laboratory test activity) to trigger actions (e.g. if number diagnosed is greater than number started on treatment).
    - **District level and above**: focus on epidemiological indicators, comparison between areas using maps and charts (e.g. ratios such as pulmonary/extra-pulmonary cases, case notification rates and trends, mortality rates and trends) to identify unusual trends or outliers which can then be investigated by district officers. This also permits the monitoring of programme and resource management indicators, and the timeliness, accuracy and completeness of reported data.

2.1.2 Target end-users

- Front-line health care workers in the national programmes for TB and tobacco control, and those working in the private sector or non-governmental agencies
- NTP and Ministry of Health
- Public health stakeholders inside and outside the NTP, including the private sector
- Academic institutions and health care facilities
- Other governmental and nongovernmental organizations (domestic and international) engaged in the surveillance, prevention and control of TB and tobacco
- General public

2.1.3 Value to the target end-user and other beneficiaries

- Brings data to life, particularly if facilities usually only use paper-based systems
- Provides feedback to health care workers who often spend a great deal of time and effort recording and reporting TB and tobacco data (e.g. can be used during regular supervisory visits)
- If case-based data are available then aggregated visualisations and associated data tables can be generated automatically without the need for laborious, error-prone and time-consuming manual compilation of aggregate quarterly reports
- Advocacy value for workers, public and activists on the effectiveness of TB control efforts ("Last year, *x* people were cured of TB in our district" or "Last year, *y* people successfully quit smoking in our district")
- Makes it easier to spot deviations in the data for further investigation, e.g. is there something wrong with the data quality or has there been a sudden change in epidemiology or in service provision? Where have the changes occurred (so supervisors can prioritise areas to visit)? It is important that such investigations result in a constructive process of continual improvement rather than a punitive approach towards staff
- Complements training for end-users, including those involved in public health decision making, on how to interpret TB information and utilize it for informed public health action and policy making
- Trends for large areas (districts and above) can inform forecasting, supply and resource management activities
- Timely dissemination of TB information to facilitate effective and efficient public health response to prevent and control TB and TB outbreaks, and to advocate for resources to continue the work
- Automatically updated as new data becomes available
- Overcoming logistical and environmental inefficiencies of paper reporting system
- If the product is designed with flexibility in mind it could potentially be re-used as a platform for visualising other health data

2.1.4 Strategic fit

The dashboard is incorporated into the existing TB surveillance system in the country, which may already include in-built functions for the analysis and dissemination of TB data. The dashboard would be a useful "rallying point", summarising the crucial indicators for the main users of the system and promoting further discussion and evolution. The outputs will be useful for programme management and for advocacy purposes.

2.1.5 Rationale for prioritization

- Data collected by surveillance systems are often under-utilized for public health action
- Need for evidence-based public health resource allocation and decision making at different levels
- Improving TB surveillance information by focusing on essential indicators such as case notification rates, and proportion of deaths and loss to follow up in patient cohorts (for more details on important indicators see(8),(9))
- Facilitates the task for health workers to generate reports (especially those located in a decentralised setting) and provide more illustrative outputs (e.g. for lectures and donor reports)
- Stimulating monitoring and evaluation, more in-depth analysis and research (including operational research) for evidence-based TB service/programme planning and implementation
- Data quality problems are common but can be hard to spot in the absence of systematic examination of the data to look for outliers or unusual trends

2.1.6 Optimal requirements

The final product should achieve <u>most</u> of these criteria:

- Simple to use through most mobile and desktop devices
- Customisable to the most commonly used languages in the country
- Charting software is flexible and independent of the method of generating the underlying data

2.1.7 Minimal requirements

The final product should achieve <u>all</u> of these criteria

- Produces appropriate visualisations at different administrative levels (e.g. district, region, national)

- Produces indicators as proposed by WHO(8)
- Allow users to create and change charts, maps and tabulations as they require
- Be based on open standards and data dictionaries, including standard facility lists (preferably geocoded), sub-national division names, boundaries and population sizes
- Can use external data files (e.g. simple spreadsheets in MS Excel) as input provided they are structured according to a standard specification
- Customisable to at least one official language in the country
- Approved and supported by the respective Ministry of Health
- Available to all relevant public health stakeholders and front-line health care workers inside and outside the NTP free of charge
- Can be integrated with the existing health information systems in the country covering TB and tobacco control

2.1.8 Factors for success

- Top-level commitment to producing, understanding and acting upon TB surveillance data, including promoting the dashboard amongst data management officials and end-users
- Establishing clear rules on who has access to what data to ensure users' trust in the system
- Agile software development process that fosters active collaboration between developers and users in planning and continuous improvement of the software (in particular "open-source" applications or operating under socially-responsible licensing)(10),(11),(12),(13)
- Active engagement of surveillance end-users (e.g. TB programme managers, public health officers) in planning data selection and data analysis so that the disseminated surveillance information responds to their needs and expectation
- Availability of standardised, up-to-date information on sub-national divisions (e.g. names, geocoded boundaries and population sizes). These divisions could be administrative or health-related (e.g. NUTS for European Union countries(14))
- Training of and ongoing technical support to relevant public health workers in the NTP in epidemiology and descriptive data analysis

