

SMART GUIDELINES

Digital adaptation kit for tuberculosis

**Operational requirements for
implementing WHO recommendations
in digital systems**

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Digital adaptation kit for tuberculosis: operational requirements for implementing WHO recommendations in digital systems

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Implementation tools

Core data dictionary	smart.who.int/dak/tb/dictionary
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Functional and non-functional requirements	smart.who.int/dak/tb/system-requirements

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Abbreviations

ART	antiretroviral therapy	MDR-TB	multidrug-resistant tuberculosis
ARV	antiretroviral	MTB	<i>Mycobacterium tuberculosis</i>
BMI	body mass index	MTBC	<i>Mycobacterium tuberculosis</i> complex bacteria
CXR	chest radiograph (chest X-ray)	mWRD	molecular WHO-recommended rapid diagnostic test
DAK	digital adaptation kit	PLHIV	people living with HIV
DHIS2	District Health Information Software 2	RIF	rifampicin
DMN	Decision Model Notation	RR-TB	rifampicin-resistant tuberculosis
DR-TB	drug-resistant tuberculosis	SMART	standards-based, machine-readable, adaptive, requirements-based and testable
DST	drug susceptibility testing	TB	tuberculosis
DS-TB	drug-susceptible tuberculosis	TBST	<i>Mycobacterium tuberculosis</i> antigen-based skin test
DTDS	digital tracking and decision support	TST	tuberculin skin test
HMIS	health management information system	TPT	tuberculosis preventive treatment
Hr-TB	rifampicin-susceptible, isoniazid-resistant tuberculosis	UHC	universal health coverage
IGRA	interferon-gamma release assay	WHO	World Health Organization
LF-LAM	lateral flow urine lipoarabinomannan assay	WRD	WHO-recommended rapid diagnostic test
INH	isoniazid	XDR-TB	extensively drug-resistant tuberculosis
LFT	liver function test		

Glossary

Business process	A set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals (1, 2).	Health management information system	An information system specifically designed to assist in the management and planning of health programmes, as opposed to delivery of care (6).
Data dictionary	A centralized repository of information about the <i>data elements</i> that contains their definition, relationships, origin, use and type of data. For this DAK, the data dictionary is provided as a spreadsheet.	Inter-operability	The ability of different applications to access, exchange, integrate and use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes.
Data element	A unit of data that has specific and precise meaning.	Non-functional requirement	General attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include the ability to work offline, multiple language settings and password protection.
Decision-support logic	A set of decision rules for standard and exceptional cases that is separate from the <i>business process</i> . This would help reduce the complexity of the business process depiction without losing the detail necessary for coding the rules required for system functionality.	Persona	A generic aggregate description of a person involved in or benefitting from a health programme.
Decision-support (for health workers)	Digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions (3, 4).	SMART guidelines	WHO standards-based, machine-readable , adaptive , requirements-based and testable (SMART) guidelines.
Decision-support table	Semi-structured way to depict each discrete decision that will need to be embedded in the system. Depending on the complexity of the clinical guidelines, there will likely be multiple decision-support tables.	Standard	In software, a standard is a specification used in digital application development that has been established, approved and published by an authoritative organization. These rules allow information to be shared and processed in a uniform, consistent manner independent of a particular application.
Digital health	The systematic application of information and communications technologies, computer science and data to support informed decision-making by individuals, the health workforce and health systems, to strengthen resilience to disease and improve health and wellness (1, 5).	Task	A specific action in a <i>business process</i> .
Digital tracking	The use of a digitized record to capture and store clients' health information to enable follow-up of their health status and services received. This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic medical records linked to uniquely identified individuals (3, 4).	Terminologies	For clinical care, terminologies are structured vocabularies covering health-related concepts, such as diseases, diagnoses, laboratory tests and treatments, to enable the storage, analysis and exchange of data in a consistent and standard way (7).
Functional requirement	Capabilities the system must have to meet the end users' needs and achieve tasks within the <i>business process</i> .	Workflow	A visual representation of the progression of activities (tasks, events, decision points) in a logical flow illustrating the interactions within the <i>business process</i> (2).
Health information system	A system that integrates data collection, processing, reporting and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of the health services (6).		

Note: Terms in the definitions also defined in this glossary are shown in *italics*.

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Part 1.
Overview
of SMART
guideline digital
adaptation kits



Background

Digital health – defined broadly as the systematic application of information and communications technologies, computer science and data to support informed decision-making by individuals, the health workforce and health systems, to strengthen resilience to disease and improve health and wellness (1) – is increasingly being applied as an essential enabler of health-service delivery and accountability. Ministries of health have recognized the value of digital health as articulated within the World Health Assembly resolution (2) and the *Global strategy on digital health* (3). Likewise, donors have advocated for the rational use of digital tools as part of efforts to expand the coverage and quality of services and promote data use and monitoring efforts (4–6). Despite the investments into and abundance of digital systems, there is often limited transparency in the health data and logic contained in these digital tools, or the relationship with evidence-based clinical or public health recommendations, which not only undermines the credibility of such systems, but also impedes opportunities for interoperability and threatens the potential for continuity of care.

Evidence-based recommendations, such as those featured in World Health Organization (WHO) guidelines, establish standards of care and offer a reference point for informing the content of digital systems that countries adopt. However, guidelines are often only available in a narrative format that requires a resource-intensive process to be elaborated into the specifications needed for digital systems. This translation of guidelines for digital systems often results in subjective interpretation for implementers and software vendors, which can lead to inconsistencies or inability to verify the content within these systems, potentially leading to adverse health outcomes and other unintended effects. Where digital systems exist, the documentation of the underlying data and content may be unavailable or proprietary, requiring governments to start from scratch and expend additional resources each time they intend to deploy such a system. This lack of documentation of the health content can lead to dependence on one vendor and haphazard deployments that are unscalable or difficult to replicate across different settings.

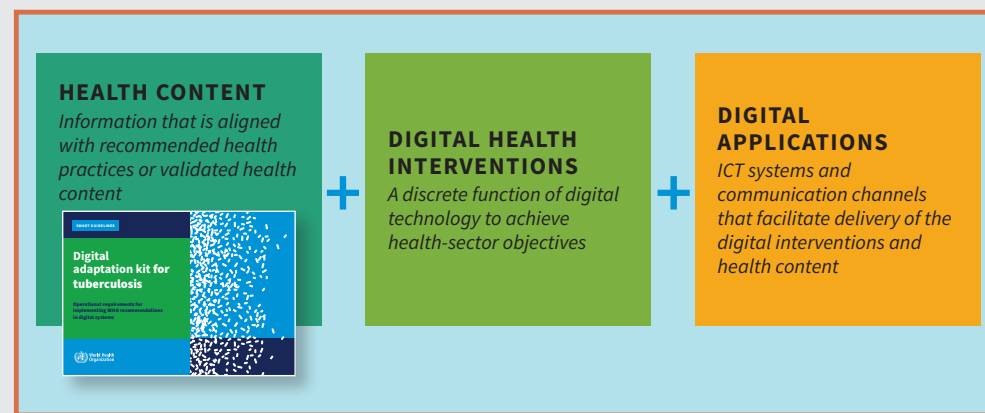
WHO standards-based, machine-readable, adaptive, requirements-based and testable (SMART) guidelines provide essential ingredients to facilitate digital health transformation of health programmes in a way that is consistent with recommended clinical, public health and data practices and interoperability standards. As a type of SMART guideline, digital adaptation kits (DAKs) are designed to facilitate the accurate reflection of WHO's clinical, public health and data use guidelines within the digital systems countries are adopting. DAKs are operational, software-neutral, standardized documentation that distils clinical, public health and data use guidance into a format that can be transparently incorporated into digital systems. Although digital implementations comprise multiple factors, including (1) health domain data and content, (2) digital intervention or functionality, and (3) digital application or communication channel for delivering the digital intervention, DAKs focus primarily on ensuring the validity of the health content (Fig. 1) (1, 7). Accordingly, DAKs provide the generic content requirements that should be housed within digital systems, independently of a specific software application and with the intention that countries can customize them to local needs.

For this particular DAK, the requirements are based on systems that provide the functionalities of digital tracking and decision support (DTDS) (Box 1) and include components such as personas, workflows, core data elements, decision-support algorithms, scheduling logic and reporting indicators. Operational outputs, such as spreadsheets of the data dictionary and the detailed decision-support algorithms, are included as part of the DAK as practical resources that implementers can use as starting points when developing digital systems. Furthermore, data components within the DAK are mapped to standards-based terminology, such as the International Classification of Diseases, to facilitate interoperability.

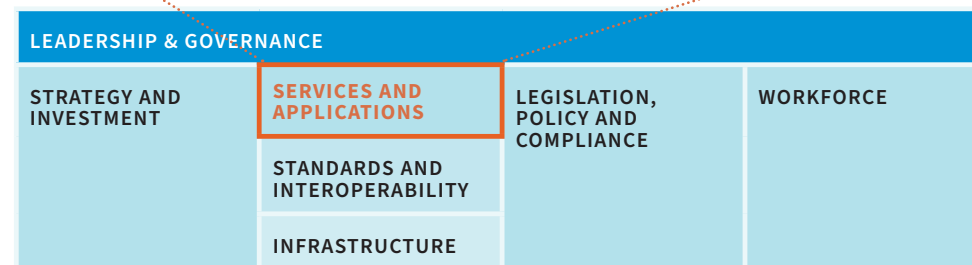
DAKs follow a modular approach in detailing the data and content requirements for a specific health programme area, such as antenatal care and HIV, among the different health areas for which DAKs have been developed. **This DAK focuses on providing the content requirements for a digital tracking and decision-support system used in primary health care settings by health workers for tuberculosis (TB).**

Fig. 1

Digital adaptation kits and their role within digital health implementations



Foundational Layer: ICT and enabling environment



ICT: information and communications technology.

Box 1

What is DTDS?

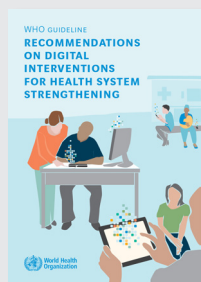
Digital tracking is the use of digitized records to capture and store clients' health information to enable follow-up of their health status and services received (8). This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic patient records linked to uniquely identified individuals (7, 8).

Digital tracking makes it possible to register and follow up patient services, and may be done through an electronic medical record or other digital forms of health records. Digital tracking aims to reduce lapses in continuity of care by stimulating timely follow-up contacts, and may incorporate decision-support tools to guide health workers in executing clinical protocols to deliver appropriate care; scheduling upcoming services; and following checklists for appropriate case management at point of care. Some other descriptors include: digital versions of paper-based registers for specific health domains; digitized registers for longitudinal health programmes, including tracking of migrant populations' benefits and health status; and case management logs within specific target populations, including migrant populations (8).

Health worker decision support is defined as digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions (8). Thus, a person-centred DTDS system is one used by health workers at the point of care; it includes a persistent record of health events and encounters that links to clinical decision-support systems to reinforce good practice. It also links to reporting and management tools to reinforce accountability. A DTDS record includes all the information required for detailing an individual's health status and the health interventions provided to them.

DTDS end users are all cadres of health workers operating at all care levels, including those operating outside formal health-care facilities (e.g. community health workers, health volunteers). DTDS systems emphasize the use of "collect once, use for many purposes" (9), in which data collected for service delivery can also be used for accountability (i.e. they can be used to calculate aggregate indicators required for reporting, including monitoring provider, stock and system performance).

WHO has provided the following context-specific recommendation for the use of an integrated system that provides both a digital track of client's health status and decision support (7).



Effective coverage Accountability coverage

Digital tracking of clients' health status and services (digital tracking) combined with decision support

RECOMMENDATION 8: WHO recommends digital tracking of clients' health status and services, combined with decision support under these conditions:

- ▶ in settings where the health system can support the implementation of these intervention components in an integrated manner; and
- ▶ for tasks that are already defined as within the scope of practice for the health worker.

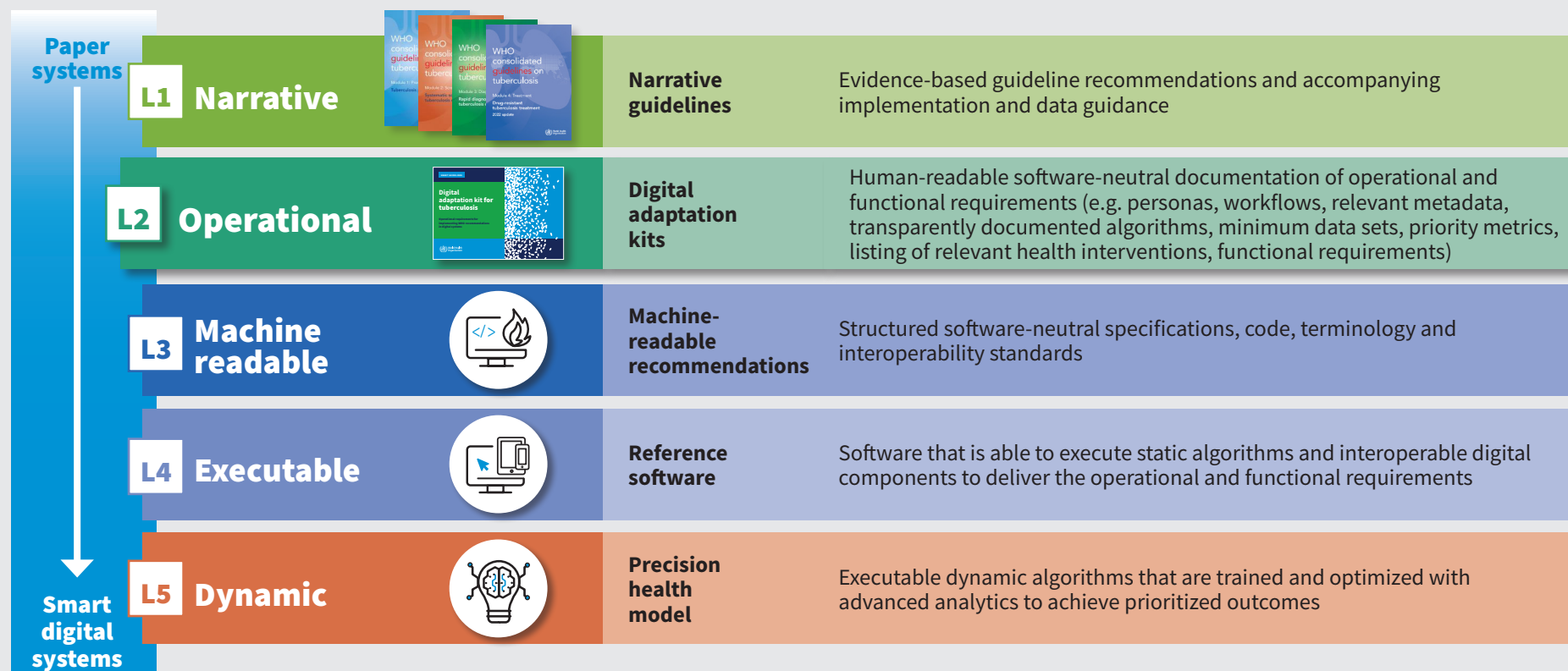
(Recommended only in specific contexts or conditions)

Digital adaptation kits within a strategic vision for SMART guidelines

The operational and standardized documentation reflected within the DAKs represents one of the steps within a broader vision of **s**tandards-based, **m**achine-readable, **a**daptive, **r**equirements-based and **t**estable (SMART) guidelines. SMART guidelines aim to maximize health impact through improved fidelity and uptake of recommendations within standards-based digital systems through a systematic process for transforming guideline development, delivery and application (10, 11). Within this vision, DAKs serve as a prerequisite for developing computable, or machine-readable, guidelines, as well as executable reference software and advanced analytics for precision health. Fig. 2 provides an overview of the different layers of the SMART guideline continuum and where DAKs fit within this strategy (10).

Fig. 2

Progressive layers across SMART guideline components



Objectives

This DAK focuses on TB and aims to provide a common language across several audiences – TB programme managers, software developers and implementers of digital systems – to ensure a common understanding of the appropriate health information content within a defined health programme area, as a mechanism to catalyse the effective use of these digital systems. The key objectives of the DAK are:

- » to ensure adherence to WHO clinical, public health and data use guidelines, and facilitate consistency of the health content that is used to inform the development of a person-centred DTDS system;
- » to enable both health programme leads and digital health teams (including software developers) to have a joint understanding of the health content within the digital system, with a transparent mechanism to review the validity and accuracy of the health content; and
- » to provide a starting point of the core data elements and decision-support logic that should be included within DTDS systems for TB.




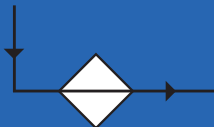
Information detailed in this DAK reflects generic workflow processes, data and decision-support algorithms, as derived from TB and other related WHO documents described below. Note that the outputs of the DAKs are intentionally generic and will need to be contextualized to local policies and requirements.

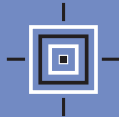
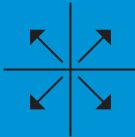

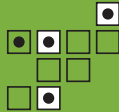
DAKs have also been developed for antenatal care, family planning and HIV, and this approach is being expanded to additional health domains, such as immunizations, postnatal care and child health. All of these DAKs work towards a comprehensive approach for standardized software requirements for primary health care settings.

Components of a digital adaptation kit

The DAK consists of eight interlinked components: (1) health interventions and recommendations; (2) generic personas; (3) user scenarios; (4) generic business processes and workflows; (5) core data elements; (6) decision-support logic; (7) indicators and performance metrics; and (8) high-level functional and non-functional requirements. **Table 1** provides an overview of each of the contributing components of the DAK, which this document then elaborates. All information within the adaptation kit represents a generic starting point, which can then be adapted according to the specific context. **Box 2** provides notation guidance that is used in the Web annexes.

Table 1 Overview of DAK components

Component	Description	Purpose	Outputs	Adaptation needed
1. Health interventions and recommendations 	<p>Overview of the health interventions and WHO recommendations included within this DAK. DAKs are meant to be a repackaging and integration of WHO guidelines and guidance documents in a particular health domain. The list of health interventions is drawn from the universal health coverage (UHC) menu of interventions compiled by WHO (12).</p>	<p>Setting the stage to understand how this DAK would be applied to a DTDS system in the context of specific health programmes and interventions</p>	<ul style="list-style-type: none"> » List of related health interventions based on WHO's UHC essential interventions » List of related WHO recommendations based on guidelines and guidance documents 	<ul style="list-style-type: none"> » Contextualization to reflect current or planned national policies
2. Generic personas 	<p>Depiction of the end users, supervisors and related stakeholders who would be interacting with the digital system or involved in the care pathway.</p>	<p>Contextualization to understand the wants, needs and constraints of the end users</p>	<ul style="list-style-type: none"> » Description, competencies and essential interventions performed by targeted personas 	<ul style="list-style-type: none"> » Greater specification and details on the end users based on real people (e.g. health workers) in a given context » High-level information to describe the provider of the health service (e.g. the general background, roles and responsibilities, motivations, challenges and environmental factors)
3. User scenarios 	<p>Narratives that describe how the different personas may interact with each other. The user scenarios are only illustrative and are intended to give an idea of a typical workflow.</p>	<p>Contextualization to understand how the system would be used, and how it would fit into existing workflows</p>	<ul style="list-style-type: none"> » Example narrative of how the targeted personas may interact with each other during a workflow 	<ul style="list-style-type: none"> » Greater specification and details on the real needs of end users in a given context
4. Generic business processes and workflows 	<p>A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, diagnosis and referral (1, 13). Workflows are a visual representation of the progression of activities (tasks, decision points, interactions) that are performed within the business process (1, 13).</p>	<p>Contextualization and system design to understand how the digital system would fit into existing workflows and how best to design the system for that purpose</p>	<ul style="list-style-type: none"> » Overview matrix presenting the key processes in TB care » Workflows for identified business processes with annotations 	<ul style="list-style-type: none"> » Customization of the workflows, which can include additional forks, alternative pathways or entirely new workflows

Component	Description	Purpose	Outputs	Adaptation needed
5. Core data elements 	<p>Data elements that are required throughout the different points of the workflow.</p> <p>These data elements are mapped to the International Classification of Diseases 11th revision codes and other established concept mapping standards to ensure that the data dictionary is compatible with other digital systems.</p>	<p>System design and interoperability to know which data elements need to be logged and how they map to other standard terminologies (e.g. ICD, SNOMED) for interoperability with other standards-based systems</p>	<ul style="list-style-type: none"> » List of data elements » Link to data dictionary with detailed data specifications in spreadsheet format (available here). 	<ul style="list-style-type: none"> » Translation of data labels into the local language and additional data elements created depending on the context
6. Decision-support logic 	<p>Decision-support logic and algorithms to support appropriate service delivery in accordance with WHO clinical, public health and data use guidelines.</p>	<p>System design and adherence to recommended clinical practice to know what underlying logic needs to be coded into the system</p>	<ul style="list-style-type: none"> » List of decisions that need to be made throughout the encounter » Link to decision-support tables in spreadsheet format with inputs, outputs and triggers for each decision-support logic (available here) » Link to scheduling logic for services (available here) 	<ul style="list-style-type: none"> » Change of specific thresholds or triggers in a logic (IF/THEN) statement, for example, BMI cut off, age trigger for youth-friendly services » Additional decision-support logic formulae depending on the context
7. Indicators and performance metrics 	<p>Core set of indicators that need to be aggregated for decision-making, performance metrics, and subnational and national reporting.</p> <p>These indicators and metrics are based on data that can feasibly be captured from a routine digital system, rather than survey-based tools.</p>	<p>System design and adherence to recommended health monitoring practices to know what calculations and secondary data use are needed for the system, based on the principle of collect once, use many (9)</p>	<ul style="list-style-type: none"> » Link to indicators table with numerator and denominator of data elements for calculation, along with appropriate disaggregation (available here) 	<ul style="list-style-type: none"> » Changing the calculation formulae of indicators » Adding indicators » Changing the definition of the primary data elements used to calculate the indicator based on the available data
8. High-level functional and non-functional requirements 	<p>List of core functions and capabilities the system must have to meet the end users' needs and achieve tasks within the business process.</p>	<p>System design to know what the system should be able to do</p>	<ul style="list-style-type: none"> » Link to functional and non-functional requirements tables with the intended end user of each requirement, and why that user needs that functionality in the system (available here) 	<ul style="list-style-type: none"> » Adding or reducing functions and system capabilities based on budget and end user needs and preferences

BMI: body mass index; ICD: International Classification of Diseases; SNOMED: Systematized Nomenclature of Medicine.

Box 2

Notation guidance

Throughout the DAK, there are identification numbers to simplify tracking and referencing each of the components. Note that the DAK represents an overview across the different components, while the comprehensive and complete outputs of each component (e.g. data dictionary, decision-support tables) are included in the appended spreadsheets. The notation guidance is as follows.

Component 1: Health interventions and recommendations

No notations used.

Component 2: Generic personas

No notations used.

Component 3: User scenarios

No notations used.

Component 4: Business processes and workflows

- » Each workflow should have a “process name” and a corresponding letter. Each workflow should also have a “**process ID**” that should be structured as the “**abbreviated health domain**” and “**corresponding letter for the process**” (e.g. TB.B).
- » Each activity in the workflow should be numbered with an “**activity ID**” that should be structured as “**process ID**” and “**activity number**” (e.g. TB.B7).

Component 5: Core data elements (data dictionary)

- » Each data element should have a “data element (DE) ID” that should be structured as “**activity ID**”, “DE” and “sequential number of the data element” (e.g. TB.B7.DE.1, TB.B7.DE.2).

Component 6: Decision-support logic

- » Each decision-support logic table should have a “**decision-support table (DT) ID**” that should be structured as “**activity ID**” and “DT” (e.g. TB.B3.DT, TB.B5.DT).

Component 7: Indicators and performance metrics

- » Each indicator should have an “**indicator ID**” that should be structured as “**abbreviated health domain**”, “IND” and the “sequential number of the indicator” (e.g. TB.IND.1, TB.IND.2).

Component 8: High-level functional and non-functional requirements

- » Each functional requirement should have a “**functional requirement ID**” that should be structured as “**abbreviated health domain**”, “FXNREQ” and “sequential number of the functional requirement” (e.g. TB.FXNREQ.1, TB.FXNREQ.2).
- » Each non-functional requirement should have a “**non-functional requirement ID**” that should be structured as “**abbreviated health domain**”, “NFXNREQ” and “sequential number of non-functional requirement” (e.g. TB.NFXNREQ.1, TB.NFXNREQ.2).

Methods for content development

A mapping of existing WHO guidelines, guidance and tools relevant for the development of a DAK for TB was carried out first. Key resources that were identified included all WHO TB-related clinical guidelines and their associated operational handbooks, relevant TB guidance documents and the specifications for existing digital tools, such as the PREVENT TB app and WHO District Health Information Software 2 (DHIS2) aggregate and case-based packages for TB surveillance. Upcoming WHO TB guidelines and guidance documents were also considered to ensure that the TB DAK will remain relevant in the context of upcoming recommendations.