- Training end-users, including local/regional/NTP managers, on how to interpret TB information and utilise it for informed public health action and policy making
- Adequate financial and technical support to public health staff in the NTP in charge of data management, data analysis and dissemination
- Active monitoring of local/regional/national public health managers for visualizing and understanding the dashboard information (e.g. by simple text quizzes)
- One centralized system of surveillance for TB in the country to which various providers report, with timely and effective data management.
- Regular evaluation of the dashboard to assess:
    - Validity and representativeness of visualisations
    - Acceptability and utilisation of the system by users
    - Health outcomes and impact on public health

2.1.9 Key risks (threats) for its development

- Lack of commitment (at different levels) to using the dashboard
- Inadequate consultation with intended users in planning the product
- Unclear or opaque rules on and implementation of data access and use, leading to loss of trust
- Visualisations have negative repercussions and disincentives to the poor performers rather than help identify problems to improve performance
- Inadequate utilization of available data by local, regional and national stakeholders (e.g. during regular supervisory visits) due to lack of motivation or inadequate training of the responsible public health staff
- Showing epidemiological targets in the visualisations. This should be avoided, especially if they are based on estimates that are not tailored to local conditions. Such targets do not make sense, can distort perceptions and may have unintended consequences such as inaccurate data reporting
- Including sub-district divisions in choropleth maps. This should be avoided because population denominators are uncertain.
- Excessive costs if not planned and implemented carefully (financial, staff time)

- Inadequate resources to provide promised technical support to public health staff who are responsible for data analysis and dissemination, and those involved in public health decision making
- Lack of ongoing monitoring and evaluation of usability, acceptability and quality of the reporting system

2.2 Digital notification of TB cases

2.2.1 Goals, scope and description

In order to reduce under-reporting of TB cases to the national surveillance system for TB, front-line health care workers outside the National TB Programme (NTP) can utilise a simple digital system to notify TB cases.

While this TPP focuses on the oft-problematic notification from outside the NTP, the product could also address weaknesses *within the NTP* where under-reporting may be an issue as a result of deficiencies in the information management systems.

An application for front-line health care workers outside the NTP which provides for the comprehensive and timely notification of TB cases to the national TB surveillance database. A number of efforts have been made to promote electronic notification of TB, such as in India(15).

The product has the following features:
- Adherence to WHO case definitions to standardize case notification
- Simple fields with menu-driven data entry to ensure that the TB surveillance system captures a minimum set of variables for all reported TB cases (as described in (16))
- Unique patient identifier to facilitate linking the data to existing surveillance systems in the country and to reduce the probability of data duplication. This unique identifier will facilitate the linkage of health data for a given individual from different health reporting systems in the country, including the laboratory and drug-safety surveillance data
- A simple ''yes'' or ''no'' question on whether the provider needs additional services to provide care for this patient. A list of available clinical and public health services in the region/country can be provided to specify the area of needed support. For example:

    - Provision of clinical testing for patient including laboratory test (e.g. WHO-approved rapid diagnostics or sputum culture for TB and drug susceptibility testing and HIV test) and TB radiological exam
    - Provision of TB medications (including medications for resistant TB and TB-HIV therapy)
    - Provision of patient support
    - Referral to smoking cessation services
- A simple ''yes'' or ''no'' question on whether the provider needs support to manage close contacts of this index patient.
- If the provider requests support then a public health officer from the NTP will contact the provider for further information and to arrange for supportive patient care and/ or contact management.
- Provides reports to providers on the number of TB cases notified and their follow up.
- The system can either accommodate additional information important for the follow-up of the patient (e.g. bacteriology results, record of treatment compliance, adverse events or outcomes of treatment) or can interoperate with a separate database used for this purpose

2.2.2 Target end-users

- Health care workers outside the national TB programmes including those in the private sector
- NTP and Ministry of Health
- Academic institutions and health care facilities
- Other governmental and nongovernmental organizations engaged in TB surveillance, prevention and control

2.2.3 Value to the target end-user and other beneficiaries

- Contributes to a more complete picture of TB epidemiology and response in a country where many people seek care outside the NTP
- Provides information on the number of TB cases reported by each facility
- Can assess the effect of measures introduced to mandate or promote the notification of TB
- Facilitates effective and efficient public health response to prevent and control TB

- Facilitates the support to the front-line health care workers for the management and follow-up of TB cases and their contacts (e.g. expert consultation, drug supply)
- If information about treatment regimens is collected it can be used to quantify medicine consumption, to support supply management decisions, and improve forecasting of medicines needed
- An incentive-based system health care workers in the public and private systems who report cases could be added

2.2.4 Strategic fit

This product will link to an existing national surveillance system for TB and other notifiable infectious conditions, when applicable. The product could serve as a model for the reporting of other notifiable diseases

2.2.5 Rationale for prioritization

Recent TB prevalence surveys and inventory studies have demonstrated that in many countries TB rates reported by the NTP are gross underestimates of the true TB burden. In addition to under-reporting from within the NTP, many cases diagnosed and treated outside the NTP are not notified to the national TB surveillance system. Therefore the knowledge base upon which health service planning and decisions (including resource allocation) are made is incomplete.

2.2.6 Optimal requirements

The final product should achieve most of these criteria

- Simple to use through most mobile and desktop digital devices
- Integrated and interoperable with the existing TB health information system in the country
- Enables the capture of more fields than the minimum set required, such as on treatment regimen (composition, duration, drug dosage) and associated risks (e.g. tobacco smoking)
- Has a reporting feature which enables users to summarise data entered
- Incorporates activity monitoring, such as a log of the location of reporters
- Has user guides or standard operating procedure (SOP) and training materials

- Has internal data quality controls to minimize errors and inconsistencies, e.g. date fields selected from a calendar instead of entered manually

2.2.7 Minimal requirements

The final product should achieve all of these criteria

- Captures a standard minimum set of data items for each notified TB case needed for epidemiological surveillance[2]
- Customisable to at least one official language in the country
- Approved and supported by the respective Ministry of Health
- Conforms to WHO definitions and reporting frameworks(9),(17)
- Robust measures for system security/encryption and data confidentiality which conform to the data protection and privacy laws and regulations of individual countries
- Available to all front-line health workers inside and outside the NTP free of charge

2.2.8 Factors for success

- A policy of mandatory TB notification
- Top-level political commitment by Government to engage the non-NTP sector in TB surveillance and to promote the participation of health system stakeholders in TB surveillance
- Agile software development process that fosters active collaboration between developers and users in planning and continuous improvement of the software (in particular "open-source" applications or socially-responsible licensing)(10),(11),(12),(13)
- Inbuilt mechanism for users to evaluate the performance of the tool
- Accessible technical support for software maintenance, updating and trouble shooting
- Establishing clear rules on who can access what data and the rights to modify, in order to ensure users trust in the system
- Integrated with health information system for HIV and other notifiable infectious diseases
- A coordinated TB surveillance system in the country which can consolidate case notification and follow-up data from all providers of health services

[2] See Standard B.2 in (16)

- Avoiding over-burdening providers by restricting the data needed to notify and follow-up a TB case to a minimum
- Providing incentives for health care workers to report data on TB cases. These could consist of monetary credits to non-NTP front-line workers for each TB patient they notify, or other forms of rewards, such as information or training credits
- Implementing auditing processes to verify notifications, especially if financial incentives are used
- Training on TB care and TB case reporting (based on national and international standards of TB care) for front-line health care workers
- Collaboration between the NTP, domestic academic institutions and relevant international experts so that the NTP can provide support and expert consultation to front-line health care workers for efficient TB case and contact management.
- Regular evaluation of the system to assess:
    - Consistency, accuracy and representativeness of data
    - Acceptability and utilisation of the system by users
    - Health outcomes and impact on public health

2.2.9 Key risks (threats) for its development

- Lack of commitment at Government and other levels to improve the national surveillance system for TB (and other infectious diseases)
- Inadequate consultation with intended users in planning the product
- Vertical data collection system misaligned with other existing health information systems, including for TB
- Unclear or opaque rules on the implementation of data access and use, leading to loss of trust and reluctance to use the system (e.g. fear of endangering the patient-doctor relationship if patient data confidentiality could be compromised)
- Sub-optimal data management: analysis, interpretation and dissemination of data
- Inadequate utilization of available data by local, regional and national stakeholders to prevent and control TB
- Excessive costs if not planned and implemented carefully (e.g. software license fees, maintenance and correction of bugs, staff time, training)
- Inadequate resources to provide promised incentives and technical/support (e.g. limited availability of TB experts, TB

medications, other public health resources for TB outbreak management)
- Lack of ongoing monitoring and evaluation of usability, acceptability and quality of the reporting system
- Continued user preference for paper registration owing to failures in the electronic system provider or persisting lack of trust in digital records

2.3 Digital application for active TB drug safety monitoring

2.3.1 Goals, scope and description

In order to monitor effectively the adverse effects of TB medicines and to improve patient safety, national programmes should be able to benefit from technologies which enhance active monitoring of drug-safety concerns and toxicity.

The digital application will facilitate the work of health care workers to register safety data. This product is primarily intended for contexts where new drugs and novel regimens are being introduced - particularly for drug-resistant disease - where uncertainty about the risk to benefit of an intervention is relatively high. However, the product could also have a role in the treatment of TB with conventional regimens and legacy drugs, as well as conditions other than TB (e.g. concomitant treatment of HIV and other comorbidities). The information from the digital drug-safety monitoring system can facilitate timely action ("early warning") to mitigate drug-related harms in the individual patients and the effective management of patient cohorts on new TB therapies at the country level. It is also a means to operationalise active TB drug safety monitoring and management (aDSM) as recommended by WHO(5),(9).