A desk review of the above resources was conducted, where the recommendations from clinical guidelines were extracted and synthesized to form the components of the TB DAK. This process also guided the development of the workflows for key TB programmatic and data processes, decision-support logic algorithms and a data dictionary. The indicators and performance metrics included in the TB DAK were informed by the TB surveillance guidance. The data elements required to calculate the indicators and to build the algorithms in the decision-support logic were based on the relevant clinical guidelines and TB surveillance guidance document. The data elements were mapped onto standardized terminologies and classifications by a medical terminologist to facilitate the adoption of interoperability standards into digital systems.

All components of this TB DAK were refined through a series of in-depth technical consultations with relevant teams from the Global Tuberculosis Programme, which were responsible for developing the WHO guidelines and guidance used to guide the development of this DAK; DAKs are derivative guidance documents to support the implementation of WHO guidelines and guidance in digital systems. These teams also reviewed and validated the sections of the TB DAK relevant to their area of expertise to ensure that each component reflects the narrative in WHO guidelines and guidance.

Other published DAKs, including the team responsible for their development, were consulted as needed to ensure alignment across the SMART guidelines programme.

How to use this digital adaptation kit

Target audience

The primary target audience for this DAK is health programme managers within the ministry of health, who will be working with their digital or health information system counterparts in determining the health content requirements for a TB DTDS system. The health programme manager is responsible for overseeing and monitoring the implementation of the clinical practices and policies for the health programme area, in this case TB.

The DAK also equips individuals responsible for translating health system processes and guidance documents for use within digital systems with the necessary components to kick-start the process of developing a DTDS system in a standards-compliant manner. These individuals are also known as business analysts who interface between health content experts and software development teams. Specifically, the DAK contains key outputs, such as the data dictionary and decision-support algorithms, to ensure the validity and consistency of the health content with the DTDS system.

Additionally, using this DAK requires a collaboration between health programme managers responsible for TB and counterparts in digital health and health information systems. Although each DAK focuses on a particular health programme area (in this case TB), DAKs are envisioned to be used in a modular format and link to other health programme areas within primary health care settings, in an effort to support integration across services.

Scenarios for using the DAK

The DAK may be used across several scenarios, some of which are listed here.

Scenario 1 **Incorporating WHO guideline content into existing DTDS systems**

Countries that already have digital systems in place, such as electronic medical records and decision-support tools, may use the information in the DAK to cross-check whether the underlying content and data for specific health programme areas are aligned to WHO guidelines. Users of the DAK can identify and extract specific decision algorithms that would need to be incorporated into their existing digital systems. By reviewing this systematic documentation, health programme managers and implementers can more readily identify differences in workflows, data inputs and decision-support logics to examine the rationale for deviations and understanding local adaptations of guideline content.

Scenario 2
Transitioning from paper to DTDS systems

Some countries may currently have paper-based systems that they would like to digitize. The process of optimizing paper-based client-level systems into digital records and decision support may be overwhelming. Users in this scenario may review the DAK as a starting point for streamlining the necessary data elements and decision support that should be in the optimized client-level digital system. Users may also then refer to the paper-based tools to determine whether there are missing fields or content that should also be included within the digital system.

Users should also review the WHO *Digital transformation handbook for primary health care (14)*, which provides stepwise guidance on how to map data on paper-based forms into a digital system, including ways of accounting for data elements that are redundant or may not add value to the health system.

Scenario 3
Linking aggregate health management information system (HMIS) (e.g. DHIS2) to DTDS systems used at point of care

In some instances, countries may already have a digital system for aggregate reporting and HMIS, but may not yet have implemented digital systems that function at the service delivery level. The DAK can guide the development of a digital client record system that operates at point of care, and ensure that there are links between the aggregate and service delivery levels (e.g. community or facility level).

As such, a component of the DAK provides aggregate indicators derived from individual-level data to provide the link between these different levels. Complementary guidance dedicated specifically to aggregate-level data, such as *WHO consolidated guidance on tuberculosis data generation and use – Module 1: Tuberculosis surveillance (15)*, should also be consulted for supporting the use of routine data at the facility management and district levels.

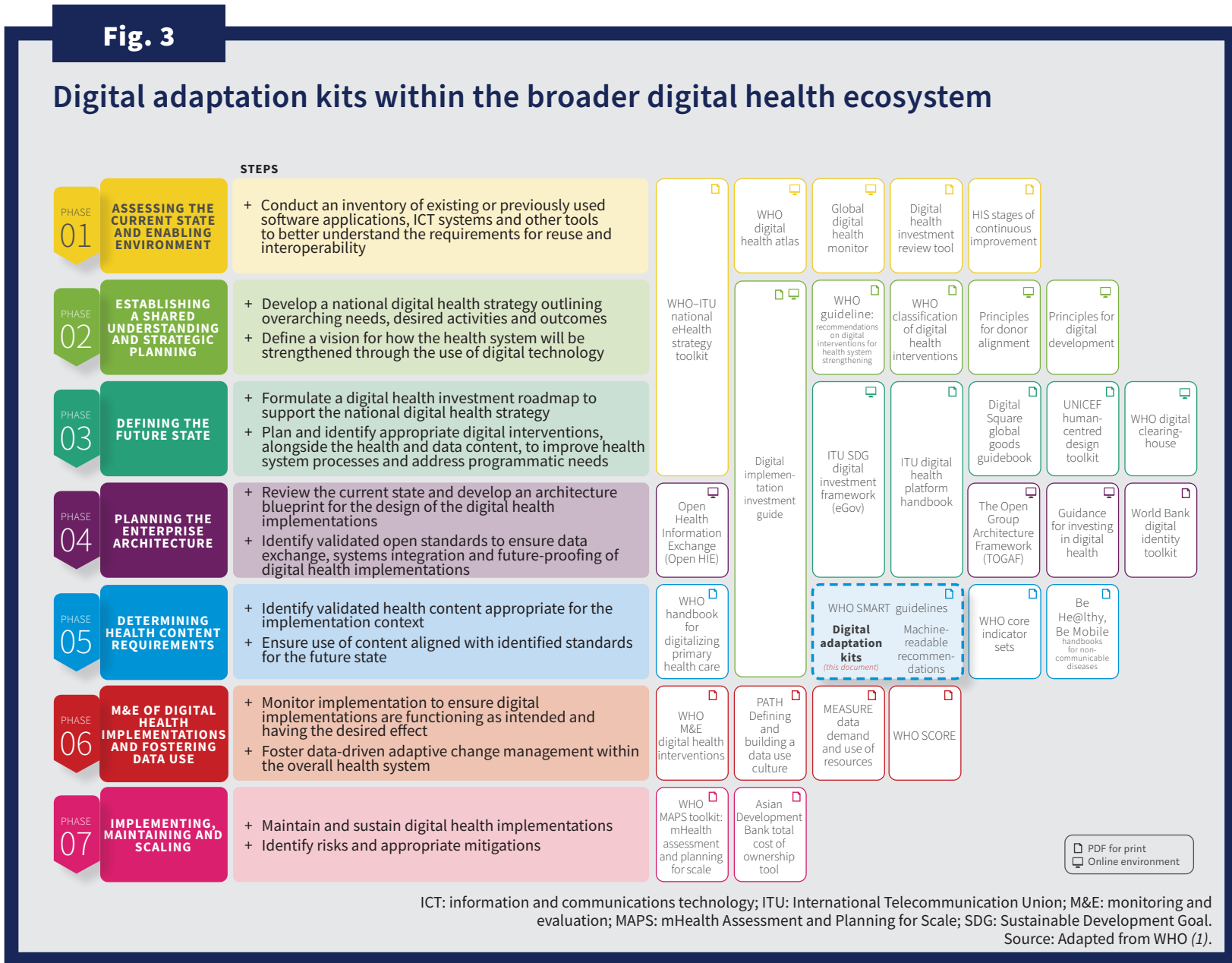
Scenario 4
Leveraging data standards to promote interoperability and integrated systems

This DAK includes data elements mapped to International Classification of Diseases (ICD) codes, and other standards, to support the design of interoperable systems. The **data dictionary** provides the necessary codes for the different data elements, thus reducing the time for implementers to incorporate these global standards into the design of their digital systems.

In addition, a critical part of service delivery in any health domain relies on engaging with clients. Digital interventions aimed at clients themselves, such as on-demand information services, targeted client communication (e.g. transmitting health information and reminders), reporting of health system feedback by clients on the quality of care, accessing their own medical records and home-based records, and self-monitoring of their health and diagnostic data (8), are all emerging approaches for complementing the services provided by health workers.

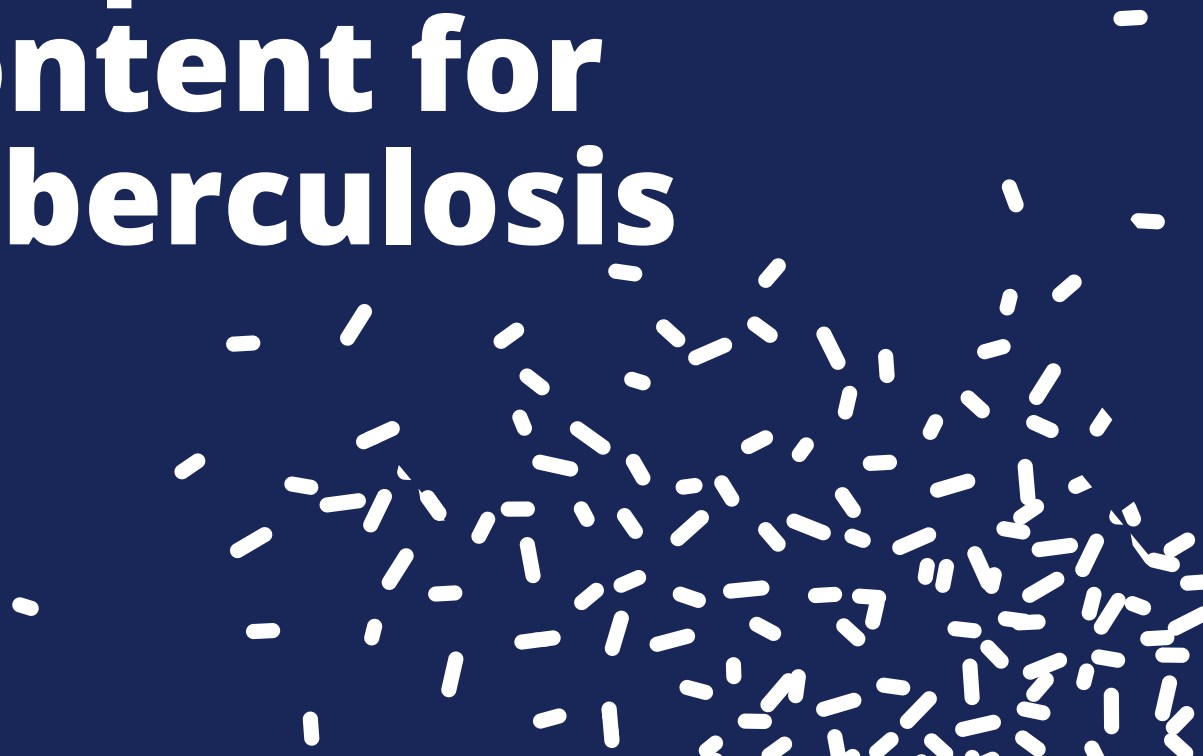
Links to the broader digital health ecosystem

DAKs represent one piece of the resources in the broader digital health ecosystem and should be used once there is a strategic vision by the ministry of health to use a DTDS system. In contexts where such vision may not exist, users should first consult the WHO–International Telecommunication Union *National eHealth strategy toolkit (16)*, WHO *Recommendations on digital interventions for health system strengthening (7)* and the WHO *Digital implementation investment guide (1)* to establish a better understanding of how to select and apply appropriate digital health interventions. **Fig. 3** situates DAKs within the broader set of resources for planning and implementing digital health systems.

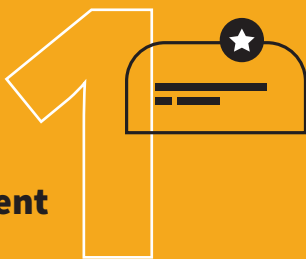


2

Part 2. Digital adaptation kit content for tuberculosis



Component



Health interventions and recommendations

This DAK focuses on the following health interventions and recommendations related to TB.

1.1 Interventions referenced in this DAK

The key interventions for TB referenced in this DAK, as defined in the WHO universal health coverage (UHC) list of essential interventions and WHO TB guidelines and guidance documents, are the following.

» Prevention by implementing:

- Bacillus Calmette–Guérin vaccination based on individual characteristics;
- social protection and poverty alleviation measures and actions on determinants of TB (17);
- TB preventive treatment (TPT), preferably using shorter regimens.

» Screening by means of:

- active case-finding for TB among at-risk populations;
- screening for tuberculosis among clinically at-risk groups and vulnerable populations to exclude active TB disease.

» Case detection and diagnosis of tuberculosis by using:

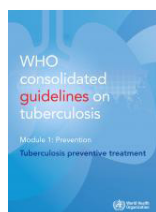
- targeted history and physical examination for TB;
- laboratory work;
- imaging studies;
- diagnostic procedures.

» Management of TB by means of:

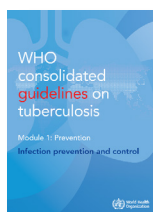
- non-pharmacological treatments;
- oral medications;
- injectable agents;
- procedures (including surgeries);
- management of TB and comorbidities;
- rehabilitation services;
- treatment monitoring.

1.2 WHO guidelines, recommendations and guidance

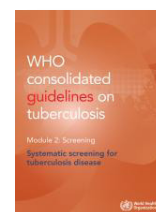
DAKs are intended to reflect health recommendations and content that has already been published in WHO guidelines and guidance documents. The health content and interventions for this DAK are based on the following WHO documents.



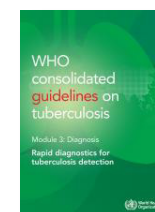
WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)



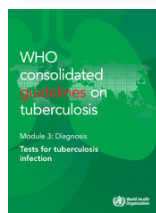
WHO consolidated guidelines on tuberculosis – Module 1: prevention (infection prevention and control) (19)



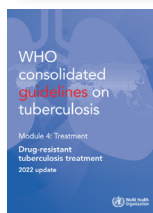
WHO consolidated guidelines on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (20)



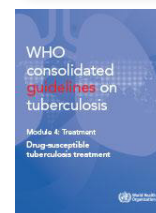
WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (21)



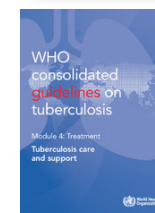
WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (22)



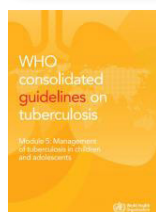
WHO consolidated guidelines on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update) (23)



WHO consolidated guidelines on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment) (24)



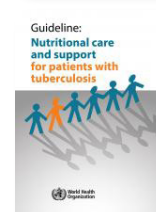
WHO consolidated guidelines on tuberculosis – Module 4: treatment (tuberculosis care and support) (25)



WHO consolidated guidelines on tuberculosis – Module 5: management of tuberculosis in children and adolescents (26)



Joint WHO/ILO policy guidelines on improving health worker access to prevention, treatment and care services for HIV and TB (27)



Guideline: nutritional care and support for patients with tuberculosis (28)



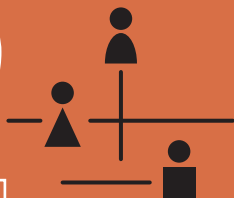
WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)

Other WHO documents represented in the DAK include:

- » [WHO operational handbook on tuberculosis – Module 1: prevention \(tuberculosis preventive treatment\) \(29\)](#)
- » [Tuberculosis laboratory biosafety manual \(30\)](#)
- » [WHO operational handbook on tuberculosis – Module 2: screening \(systematic screening for tuberculosis disease\) \(31\)](#)
- » [WHO operational handbook on tuberculosis – Module 3: diagnosis \(rapid diagnostics for tuberculosis detection, 2021 update\) \(32\)](#)
- » [WHO operational handbook on tuberculosis – Module 3: diagnosis \(tests for tuberculosis infection\) \(33\)](#)
- » [WHO operational handbook on tuberculosis – Module 4: treatment \(drug-resistant tuberculosis treatment, 2022 update\) \(34\)](#)
- » [WHO operational handbook on tuberculosis – Module 4: drug-susceptible tuberculosis treatment \(35\)](#)
- » [WHO operational handbook on tuberculosis – Module 4: treatment \(tuberculosis care and support\) \(36\)](#)
- » [WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents \(37\)](#)
- » [Framework for collaborative action on tuberculosis and comorbidities \(38\)](#)
- » [Ethics guidance for the implementation of the End TB strategy \(39\)](#)
- » [WHO operational handbook on tuberculosis – Module 6: tuberculosis and comorbidities – mental health conditions \(40\)](#)
- » [Policy brief on tuberculosis-associated disability \(41\)](#)

Component

2



Generic personas

A persona is a depiction of a relevant stakeholder, or end user, of the system. Although the specific roles and demographic profiles of the personas will vary depending on the setting, generic personas are based on WHO core competencies and credentials of different health worker personas. Please note that these are developed based on synthesis across multiple contexts as a starting point; further contextualization will be required according to the needs, motivations and challenges of the targeted personas in each setting. The personas providing care, described in [Table 2](#), might be practising activities in private, public or both type of health clinics.

2.1 Targeted generic personas

In the case of TB, physicians, nurses and clinical officers are the primary personas for the digital client health record and decision-support system. In the health systems surveyed for this DAK, the common combination of service providers was a physician along with a nurse. The key competences of physicians, nurses and clinical officers are defined by WHO ([Table 2](#)) (42).

Table 2 Descriptions of key generic personas

Occupational title	Description	Different names	International Standard for Classification of Occupations code (43)
Physician	A legally qualified and licensed practitioner of medicine, concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury, through the science of medicine and the applied practice of that science. A medical doctor requires training in a medical school. Depending on the jurisdiction and on the university providing the training, these may be either undergraduate- or graduate-entry courses. Gaining a basic medical degree may take 5–9 years, depending on the jurisdiction and the university providing the training.	Family doctor, general practitioner, medical doctor, specialist doctor (e.g. paediatrician, pulmonologist, psychiatrist), non-specialist doctor	2211 (generalist medical practitioner) 2212 (specialist medical practitioner)
Nurse	A graduate who has been legally authorized (registered) to practise after examination by a state board of nurse examiners or similar regulatory authority. Education includes 3, 4 or more years in nursing school, and it leads to a university or postgraduate university degree, or the equivalent. A registered nurse has the full range of nursing skills.	Registered nurse, nurse practitioner, clinical nurse specialist, advance practice nurse, practice nurse, licensed nurse, diploma nurse, BS nurse, nurse clinician	2221 (nursing professionals)
Clinical officer	Health professionals who provide advisory, diagnostic, curative and preventive medical services more limited in scope and complexity than those carried out by medical doctors. They work autonomously or with limited supervision of medical doctors, and perform clinical, therapeutic and surgical procedures for treating and preventing diseases, injuries and other physical or mental impairments common to specific communities.	Primary care paramedic, advanced care paramedic	2240 (paramedical practitioners)

BS: Bachelor of Science.

2.2 Related personas

In addition to the targeted personas detailed in [Table 2](#), there may be value in exploring other cadres and personas within the context of TB services, such as laboratory technicians or community health workers. However, these were not identified as the central personas for the data and decision-support content detailed in this DAK. Additional related personas are listed in [Table 3](#).

Table 3 Descriptions of related personas

Name	Description	Different names (if relevant)	International Standard for Classification of Occupations code (if relevant) (43)
Client	In the context of this document, a client is a person who is given medical care, which may include TB prevention, screening, diagnosis, care or treatment services. Clients may be TB-confirmed, TB-presumptive or they may not know their TB status.	Patient, health service user, individual seeking care, person with TB	N/A

Name	Description	Different names (if relevant)	International Standard for Classification of Occupations code (if relevant) (43)
At-risk group	<p>A member of an at-risk group is someone who manifests an increased risk of progression from TB infection to active TB disease, due to specific clinical conditions, social conditions or the activities this person performs. At-risk groups also often have legal and social issues related to their behaviours that increase their vulnerability to TB.</p> <p>Three key populations are included in this kit: (1) people living with HIV; (2) contacts (household contacts or close contacts); (3) other people at risk (people who are initiating anti-tumour necrosis factor treatment, or receiving dialysis, or preparing for an organ or haematological transplant, or who have silicosis, prisoners, health workers, immigrants from countries with a high TB burden, homeless people, people who use drugs, people with diabetes, people who engage in the harmful use of alcohol, tobacco smokers and underweight people). At-risk groups are important to the dynamics of TB transmission and are essential partners in an effective response to the epidemic.</p>	Vulnerable groups	N/A
Contact	<p>A contact is any individual who has been exposed to a person with TB disease.</p> <p>There are two types of contacts.</p> <p>(1) Close contact, that is, a person who is not in the household but has shared an enclosed space, such as at a social gathering, workplace or facility, for extended periods during the day with the index patient during the 3 months before commencement of the current TB treatment episode.</p> <p>(2) Household contact, that is, a person who has shared the same enclosed living space as the index case (the initially identified person of any age with new or recurrent TB) for one or more nights or for frequent or extended daytime periods during the 3 months before the start of current treatment (29).</p>	Household contact, close contact	N/A
Community health worker	Community health workers provide health education, referral and follow-up; case management and basic preventive health care; and home visiting services to specific communities. They provide support and assistance to clients seeking TB-related services and their families in navigating the health and social services system.	Health extension worker, community health volunteer, village health worker, treatment supporter, outreach worker, lay health worker, peer counsellor	3253 (community health workers) 3259 (health associate professionals not classified elsewhere)
Counsellor	A person who provides counselling, therapy and mediation services to individuals, families, groups and communities in response to social and personal difficulties. They assist clients to develop skills and access resources and support services needed to respond to issues arising from health problems, life transitions, addictions and other personal, family and social problems. They liaise with other social service agencies, educational institutions and health-care providers to advocate for client and community needs. They have a key role in palliative care, which represents the prevention and relief of the physical, psychological, social and spiritual suffering of adults and children with serious illnesses and offering psychosocial support services for their families.	Psychotherapist, psychologist, social worker	2634 (psychologists) 2635 (social work and counselling professionals)
Laboratory technician	A person who performs clinical tests on specimens of bodily fluids and tissues to get information about the health of a patient or cause of death. They use approved assays (e.g. phenotypic culture-based, line-probe assays) and operate equipment such as microscopes, polymerase chain reaction machines and flame photometers for analysis of biological material including sputum, stool, blood, urine, pleural fluid, cerebrospinal fluid and respiratory samples. This category includes occupations for which competent performance usually requires formal training in biomedical science, medical technology or a related field.	Medical laboratory technician, pathology laboratory technician, medical laboratory assistant, pathology technician, laboratory personnel, laboratory worker	3212 (medical and pathology laboratory technician3)

Name	Description	Different names (if relevant)	International Standard for Classification of Occupations code (if relevant) (43)
Pharmacist	Pharmacists store, preserve, compound and dispense medicinal products. They counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors and other health professionals. They contribute to researching, testing, preparing, prescribing and monitoring medicinal therapies for optimizing human health.	Chemist, clinical pharmacist, community pharmacist, hospital pharmacist, retail pharmacist, dispensing chemist	2262 (pharmacists)
Health information officer	A manager supervising the monitoring system to track quality of care and data. This person provides a link between the health centre and central level to ensure that patient monitoring needs are met (e.g. adequate staffing, tools and other resources) and implements changes to data standards or norms.	District health manager, health management information systems focal point, monitoring and evaluation focal point, facility supervision manager, district health information officer, national monitoring and evaluation officer	1342 (health service manager)
Data entry clerk	An individual who helps to record, organize, store, compute and retrieve information, including patient records and registers. The knowledge and skills required are usually obtained through on-the-job training but may include post-secondary education. Clerks may also transcribe data, tally data, fill in routine reports and review the quality of data with others.	Data capturer	4132 (data entry clerks)
Medical office receptionist	An individual responsible for receiving and welcoming visitors, guests or clients; making appointments for clients; dealing with telephone requests for information or appointments; directing clients to an appropriate location or person; supplying information pamphlets, brochures or forms. Skills required: relatively advanced literacy and numeracy skills, good interpersonal communication skills and a high level of manual dexterity. The knowledge and skills required are usually obtained because of secondary education and, in some cases, specialized post-secondary vocational education or prolonged on-the-job training.	General office clerk, general receptionist, accounts clerk, health insurance clerk, medical appointments schedule clerk	4226 (receptionists [general])

2.3 Additional considerations for contextualizing personas

Although this section provides an overview of the generic roles of the targeted personas, it is important to contextualize these personas to your setting. The generic personas described in [Tables 2](#) and [3](#) can be supplemented by reflecting on these additional considerations:

- » **Background and demographics:** for example, sex, age, whether they are from the community, familiarity with digital devices, whether they own a mobile phone or smartphone.
- » **Local environment and any relevant contextual information about their surroundings:** for example, work-site characteristics; rural or urban; availability of electricity, water, internet; distance from nearest referral facility.
- » **Expected roles and responsibilities:** What are the expected roles and responsibilities based on the country context? How does this differ from the roles and responsibilities defined by WHO?
- » **Actual roles and responsibilities:** What are their actual roles and responsibilities, if there is any difference from what is expected?