The application is envisaged to have the following features:

- Built around standardized digital questionnaires (see templates annexed in reference (9)), for:
    - Initial (pre-treatment) assessment of patient's history, clinical status and laboratory tests
    - Review of patient's status while on treatment and after it ends
- Staff at the NTP or the national authority responsible for drug safety will receive the digital questionnaires and analyze the TB drug safety information for the indicators, causality and signals
- The product will adhere to the minimum data elements list(18)

- Unique patient identifier to facilitate the linkage of the data to existing health and vital registration systems in the country and to reduce the likelihood of record duplication
- The adverse events observed in association with TB therapy are recorded on the system with information on the severity and seriousness of an event. This also includes data on laboratory tests as indicated in the programme's active drug-safety surveillance standard operating procedure (SOP; e.g. (19))
- In the absence of a functional national drug-safety monitoring system the digital product could be linked to the patient electronic medical records or TB surveillance system(s) in use locally

2.3.2 Target end-users

- The NTP and national authority responsible for drug safety
- Health care workers inside and outside the national health programmes (including those in the private sector)
- Other governmental and nongovernmental organizations engaged in TB care and / or drug-safety (including academic institutions and hospital sector)
- World Health Organization (via mechanisms that pool data across different programmes)
- Drug manufacturers

2.3.3 Value to the target end-user and other beneficiaries

- Facilitates timely reporting of drug-safety information by health care workers (with positive externalities to drug-safety monitoring for conditions other than TB)
- Alerts the surveillance experts to problems faced by technical staff in the management of cases with a clinical picture suggestive of adverse drug reactions
- Replaces paper-based forms and mechanisms for cohort event monitoring and improves the flow of information
- Allows flexibility for regular updates (e.g. based on the feedback from users, evolving information on new drugs and regimens, and TB guidelines) without much extra workload for the front-line health care workers
- Facilitates the reporting of adverse events from the country level to a global database

- Provides an early warning system for harms linked to the target medication and quickens the pace for any necessary action and communication about product safety(20).

2.3.4 Strategic fit

The product functions as one component of a larger framework of digital applications for TB patient care. It will be integrated with any other drug-safety mechanism which exists in the country, particularly for new drugs and regimens and for other infectious diseases. If no functional drug-safety monitoring system exists in the country the product could be linked to other digital systems used for patient care or for TB surveillance. Following the conditional release of two new TB drugs since 2013(21),(22), the use of shorter MDR-TB treatment in recent years which is destined to increase in the coming years(23), the expected introduction of more novel TB regimens in a near future, and the paucity of electronic tools to report drug-safety data tailored to the express needs of TB programmes, the demand by national programmes to implement aDSM under field conditions and to contribute to the global knowledge base about these experiences is high. This affords the product its legitimacy and gives it an excellent strategic fit.

2.3.5 Rationale for prioritization

- The product can strengthen under-developed systems for drug-safety monitoring in developing countries
- It can contribute to improve patient safety
- It would be an indispensable tool for aDSM, a crucial issue for countries introducing bedaquiline and delamanid as per WHO policy(21),(22)
- The product – and inferences drawn from the data it gathers – could contribute to the growing knowledge-based on how to optimize the management of patients with drug-resistant TB and improve resource allocation when limited therapeutic options exist

2.3.6 Optimal requirements

The final product should achieve most of these criteria:

- Simple to use through most digital devices (mobile and desktop)
- Customisable to most commonly-used languages in the country

- Captures a standard minimum set of data items for all patients before and during treatment with TB drugs and regimens, particularly when novel drugs are used(5),(18)
- Enables users to customise data entry
- Has user guides or standard operating procedure (SOP) and training materials
- Internal data quality controls to minimize errors and inconsistencies, e.g. date fields selected from a calendar instead of entered manually

2.3.7 Minimal requirements

The final product should achieve all of these criteria:

- Customisable to at least one official language in the country
- Endorsed and supported by the country's Ministry of Health
- Robust system security and data confidentiality
- Available free of charge to all front-line health workers inside and outside the NTP
- The application should comply with requirements of, and if possible be integrated and interoperable with, the existing drug-safety monitoring and/or TB information systems in the country(18),(19)

2.3.8 Factors for success

- Top-level national commitment in engaging front-line health care workers inside and outside the NTP to improve drug safety for patients on new TB therapies
- Agile software development for an easy-to-use system that promotes active collaboration between developers and users in planning and continuous improvement of the software (preferably operating under open-source or socially-responsible licensing agreements, ensuring free or affordable installation and servicing)
- Accessible technical support for software maintenance, updating and trouble shooting
- Establishing clear rules on user access to view, comment or modify the data to improve trust in the system
- Integrated with existing drug-safety monitoring systems although the product may be implemented as part of a standalone system for patients on TB medication
- Ideally, one centralized system of TB drug-safety monitoring for the country allowing patient-specific reports from various providers being registered, analysed and summarised in one site

- Collecting ''minimal'' relevant drug-safety monitoring information required for targeted action to improve patient care and safety(18)
- Providing simple rewards to incentivize caregivers who report and monitor patients on new TB therapy by using the system (e.g. financial, logistical, informational)
- Encouraging real-time reporting of drug-safety monitoring information by the health care worker who is assessing a given patient (versus retrospective chart review by other health care workers) to improve accuracy and completeness of information
- Providing health care workers with training as needed on patient interviewing, patient assessment and reporting for patients on new TB drugs or regimens
- Collaboration between the NTP, the national drug-safety monitoring programme, domestic academic institutions and relevant international experts in providing technical support and expert consultation to front-line health care workers for effective assessment and management of patients on new TB drugs and regimens
- Planned monitoring and evaluation of the system on a periodic basis internally and/ or by an external partner. This will mainly focus on:
    - Data quality
    - Acceptability and utilization of the system by end-users
    - Auditing processes to verify reporting, especially if financial incentives are used

2.3.9 Key risks (threats) for its development

- Lack of commitment at different administrative levels to improve the national TB drug-safety monitoring (and other infectious diseases)
- Fragile health systems and inadequate resources to introduce new TB drugs and regimens effectively
- Inadequate utilization of available drug-safety monitoring data by local, regional and national stakeholders in effectively managing patients on new TB therapies, in order to prevent harm and improve patient safety and health outcome
- The digital product fails to align itself and to be integrated with other existing drug-safety monitoring or TB information systems in the country

- Inadequate consultation with local end-users in planning the product
- Suboptimal data management, analysis, interpretation and communication of inferences made in the process of drug-safety monitoring
- Lack of ongoing monitoring and evaluation of usability, acceptability and quality of the product
- Costly in terms of financial, time and human resource investment with little visible returns
- Inadequate resources to provide promised incentives and technical/support to front-line health care workers caring for TB patients on new drugs or regimens (e.g. limited availability of drug-safety monitoring experts, TB medications, laboratory facilities).

3. Diagnostic device connectivity for TB

Only one TPP is proposed under this area.

3.1 Goals, scope and description

The goal is to have diagnostic test devices which support "*connectivity*" tailored to the needs of centralised and decentralised testing facilities in low resource settings. The product fits within a larger picture of a diagnostic system which reports test results directly to data servers for use by clinicians (including transmission via SMS or email) or entities (e.g. electronic health records) that require these data.

Whilst growing in number and diversity, most of today's medical devices and diagnostic tests in low and middle income countries have no or only limited connectivity capabilities. Most diagnostic results are captured in paper format, spreadsheets or, at times, entered onto customised databases or hospital information systems (HIS). Wherever the data are stored electronically this almost invariably requires one or more stages of manipulations by staff, such as the transcription of a result from paper to machine.

The focus of this TPP is on a data exchange mechanism which is broadly-applicable to different settings, which is suitable for basic diagnostic and computer devices, and which is embedded within the surrounding laboratory information system (LIS) or HIS.

3.2 Target end-users

The product is expected to benefit primarily:

- Laboratory managers and staff who will be sending results for centralised collection and analysis
- Other staff of the national programmes responsible for TB, HIV and integrated disease surveillance and response (e.g. supply chain managers, EQA professionals, IT support teams and supervisors)
- In the case of tests performed in decentralised facilities outside of a laboratory setting, clinicians and/or other health workers may be targeted
- Manufacturers' product teams who need to understand device usage, faults, and envision enhancements

3.3 Value to the target end-users and other beneficiaries

For Ministries of Health, NTPs and laboratory managers

- Faster reporting and recording of test results
- Faster turnaround time for transmission and linkage of results to medical encounters
- Reduction in data transcription errors
- Deduplication of results data from the same patients or same biological specimens being tested using different techniques
- Real-time laboratory network management data and epidemiological surveillance
- Improved overall systems traceability

For manufacturers

- Insight into utilization patterns of devices
- Greater forecasting ability for cartridge and reagents
- Visibility of deployed device performance metrics

When embedded in a locally existing national eHealth system, connected medical devices allow for:

- higher efficiency, effectiveness and speed through the elimination of manual data management
- faster and improved patient response and care
- shorter turn-around times
- reduction of transcription errors
- optimized workflows
- better use of resources

- better understanding of the demand volumes across different diseases and other dimensions (e.g. geographic, demographic, patient profile)
- improved integration of different sectors of the health care system (private/public; different disease programs)
- improved after-sales support and maintenance of laboratory infrastructure

Once all three components of an enhanced laboratory information system are in place, the ultimate beneficiaries will be the clinicians, who receive reliable results faster, and patients, whose treatment is based on the most recent results.

3.4 Strategic fit

This TPP addresses only the diagnostic device connectivity functions and thus focuses on data communication. The product fits into the current landscape where diverse proprietary equipment from different vendors often coexist in the same diagnostic site; there is a necessity or desire for devices from multiple manufacturers to interoperate(24); the increasing focus on integrated health information systems in developing countries (enabled by complementary initiatives such as OpenELIS(25), OpenMRS(26), OpenHIE(27), BID Initiative(28), HISP(29) and DHIS2(30)), and a drift by the industry towards systems architectures that embrace the Internet of Things (IoT). Linking in laboratory devices is thus a logical strategic fit. Users - particularly NTPs - could save time and money on integration efforts for new devices.

The TPP is primarily aimed at newer electronic diagnostics in two scenarios: (i) those which are already in operation (e.g. GeneXpert) but only where a change in connectivity methods should avoid any lengthy process of recertification of devices or operational disruption; and (ii) those diagnostics which are still in the development stage and where considerations for device connectivity should be in place from inception.