- » **Context:** What is the level of internet connectivity? How are they compensated? How far away is the nearest referral facility? What other personas or health workers do they interact with?
- » **Challenges:** What are the day-to-day challenges the end user might face?
- » **Motivations:** What does success look like to them? Are there targets they need to achieve?

See [Annex 1](#) for examples of contextualized personas. For more details on persona development, please refer to the *WHO Handbook for digitalizing primary health care: optimizing person-centred tracking and decision-support systems across care pathways (14)*.

2.4 Additional considerations for at-risk groups

Data relating to an individual’s risk behaviour and at-risk group status are important to provide appropriate services and for programme monitoring. However, in many settings, TB status, HIV status, drug use and possession, and alcohol use are criminalized and associated with stigma and discrimination. Collecting identifiable information linked to these behaviours and clinical status from individuals accessing health services raises the potential for negative consequences both to individuals and to service providers. Because of these sensitivities it is recommended that data collected on criminalized and stigmatized populations remain anonymous (39).

It is important to keep confidential all private information of persons with, or being investigated for TB, in keeping with the necessary public health functioning of a TB programme or unit. Keeping people’s TB status private will also help combat the stigma that is still associated with TB and help ensure the trust of patients and their communities. TB prevention services can be provided effectively and efficiently, and individuals can be followed longitudinally using anonymous unique identification codes, without the collection of personally identifying information.

In the context of TB treatment services where personally identifying information is routinely collected on treatment recipients, it is not recommended to collect information that might indicate an individual’s engagement in stigmatized or criminalized behaviours or their at-risk group status. Only information that is clinically relevant should be included in clinical records where individuals are personally identified.

Any data collection or data sharing scheme must have in place adequate safeguards to protect privacy and confidentiality, to minimize, mitigate or eliminate the risks of bias and stigma, and to ensure correct use by appropriate users.

Component



User scenarios

User scenarios are a narrative description of how the end user would interact with the digital system. The user scenario is provided to help the reader better understand how the system will be used and how it would fit into existing workflows. It is to provide context in a story telling format. Furthermore, within the user scenario, it should be possible to derive the key components that are further elaborated in the rest of the DAK. This includes the core data elements, decision-support logic and core functionality of a digital system that would be needed. Although there is no clear template for a user scenario, it should:

- » include personas involved based on the generic personas component;
- » have narrative description of who and how a digital system would be used;
- » provide details on what kinds of data are collected and decisions are made; and
- » reflect the workflows that will be further elaborated on in **Component 4: Business processes and workflows**.

3.1 How to interpret user scenarios

User scenarios are helpful tools not only to better understand the context in which a digital tool would operate, but also for some insights into what key data elements would need to be recorded and accounted for in the database. Additionally, the context in which the tool would operate, illuminated by the user scenarios, provides insight into some functional and non-functional requirements that the system would also need. For example, **highlighted in orange** are some key data elements that need to be recorded or calculated. **Highlighted in blue** is the decision-support logic that can be automated in the system. **Highlighted in green** are some key functional and non-functional requirements that should be included in the system.

For example, the interpretation of the user scenario “Household contact: tuberculosis (TB) screening and infection testing” is shown in **Table 4**.

Table 4 Interpretation of the scenario “Household contact: tuberculosis (TB) screening and infection testing”

Data elements to be collected		Decision logic to be embedded	Functional and non-functional requirements
» Risk group	» Sex	» Determine the screening algorithm	» Search for a client using at least two identifiers
» Age	» Phone number	» Determine if the TB infection test is relevant	» Possibility to work offline
» First name	» Occupation		» Possibility to send referral letters via email
» Last name	» Email address		» Possibility to send SMS (text message) reminders

3.2 User scenarios for tuberculosis screening and tuberculosis preventive treatment

3.2.1 Household contact: tuberculosis (TB) screening and infection testing

Key personas **Community health worker: Arno**
Client: Mieke
Household contact: Johan, a 21-year-old man

Arno is a community health worker working for a health clinic. Today he is in the field, in a small village, to perform TB screening and TB infection testing on the household contacts of individuals with confirmed TB disease. Because there is a high HIV prevalence in the country, HIV testing is also offered. He used his tablet to access the digital system and obtain the list of contacts to be visited, which were entered into the system by the nurse working in the health clinic.

Arno is visiting the house of Mieke, a 41-year-old woman who was recently diagnosed with pulmonary TB disease and who provided information about her household contacts. Mieke agreed in advance to receive the visit.

Arno meets Johan, Mieke's son and finds out that he is 21 years old. Arno opens on the tablet the application he is using for client management and contact tracing and searches using Johan's first and last name, but the app warns him that there is no internet connection; therefore, no results are returned. The app then suggests saving Johan's data locally, temporarily, until the app goes back online. Once the app is connected to the internet, it will check whether a client with Johan's identifiers exists on the system or not; based on the result, it will propose creating a new client or updating an existing one, matching Johan's data. After entering into the system basic personal and demographic information about Johan, such as sex, telephone number and occupation, Arno asks the young man if he lives in the same house as Mieke. Johan confirms and explains that occasionally he goes outside of his town for several days because of his work, but most days he is living in the same house as his mother.

As soon as the registration process finishes, Arno informs Johan about the purpose of the visit, the benefits and risks of the screening process, the chosen screening algorithm and the tuberculin skin test (TST) for TB infection. Arno highlights the importance of a follow-up visit in 48–72 hours when the TST result shall be read. He also suggests that Johan should take an HIV test and explains the reason for the test (the high HIV prevalence), outlining that people living with HIV (PLHIV) are around 20 times more likely to develop TB disease than those without HIV infection. Arno asks the young man if he has any questions or concerns related to what was presented and asks for his verbal informed consent before starting the screening process.

Next, Arno checks if Johan has any signs or symptoms suggestive of TB. Because none are present, Arno decides to administer a TST on site. Then, Arno informs Johan about the next steps, which consist of reading the TST result and performing a chest X-ray (CXR) at the clinic, followed by further diagnostic tests if the CXR looks abnormal. If the CXR does not present any abnormalities and the TST result is positive, then Johan will be evaluated for TPT eligibility. Arno briefly provides counselling on what TPT is and its benefits. The TST reading and CXR will be performed during the same visit to limit the inconvenience related to multiple visits to the clinic, such as time lost due to travel, financial expenses and delays in obtaining the test results. Because the TST should be read within a maximum of 72 hours from when it is administered, Johan agrees with Arno to schedule a follow-up visit at the clinic in 2 days' time. A rapid antibody HIV test is also administered because Johan has given his consent for this test to be carried out; this test is negative.

He then asks Johan if he would like to receive the referral letter for the CXR via email, using the email address provided during registration (i.e. Johan could receive the referral letter immediately via email), instead of a hard copy at the end of the consultation. This could help with faster check-in at the clinic and avoid other inconveniences, such as losing it. Johan agrees.

He also checks with Johan if he would like to receive SMS (text message) reminders for the next visits. As Johan agrees, Arno ticks the corresponding checkbox in the app, which indicates that the client has given the permission to receive this kind of notification.

Arno asks if Johan has any other concerns or questions.

Corresponding business processes (Component 4)	This scenario refers to the following business processes:
	A. Registration
	B. Screening
	E. TPT
	F. Referral

3.2.2 TPT assessment and counselling

Key personas
Nurse: Annika
Receptionist: Lerato
Client: Johan, a 21-year-old man

Johan presents to the health clinic for the follow-up visit scheduled 2 days ago. He shows the receptionist at the registration desk the referral sent to his email address by Arno, at the previous visit.

Lerato, the receptionist, checks if Johan has any appointment scheduled by searching the digital system using Johan's national health ID. The system returns a result that matches Johan's data and displays a pop-up informing the receptionist that the visit should start in 30 minutes. Lerato suggests to Johan having the CXR before going for the consultation. Because of the new technology available at the clinic, computer-aided detection, which is used to interpret the digital CXR images, the waiting time is only 5–10 minutes. She tells Johan how to find the room where the CXR is going to be performed and then tells him the consultation room number where he should meet Annika, the nurse waiting for him.

With the results of the CXR, Johan makes his way to the consultation room indicated by Lerato. After reading the TST, Annika tells Johan that the result is positive. The CXR showed no abnormalities in the lungs. She then explains to Johan that the TB infection detected by the test does not mean that he has TB disease or that he is infectious, and that the best way to avoid developing TB disease would be by taking TPT. Annika provides further counselling on TPT, which includes the rationale for TPT and benefits to the individual, the household and the wider community. She also asks about medical conditions that would contraindicate TPT and discusses the potential risks of treatment.

Johan shows interest in TPT, so Annika checks in the system if the information provided during the previous encounters would allow a complete TPT eligibility evaluation. This is not the case, so she starts asking Johan about his personal history, which may be relevant for TPT initiation, such as allergy to TB drugs, previous TPT use, alcohol use, smoking and concurrent medication(s).

While registering the information on the system, Annika reassures Johan that all the information collected and his decision on whether to take TPT or not, will be kept confidential.

The assessment reveals that the benefits of TPT outweigh the potential risk of acquiring TB or drug toxicity, so Johan decides to take TPT. He is the primary breadwinner in the household and is concerned that losing his job because of TB could have important consequences. Hearing that, Annika decides to promptly introduce Johan to the national nutritional and financial support programmes available that could lessen the financial burden for his family in case of need.

After discussing the treatment regimen options, Johan decides to take a shorter rifamycin-based TPT regimen because it is shorter and has fewer adverse events. Nevertheless, Annika discusses the potential adverse drug reactions associated with rifamycins, such as gastrointestinal reactions (abdominal pain, nausea, vomiting), hepatitis and discolouration of bodily fluids.

Annika works out the medication dosage, provides medication for the next month and agrees with Johan to schedule a follow-up visit in 1 month. She then asks Johan if he would like to receive SMS reminders on the days when he needs to take the treatment. Johan likes the idea and accepts. Annika registers this information on the system.

Before leaving the room, Annika makes sure that Johan knows how and who to contact in case of any signs or symptoms of adverse drug reactions or other TPT-related issues.

Corresponding business processes (Component 4)	This scenario refers to the following business processes:
	A. Registration
	B. Screening
	E. TPT

3.2.3 Active case-finding (ACF) campaign

Key personas

Nurse: Azeeb

Data entry clerk: Maira

Client: Rohaan, a 38-year-old man

Azeeb is a nurse working for a district health clinic in a large rural district. The clinic started an ACF campaign that focuses on TB detection and today Azeeb is in the field, together with his colleague Maira, on a mobile outreach screening campaign to a small mine in the district.

Maira, the data entry clerk, invites the next man in the line to take a seat. His name is Rohaan, a 38-year-old man who has worked in the mining sector for the last 5 years. Maira registers Rohaan as a new client because he was not yet registered in the electronic system.

Once Rohaan is fully registered, he waits for the nurse to call him into the screening room. Azeeb invites Rohaan to the room and checks if he attended the group information session where the purpose of the campaign, the benefits and risks of the screening process and the screening algorithm were presented. As Rohaan attended the session, Azeeb asks if he has any questions or concerns related to what was discussed.

After obtaining Rohaan's verbal **informed consent** to start the screening process, Azeeb asks questions about any current TB symptoms and when it was the last time he had a CXR.

As Rohaan has not had a CXR recently, Azeeb performs a CXR using a mobile X-ray device. The image shows no abnormal results.

Rohaan does not manifest any TB symptoms; Azeeb tells him that he might be eligible for TPT, as someone who has been **exposed to silica**. After recording the screening results on his tablet, Azeeb offers Rohaan counselling on TPT.

Rohaan looks interested in getting TPT, so Azeeb continues with assessing his **TPT eligibility**. The digital system helps Azeeb by **offering examples of questions he should ask** related to Rohaan's personal and medication history, and social and financial status.

He then asks for permission to perform an interferon-gamma release assay (IGRA) test, which may increase the certainty that TPT would be beneficial for Rohaan.

Azeeb asks Rohaan if he would like to be called on his phone number, collected during the registration, to be told about the test result. As Rohaan has nothing against this, Azeeb marks in the system that the client accepts to be **contacted using this communication channel**.

Rohaan receives a phone call on the second day after seeing Azeeb, when he finds out that the IGRA test is positive. He then schedules a visit to the clinic where Azeeb is working to be counselled further on TPT and decide about his preferred TPT regimen.

Corresponding
business
processes
(Component 4)

This scenario refers to the following business processes:

- A. Registration
- B. Screening
- E. TPT

3.3 User scenarios for tuberculosis diagnosis and treatment

3.3.1 Diagnosis of pulmonary TB for a child (*Mycobacterium tuberculosis* complex bacteria [MTBC] not detected with molecular WHO-recommended rapid diagnostic test [mWRD])

Key personas **Clinical officer: Retha | Client: Iso, a child aged 1 year and 9 months | Household: Thandi, Iso's mother | Receptionist: Luan**

Luan is a receptionist at a health centre.

A young mother, Thandi, comes to the registration desk with her little girl, Iso. When asked about the reason for today's visit, Iso's mother mentions that she is a bit worried about her daughter's health and that she would like Iso to be seen by a health worker (HW). Luan asks Thandi for Iso's national ID and searches in the system using this ID. The system retrieves one record that matches Iso's profile. Luan can see in the system that Thandi already gave permission to collect and process her daughter's personal data for clinical investigations and treatment purposes.

Luan verifies in the system whether there are HWs available who could take over the case. Retha, the clinical officer, is available in 20 minutes. After confirming with Thandi that the waiting time is OK, Luan directs Thandi and her daughter to the appropriate room.

When entering the consultation room, Iso notices the wall stickers representing some of her preferred cartoon characters. Retha starts the visit by showing Iso the characters on the wall.

After interacting for a few minutes with the child, the HW can see that the little girl is feeling more relaxed and comfortable. She then starts asking her mother more information about what worried her and what is different lately in Iso's behaviour. Iso's mother explains that Iso has not been very playful in the last few weeks, as she used to be, and that she had a few episodes of fever and cough lately. She also mentions that she saw some weight loss in the last months and that sometimes she thinks Iso has difficulty breathing.

After performing a quick check for danger signs (none identified), the clinical officer continues the clinical examination on Iso, including checking for an elevated temperature (fever) and increased respiratory rate, measuring her weight and checking other clinical signs through a thorough physical examination, which is followed by recording the information collected on the digital system. She then verifies the growth curve generated by the system and identifies that the growth curve has flattened since the last visit.

Retha continues the evaluation by asking if Iso was recently in contact with anyone with TB or with a chronic cough. The mother tells the HW that 6 months ago Iso spent 2 weeks with her grandfather who was recently diagnosed with TB.

As Iso presents with TB symptoms (fever and cough episodes, increased respiratory rate, poor weight gain, reduced playfulness in the last few weeks), Retha suspects she may have pulmonary TB.

She decides to perform an mWRD test to obtain bacteriological confirmation. Retha explains to the mother the advantages of using stool as a specimen (non-invasive, can be collected anytime). Because it was not possible to collect the specimen on the spot, Retha asks the mother to collect the specimen, whenever feasible, and return with it to the clinic as soon as possible. A CXR is also available in the health centre, so Retha suggest doing a chest radiography, in parallel with the mWRD test, to help with the clinical diagnosis. Thandi agrees with this intervention, so that Iso can get it done before leaving the health-care facility.

The digital system alerts Retha with a pop-up message that a test for HIV is recommended for clients investigated for TB with unknown HIV status. Retha finds this alert useful, so she suggests to Thandi to perform an HIV test for Iso because this test might be important for an eventual TB treatment decision and provision of timely HIV care in case of a positive result. The mother agrees, so Retha performs the test.

The next morning, Thandi and her daughter are back to the clinic with a stool sample. Thandi asks Luan if it is possible to see Retha. He quickly checks on the digital system the appointments scheduled for that day and finds a free time slot in the afternoon on Retha's calendar. Thandi confirms that they can come back in the afternoon for the visit, as they have stuff to do in the city until that time anyway, so it will not be difficult for them to return. Luan confirms with Retha her availability; Retha asks the data entry clerk to inform Thandi that the results of all the tests will also be ready by then. Luan communicates this information and creates the appointment on the system.

A few hours later, the clinical officer is in the consultation room with Iso and her mother. She informs Thandi that the result of the HIV test is negative and communicates the result of the mWRD test, which indicates "MTBC not detected". Nevertheless, based on the clinical examination and Iso's history of close contact with a patient with TB (her grandfather) in the previous 12 months, clinically diagnosed pulmonary TB is established. To assess the severity of pulmonary TB disease, which is required to determine the TB treatment regimen, Retha needs the CXR results. The chest radiography image is available and because Retha is experienced in reading paediatric CXR, she reads the CXR, which shows dense alveolar opacification in a segment of the right lower lobe. There are also enlarged hilar lymph nodes on the right side, without airway compression. There is no pleural effusion and no miliary picture. Retha assesses that the features of the CXR show non-severe pulmonary TB.

Based on the clinical assessment and the CXR result, Iso is eligible for the 4-month TB treatment regimen; the medication Iso will take consists of 2 months of isoniazid, rifampicin and pyrazinamide followed by 2 months of isoniazid and rifampicin. Retha tells Thandi that dispersible, child-friendly, fixed-dose combined formulations are available for this regimen and explains how the medication will be administered.

All the information given, and the actions taken by Retha, make Thandi confident about the skills and goodwill of the care provider, so that at the end of the visit she is comfortable with starting the treatment for her daughter. Retha enters the information about the diagnosis and treatment initiation into the electronic system.

Retha ends the visit by letting Thandi know that the health-care team is there to answer any other questions she or her family might have. She also schedules, on the dates suggested by the digital system, a follow-up encounter for Iso and an initial TB assessment visit for her mother.

Corresponding business processes (Component 4)

This scenario refers to the following business processes:
A. Registration C. Diagnosis D. TB treatment

3.3.2 Diagnosis of drug-susceptible extrapulmonary TB for an adult

Key personas
Client: David
Physician: Laura
Nurse: Emily
Receptionist: Amy

David, a 39-year-old man, arrives at the reception desk of the local health-care facility. He has an appointment scheduled today and when Amy, the receptionist, asks for identification information, he shows a quick response (QR) code. Amy is able to find David's record and verifies his personal information.

After being checked in, David waits to be called into the consultation room. Laura, the family doctor, welcomes him. David underwent a series of examinations in the last few weeks, triggered by the appearance of an excrescence in the neck area and general apathy. He took antibiotics, but the treatment did not help.

This time Laura proposes TB investigations because the non-tender, enlarged cervical lymph node David has could be a sign of extrapulmonary TB.

She starts by assessing the TB contact history. As far as he knows, David has not interacted with a person confirmed with TB, but a few months ago he returned from a 3-month work trip in a country with high TB burden.

Laura also looks for signs and symptoms of pulmonary TB. No signs or symptoms of pulmonary TB are identified. Laura suggests that David should undergo diagnostic testing for TB, for both pulmonary and extrapulmonary TB, because, according to Laura, the two forms can coexist. David accepts, so he goes to the test room, accompanied by Emily, the nurse, where a sputum specimen is collected. This specimen will be used to test for pulmonary TB using a molecular WHO-recommended rapid diagnostic test (mWRD).

Knowing that the testing capability for extrapulmonary TB is not available at the clinic, Laura issues a referral to the regional hospital, asking for a TB diagnostic test using a lymph node aspirate or biopsy specimen. Laura decides to add in the referral note a request for an initial diagnostic test that detects resistance to rifampicin (RIF) and isoniazid (INH). Because this clinic is the custodian of David's electronic record, in the referral Laura requests to receive a copy of the test result using the digital system as soon as the result is available.

A few hours are needed before getting the test result of the mWRD test performed on the sputum, so Laura suggest communicating the result to David by calling him on the phone number shown on the digital system and scheduling an in-person visit once the extrapulmonary TB test result is ready. David thinks this is a good idea. Laura advises performing the test for extrapulmonary TB as soon as possible so that the diagnosis can be made based on the results of both tests.

The following day Laura informs David that the result of the mWRD test is "MTBC not detected". Three days later, David is back in the consultation room. The result of the extrapulmonary TB test was sent to Laura, so she scheduled a follow-up visit.

Laura communicates the results of the test: "MTBC detected, RIF resistance not detected, INH susceptible". Therefore, the diagnosis is extrapulmonary TB. Laura prescribes a 6-month regimen (2HRZ/4HR: 2 months of INH, RIF and pyrazinamide, followed by 4 months of INH and RIF). Because HIV, diabetes, smoking, alcohol consumption and mental disorders are factors associated with poorer TB treatment outcomes, Laura asks a series of questions, suggested by the system, to assess the presence of these comorbidities. She also performs, after obtaining David's consent, a rapid antibody HIV test (the result is negative) and collects a blood specimen that will be used to screen for diabetes. If diabetes or other comorbidities are identified, a referral to the nearest appropriate health service might be necessary for further management.

Next, she uses the system to generate the follow-up visit schedule and links it to David's profile. David is also interested in having a copy, so Laura sends the PDF version to him via email. According to the schedule, the first follow-up visit is due the following week to assess whether David tolerates the treatment, and to monitor adverse events and discuss the result of the diabetes screen.

When checking out, David tells Amy that he would like to receive SMS reminders for the next follow-up visits, so the receptionist saves this information on the system. The next stop is the pharmacy, where David picks up the medication for the first week as prescribed by Laura.

Corresponding business processes (Component 4)
 This scenario refers to the following business processes:
 A. Registration
 C. Diagnosis
 D. TB treatment

3.3.3 Adult with two TB episodes: drug-susceptible TB (DS-TB) followed a few years later by multidrug-resistant TB (MDR-TB)

FOLLOW-UP VISIT FOR AN ADULT DIAGNOSED WITH DS-TB

Key personas **Nurse:** *Aria*
Client: *Amar*

Amar is a 32-year-old man who lives in a poor rural community in an isolated area. One month ago, he was diagnosed with DS-TB and today he presents to the health-care facility for a follow-up visit. He had to take the bus because his village is 20 km away from the health centre.

Aria, the nurse, welcomes Amar and invites him to the consultation room. The consultation starts with searching the system for Amar's record and to validate his details. The visit continues with the clinical assessment: the health worker checks for resolution or persistence of TB-related symptoms and for signs of medication side-effects. Amar's weight is also measured. The results reveal symptomatic improvement and a slight weight gain.

Aria verifies if Amar took the drugs as prescribed. Amar tells her that he took the pills regularly.

Aria continues with the assessment and counselling on treatment adherence. To make sure that the risk of financial hardship due to TB is minimized, the nurse provides information and education on available social protection services, such as nutritional support, employment guarantee, safe housing and poverty alleviation.

At the end of the visit, Aria records the results of the examination performed on the system. She then checks the monitoring examination schedule to see when Amar should be scheduled for the next follow-up visit and what examinations should be performed at that time.

Aria schedules the next visit in 1 month and provides a 1-month prescription. As smears and culture after the second month of treatment are necessary to monitor treatment response, Aria gives Amar a sputum container so that he can bring back a sputum sample at the next visit. Then, she gives to Amar an appointment card detailing the date and time of the next follow-up visit.

Corresponding business processes (Component 4)	This scenario refers to the following business processes: A. Registration D. TB treatment
------------------------------------------------	-------------------------------------------------------------------------------------------------

DIAGNOSIS OF MDR-TB FOR AN ADULT WITH A PREVIOUS DS-TB EPISODE

Key personas

Nurse: Navi

Client: Amar

Amar is 35 years old. He moved from his small village 2 years ago to a city where he got employment in a penitentiary facility. He has a cough that does not go away, so he has come to the health-care facility, where he is currently registered, for a consultation.

Navi, the nurse, searches the system using Amar's first name and date of birth. The system retrieves an exact match. Because Amar is already registered in the system, Navi only needs to validate his details and moves on to the clinical evaluation.

During the discussion, Navi finds out that Amar's cough started 3 weeks ago. Amar also mentions that lately he sweats during the night, which is something new for him. While registering the findings in the digital system, Navi also checks his medical history. He finds out that a TB episode, which occurred 3 years ago, with a "lost to follow-up" outcome, is registered on the system. When asked about his previous TB episode, Amar confirms that he took the treatment for around 2 months, but decided not to continue after feeling much better and because the distance between his house and the health centre was quite significant.