3.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current situation are that:

- the development of a framework for device connectivity, and associated landscape analysis of connectivity requirements is the agreed logical first step to achieving the defined architecture

- various efforts are already under way which require strategic guidance beyond the technical objectives governing current systems research and development
- actors would greatly benefit even if only the device connectivity component of the architecture is implemented as it could catalyse other interoperability processes
- development of products according to the agreed parameters would be hugely reassuring to potential users and system developers who are often uncertain on how to approach an intervention for which the evidence is still incomplete
- having systems interoperable would present great value to the end user

3.6 Optimal requirements

The final product should achieve most of these criteria:

- Customised routing for device performance data and clinical test results should be supported using the same transmission protocols
- The device should support "over-the-air programming" (OTA) for remote configuration purposes
- The device should support bi-directional communication for remote product support purposes
- The device should be able to support SMS result transmission for areas without GSM or wired data connectivity
- The data can interact directly with LIS and HIS complying with widely-used interoperability standards
- Allow different levels of data encryption per field of data generated i.e. patient identifiable could have more encryption than date/time stamp
- Allow for targeted transmission or availability of data for specified roles or categories of access (e.g. access to personal identifiers may be restricted)

3.7 Minimal requirements

The final product should achieve all of these criteria:

- Data should be in industry-recognised formats
- Be able to transmit all data generated by the device including device performance data and associated data inputted by the user
- Support data transmission via mobile networks (GSM)
- Support data transmission via Local Area Networks (LAN)

- Transmission of data should be secured. An overarching rule is that patient data with personal identifiers must not be accessible to those who do not have permission[3]
- Should be easy for a non-technical user to configure connectivity via a device physical interface
- Options to send data automatically and "on-demand" by user. The case for transmission on demand is needed were result validation is necessary before transmission, to avoid false results
- Ability to test connectivity settings
- Ability to see status of connectivity transmissions
- Ability to recognise failed transmission and cache results for retry

3.8 Factors for success

The following factors are essential for the successful implementation of the product:

- The system must be useful for Ministries of Health and show positive impact on laboratory workflows and patient data management in the short term
- Multiple manufacturer buy-in and adoption at correct stage of product development cycle
- No disclosure of data which may be sensitive to the manufacturer (beyond those required for patient care, surveillance and programme management)
- Consensus on data format
- Consensus on minimum data content
- Security of data transmission and protection of privacy
- Demand for eHealth and connectivity in national health strategies

3.9 Key risks (threats) for its development

- Device manufacturers persist with their own proprietary systems and are not motivated to make their software interoperable
- eHealth system serves the manufacturers but has a limited impact from the local laboratory or health programme perspectives
- Solutions continue to be developed that are technology-driven rather than being guided by health systems management and public health requirements

[3] The US Health Insurance Portability and Accountability Act (**HIPAA**) contains rules which are commonly used to define standards for privacy

- System functions in isolation, detached from other patient workflow information
- Countries do not own or sustain the implementation
- The product is implemented but does not scale-up or move beyond the pilot stage
- Absence of sufficient sensitivity to privacy/confidentiality issues, device security and liability leads to products that cannot be deployed in a wide cross-section of settings

4. eLearning

4.1 Information resources platform for patients on TB and smoking cessation

4.1.1 Goals, scope and description

The platform will incorporate a forum for sharing patient experiences and educational anecdotes, and use "gamification" elements to retain the users' attention and interest. Gamification refers to the use of game techniques and mechanisms for purposes other than games, such as to improve knowledge retention and user engagement. The use of quizzes and games can be a way to increase the uptake of the educational messages by the target group and achieve behavioural changes, and there is now trial evidence in favour of video games as an effective means to improve knowledge and self-management in patients with chronic conditions(31). Game mechanics may be particularly well-suited for patient education, as they can provide incentives to reward health-promoting behaviour such as adherence to medication or taking physical exercise(32),(33),(34).
This product shares features with Target Product Profile 1.2 (see above) but has a slant on public and patient *education* rather than *information on access to services.*

4.1.2 Target end-users

- TB patients
- Relatives of patients
- Tobacco smokers

4.1.3 Value to the target end-user and other beneficiaries

- To improve patient care, to help patients understand adverse effects of treatment, and as an adjunct to providing informed consent (e.g. about use of new drugs)
- Help TB patients receive trustworthy information on their medication and options for cure
- Help TB patients access self-help resources on Internet to stop smoking (e.g.(35))

4.1.4 Strategic fit

- This product will build upon established eLearning concepts, including gamification for education of the general public
- Articulates well with the general drive to diversify the media options for patient education/information
- Fits into existing national strategies for eHealth and mEducation

4.1.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current landscape are that:

- It can reach a large segment of the public efficiently
- A strong need for such a utility was expressed in the online poll ahead of the WHO/ERS consultation

4.1.6 Optimal requirements

The final product should achieve most of these criteria:

- Sound, well thought-out and effective evaluation design/feedback of impact
- Built around visual aids rather than “block text”
- Be attractive, fun and easy to use
- Personalisation options

4.1.7 Minimal requirements

The final product should achieve all of these criteria:

- Sound, well thought-out, and effective design/feedback of impact
- Compatible with the most widely-used mobile operating systems and browsers as well as PCs and Apple computers
- Inbuilt collection of user statistics, bugs and feedback/suggestions for improvement from the end user
- Allows localization and adaptation of content including languages