Based on the symptoms and the clinical examination, Navi suggests that Amar should have an Xpert MTB/RIF test using a sputum specimen. Amar accepts and is invited to the test room, where the specimen can be collected safely by following biosafety and infection prevention and control best practices. Once the procedure is done, Navi asks Amar if they can meet again in the afternoon to analyse the test result and discuss the next steps. Amar is living close by and he is free that day, so he confirms his availability.

Four hours later, Amar is in the consultation room with Navi. Pulmonary TB, resistant to RIF, is confirmed by the mWRD test. After entering the test result in the digital system, the system alerts Navi that a follow-on test for additional evaluation of resistance to other anti-TB drugs is recommended in Amar's case. A low-complexity automated nucleic acid amplification test (LC-aNAAT) is available at the health centre; therefore, the nurse recommends follow-on testing to Amar. He accepts, so they go one more time to the test room where a new specimen is collected. The second test reveals INH resistance and fluoroquinolone susceptibility.

The next day, Amar meets Navi again in the consultation room. This time Navi tells Amar that he has MDR-TB based on the results of the mWRD tests.

To ensure appropriate co-management of TB and comorbidities and to decrease the risk of a poor TB outcome, the nurse performs an assessment for comorbid conditions and other risk factors, such as diabetes, disorders due to alcohol or drug use, HIV, smoking, undernutrition, coronavirus disease 2019, mental disorders and viral hepatitis. Because additional examinations and tests that are part of the baseline assessment need to be performed before starting MDR-TB treatment, Navi decides to issue a referral to a hospital where Amar can get the necessary examinations done and initiate treatment. He explains that once treatment has been initiated, Amar can continue treatment at this health-care facility.

With all the information provided and the care Navi showed in quickly assessing Amar's health, Amar is feeling confident in taking the next step and accepts being referred to follow the necessary baseline examinations and start treatment.

Corresponding business processes (Component 4)	This scenario refers to the following business processes: A. Registration C. Diagnosis D. TB treatment F. Referral
------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------

A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals (1, 13). Workflows are a visual representation of the progression of activities (tasks, events, interactions) that are performed within the business process (13). The workflow provides a “story” for the business process being diagrammed and is used to enhance communication and collaboration among users, stakeholders and engineers.

This DAK focuses on the key business processes conducted by the personas (described in [Component 2](#)) as part of TB care service provision. These business processes are described in [Table 5](#). For each of these business processes, the corresponding business processes, data elements and decision-support needs are detailed within the following sections of this document.

Table 5 Overview of key TB module business processes^a

No.	Process name	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the DAK	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
A	Registration	TB.A	<ul style="list-style-type: none"> » Client (TB-confirmed, TB-presumptive or unknown TB status) » Contact » Data entry clerk, medical office receptionist or health worker 	To identify and register or update the client’s personal details so that they can benefit from TB-related services.	Starting point: The client arrives at the facility and checks in with clerk, receptionist or health worker. Another option is when the health worker makes contact with the client at his location (home, workplace, detention place). <ul style="list-style-type: none"> » Search for client record » Review and update client record » Create a new client record

No.	Process name	Process ID	Personas	Objectives	Task set
B	Screening	TB.B	<ul style="list-style-type: none"> » Client » Contact » Health worker (physician, nurse or community health worker) 	To reach people who are not reached by the patient-initiated pathway and to detect TB disease early, thereby improving outcomes for individuals and reducing transmission and incidence at the population level.	<p>Starting point: The client or contact has been registered and called in for screening activities. TB screening can happen alongside other health services (e.g. HIV testing, nutrition counselling, child immunizations).</p> <ul style="list-style-type: none"> » Provide pre-screening information » Assess medical history and risk factors » Screen for TB using a screening algorithm
C	Diagnosis	TB.C	<ul style="list-style-type: none"> » Client » Health worker » Laboratory technician 	To determine TB status in clients by performing bacteriological and clinical investigations.	<p>Starting point: The client has been screened positive (provider-initiated pathway) or the client is seeking care at the health-care facility (patient-initiated pathway) and further investigation is needed to confirm or rule out TB disease. At this stage, for patients with confirmed TB, drug susceptibility testing (DST) will be performed.</p> <ul style="list-style-type: none"> » Clinically evaluate the client » Collect specimens » Perform initial diagnosis tests using a diagnosis algorithm » Perform follow-on testing for evaluation of resistance to anti-TB drugs » Interpret and review results » Take diagnostic decision
D	TB treatment	TB.D	<ul style="list-style-type: none"> » Client » Health worker » Pharmacist 	To initiate the appropriate TB treatment and perform necessary follow-up examinations to ensure that the correct treatment is followed, and that the patient adheres to it.	<p>Starting point: The client has been diagnosed with TB disease.</p> <ul style="list-style-type: none"> » Perform additional clinical examinations: evaluate risk for drug–drug interactions, assess for comorbidities, consider corticosteroid use, perform baseline evaluations » Determine treatment regimen and dosage » Develop monitoring examinations schedule » Initiate treatment and discuss treatment adherence » Monitor treatment considering the monitoring examinations schedule » Report treatment outcome

No.	Process name	Process ID	Personas	Objectives	Task set
E	TPT	TB.E	<ul style="list-style-type: none"> » Client » Health worker » Pharmacist 	To identify clients eligible for TPT, select the appropriate TB preventive treatment regimen for each client and ensure treatment adherence.	<p>Starting point: The client has been screened negative for TB or TB disease has been ruled out after TB diagnosis activities.</p> <ul style="list-style-type: none"> » Provide TPT counselling » Test for TB infection » Perform TPT eligibility evaluation » Determine TPT regimen and dosage » Develop TPT adherence plan » Report TPT completion
F	Referral	TB.F	<ul style="list-style-type: none"> » Client » Health worker 	To provide timely and appropriate referrals to another health-care facility that can provide services unavailable within this facility.	<p>Starting point: The clinician determines client needs for services that are not available at this facility.</p> <ul style="list-style-type: none"> » Determine whether it is an emergency referral » Discuss referral locations » Contact destination facility » Provide information to destination facility » Discuss any questions with the client
G	Aggregate reporting and data use	TB.G	<ul style="list-style-type: none"> » Health worker » District health information officer 	To aggregate client-level data into validated, aggregate reports, use the data and submit reports at the facility level.	<p>Starting point: Time for periodic (usually monthly) reporting.</p> <ul style="list-style-type: none"> » Check data quality » Correct fixable errors » Generate and review aggregate reports » Submit for approval » Provide feedback and any changes required

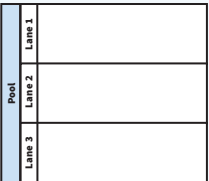
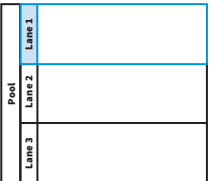







DST: drug susceptibility testing; TB: tuberculosis; TPT: tuberculosis preventive treatment.

^a The business processes described in the DAK are the ones listed in this table. Processes that are part of TB service delivery but are not included in this DAK include billing, dispensing and the definition of the TB strategy (coloured in grey in the overview of key TB processes diagram [Fig. 4]). These processes may be required, although this is highly country-specific and context-specific. If applicable, the billing business process could include an insurance or coverage check, which could take place at any one of many points during a TB visit. All the processes that are part of TB service delivery are shown in Fig. 4. The editable files of each business process in .bpmn format can be found in [here](#).

4.1 Overview of key processes

This section illustrates the workflows of the identified processes using standardized notations for business process mapping (Fig. 4). Table 6 provides an overview of this notations.

Table 6 Notations used in business process mapping

Symbol	Symbol name	Description
	Pool	A pool consists of multiple “swim lanes” that depict all the individuals or types of users involved in carrying out the business process or workflow. Diagrams should be clear, neat and easy for all viewers to understand the relationships across the different swim lanes. For example, a pool would depict the business process of conducting an outreach activity, which involves multiple stakeholders represented by different lanes in that pool.
	Swim lane	Each individual or type of user is assigned to a swim lane , a designated area for noting the activities performed or expected by that specific actor. For example, a TB health worker may have one swim lane; the supervisor would be in another swim lane; and the clients or patients would be classified in another swim lane.
	Start event or trigger event	The workflow diagram should contain both a start and an end event , defining the beginning and completion of the task, respectively.
	Start event message	The flow starts with a message . The meaning of “message” in business process model and notation (BPMN) is not restricted to letters, emails or calls. Any action that refers to a specific addressee and represents or contains information for the addressee is a message.
	End event	There can be multiple end events depicted across multiple swim lanes in a business process diagram. However, for diagram clarity, there should only be one end event per swim lane.
	Activity, process, step or task	Each activity should start with a verb, for example, “register client”, “calculate risk”. Between the start and end of a workflow, there should be a series of activities noting the successive actions performed by the actor in that swim lane. There can also be subprocesses of each activity.
	Activity with subprocess	This denotes an activity that has a much longer subprocess to be detailed in another diagram. If the diagram starts to become too complex and unhelpful, the subprocess symbol should be used to reference another process depicted on another page.
	Activity with business rule	This denotes a decision-making activity that requires the business rule , or decision-support logic, to be detailed in a decision-support table. This means that the logic described in the decision-support table will come into play during this activity, as outlined in the business process. This is usually reserved for complex decisions.
	Sequence flow	This denotes the flow direction from one process to the next. The end event should not have any output arrows. All symbols (except for start event) may have an unlimited number of input arrows. All symbols (except for end event and gateway) should have one and only one output arrow, leading to a new symbol, looping back to a previously used symbol or to the end event symbol. Connecting arrows should not intersect (cross) each other.

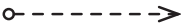
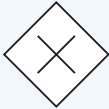







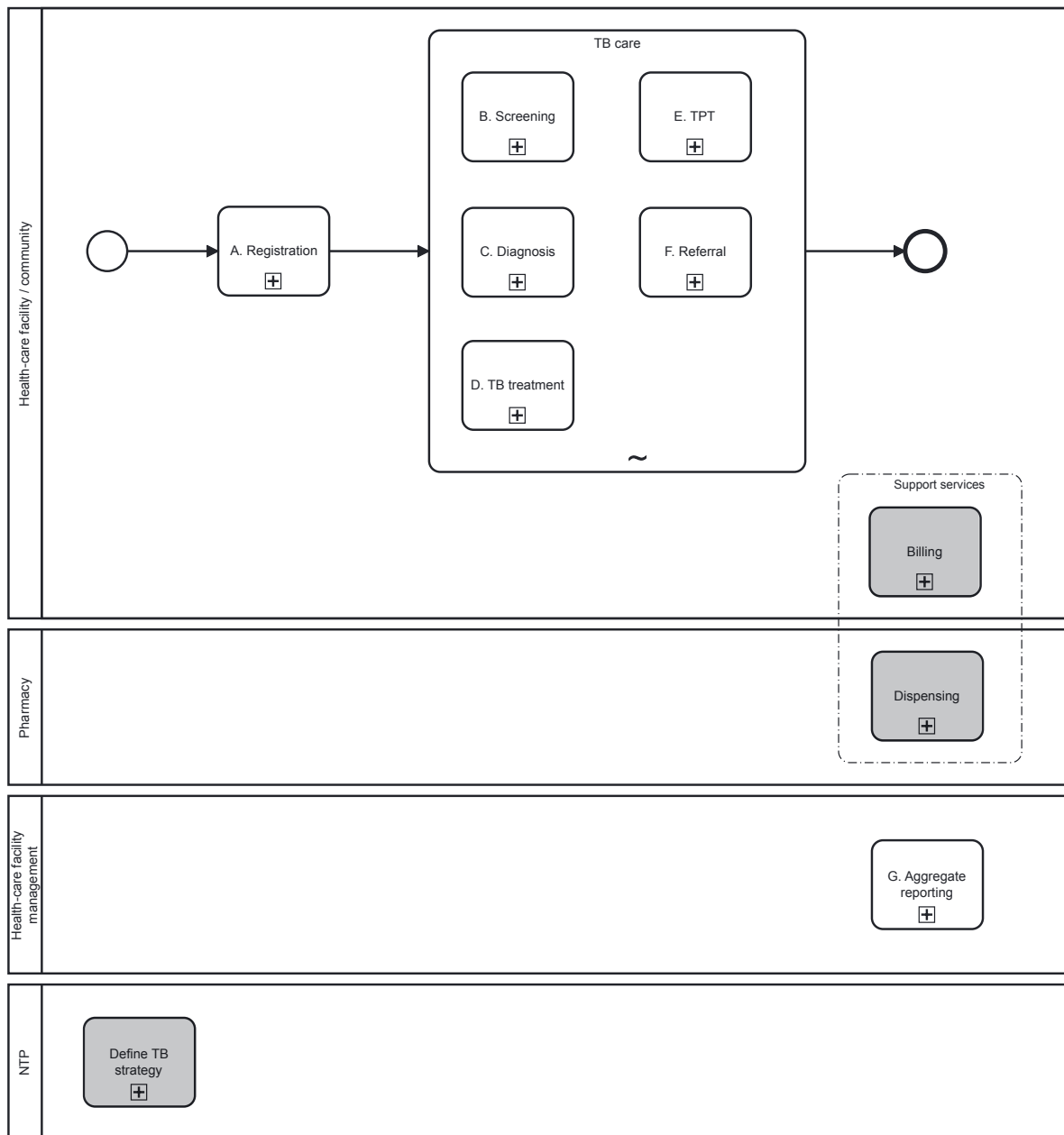
Symbol	Symbol name	Description
	Message flow	This denotes the flow of data or information from one process to another. This is usually used for when data are shared across swim lanes or stakeholder groups.
	Exclusive gateway	This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (e.g. yes/no) filter with two corresponding output arrows, or a different set of outputs. There should only be two different outputs that originate from the decision point. If you find yourself needing more than two output or sequence flow arrows, you most likely are trying to depict decision-support logic or a business rule. This should be depicted as an activity with business rule (above) instead.
	Parallel gateway	The parallel gateway can be used to model concurrency in a process. This type of gateway allows forking into multiple paths of execution or joining multiple incoming paths of execution. An important difference with other gateway types is that the parallel gateway does not evaluate conditions.
	Terminate end event	A terminate end event indicates that all activities in the process have to be immediately ended, including all the instances of multi-instance activities. The process will be ended without any compensation or event handling. It marks the fact that the business process terminated without reaching the intended end.
	Throw - link event	The throw - link event serves as the start of an off-page connector. It is the end of the process when there is no more room on your page for that workflow. It is the end of a process on your current page or the end of a subprocess that is part of a larger process. A catch - link will need to follow the throw - link .
	Catch - link event	The catch - link serves as the end of an off-page connector. It is the start of the new process on a different page from the throw - link or the start of a subprocess that is part of a larger process. A throw - link must be aligned to the catch - link .
	Annotations	Annotations are used to supplement the diagrams. Annotations contain useful (additional) information and can be connected to other elements with associations.
	Ad hoc marker	A container with an ad hoc marker can contain multiple activities (tasks or subprocesses), which can be executed in any order, executed several times, or skipped. However, not all these activities need to be finished before moving on to the next activity.
	Loop marker	A loop marker indicates that the activities inside the container repeat until a defined condition either applies or ceases to apply. The condition on which a loop executes is included as an annotation.

Fig. 4 Overview of key TB processes^a



NTP: National TB programme; TB: tuberculosis; TPT: tuberculosis preventive treatment.

^a For the key TB processes, see [Table 5](#).

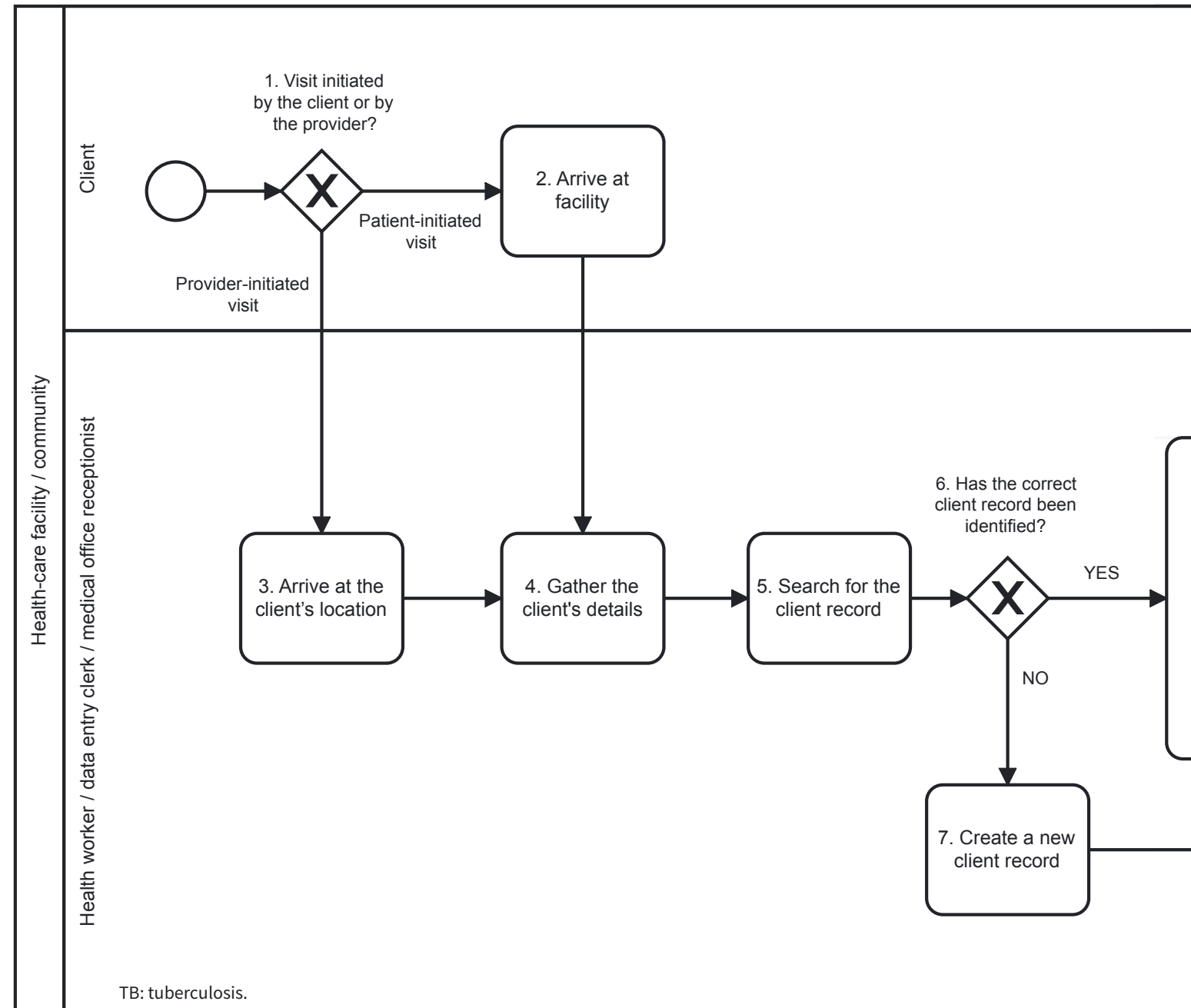
4.2 Workflows

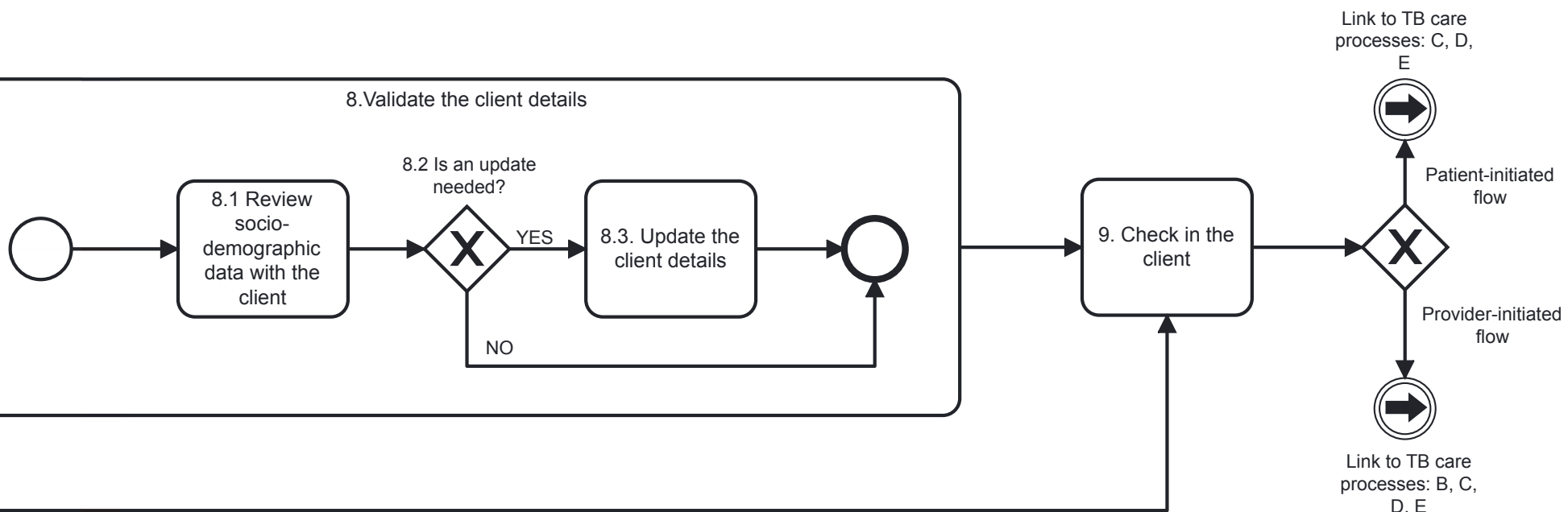
Workflows represent the progression of activities performed within the business process. They help users and stakeholders understand the relationship between activities, data elements and decision-support needs. The workflows shown depict processes that have been generalized and may not reflect variation and nuances across different settings. Also, the simplicity of the workflow may not adequately illustrate non-linear steps that may occur. Even though in some workflows counselling and obtaining informed consent activities are illustrated and described only in one activity, those actions occur throughout the entire TB care process.

A. Business process for registration

Objective: To identify and register or update the client's personal details so that they can benefit from TB-related services (Fig. 5).

Fig. 5 Workflow A: registration business process





REGISTRATION BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

Registration may be conducted as a stand-alone process by a data entry clerk or administrative persona ahead of the encounter in which TB-specific services (screening, diagnosis, treatment) are offered or it may be conducted directly by the health worker as part of the overall encounter. These activities can be performed either in the health-care facility or in the community (e.g. client's home, workplace, mobile van), depending on where the encounter takes place.

1. Was the visit initiated by the client or by the provider?

- » Depending on the reasons that triggered the encounter, the starting activity could be represented either by client's arrival at the health-care facility or by the health worker's arrival at the client's location. Client's arrival at the health-care facility could also happen as part of a provider-initiated pathway (e.g. client referred for additional screening activities, people living with HIV [PLHIV] screened for TB by the health worker in the HIV clinic).
- » Patient-initiated health-care pathway: The patient-initiated pathway to TB diagnosis relies on patients seeking care and on health systems to respond quickly and appropriately.
- » Provider-initiated TB screening pathway: The provider-initiated TB screening pathway systematically targets people at high risk of exposure to or of developing TB disease and screens them by assessing symptoms, using tests, examinations or other procedures to identify those who might have TB, following up with a diagnostic test and additional clinical assessments to make a definite diagnosis.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31).*

2. Client arrives at facility

- » The client arrives at the health-care facility and notifies the outpatient department of their arrival to be further guided.
- » The client could already be registered at the health-care facility for another service, for example, HIV, diabetes.

- » When digital tools, such as video-supported treatment, are used for communicating with the client (e.g. follow-up checks) this activity could be initiation of a video call, phone call or other appropriate digital interaction.

3. Arrive at the client's location

- » The health worker arrives at the client's location.

4. Gather the client's details

- » Ask the client whether they have previously been issued with a unique identifier.
- » Does the client have a card, number or barcode?
- » Does client say they are a returning or referred client?
- » If a referral, check for the referral slip or data from the community.
- » Determine whether the client is new to the health-care facility or health post.
- » For returning clients, details will be retrieved from the registry of clients or, if possible, from a central client registry.

5. Search for the client record

- » This search process can be done through several different means depending on what mechanisms are available in-country. For example, clients can be searched for by using their name, unique identifier, a quick response (QR) code or even biometrics.

6. Has the correct client record been identified?

- » If multiple records are found for the client, consider merging or deleting duplicate records, according to the HMIS guidelines.
- » It is also possible for the same episode of TB disease in a given individual to be recorded multiple times in the system. Any duplicate records of the same episode of TB must be removed (de-notify duplicate case) to avoid over reporting.

7. Create a new client record

- » Issue a unique identifier if used and possible at the facility.

8. Validate the client details

- » Review and update client record.
 - 8.1. Review the sociodemographic data with the client
Review the client’s non-clinical information, that is, name, address, contact information, etc.
 - 8.2. Is an update needed?
Has the client moved? Have they changed their contact information or has any other sociodemographic information changed?
 - 8.3. Update the client details
The client can provide updated information if they have moved or changed their details recently.
- » Merge or update client records.
- » This activity could also happen during other TB-specific processes, for example, screening, diagnosis, TB treatment, TPT.