- Barrier-free for people with disabilities
- Based on latest WHO and ERS recommendations and evidence
- Endorsed by the relevant authorities based on the country setting
- Does not require the user to provide identification
- Free of charge for the users

4.1.8 Factors for success

- Platform actively publicised online as well as by more traditional means e.g. doctors give out flyers with website address
- Articulates with other programmes to support TB treatment adherence and smoking cessation (including mCessation)
- Reaching a critical mass of contributors
- Competent moderators
- Ease of use and easy ways to personalize it
- Accessibility on mobile devices
- Communication is patient-friendly using acceptable, non-technical language and also uniform with other products

4.1.9 Key risks (threats) for its development

- No clear ownership of the function by the promoters
- Patients opt for other sources of information (no added value over what is already accessible)
- Updating of the content and moderating any social media forum prove too laborious.

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

4.2.1 Goals, scope and description

The product will be a self-directed and problem-based learning tool for primary health care providers.
Self-directed eLearning courses are available separately for both TB and smoking cessation; however no web-based course satisfactorily links both aspects satisfactorily(36),(37). The web-based course, equipped with visual instruction aids and built-in self-evaluation functions, will help to build the capacity and skills of health professionals and ultimately facilitate the detection of TB among smokers as well as help TB patients who smoke to quit. The web-based courses on tobacco cessation would be based on WHO's existing training package on brief

tobacco interventions in primary care as well as mobile cessation (mCessation)(38). The product will be optimised for use on mobile devices.

4.2.2 Target end-users

- Primary care workers : general practitioners, nurses and other health professionals
- TB and lung specialists

4.2.3 Value to the target end-user and other beneficiaries

- Lung specialists often have to deal with both TB and tobacco-related diseases
- TB care providers are in the unique position to help TB patients who smoke to quit because they will be in regular contact with them for a minimum of six months. However, in many settings, smoking cessation is not covered in medical education and TB care providers may not be aware of tobacco cessation interventions and web-based training courses could help fill in this gap in knowledge and skills
- Facilitate the detection of TB among smokers
- Increase the number of people who stop smoking, including TB patients who are at special risk

4.2.4 Strategic fit

- The scientific basis in support of joint action on TB and tobacco is strong
- Smoking plays an important role in TB reactivation, disease outcomes and relapse
- Quitting smoking has been shown to have a positive effect on TB treatment outcomes
- This product will build upon established eLearning concepts which have been employed for other fields of medicine
- Fits well within the larger eHealth and mEducation frameworks of the government

4.2.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current landscape are that:

- It has the potential to reach people *en masse* in an efficient way

- A strong need was expressed in the online poll ahead of the WHO/ERS consultation

4.2.6 Optimal requirements

The final product should achieve most of these criteria:

- Aligned with other priority digital health products for TB (e.g. TPP 1.2)
- Problem-based, including case studies
- Self-testing module
- Operates under open-source or socially-responsible licensing, avoiding rigid conditions for updating and servicing
- Localization and adaptation including languages
- Barrier-free/ friendly for health care workers with disabilities
- Endorsement by relevant authorities based on the country setting
- CME accreditation
- Confidentiality
- Possibility for offline delivery and update (via external disk drive)

4.2.7 Minimal requirements

The final product should achieve all of these criteria:

- Free of charge for the end user
- Compatible with different mobile phone operating systems and browsers
- Conforms to the latest evidence and WHO/ERS recommendations
- Can function when not connected to internet (base files stored in mobile device and with additional functions such as video clips and chat accessible when the user is online)
- Computational requirements do not exceed the capacity of the most widely available smartphones
- Final evaluation/feedback of users can easily be routed to the developers to inform future updates

4.2.8 Factors for success

- Continued support, recognition and endorsement by relevant authorities and professional associations
- Effective pretesting with a broad cross-section of users
- Updating function

- Incentives for care providers to use the platform including certification and accreditation mechanisms based on the country settings
- Incorporation in educational settings
- Sound business model for scalability
- Clear responsibility to maintain and update the product is assigned (e.g. national professional society or state agency)

4.2.9 Key risks (threats) for its development

- Bandwidth requirements exceed local capacity
- Exceeds the capabilities of most mobile devices in circulation
- The product is not used or user acceptance is low
- Lack of a sustainable mechanism for updates and clear ownership for the maintenance of the product

4.3 Clinical decision support systems for TB treatment and smoking cessation

4.3.1 Goals, scope and description

The application will allow users to generate treatment suggestions based on the data that they input. A single interface will provide general practitioners, nurses and other healthcare workers with access to both automated responses through inbuilt algorithms and expert advice via interaction with existing networks (e.g.(39)), based on clinical scenarios. These tools could in future exploit "big data" gleaned from clinical information which is underused (e.g. through multi-country networks providing secure access to TB patient medical records). The application will facilitate the daily work of the practitioner and optimise the treatment of TB patients who may have other comorbidities or health risks (e.g. HIV, NCDs, smoking).