9. Checking in the client

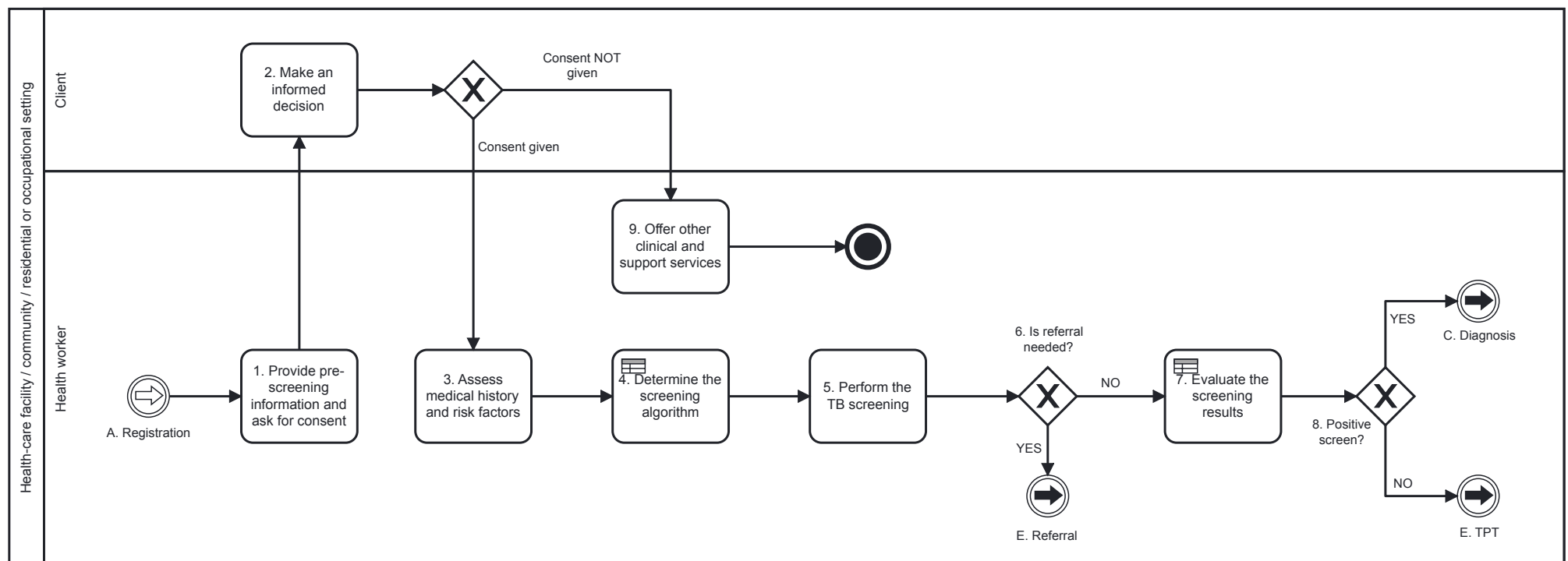
- » Record the client’s updated details in the client registry.
- » Add the client to the relevant queue for TB-related services. In case of patient-initiated flow, new clients will be redirected to “C. Diagnosis” while existing clients could continue the workflow with any of “C. Diagnosis”, “D. TB treatment” or “E. TPT business processes”. For new clients following a provider-initiated flow, the workflow continues with “B. Screening” while existing ones might be redirected to any of “B. Screening”, “C. Diagnosis”, “D. TB treatment” or “E. TPT business processes”.
- » Send or share intake confirmation to or with the referring facility as warranted.

B. Business process for screening

Objective: The primary goal of TB screening is to reach people who are not reached by the patient-initiated pathway and to detect TB disease early, thereby improving outcomes for individuals and reducing transmission and incidence at the population level (Fig. 6).

Secondary goals of TB screening are to: (1) rule out TB disease to identify people who are eligible for TPT; (2) identify people who are at particularly high risk of developing TB disease and thus may require repeated screening, such as people with an abnormal CXR (e.g. fibrotic lesion) that is compatible with TB but who were not diagnosed with TB disease at the time of screening, people living with HIV, health workers and prisoners; and (3) better characterize TB risk factors by combining screening for TB with screening for TB risk factors (such as HIV, diabetes mellitus, chronic obstructive pulmonary disease, undernutrition or smoking) to map individual or community-level risk factors and socioeconomic determinants that should be addressed to prevent the disease more effectively. This may be an additional objective in settings where information about the prevalence and distribution of TB risk factors is lacking.

Fig. 6 Workflow B: screening business process



TPT: tuberculosis preventive treatment.

SCREENING BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

Systematic screening for TB fulfils the classic screening criteria. The following key principles are to be considered when planning a TB screening initiative.

- » Principle 1: TB screening should always be done with the intention to follow up with appropriate medical care and ideally implemented where high-quality TB diagnostic and treatment services are available. If a community lacks access to appropriate follow-up care but would benefit from TB screening, this should be an impetus for investment by national TB programmes in TB diagnosis and treatment services to complement TB screening.
- » Principle 2: Screening should reach people at the greatest risk of developing TB disease, including high-risk groups and communities with a high prevalence of TB. Prioritization of risk groups for screening should be based on an assessment for each group of the potential benefits and harms, the feasibility and acceptability of the screening approach, the number needed to screen and the cost-effectiveness of screening. The benefits and harms of TB screening in different groups and populations need to be carefully assessed to maximize the common good while minimizing harm to individuals. TB threatens the health not only of an affected individual but also of their communities and the broader population.
- » Principle 3: TB screening should follow established ethical principles for screening for infectious diseases, including obtaining voluntary informed consent before proceeding with screening individuals and observing human rights, and be designed to minimize the risks of discomfort, pain, stigmatization and discrimination. Informed consent is a basic right and an important means of respecting an individual's autonomy.
- » Principle 4: The choice of algorithm for screening and diagnosis is based on an assessment of the accuracy of the algorithm for each risk group, as well as the availability, feasibility and cost of the screening tests. After a positive screening test result, the diagnosis of TB should be confirmed before TB treatment is started.

- » Principle 5: TB screening should be synergized with the delivery of other health and social services. Synergies are best identified during the development and implementation of screening approaches for different target populations, which may have particular patterns of use of health and social services (e.g. TPT among relevant populations screened for TB).
- » Principle 6: A screening strategy is expected to maximize coverage and frequency of screening to achieve its aims. Regular monitoring is necessary to inform any re-prioritization of risk groups, resource use, adaptation of screening approaches and discontinuation of screening. This includes assessing the risk of false-positive diagnoses resulting from screening.

Guidelines and guidance:

- » *WHO consolidated guidelines on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (20)*
- » *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)*
- » *Framework for collaborative action on tuberculosis and comorbidities (38)*
- » *Ethics guidance for the implementation of the End TB strategy (39).*

1. Provide pre-screening information and ask for consent

- » The health worker presents the potential risks and benefits of the screening procedure and familiarizes the client with the screening tools and procedure.
- » TB screening should follow established ethical principles for screening for infectious diseases, including obtaining voluntary informed consent before proceeding with screening. It is an ongoing, dynamic process that must be continually monitored and renewed during the whole time a patient is receiving health services. It is a basic right and an important means of upholding a patient's autonomy.
- » Informed consent refers to the process of engaging patients in the delivery of health services by giving them sufficient and relevant information to enable them to make decisions for themselves.

- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)*:
 - 1.2 Principles of TB screening
 - 2.4 Identifying and prioritizing risk groups
 - *Ethics guidance for the implementation of the End TB strategy (39)*:
 - 5. Education, counselling and the role of consent.

2. Make an informed decision

- » The client makes an informed decision regarding the acceptance and continuation of the process.
- » Consent given by the client includes agreement to follow various TB screening tests and evaluations (signed or witnessed consent if the patient is illiterate, or signed or witnessed consent from a child's parent or legal guardian).
- » Patients who refuse to consent should be counselled about the risks to both themselves and the community.

3. Assess medical history and risk factors

- » Discuss medical history with the client and review available records. Examples of history may include other diagnoses and medications.
- » Capture information related to the client's occupation, socioeconomic risk factors (e.g. homelessness, imprisonment), recent interactions with individuals with confirmed TB and other health-related risk factors for TB, such as:
 - diabetes;
 - disorders due to alcohol use;
 - HIV;
 - smoking;
 - undernutrition;
 - disorders due to drug use;

- silica exposure, silicosis;
- viral hepatitis;
- other clinical risk factors, for example, treatment with anti-tumour necrosis factor α 3 (TNF α 3), dialysis, organ or haematological transplantation.

» Guidelines and guidance:

- *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)*:
 - 2.4 Identifying and prioritizing risk groups
- *Framework for collaborative action on tuberculosis and comorbidities (38)*:
 - Table 2: Health-related risk factors and TB comorbidities, with related interventions recommended in current WHO guidelines.

4. Determine the screening algorithm

- » The health worker chooses a screening algorithm based on:
 - the specific objectives of screening;
 - the accuracy and yield of the screening and diagnostic tests;
 - the risk group;
 - TB prevalence in the risk group;
 - the costs, availability and feasibility of different screening methods;
 - the ability to engage the person to be screened.
- » Decision logic: TB.B4.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)*:
 - 3.2 Algorithms for screening.

5. Perform the TB screening

- » The health worker performs a TB screening according to the screening algorithm selected.

6. Is referral needed?

- » When at least one method part of the screening algorithm is not available in the location (due to lack of skills or tools), a referral is needed to complete the screening activity.
- » A referral can also be issued when risk factors requiring close clinical management are identified to ensure that the patient receives the care they need.

7. Evaluate the screening results

- » Once the results of the screening evaluations or the test part of the screening algorithm are available, the health worker can interpret them and decide what could be the next actions to take: refer for diagnostic evaluation or assess for TPT.
- » Decision logic: TB.B7.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)*:
 - Annex 1 Screening algorithms for the general population and high-risk groups (not including people living with HIV)
 - Annex 3 Screening algorithms for adults and adolescents living with HIV
 - Annex 5 Screening algorithms for children.

8. Screen result

- » A positive or abnormal result in screening tests is an indication for referral towards a diagnostic evaluation.
- » Although systematic testing and treatment is not specifically recommended in some cases (e.g. people with diabetes, people who engage in harmful use of alcohol, tobacco smokers and underweight people), these populations may still be considered for TPT on a case-by-case basis to reduce the risk of TB, especially if they have a heightened likelihood of unfavourable outcome should the disease develop or if the person has multiple risk factors for TB.
- » In case of a negative screen result, the process will continue with “TPT” process, according to the existing national policy.

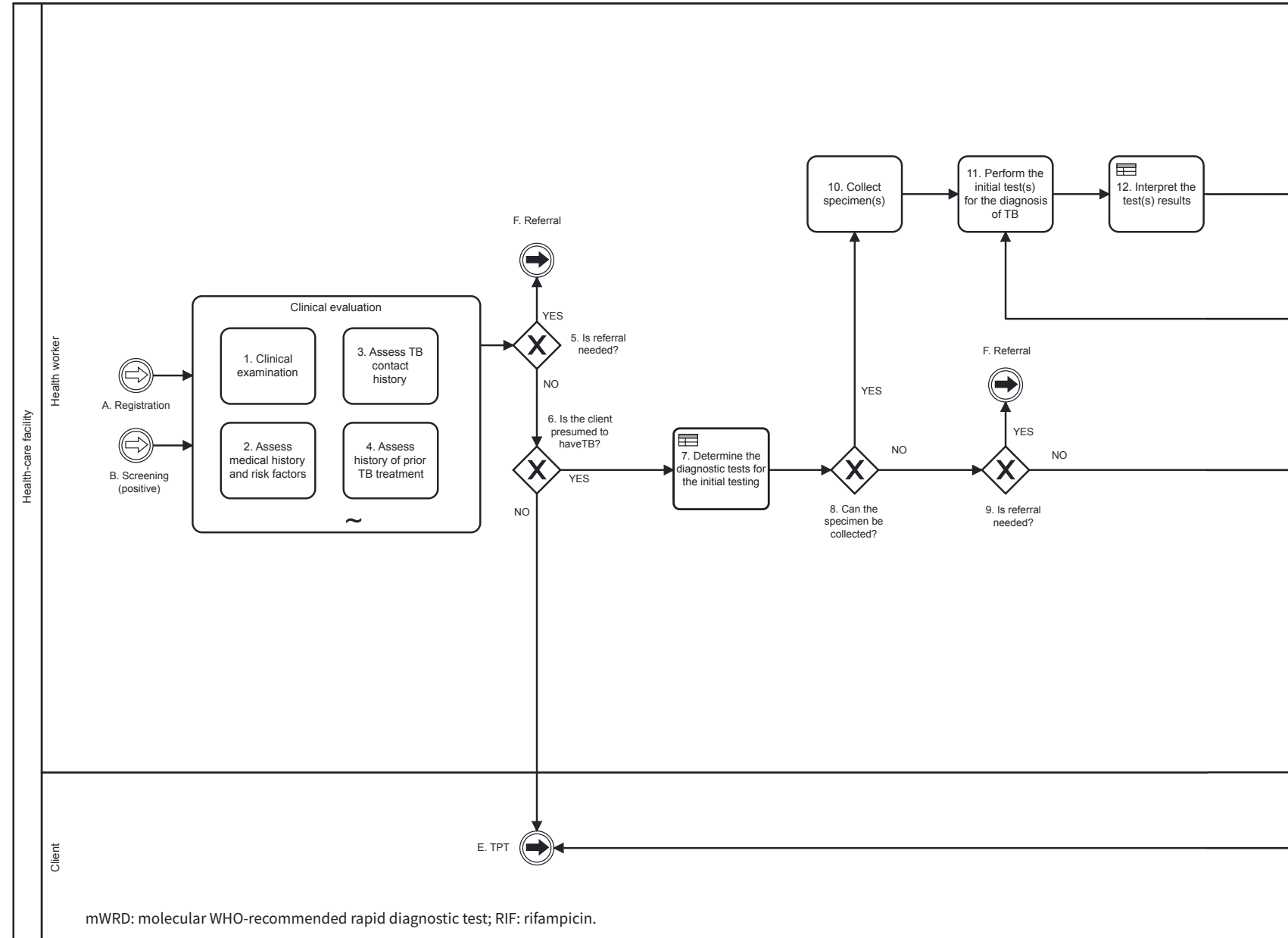
9. Offer other clinical and support services

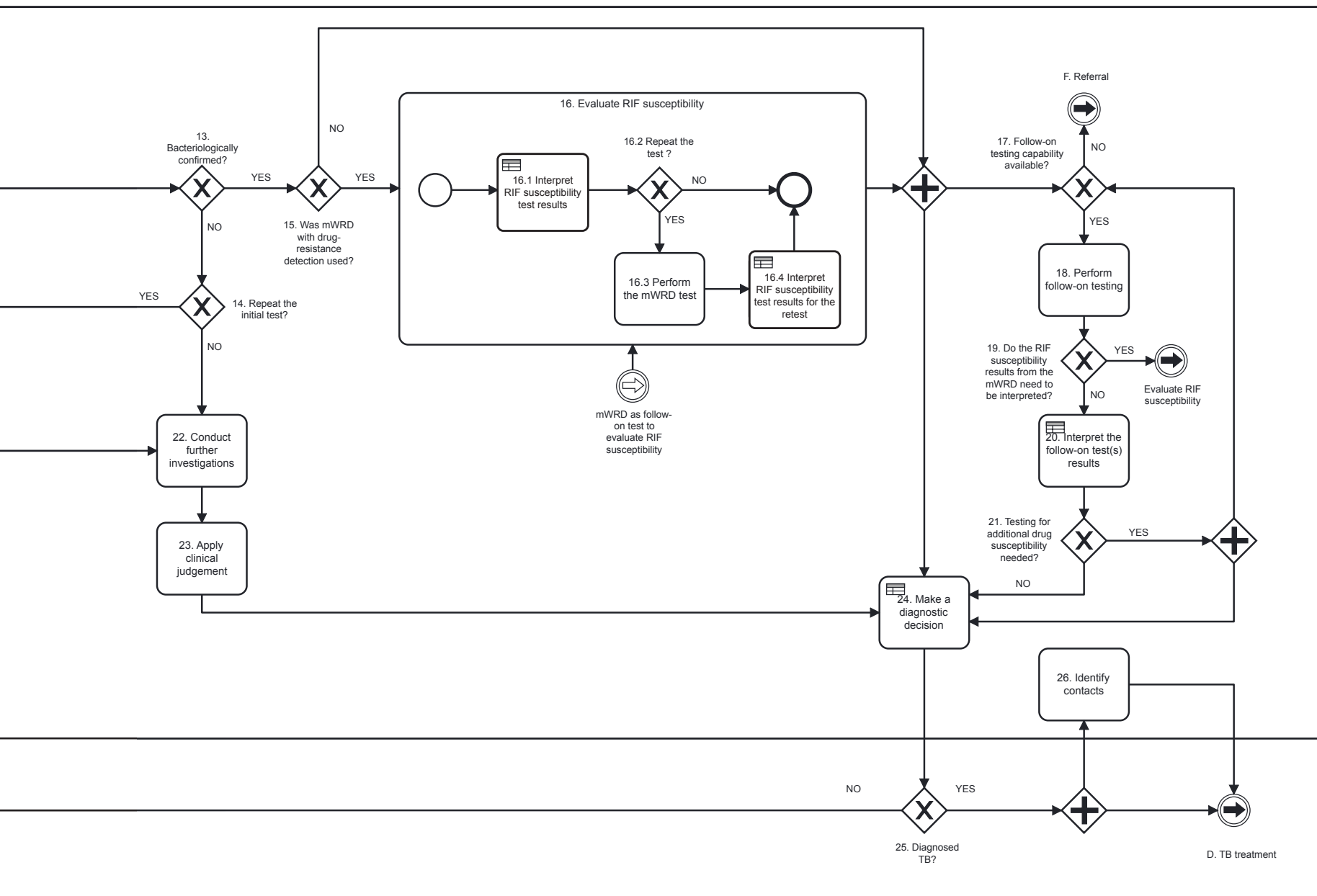
- » The health worker might offer other relevant clinical and support services to the client if the client does not give their consent for proceeding with TB screening.

C. Business process for diagnosis

Objective: To determine TB status in clients, by performing bacteriological and clinical investigations, starting TB treatment or TPT based on the results of the investigations (Fig. 7).

Fig. 7 Workflow C: diagnosis business process





DIAGNOSIS BUSINESS PROCESS NOTES AND ANNOTATIONS

Guidelines and guidance:

- » *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection, 2021 update)* (21)
- » *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32).
- » *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37)
- » *Framework for collaborative action on tuberculosis and comorbidities* (38).

1. Carry out clinical examination

- » A clinical evaluation is usually required before performing tests that would provide a bacteriological confirmation of the disease. Usually, a decision to undertake a diagnostic work-up of an individual for TB begins with assessing the symptoms and signs of TB disease. In addition, a variety of nonspecific signs are also evaluated to identify the features that raise clinical suspicion: vital signs, signs of respiratory distress, signs of advanced HIV disease, seriously ill PLHIV based on four danger signs (respiratory rate of more than 30 breaths per minute, temperature of more than 39°C, heart rate of more than 120 beats per minute and unable to walk unaided), CD4 cell count, and so on.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32)
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 4. TB diagnostic approaches for children and adolescents.

2. Assess medical history and risk factors

- » Discuss medical history with client and review the available records. Examples of history may include other diagnoses and medications.
- » Capture information related to the client's occupation, socioeconomic risk factors (e.g. homelessness, imprisonment) and other health-related risk factors for TB, such as:
 - diabetes;
 - disorders due to alcohol use;
 - HIV;
 - smoking;
 - undernutrition;
 - disorders due to drug use;
 - silica exposure, silicosis;
 - viral hepatitis;
 - other clinical risk factors, for example, treatment with anti-TNFα3, dialysis, organ or haematological transplantation.
- » For clients evaluated for TB disease, with unknown HIV status, HIV testing should be performed in accordance with national guidelines.

3. Assess TB contact history

- » Close contact with a source case with TB often involves sharing a living, learning or working space with them. Contact may also occur with a source case from outside the household (e.g. a neighbour, caregiver or relative) with whom the client has had frequent contact.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 4. TB diagnostic approaches for children and adolescents
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32).

4. Assess history of prior treatment

- » Previous TB treatment shall be discussed.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32):
 - 3. Implementing a new diagnostic test
 - 4. Model algorithms.

5. Is referral needed?

- » If, during the evaluation for TB disease, signs are identified requiring urgent medical care (e.g. gastrointestinal, circulatory, respiratory, neurological), a referral to the first referral level of care as per national guidelines, shall be considered.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - Annex 5. Treatment decision algorithms.

6. Is the client presumed to have TB?

- » Depending on the findings of the initial clinical evaluation, the health worker decides whether the client should be further evaluated for TB disease or whether a TPT eligibility evaluation should be performed. This does not mean that every client evaluated as not being “presumptive TB” will get a TPT. The evaluation for TPT will be performed according to the “E.TPT” workflow.

7. Determine the diagnostic tests for the initial testing

- » The health worker selects a diagnosis algorithm and the diagnosis tests to be used depending on HIV status, the age of the client and other criteria. When selecting the diagnosis algorithm, it is important to consider the findings of the client’s clinical evaluation and the characteristics of the population to which the client belongs.
- » Decision logic: TB.C7.DT.
- » Guidelines and guidance:

– *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (21):

- 2. Recommendations

– *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32):

- 2. Diagnostic tests with WHO recommendations.

8. Can the specimen be collected?

- » In some cases, the specimen cannot be collected. Examples of such cases are: the client cannot produce the specimen (e.g. children who cannot produce sputum), the health worker lacks the necessary skills or tools to collect the specimen, or the client refuses the intervention.

9. Is referral needed?

- » A referral to another facility may be needed if the specimen cannot be collected because of the lack of skills or tools or at client’s wish. The client might resume the workflow, with the appropriate activity, if they come back to the facility that issued the referral to continue the process (e.g. the client was referred to a secondary-level health-care facility for specimen collection and diagnostic test execution and they come back to the original facility for the interpretation of the test results and eventually for treatment initiation). Otherwise, the TB care process will be continued at the referral facility.

10. Collect specimen(s)

- » The decision on which type of specimen should be collected depends on the type of TB being evaluated (pulmonary or extrapulmonary), the tests intended to be used, age and other criteria.
- » Guidelines and guidance:
 - *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (21):
 - 2. Recommendations
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 4. TB diagnostic approaches for children and adolescents.

11. Perform the initial test(s) for the diagnosis of TB

- » At this step, the diagnostic test(s) is/are performed according to the corresponding test procedure.

12. Interpret the test(s) results

- » The test(s) results are interpreted according to the diagnosis algorithm selected to determine if TB disease is confirmed bacteriologically.
- » Decision logic: TB.C12.DT.
- » Guidelines and guidance:
 - *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (21)*:
 - 2. Recommendations
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (32)*:
 - 4.1 Algorithm 1 – mWRD as the initial diagnostic test for TB
 - 4.2 Algorithm 2 – LF-LAM testing to aid in the diagnosis of TB among PLHIV.

13. Is the TB bacteriologically confirmed?

- » When bacteriological confirmation cannot be obtained (negative test results), the recommendations could consist of repeating the test(s) and/or perform further investigations.

14. Repeat the initial test

- » When the diagnosis test gives an inconclusive result, such as “error”, “invalid”, “no result” or a negative result, the health worker might decide to repeat the test, using any portion of the sample remaining after the first test or by collecting a fresh specimen. The result of the second test is usually the result that is considered for clinical decisions.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (32)*:
 - 4.1.1 Decision pathway for Algorithm 1 – mWRD as the initial diagnostic test for TB.

15. Was mWRD with drug-resistance detection used?

- » When a molecular WHO-recommended rapid diagnostic test (mWRD) test with drug-resistance detection is used and the result confirms the presence of *Mycobacterium tuberculosis*, RIF susceptibility evaluation will be performed.
- » If a conventional diagnosis test or a WRD without drug-resistance detection was used and indicates bacteriological confirmation, the flow continues directly with diagnostic decision and follow-on testing in parallel. For example: TB was bacteriologically confirmed by lateral flow urine lipoarabinomannan assay (LF-LAM) as the initial diagnostic test; the health worker establishes the TB diagnosis result “diagnosed TB” and initiates TB treatment immediately; an mWRD test is performed in parallel with the purpose of assessing RIF susceptibility.

16. Evaluate RIF susceptibility

- » If testing was done with an mWRD test capable of detecting RIF resistance, the health worker needs to interpret the results of the RIF susceptibility test and decide on the next steps accordingly.
 - 16.1 Interpret RIF susceptibility test results
 - The health worker interprets the RIF susceptibility test results.
 - Decision logic: TB.C16.1.DT.
 - 16.2 Repeat the test?
 - Repeating the mWRD test is recommended in some cases, for example, when the RIF result is indeterminate and false RIF resistance is suspected. When there is no need to repeat the test, the subprocess ends and the workflow continues in parallel with follow-on testing and diagnostic decision-taking (e.g. when the mWRD test indicates “MTB detected, RIF resistance NOT detected”, the health worker establishes the TB diagnosis result “diagnosed TB” and initiates TB treatment with a first-line regimen; drug susceptibility testing [DST] for isoniazid [INH] is performed in parallel).
 - 16.3 Perform the mWRD test
 - The health worker repeats the mWRD test. Probe binding delay and samples with a low bacillary load have been associated with increased false resistance or an “RIF indeterminate” result. A fresh specimen should be used to repeat the test.

- 16.4 Interpret RIF susceptibility test results for the retest
The results of the second test are analysed and a decision regarding treatment initiation and the next steps is made. The subprocess ends and the workflow continues in parallel with follow-on testing and diagnostic decision-taking.

- Decision logic: TB.C16.4.DT.

» Guidelines and guidance:

- *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (21)*:

- 2. Recommendations

- *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (32)*:

- 4.1 Algorithm 1 – mWRD as the initial diagnostic test for TB.

17. Availability of follow-on testing capability

- » If the follow-on testing capability for resistance to additional anti-TB drugs is missing at the current facility, the client needs to be referred to another facility. The flow might be resumed, with the appropriate activity, at the original facility if the client returns for the interpretation of the results and treatment initiation or treatment adjustments. Otherwise, the TB care process will be continued at the referral facility.

18. Perform follow-on testing

- » Follow-on testing is used once TB disease is confirmed, with the goal of identifying resistance to TB drugs. If the results are inconclusive, such as “error”, “invalid”, “no result”, or a negative result is recorded, the health worker might decide to repeat the test. A new specimen might be needed for follow-on testing.

19. Do the RIF susceptibility results from the mWRD need to be interpreted?

- » When the goal of the follow-on test is to assess for RIF resistance using an mWRD diagnostic test (e.g. TB was bacteriologically confirmed by “microscopy – sputum” used as the initial diagnostic test, followed by a (follow-on) mWRD test with the purpose of confirming or excluding RIF resistance), the flow will continue with the subprocess “16. Evaluate RIF susceptibility”, otherwise the flow will continue with interpretation of the follow-on test results.

20. Interpret the follow-on test(s) results

- » The results of the follow-on testing are interpreted and further used for treatment adjustments, if needed.

- » Decision logic: TB.C20.DT.

- » Guidelines and guidance:

- *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (21)*:

- 2. Recommendations

- *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection) (32)*:

- 2. Diagnostic tests with WHO recommendations

- 4.3 Algorithm 3 – DST for second-line drugs for patients with RR-TB or MDR-TB

- 4.4 Algorithm 4 – mWRD as the initial or follow-on test to detect Hr-TB.

21. Testing for additional drug susceptibility

- » The health worker may recommend conducting further DST in line with the available test results. If this is necessary, the activities of “perform follow-on testing” and “interpret follow-on test results” will be repeated while concurrently modifying TB treatment, if deemed necessary.

- » Examples:

- Case 1: TB was bacteriologically confirmed using sputum microscopy as the initial diagnostic test. RIF resistance was detected using an mWRD test as the follow-on test; therefore, TB treatment will need to be reviewed (change of TB treatment regimen: from first-line to second-line treatment given that the client is at high risk of MDR-TB), while a DST for second-line drugs is performed in parallel.

- Case 2: TB susceptible to RIF was detected by mWRD as an initial test. INH resistance was detected using molecular DST as follow-on testing for INH; therefore, the treatment regimen is changed from first-line regimen to Hr-TB regimen, at the same time a specimen is referred for molecular DST for fluoroquinolone.

22. Conduct further investigations

- » When a diagnostic test cannot be performed or the test(s) is/are performed but the result is inconclusive or negative, the health worker should conduct additional investigations. Among such investigations, could be a chest X-ray (e.g. in case of a negative mWRD test or when the client cannot produce the specimen[s] necessary for bacteriological confirmation), analysis of the clinical response after treatment with antimicrobial agents or conducting additional testing (e.g. additional mWRD testing or culture in case of symptomatic persons with negative results for the initial diagnostic tests).
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection)* (32):
 - 4.1.1 Decision pathway for Algorithm 1 – mWRD as the initial diagnostic test for TB
 - 4.2 Algorithm 2 – LF-LAM testing to aid in the diagnosis of TB among PLHIV.

23. Apply clinical judgement

- » The health worker assesses all the information available before making a diagnostic decision.

24. Make a diagnostic decision

- » Clinical decisions should be made based on clinical judgement, the results of available laboratory tests or the results of further investigations (or both).
- » Currently, there are algorithms in the TB guidelines regarding making diagnostic decisions for children (<10 years old); therefore, the decision logic mentioned below refers to children younger than 10 years.
- » Decision logic: TB.C24.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - Annex 5. Treatment decision algorithms.

25. When TB is diagnosed

- » Clients diagnosed with TB will need TB treatment whereas clients in whom TB disease was ruled out can be evaluated for TPT.

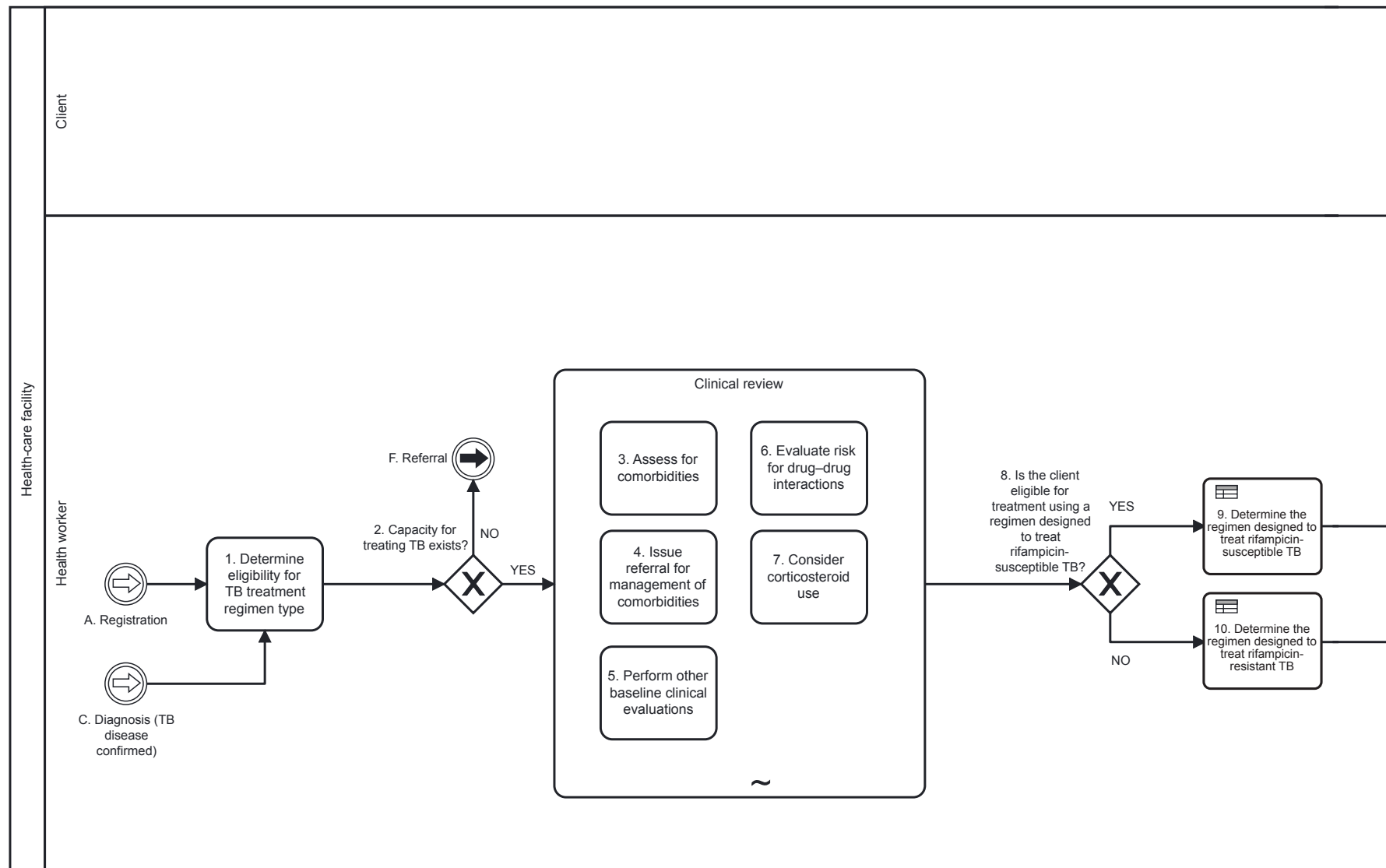
26. Identify contacts

- » Once a client is diagnosed with TB, it is important to identify their contacts as soon as possible to conduct screening activities on people recently exposed to TB with a high risk of developing the disease.

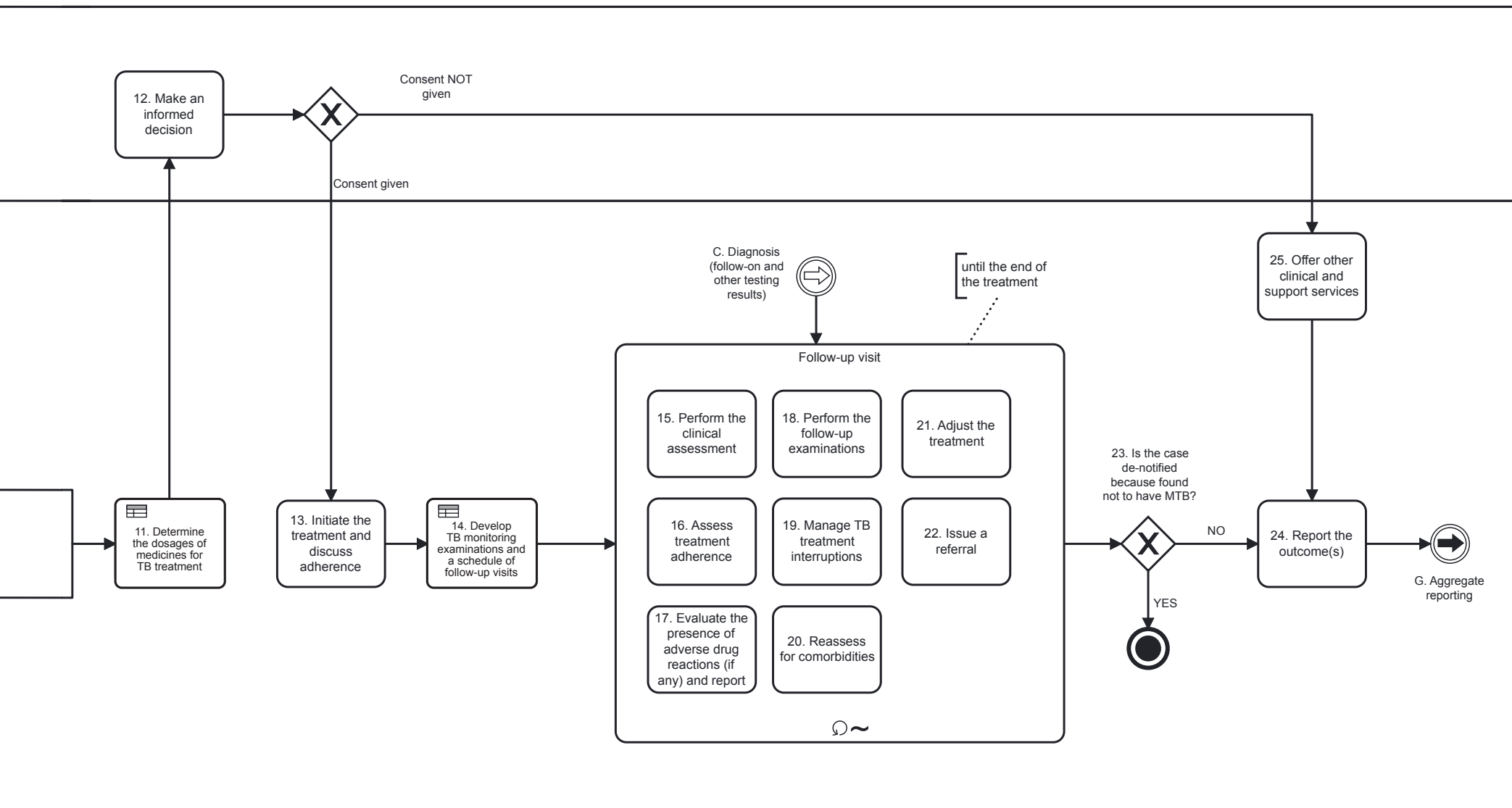
D. Business process for TB treatment

Objective: To initiate the appropriate TB treatment and perform the necessary follow-up examinations to ensure that the correct treatment is followed and that the patient adheres to it (Fig. 8).

Fig. 8 Workflow D: TB treatment business process



MTB: *Mycobacterium tuberculosis*; TB: tuberculosis.



TB TREATMENT BUSINESS PROCESS NOTES AND ANNOTATIONS

Guidelines and guidance:

- » *WHO consolidated guidelines on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (23)
- » *WHO consolidated guidelines on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (24)
- » *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34)
- » *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35)
- » *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37)
- » *Framework for collaborative action on tuberculosis and comorbidities* (38).

1. Determine eligibility for TB treatment regimen type

- » The health worker determines whether the client is eligible based on laboratory results and previous clinical evaluation, for a regimen designed to treat rifampicin (RIF)-susceptible TB or if a regimen for TB resistant to RIF is more appropriate.

2. Capacity for treating TB exists

- » When treatment cannot be started or continued in the current facility (e.g. lack of skills, knowledge, stock of medicines), a referral is issued to transfer the patient to a new treatment facility.
- » All children and adolescents with severe forms of TB (tuberculosis meningitis [TBM], peritonitis, pericarditis, renal, spinal, disseminated or osteoarticular TB) and those suspected of having MDR/RR-TB (in contact with a person with confirmed or suspected MDR/RR-TB, or children and adolescents diagnosed with TB who are not responding to first-line TB treatment) should be referred to a specialist for further management if management capacity where they present is insufficient.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 5.2.8.1. Indications for referral and hospitalization.

3. Assess for comorbidities

- » There are some comorbidities and risk factors that increase the risk of poor TB treatment outcomes, or further transmission, which may require close clinical management. The assessment of comorbidities and risk factors (e.g. diabetes, disorders due to alcohol or drug use, HIV, smoking, undernutrition, coronavirus disease 2019, mental disorders, viral hepatitis) as part of the baseline clinical review is also important to determine additional needs for co-management, to correctly interpret adverse drug reactions, if such reactions are identified during or after the treatment ends, and for providing advice and counselling as necessary.
- » Guidelines and guidance:
 - *Guideline: nutritional care and support for patients with tuberculosis* (28)
 - *Framework for collaborative action on tuberculosis and comorbidities* (38):
 - Table 2. Health-related risk factors and TB comorbidities, with related interventions recommended in current WHO guidelines
 - *WHO operational handbook on tuberculosis – Module 6: tuberculosis and comorbidities – mental health conditions* (40)
 - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (44)
 - *HEARTS D: diagnosis and management of type 2 diabetes* (45)
 - *mhGAP intervention guide Mental Health Gap Action Programme version 2.0 for mental, neurological and substance use disorders in non-specialized health settings* (46)
 - *A WHO/the Union monograph on TB and tobacco control: joining efforts to control two related global epidemics* (47)
 - *Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact* (48).

4. Issue referral for management of comorbidities

- » Beyond the impact on TB, collaborative action on TB and comorbidities may also improve efficiency of resource use, reduce health-care visits, address fragmentation in health systems and improve health outcomes. Therefore, the health worker must ensure that once a comorbidity or impairment is identified, the patient receives the care they need, preferably at the same place or via referral to an appropriate health service in case of need. This may include referral to mental health or substance use services, preventive and rehabilitation services, and social protection services to improve the health and social outcomes of people with TB.

5. Perform other baseline clinical evaluations

- » TB treatment poses special issues in some subgroups of patients (pregnant women, people aged over 65 years, those with chronic kidney or liver disease). For patients belonging to these subgroups, a set of baseline examinations (clinical, electrocardiography, laboratory evaluations) are recommended before starting TB treatment.

6. Evaluate drug–drug interactions

- » For patients taking other medicines (older people, people with comorbidities), interaction between the drugs taken as part of the TB treatment regimen and other drugs taken by the patient must be evaluated.

7. Consider corticosteroid use

- » Treatment with corticosteroids is recommended for tuberculous meningitis and tuberculous pericarditis because the benefits outweigh the potential harms of corticosteroid therapy.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34):
 - 8.2 Use of corticosteroids
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35):
 - 7.3 Use of adjuvant steroids in the treatment of tuberculous meningitis and pericarditis.

8. Is the client eligible for treatment using a regimen designed to treat rifampicin-susceptible TB?

9. Determine the regimen designed to treat rifampicin-susceptible TB

- » The health worker selects the most appropriate regimen designed for rifampicin-susceptible TB based on specific considerations, such as age, HIV status, site of TB disease, severity of the disease, previous TB treatment and DST results.
- » In settings where rapid, molecular-based DST is available, the results should guide the choice of regimen. In settings where rapid DST results are not routinely available to guide the management of individual patients, the approach to treatment selection can be guided by clinical judgement and consideration of the epidemiology of TB and its drug-resistant forms in the specific setting.
- » Decision logic: TB.D9.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35)
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 5.2. Treatment of drug-susceptible TB in children and adolescents.

10. Determine the regimen designed to treat rifampicin-resistant TB

- » The health worker selects the most appropriate regimen designed for TB resistant to rifampicin based on specific considerations, such as age, DST results, eligibility criteria for the drug-resistant tuberculosis (DR-TB) regimens, pregnancy status, severity of the disease.
- » The inability to undertake DST routinely for all patients despite all possible efforts should not be a barrier to starting patients on a potentially life-saving DR-TB regimen; however, treatment should always be considered in a context of the potential risk of prescribing ineffective treatment and amplifying drug resistance, with a subsequent decrease in the likelihood of treatment effectiveness.
- » The findings of the clinical review are also considered in the treatment

selection decision.

- » Decision logic: TB.D10.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34)
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 5.3 Treatment of multidrug-resistant and rifampicin-resistant TB in children and adolescents.

11. Determine the dosages of medicines for TB treatment

- » The health worker determines the dosage for the medicine part of the treatment regimen, based on age and weight band.
- » Decision logic: TB.D11.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34):
 - Annex. Weight-based dosing of medicines used in multidrug-resistant TB regimens, adults and children
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35):
 - Annex. Dosages of anti-TB medicines by weight band for treatment of DS-TB
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - 5.2.7. Recommended dosing of first-line medicines in children
 - Annex 6. Dosing of medicines used in second-line multidrug-resistant TB regimens by weight band (below 46 kg).

12. Make an informed decision

- » All treatment delivered should align with WHO-recommended standards, including obtaining informed consent where necessary (signed or witnessed consent if the patient is illiterate, or signed or witnessed consent from a child's parent or legal guardian).
- » Patients who refuse to consent to TB treatment should be counselled about the risks to both themselves and the community.

13. Initiate the treatment and discuss adherence

- » Once the appropriate treatment regimen is identified, the correct medicine dosages are determined and the consent from the patient (parent or legal guardian in case of children or adolescents) is obtained, treatment can be initiated.
- » The health worker should undertake the relevant measures to support adherence and ensure favourable treatment outcomes, such as:
 - consider directly observed treatment;
 - optimize access of the patient to social protection services;
 - provide psychosocial support (psychosocial assessment should offer an opportunity to assess supportive factors for treatment adherence and should be directly linked to relevant interventions wherever possible, as per country-specific questionnaires);
 - consider the use of digital technologies.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (tuberculosis care and support)* (36):
 - 4.4. Counselling to provide information about TB treatment and to ensure adherence to treatment
 - 4.5. Counselling to provide psychological support
 - *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents* (37):
 - Box 7.6 Proposed interventions to address needs of adolescents with or at risk of TB
 - 5.2.11. Treatment adherence.

14. Develop TB monitoring examinations and a schedule of follow-up visits

- » Patients should undergo appropriate evaluation at baseline, as well as during and after treatment. This should include necessary clinical evaluations (e.g. laboratory tests, electrocardiography), and bacteriological and radiological examinations.
- » Clinical visits should coincide with bacteriological and clinical laboratory examination schedules, to limit time and transportation constraints for the patient.
- » Decision logic: TB.D14.S.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34):
 - 4.5 Treatment monitoring
 - 5.5 Treatment monitoring
 - 6.5 Treatment monitoring
 - 7.4 Treatment monitoring
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35):
 - 3.5 Treatment monitoring
 - 4.5 Treatment monitoring
 - 5.5 Treatment monitoring
 - 9 Monitoring treatment response.

15. Perform the clinical assessment

- » Clinical assessment should focus on monitoring response to treatment and addressing common symptoms associated with TB treatment and long-term antibiotic use, with the goal of supporting adherence. Persistent fever, weight loss or recurrence of any of the classic symptoms of TB should prompt investigation for possible treatment failure, undetected resistance to one or more drugs in the current treatment regimen or untreated comorbidities.

- » TB-associated disabilities can be long term or temporary and may result from TB disease affecting tissues and organs, adverse reactions to TB medicines and comorbid mental health disorders. Therefore, clinical evaluation may also include early identification and screening for impairments, disabilities and subsequent rehabilitation needs.

16. Assess treatment adherence

- » The most common challenge in TB care is when a patient discontinues taking medicines or misses treatment appointments. Measures to support patient adherence tailored to patient needs are important to retain patients on treatment and ensure good treatment outcomes. Support should be provided through an effective model of care and measures should include support in the community or at home, social support and digital health interventions for communication with the patient.
- » The following actions should be taken in case of poor adherence:
 - home visit to engage with the patient;
 - assess the reasons for discontinuing treatment;
 - discuss the patient's concerns that caused non-adherence;
 - educate the patient about the need to continue treatment;
 - counsel and support the patient to resume treatment promptly; and
 - engage community health workers, family members and caregivers to ensure treatment adherence.

17. Evaluate the presence of adverse drug reactions (if any) and report

- » Active pharmacovigilance should be performed, as well as proper management of adverse events and prevention of complications from drug–drug interactions. An appropriate schedule of laboratory tests and clinical examinations should be included on the patient's treatment chart to identify adverse events.
- » All patients, their treatment supporters and health workers should ideally be instructed to report the appearance, persistence or reappearance of adverse drug reactions.

- » Adverse drug reactions should be reported to the spontaneous pharmacovigilance systems required by national regulations, as for other drug-related harms. Where digital tools are not available, at least a written record of all medications given, bacteriological response and adverse events should be maintained for every TB patient on the TB treatment card. In settings where active TB drug safety monitoring and management has not yet been fully rolled out and national guidelines have not been updated, patients should not be left to wait until all programme components are fully in place before they can receive potentially life-saving interventions.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment 2022 update)* (34):
 - 3.2 Safety monitoring and management, provision of patient support and management of comorbidities
 - *WHO operational handbook on tuberculosis – Module 4: treatment (drug-susceptible tuberculosis treatment)* (35):
 - 9 Monitoring treatment response.

18. Perform the follow-up examinations

- » Regular microscopy and culture of sputum or other specimens are important to assess response to treatment. Other examinations, according to the monitoring examination schedule (if available), should be performed to identify in a timely manner adverse events and to manage comorbidities appropriately.

19. Manage TB treatment interruptions

- » In clients who have had treatment interruption, the reason for the interruption should be addressed, such as medicine stock-outs, adverse events from medicines or need for additional patient or provider education. The duration, time on treatment at which the interruption occurs and the bacteriological status of the client before and after the interruption should be considered.
- » The health worker should take the opportunity to express support for the patient and their family and to address any issues that may require referral

or treatment. Counselling should be offered in a way that makes the client feel empowered in their choice to continue the treatment.

20. Reassess for comorbidities

- » Some undetected comorbidities mimic treatment failure through clinical and chest radiographic deterioration that occurs simultaneously with repeated culture-negative and smear-negative results. These comorbidities (e.g. non-tuberculosis mycobacteria, fungal infections, lung infections or a pulmonary malignancy) should be diagnosed and treated appropriately. Illnesses that may decrease absorption of medicines (e.g. chronic diarrhoea) or may result in immune suppression (e.g. HIV infection) should also be excluded.
- » Additionally, people at the end of anti-TB treatment may also be assessed for mental health conditions or substance use disorders if they were previously identified as having mental health or substance use issues (as part of follow-up visit).
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis. Module 6: Tuberculosis and comorbidities – Mental health conditions* (40).