4.3.2 Target end-users

- Healthcare workers dealing with TB treatment
- Healthcare workers helping tobacco smokers to quit

4.3.3 Value to the target end-user and other beneficiaries

The system will help the user to select the most appropriate options for the treatment of TB patients and at the same time improve the knowledge of practitioners

- The added value for the user over the alternatives is that it will help them make the best-informed decisions on the diagnosis and to optimise the therapeutic interventions for TB patients, particularly those with more complicated forms of disease (e.g. drug-resistant TB) or who have associated health risks (e.g. smoking)
- In the process the health care workers improve their own knowledge of disease and treatment

4.3.4 Strategic fit

- Improve the knowledge of health care professionals while at the same time increase their effectiveness, within a context of limited human resources
- Promote evidence-based working
- Links up with other products being developed for the Patient Care function (see TPP 1.2 above)
- Builds upon established concepts for eLearning

4.3.5 Rationale for prioritization

The main reasons why the group believes that this product should be prioritized in the current landscape are that:

- TB may be missed in the diagnostic algorithms of lung conditions
- Increasing therapeutic interventions on smokers will reduce morbidity and mortality associated to tobacco consumption
- Many healthcare professionals do not intervene in tobacco control because they do not have enough knowledge and this product could thus encourage them to do so
- Much of the evidence-based policy in TB care relies on low or very low quality data: in such conditions clinical aids would be helpful for patients and professionals to make the most advantageous informed decisions jointly

4.3.6 Optimal requirements

The final product should achieve <u>most</u> of these criteria:

- Easy to use
- Responsive design (adapts to size of screen of mobile device)
- Preferably operating under open-source or socially-responsible licensing agreements, ensuring free or affordable installation and servicing

- Inbuilt collection of user statistics, bugs and feedback / suggestions for improvement from the end user
- Links provided to the source of the evidence behind certain decisions and algorithms (for further reading by users)
- Option to customize the decision pathway to adapt it to local requirements

4.3.7 Minimal requirements

The final product should achieve all of these criteria:

- Functions on the different operating systems most commonly used by handheld devices (smartphones, tablets, laptops)
- Intuitive algorithms fit into the clinical practice to which many health professionals are familiar (e.g. the differential diagnosis routines)
- Decisions provided tally with the expert recommendations for TB care and smoking cessation and evidence
- Customizable (e.g. translation, layout, branding)
- The base functions are available in offline mode

4.3.8 Factors for success

- The users trust the accuracy of the information provided
- The system is easy to use and not expensive for the clinician
- The information is secure and privacy guaranteed
- Synchronization with other tools across a “continuum of care” (EMR, hospital management system)

4.3.9 Key risks (threats) for its development

- Legal and ethical issues (liability)
- Potential for deductive disclosure of patient identity if the data entered have substantial detail
- Shortage of experts willing to provide advice
- Unclear ownership and maintenance model

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Glossary of terms and acronyms

Some terms and acronyms featuring in this article may be unfamiliar to the reader and are briefly explained in this non-exhaustive glossary

aDSM: active TB drug-safety monitoring and management

BDD : behaviour-driven development; an approach towards software development that invites collaboration between technical and non-technical partners[4]

CME: Continuing Medical Education

DOT: Directly observed treatment

Digital health: a collective term for eHealth and mHealth technologies

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

HER: Electronic Health Record

EMR: Electronic Medical Record

eLearning: the use of electronic technology in learning and teaching

eLiteracy: the basic competencies required of a user to access online resources

ERS: European Respiratory Society

FDA: US Food and Drug Administration

FIND: Foundation for innovative and new diagnostics

Gamification: the application of game techniques to education

GSM: Global System for Mobile Communications

GTB: WHO's Global TB Programme

HIS: Hospital Information System

HIPAA: US Health Insurance Portability and Accountability Act, which contains rules which are commonly used to define standards for privacy

ICD-10: 10th Revision of the International Statistical Classification of Diseases and Related Health Problems

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ICT: Information and communication technology

IDSR: Integrated Disease Surveillance and Response

Immersive learning: allows learners to be totally surrounded by a self-contained artificial or simulated scenario (e.g., augmented reality and 3-D learning environments) while experiencing it as real

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

IoT : Internet of Things; the networking of physical objects or "things" embedded with electronics, software, sensors and connectivity which enable greater value and service to be achieved through the exchange of data with the manufacturer, operator and/or other connected devices

IT: Information technology

LAN: Local Area Network

LIS: Laboratory Information System

LTBI: Latent TB infection

mCessation: Mobile-device mediated tobacco smoking cessation

MDR-TB: multidrug-resistant TB (TB strain resistance to at least rifampicin and isoniazid)

mEducation: Mobile-device mediated education resources

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

MRS: Medical Records System

NCD: Non-communicable disease

NTP: National TB Programme

NUTS: Nomenclature of Territorial Units for Statistics

OTA: over-the-air programming; refers to various methods of distributing new software updates, configuration settings, and even updating encryption keys to devices like cell-phones, set-top boxes or secure voice communication equipment

PDA: personal digital assistant
RCT: randomised controlled trial

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

SMS: short messaging service for sending text via mobile phones

SOP: standard operating procedure

TB: tuberculosis

TPP: Target product profile

USAID: United States Agency for International Development

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

XDR-TB: extensively drug-resistant TB (TB strain resistance to at least rifampicin, isoniazid, a fluoroquinolone and a 2nd line injectable TB medicine)