21. Adjust the treatment

- » Based on the examination results, comorbidity assessment, adverse drug reaction evaluation and the patient's medical condition, treatment composition or duration may require modifications. The health worker needs to assess treatment efficiency and adjust the treatment accordingly.
- » Reasons for adjusting the dosages of the medicine part of the TB treatment regimen might include weight gain, malabsorption and co-management of comorbidities.
- » Changing the treatment regimen should also be considered. If the decision taken is to change the treatment regimen, then the health worker will assess the capacity for initiating and continuing the new regimen. When capacity exists, all (previously described) activities needed to identify and initiate the appropriate (new) treatment regimen should be performed. A referral should be issued if capacity to further treat the patient does not exist. Treatment outcome should be reported for a failed treatment regimen.

22. Issue a referral

- » Referrals may be needed for ongoing management of TB-associated disability and comorbidities on completion of TB treatment. This may include referral to mental health or substance use services, preventive and rehabilitation services, and social protection services to improve the health and social outcomes of people with TB. The preferences of the person with TB and comorbidities should be considered, for example, separate services may be appropriate to maintain continuity of care for pre-existing comorbidities, to provide highly specialized medical care, or may be preferred among people who experience stigma in relation to comorbidities, such as injecting drug use.
- » Patients with systemic adverse events might require referral to specialized care.
- » Change of treatment regimen may lead to referrals if capacity to further treat the patient does not exist in the current health-care facility.
- » In the absence of co-located services, clear referral pathways should be ensured.

23. Is the case de-notified because found not to have MTB?

- » Sometimes people are treated for TB disease, when in fact they do not have TB. This can occur, for example, because of delays in receiving laboratory speciation results, and it subsequently transpires that an individual does not have TB but is instead infected with a non-tuberculous mycobacterium. When such a situation occurs, records of a non-TB disease episode must be de-notified.
- » Reason for de-notification should be recorded.
- » Change of TB diagnosis (TB ruled out) can also happen before initiating TB treatment.

24. Report the outcome(s)

- » It is important to monitor TB treatment outcomes both for individual care and programme management. TB treatment outcomes should be recorded and reported for each individual diagnosed with TB, regardless of whether treatment was started.

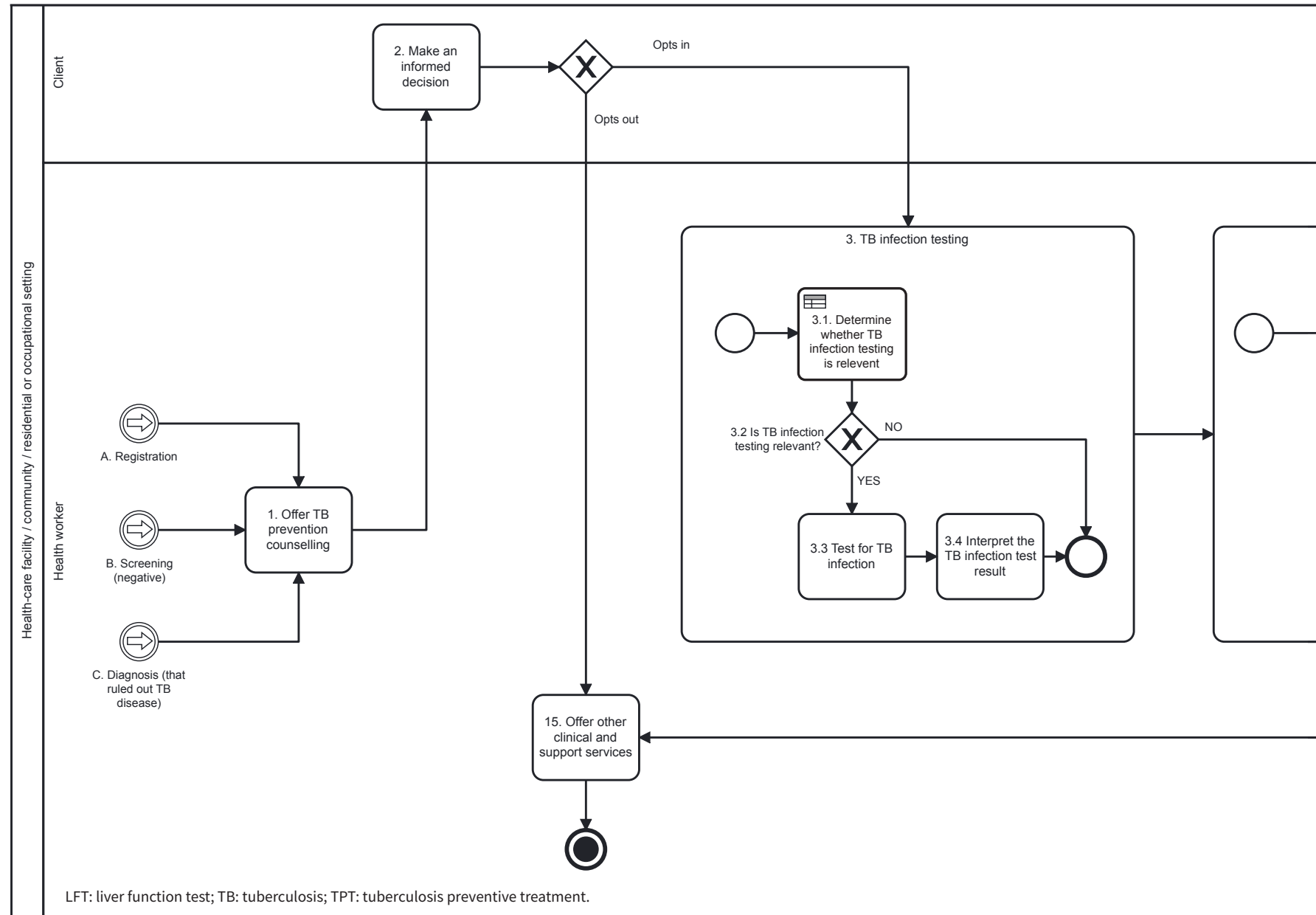
25. Offer other clinical and support services

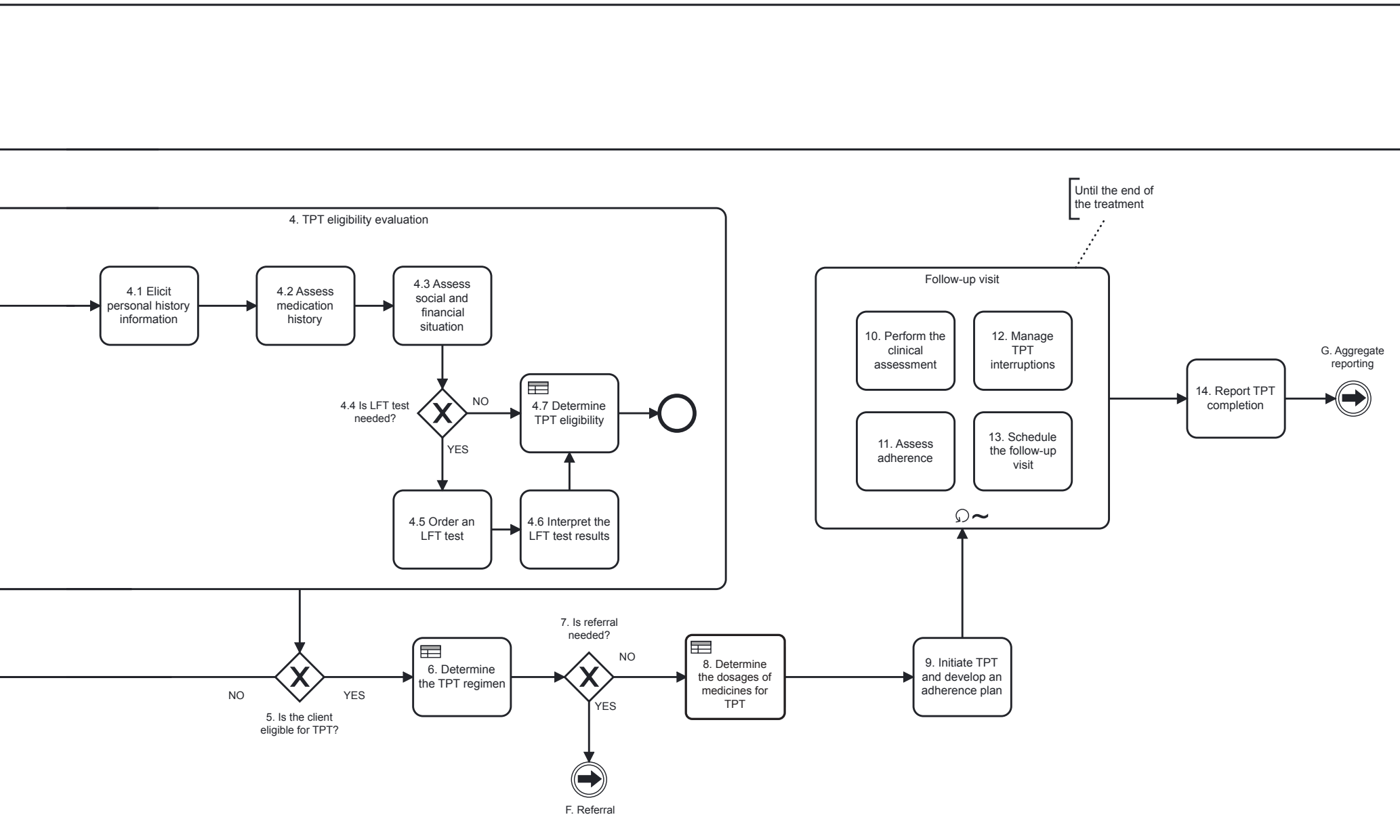
- » The health worker might offer other relevant clinical and support services to the client if the consent for initiating TB treatment is not given or treatment could not be started because of other reasons. Nevertheless, a treatment outcome should be reported for these cases.

E. Business process for TPT

Objective: To identify clients eligible for TPT, select the appropriate TB preventive treatment regimen for each client and ensure treatment adherence (Fig. 9).

Fig. 9 Workflow E: TPT business process





TPT BUSINESS PROCESS NOTES AND ANNOTATIONS

Guidelines and guidance:

- » *WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)*
- » *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*
- » *WHO operational handbook on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (33)*
- » *WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents (37).*

1. Offer TB prevention counselling

- » Provide information on TB infection, the rationale for TPT and the benefits from completing the course to the individual, the household and the wider community.
- » Mention possible adverse effects and the likelihood of their manifestation.
- » Educate the client regarding the risk of not taking the TPT.
- » Inform the client about the TPT short regimens that can be completed in 4–12 weeks, unlike the treatment of TB disease, which lasts 6 months or longer.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29):*
 - TPT initiation and pre-TPT baseline assessment
 - Key implementation steps in contact investigation
 - Messages for the community.

2. Make an informed decision

- » Explicit consent is generally required for TPT since the subject does not pose an immediate risk to others and the potential benefits are highly context-specific and may be outweighed by risk of harm for some individuals. The provider usually has a professional obligation to do this. Whether this is documented in writing or not depends on local practice. Informed consent requires effective and adequate communication of

the possible uncertainties, as well as prospects of risk reduction (often uncertain due to risk of reinfection).

- » Consent given by the client includes agreement to follow various tests as part of TPT evaluation and to follow treatment if indicated (signed or witnessed consent if the patient is illiterate, or signed or witnessed consent from a child's parent or legal guardian).
- » Patients who refuse to consent should be counselled about the risks to both themselves and the community.
- » It is important that an informed decision to not take treatment by a person offered TPT is respected; people should not feel coerced to take treatment.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29):*
 - Chapter 9. Ethics and TB preventive treatment.

3. TB infection testing

- » Just as excluding TB disease is a critical step before starting TPT, confirming TB infection before starting TPT may increase the certainty that individuals targeted for TPT would benefit from it.
 - 3.1 Determine whether TB infection testing is relevant
 - The decision on whether to test for TB infection before TPT is influenced by the expected prevalence of TB infection in the at-risk population, risk of progression to TB disease and the risk of harms due to unnecessary TPT.
 - Decision logic: TB.E3.1.DT.
 - 3.2 Is TB infection testing relevant?
 - Some risk groups, such as PLHIV who are on antiretroviral therapy (ART), benefit from TPT regardless of whether they test positive or negative for TB infection. Similarly, children under 5 years who are contacts of a patient with bacteriologically confirmed TB have a high risk of TB and would benefit from TPT regardless of the test result. Therefore, TB infection testing is not relevant in such cases and the recommendation is to consider TPT.

- 3.3 Test for TB infection
A tuberculin skin test (TST), *Mycobacterium tuberculosis* antigen-based skin tests (TBSTs) or interferon-gamma release assay (IGRA) can be used to test for TB infection.
- 3.4 Interpret the TB infection test result
Once the test result is available, a health worker with the appropriate level of knowledge will interpret it. Older contacts and other risk groups who test positive are likely to benefit more than those with a negative test.
- » Guidelines and guidance:
 - *WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)*:
 - 1.3 Testing for latent tuberculosis infection
 - *WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (22)*
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - 4. Testing for TB infection
 - *WHO operational handbook on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (33)*.

4. TPT eligibility evaluation

- » Once TB disease is ruled out, and the decision to consider TPT is made, baseline assessment to determine the eligibility of an individual for TPT should be undertaken. The baseline assessment includes personal and medication history and investigations as per national guidelines.
- 4.1 Elicit personal history information
Information relevant for TPT initiation and continuation should be asked, such as allergy to TB drugs, previous intake of TPT, alcohol use, smoking, concurrent medication, contacts with drug-resistant TB and potential contraindications to TPT.
- 4.2 Assess medication history
Elicit medication history to guide the choice of TPT regimen. Certain drug classes, for example, antiretroviral (ARV) drugs, opioids and antimalarials, often affect TPT.

- 4.3 Assess social and financial situation
The social and financial situation of the family should be assessed and the support required to overcome the barriers for TPT completion should be identified.
- 4.4 Assess the need for liver function test (LFT)
There is insufficient evidence to support mandatory or routine LFT at baseline, and perhaps the benefit of TPT without LFT would likely outweigh the harms, particularly with a less hepatotoxic regimen. Where feasible, baseline testing is strongly encouraged for individuals having risk factors – such as history of liver disease, regular use of alcohol, chronic liver disease, HIV infection, age more than 35 years and pregnancy or immediate postpartum period (within 3 months of delivery). In individuals having abnormal baseline LFT results, sound clinical judgement is required to determine if the benefit of TPT outweighs the risk of adverse events. These individuals should be tested routinely at subsequent visits.
- 4.5 Order an LFT test
Collect a blood sample and order an LFT test from the laboratory if the decision is to perform an LFT.
- 4.6 Interpret the LFT test results
Once the test result is available, a health worker with the appropriate level of knowledge will interpret it.
- 4.7 Determine TPT eligibility
Based on the information gathered in the previous steps, a decision will be made on whether the TPT benefits outweigh the risks.
 - Decision logic: TB.E4.7.DT.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - TPT initiation and pre-TPT baseline assessment
 - Provision of TPT for special populations.

5. Is the client eligible for TPT?

- » If the decision in step 4 is that TPT is beneficial, the health worker will proceed with discussing the treatment regimen.
- » The health worker might offer other relevant clinical and support services if the client is not eligible for TPT.

6. Determine the TPT regimen

- » When choosing a regimen, the caregiver and the person taking the treatment should consider the circumstances under which TPT would be given to increase the likelihood of it being completed. The choice may also depend on the availability of resources, fixed-dose combinations, child-friendly formulations, concomitant medication (such as ARV drugs, opioid substitution therapy, oral contraception), as well as acceptability to recipients in the country context.
- » Decision logic: TB.E6.DT.
- » Guidelines and guidance:
 - *WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)*:
 - 1.4 Tuberculosis preventive treatment options
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Chapter 5. TB preventive treatment.

7. Is referral needed?

- » In some cases, the client might prefer to start TPT in another health-care facility, for example, closer to their house. In those cases, the client might need a referral.
- » If the treatment medication is not available at the health-care facility, the client will be referred to another clinic or to the pharmacy to get the necessary medication.

8. Determine the dosages of medicines for TPT

- » The health worker determines the dosages of medicines for TPT based on the client's age and weight.
- » Decision logic: TB.E8.DT.
- » Guidelines and guidance:
 - *WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)*:
 - Table 3. Recommended dosages of medicines for TB preventive treatment
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Recommended dosages of TPT medication.

9. Initiate TPT and develop an adherence plan

- » TPT is initiated if the client (parent or legal guardian in case of children or adolescents) gives their consent.
- » An adherence plan is developed in collaboration with the client. Such a plan may include information on:
 - motivators for the person to want to be TB free;
 - using the person's individual and family routines and their variations to identify the best time to take the medicines; and
 - taking medicines with food to reduce nausea and vomiting or at night 3–4 hours after dinner.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Chapter 7. Adherence to TB preventive treatment
 - Box 7.1: Example of an adherence plan.

10. Perform the clinical assessment

- » Clinical assessment should focus on monitoring response to treatment, presence of adverse drug reactions and common symptoms associated with TB treatment and long-term antibiotic use, with the goal of supporting adherence.
- » Persistent fever, weight loss or recurrence of any of the classic symptoms of TB should prompt investigation for possible treatment failure, undetected resistance to one or more drugs in the current treatment regimen, or untreated comorbidities.
- » Overall, the occurrence of serious adverse events leading to death or requiring withdrawal of TPT is rare. However, it is critical to identify any sign of drug toxicity early on and manage it vigorously. Obtaining a detailed and accurate medical history (inclusive of medicines being taken and known past adverse drug reactions) and keeping up-to-date information at every contact with the person on TPT, can help identify persons who require close monitoring and the most appropriate course of action if an adverse event emerges.
- » National programmes are encouraged to use communication technology, including SMS and video-calls, for early reporting of adverse events and prompt action by health workers. A mechanism to record data on the occurrence and management of adverse events is advised.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Chapter 6. Safety, management of adverse reactions and other drug-related issues in TB preventive treatment.

11. Assess adherence

- » Adherence to treatment is a complex behaviour that is influenced by many factors, such as personal motivation, beliefs about health, risks and benefits from treatment, comorbidities, competing demands that conflict with the taking of medicine, family environment, complexity of the drug regimen, drug toxicity, trust and relationship with the health provider. The health worker needs to reinforce supportive educational messages at each contact during treatment.

- » Guidelines and guidance:

- *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Chapter 7. Adherence to TB preventive treatment.

12. Manage TPT interruptions

- » Any interruptions in treatment should be discussed with the person on treatment and their treatment supporter, and interventions to address problems in adherence should be instituted.

13. Schedule the follow-up visit

- » The next visit is scheduled depending on the treatment regimen, clinical condition and client's availability. The visit could take place either at the health-care facility or in the community, or at the client's location.

14. Report TPT completion

- » It is important to monitor TPT completion both for individual care and programme management.
- » TPT may be considered completed when an individual takes 80% or more of the prescribed number of doses of treatment within 133% of the scheduled duration of the respective TPT regimen and remains well or asymptomatic during the entire period.
- » Guidelines and guidance:
 - *WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)*:
 - Chapter 8. Monitoring and evaluation.

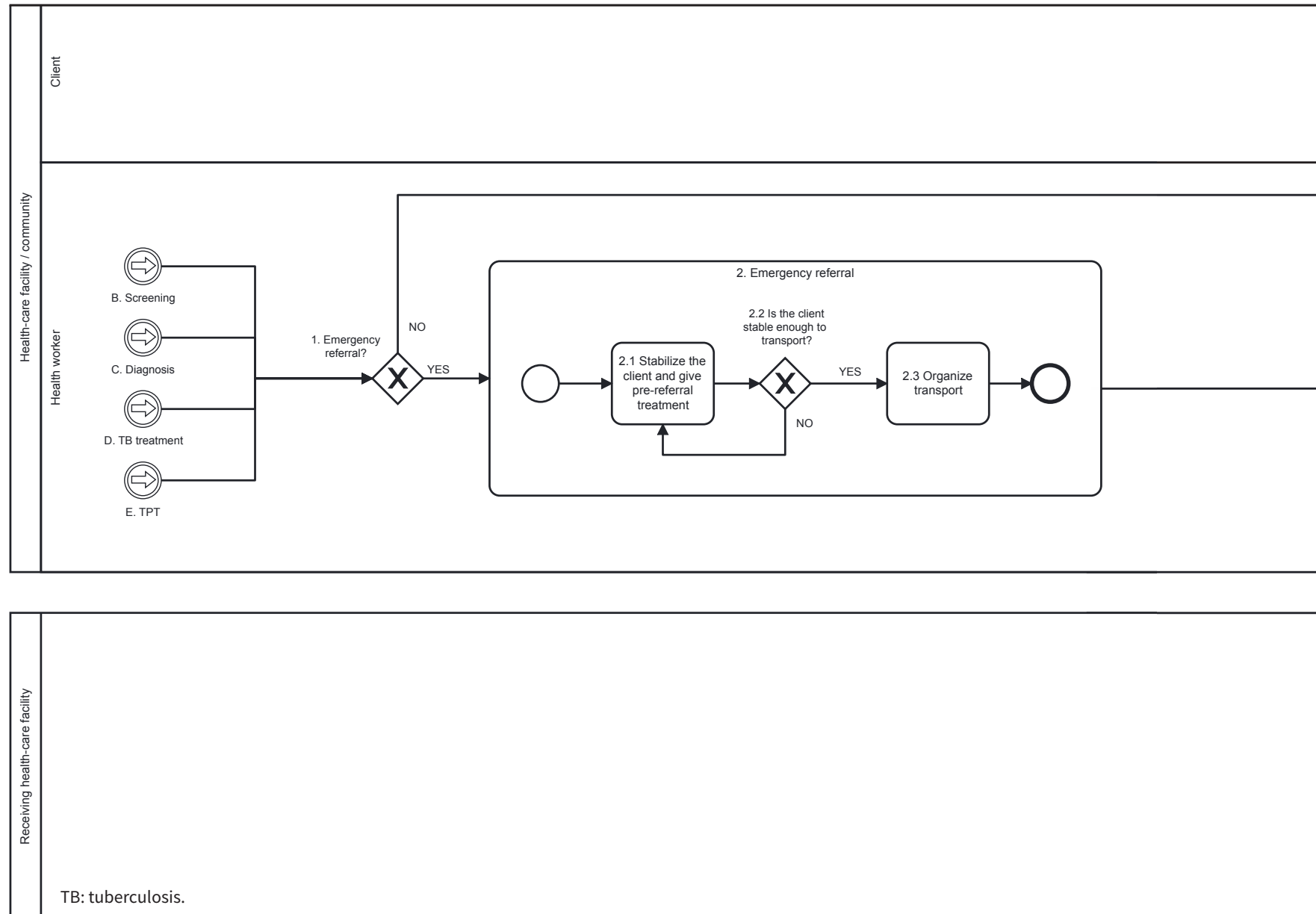
15. Offer other clinical and support services

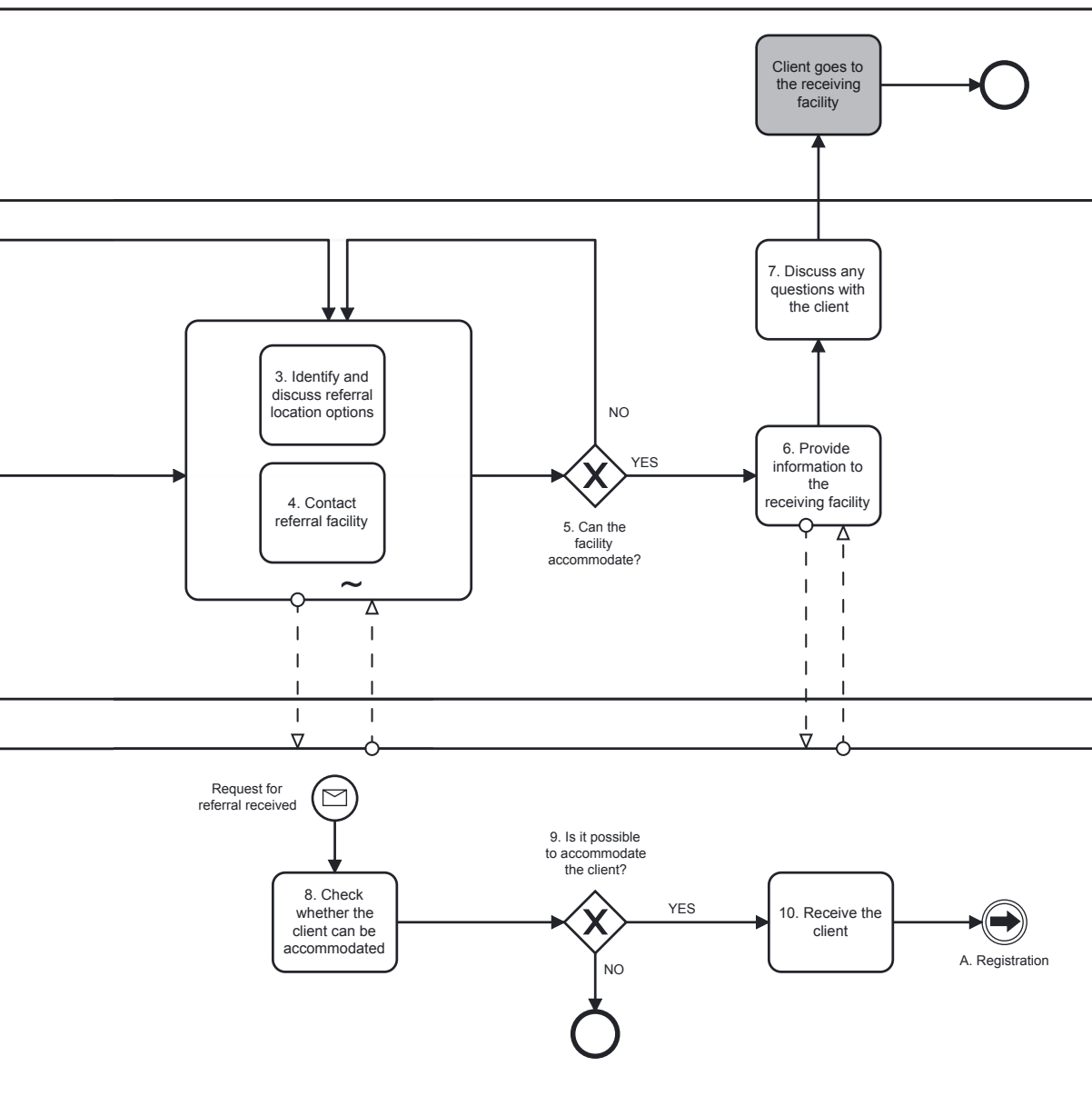
- » The health worker might offer other relevant clinical and support services to the client if the TPT is not accepted, the client is not eligible or TPT is not recommended.

F. Business process for referral

Objective: To provide timely and appropriate referrals to another health-care facility that can provide services unavailable within this facility (Fig. 10).

Fig. 10 Workflow F: referral





REFERRAL BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

Examples of reasons for referral include:

- » the health worker cannot provide the service because of a lack of training and skills;
- » the facility does not have the supplies needed to provide the service;
- » the facility cannot perform the service for other reasons;
- » there is an emergency and the client needs immediate referral.

1. Emergency referral?

- » If the client needs immediate referral due to an emergency situation, bypass standard referral steps.
- » In an emergency, a referral can be made at any time, including during diagnosis and treatment encounters.

2. Emergency referral

- » 2.1 Stabilize the client and give pre-referral treatment
The client is assumed to need emergency referral if their condition requires immediate medical attention. Stabilize the client's condition and provide any necessary treatment.
- » 2.2 Is the client stable enough to transport?
Once the client is stable enough to transport, immediately organize it. If the client is still not stable, provide pre-referral treatment for stabilization.
- » 2.3 Organize transport
For emergency referrals, the health-care facility usually arranges for an ambulance or other vehicle.

3. Identify and discuss referral location options

- » In discussion with the client and their relatives, decide where the client will be referred to. Discussions include:
 - how to get to the referral facility, including location and transportation options;
 - who to see and what is likely to happen;
 - whether to follow up on return.
- » Either the client or the client's relatives should decide on a referral location based on their preferences.

4. Contact referral facility

- » Health workers should contact the referral facility to determine whether that facility can accommodate such a referral.

5. Can the facility accommodate?

- » Check whether facility can accommodate the client and provide the services needed.
- » If the facility can accommodate the client, move on to step 6.
- » Otherwise, find a different facility that is able to accommodate the client.
- » A system can be set up to catalogue referral facilities, and what type of referral needs they can handle to accommodate a referral.

6. Provide information to the receiving facility

- » Make an appointment, if needed.
- » If not an emergency referral, the client or family arranges transport.
- » For emergency referrals, the health-care facility arranges transport, usually by phoning the district for an ambulance or other vehicle, and informing the receiving facility that the emergency client is on the way.
- » Fill out a referral form, which can include notification of the referral destination.
- » Provide the necessary clinical, sociodemographic and identity information to the referral facility. This can be done digitally if the appropriate systems are in place.

7. Discuss any questions with the client

- » Discuss any of the client's questions or concerns.

8. Check whether the client can be accommodated

- » The receiving facility evaluates the needs and assesses whether the client can receive the services needed.

9. Is it possible to accommodate the client?

- » If the receiving facility cannot accommodate the client, it will inform the source facility. If accommodation for the client is possible, move on to step 10.

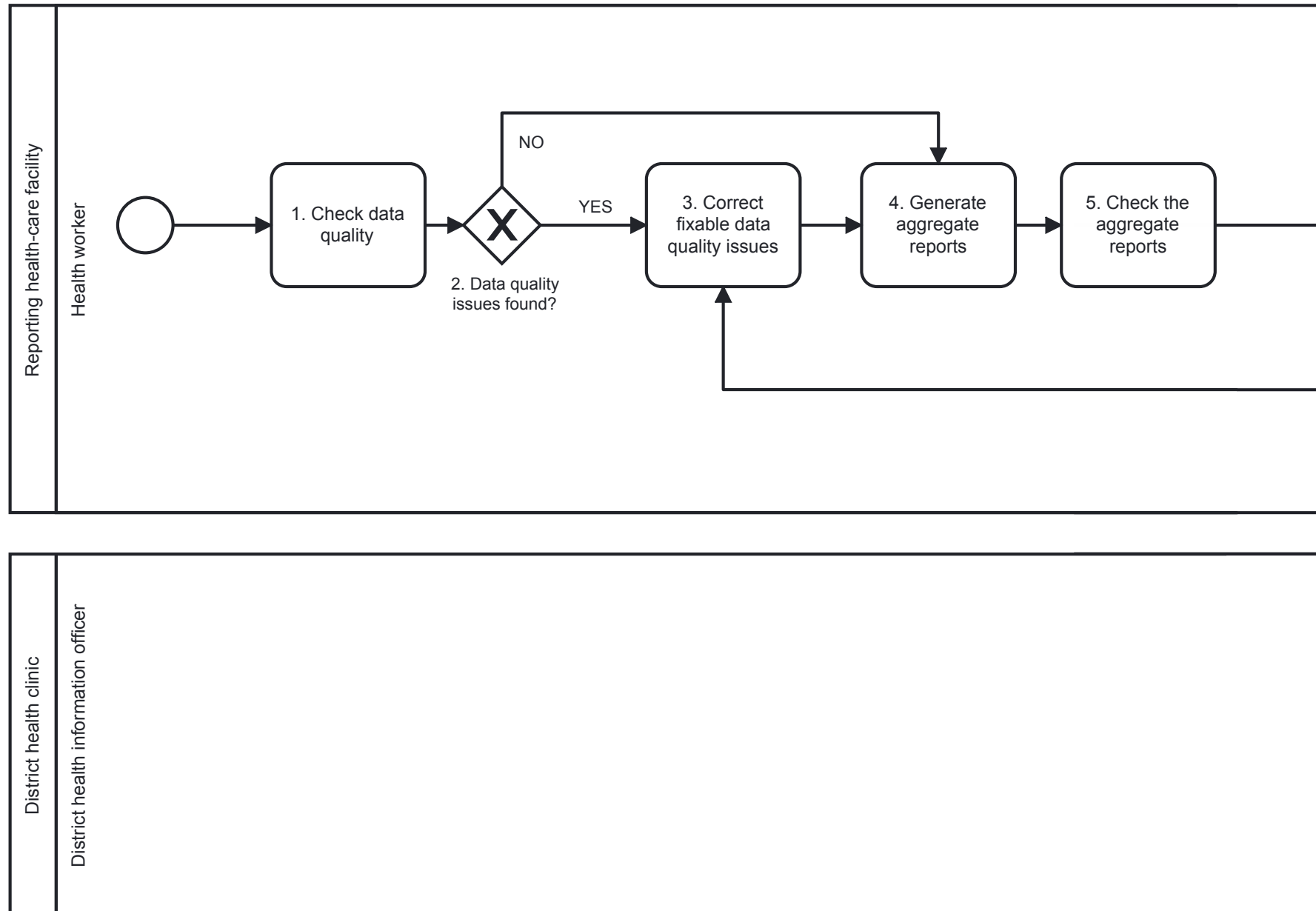
10. Receive the client

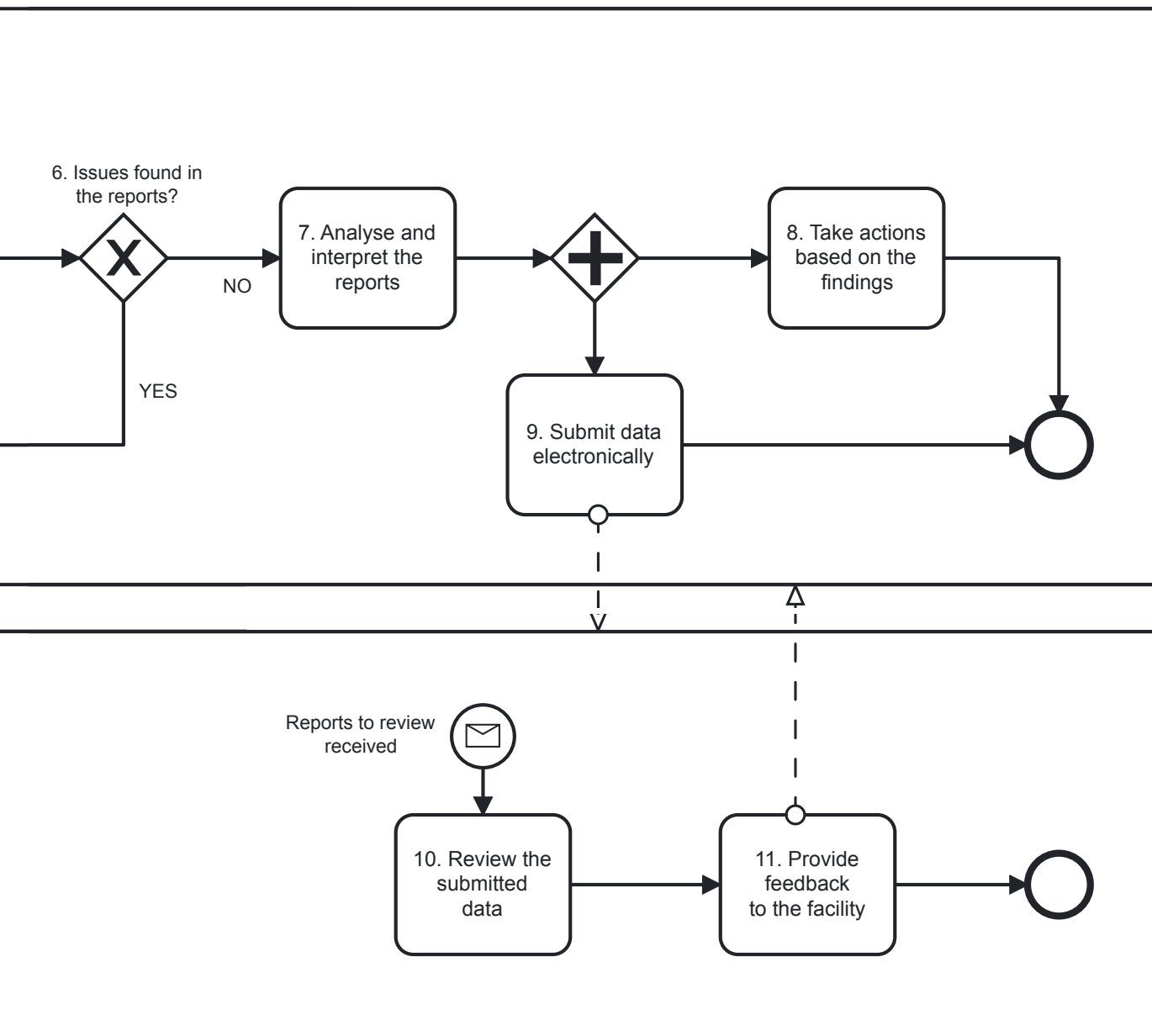
- » The receiving facility receives the client, along with all the necessary clinical, sociodemographic and identification information, and provides the services. If both facilities use digital systems with interoperability standards in place, the information can be exchanged digitally in a faster and more reliable way.

G. Business process for aggregate reporting and data use

Objective: To aggregate client-level data into validated, aggregate reports, use the data and submit reports (Fig. 11).

Fig. 11 Workflow G: aggregate reporting business process





AGGREGATE REPORTING AND DATA USE BUSINESS PROCESS NOTES AND ANNOTATIONS

General notes

National, digital, case-based surveillance systems for TB have several advantages compared with the more traditional paper-based aggregated systems, such as reduction in the recording and reporting workload of frontline workers, better data quality, faster access to data at all levels, more flexible data analysis and enhanced use of data through record linkage between databases. For this reason, WHO encourages countries to make the transition from paper-based aggregated to case-based digital TB surveillance.

1. Check data quality

- » Health-care facility data are reviewed for accuracy, validity and completeness.
- » This can be supported through automated checks in a digital system.
- » Guidelines and guidance:
 - *WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)*.

2. Were data quality issues found?

3. Correct fixable data quality issues

- » Where possible, inaccurate, invalid or incomplete data should be checked against source records and corrected according to the national standard operating procedures.
- » It is also possible for the same episode of TB disease in a given individual to be recorded multiple times in the system. Any duplicate records of the same episode of TB must be removed (de-notify duplicate case[s]) to avoid overreporting. Depending on local policy, this step might need to be delegated to a person with the appropriate data access rights.

4. Generate aggregate reports

- » The health worker generates aggregate reports of predefined indicators aligned with national monitoring and evaluation guidelines.
- » This can be automated and done digitally.

5. Check the aggregate reports

- » Check for any potential remaining data quality issues such as implausible values or outputs.

6. Were issues found in the reports?

- » If so, return to step 3.

7. Analyse and interpret the reports

- » The analyses and interpretation of the reports should identify opportunities to improve the performance of the health-care facility, such as tracing missing data or contacting patients who have not attended a clinic.
- » Data analysis and interpretation can be done regularly and should not be limited to the reporting schedule.

8. Take actions based on the findings

- » Findings from the reports can inform corrective actions.

9. Submit data electronically

- » This can be automated in digital systems.
- » Depending on the local policies and system design, an active “submission” may not be needed and the district-level, provincial-level and national-level ministry of health should be able to access data directly for reporting purposes.

10. Review the submitted data

- » The district health office reviews the quality of the submitted data.

11. Provide feedback to the facility

- » The focal person at the district level will provide feedback to the facility. If data quality issues are identified, the facility may be required to restart the process and resubmit the reports.

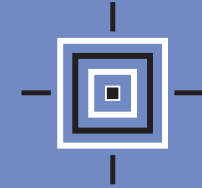
4.3 Additional considerations for adapting workflows

As a reminder, these workflows are meant to be generic and high-level workflows. They will require a level of customization and adaptation because they are being translated into a digital system for a specific context. These workflows are considered to be 80% complete, so the other 20% will need to be done through a series of human-centred design methods and mechanisms to complete the workflows for an implementation. For example, additional workflows may need to be drawn out or there might be additional activities expected of a health worker in the facility. Some workflows are not included because of the high level of contextualization required, including billing, dispensing (if separate from service provision), and defining and planning a TB strategy, which represents a high-level process, not within the scope of primary care activities. Alternatively, there might be some activities and tasks a health worker would not be expected to do. Although these workflows can be considered as a starting point, it is helpful to conduct further validation through interviews with the targeted personas or shadowing their work to obtain a better sense of the differences that would need to be reflected in the digital system.

Component

5

Core data elements



This section outlines the minimum set of data corresponding to different points of the workflow within the identified business processes. This data set can be used on any software system and lists the data elements relevant for service delivery and executing decision-support logic, and for populating indicators and performance metrics. Although this section provides a high-level overview of the data elements, a more complete data dictionary in spreadsheet form detailing the input options, validation checks and concept dictionary codes is available [here](#).

Inclusion of a data element in the table does not by itself indicate that collection of the data is required. Additionally, some data elements are dependent on other data elements (e.g. test results are only entered when a test has been performed). The collection of data should not prevent clients from accepting screening, diagnosis, TPT, TB treatment or affect clinical care. This will require review and adaptation.

5.1 Simplified list of core data elements

Table 7 provides a simplified list of core data elements and is merely a snapshot of the comprehensive [data dictionary](#). As with the workflows, this data dictionary is 80% generic with the expectation that the other 20% will be supplemented and modified through country adaptation.

Table 7 Workflow core data elements for identified business processes

Activity ID and name	Data element ID	Data element name	Description and definition
Business process TB.A: registration			
TB.A4. Gather the client's details	TB.A4.DE.1	First name	Client's first name
	TB.A4.DE.2	Last name	Client's family name or last name
	TB.A4.DE.3	Unique ID	Unique ID of the client moving through the health system. It can be based on a national unique ID, a national health ID, biometrics, a system-generated unique ID or something else
	TB.A4.DE.4	Encounter date	The date and time of the client's encounter with the health system
	TB.A4.DE.5	Source of referral	Indicates the source of the referral

Activity ID and name	Data element ID	Data element name	Description and definition
TB.A8.1 Review sociodemographic data with the client OR TB.A7 Create a new client record	TB.A7.DE.1	Date of birth	The client's date of birth, if known
	TB.A7.DE.2	Date of birth unknown	Indicates if the client's date of birth is unknown
	TB.A7.DE.3	Age	Age (number of years, rounded to the nearest integer) of the client calculated based on their date of birth. If the date of birth is unknown, the client's estimated age is stored
	TB.A7.DE.17	Sex	Sex of the client assigned at birth
Business process TB.B: screening			
TB.B2. Make an informed decision	TB.B2.DE.1	Consent for screening provided	Indicates if the client gave their consent for screening based on the information provided by the health worker
	TB.B2.DE.2	Date informed consent obtained	The date when the client gave consent for proceeding with screening or refused to do so
TB.B3. Assess medical history and risk factors	TB.B3.DE.1	Risk group	Indicates the risk group to which the client belongs, if any. A risk group is any group of people in which the prevalence or incidence of TB is significantly higher than in the general population
	TB.Comm.DE.23	Risk factors/ comorbidities	Indicates which specific risk factors or comorbidities (when TB disease is confirmed) the client presents
TB.B4. Determine the screening algorithm	TB.B4.DE.1	TB screening algorithm	Screening algorithm selected for the screening activities
TB.B5. Perform the TB screening	TB.Comm.DE.57	Symptoms of TB	Symptoms that may indicate active TB
	TB.Comm.DE.68	Symptom screening result	The result of the TB symptom screening
	TB.Comm.DE.71	Date of symptom screening result	The date when the result of symptom screening is available
TB.B7. Evaluate the screening results	TB.B7.DE.1	TB screening result	Record the result of the TB screening
Business process TB.C: diagnosis			
TB.C1. Carry out clinical examination	TB.C1.DE.2	Danger signs present	Indicates if danger signs were identified and required urgent medical care
	TB.Comm.DE.1	Body height (cm)	The client's height in centimetres
	TB.Comm.DE.3	Body weight (kg)	The client's current weight in kilograms
	TB.Comm.DE.7	z-score	The client's weight-for-height z-score
	TB.Comm.DE.8	Body mass index (BMI)	BMI for adults and adolescents
	TB.C1.DE.6	Presumptive TB	The client is presumed to have TB
	TB.C1.DE.7	Date of presumptive TB registration	The date when the client was considered a presumptive TB case

Activity ID and name	Data element ID	Data element name	Description and definition
TB.C2. Assess medical history and risk factors	TB.Comm.DE.9	Nutritional status (adults and adolescents)	Indicates the nutritional status of adults and adolescents (age ≥10 years)
	TB.Comm.DE.16	Nutritional status (children)	Indicates the nutritional status of children (age <10 years)
	TB.Comm.DE.126	HIV status	HIV status reported after applying the national HIV testing algorithm. No single HIV test can provide an HIV-positive diagnosis
TB.C3. Assess TB contact history	TB.C3.DE.1	Risk of multidrug-resistant TB (MDR-TB)	Indicates the results of the MDR-TB risk assessment for the client
	TB.Comm.DE.46	History of contact with a person with TB	Client had a history of a contact with a person with TB
	TB.C3.DE.4	TB contact in the previous 12 months	Indicates if the client had contact with a person with TB in the previous 12 months
TB.C4. Assess history of prior TB treatment	TB.Comm.DE.48	Year of previous TB treatment	Indicates the year when the previous treatment was completed or stopped. This can be calculated automatically by the system, with a greater precision when digital systems are used and already store this information
	TB.C4.DE.1	TB treatment history	History of previous TB treatment
TB.C10. Collect specimen(s)	TB.Comm.DE.72	Test sample collected	Whether a test sample was collected from the patient
TB.C11. Perform the initial test(s) for the diagnosis of TB	TB.C11.DE.1	TB diagnostic test performed	A TB diagnostic test was performed and completed
TB.C11. Perform the initial test(s) for the diagnosis of TB	TB.C11.DE.2	TB diagnostic test type	Indicates whether the test is an initial TB diagnostic test or a follow-on test
	TB.C11.DE.5	TB diagnostic test category	This is the category of diagnostic test performed to detect active TB or TB drug resistance
TB.C18. Perform follow-on testing			
TB.C16.1. Interpret RIF susceptibility test results	TB.C16.1.DE.9	Rifampicin susceptibility test result	Indicates the results of the rifampicin susceptibility testing
TB.C16.4. Interpret RIF susceptibility test results for the retest			
TB.C20. Interpret the follow-on test(s) results			

Activity ID and name	Data element ID	Data element name	Description and definition
TB.C24. Make a diagnostic decision	TB.C24.DE.1	TB diagnosis result	Final result of the TB investigation (TB confirmed or excluded)
	TB.C24.DE.4	Date of TB diagnosis	The date when the diagnosis was established
	TB.C24.DE.6	Method of diagnosis	Method used to establish the diagnosis (bacteriologically confirmed or clinically diagnosed)
	TB.Comm.DE.102	Site of TB disease	Anatomical site of TB disease
Business process TB.D: TB treatment			
TB.D1. Determine eligibility for TB treatment regimen type	TB.D1.DE.1	TB treatment regimen type	Indicates for which regimen the client is eligible, based on the diagnosis
	TB.Comm.DE.49	Hypersensitivity or allergy or contraindication to TB drugs	Indicates if the client has a personal history of allergy or hypersensitivity or potential contraindication to TB drugs
	TB.D1.DE.5	Additional eligibility criteria for drug-resistant TB (DR-TB) regimens	Contains the eligibility criteria for the DR-TB regimens
TB.D5. Perform other baseline clinical evaluations	TB.D5.DE.2	Willing to use effective contraception	The client is a premenopausal woman who is willing to use effective contraception
	TB.Comm.DE.44	CD4 count	CD4 cell count in cells per mm ³
TB.D9. Determine the regimen designed to treat rifampicin-susceptible TB	TB.D9.DE.1	TB treatment regimen	TB treatment regimen proposed to the client or taken by the client
TB.D10. Determine the regimen designed to treat rifampicin-resistant TB			
TB.D12. Make an informed decision	TB.D12.DE.1	TB treatment accepted	Indicates if the client accepted to take the TB treatment
TB.D13. Initiate the treatment and discuss adherence	TB.D13.DE.1	TB treatment started	Indicates if TB treatment was started
	TB.Comm.DE.136	Reason treatment was not started	Indicates the reason why treatment was not started
TB.D14. Develop monitoring examinations and a schedule of follow-up visits	TB.D14.DE.1	Monitoring examinations	Indicates the examinations and testing part of the monitoring examination schedules

Activity ID and name	Data element ID	Data element name	Description and definition
TB.D18. Perform the follow-up examinations	TB.D18.DE.2	Bacteriologically converted (to negative)	The client has at least two consecutive negative cultures (for DR-TB and DS-TB) or smears (for DS-TB only), taken on different occasions at least 7 days apart
	TB.D18.DE.3	Conversion date	The specimen collection date of the first negative culture or smear is used as the date of conversion
TB.D24. Report outcome	TB.D24.DE.1	Treatment outcome	Indicates client's treatment outcome
Business process TB.E: TPT			
TB.E1. Offer TB prevention counselling	TB.E1.DE.1	TB preventive treatment (TPT) counselling offered	Whether the client was provided with TPT counselling
TB.E2. Make an informed decision	TB.E2.DE.1	TB prevention services accepted	Indicates if the client accepts to be evaluated for TB infection and take the treatment if they are eligible
TB.E3.1. Determine whether TB infection testing is relevant	TB.E3.1.DE.1	TB infection test recommended	Indicates if the client should be tested for TB infection
TB.E3.3. Test for TB infection	TB.E3.3.DE.1	TB infection test performed	Indicates if a TB infection test was performed
TB.E3.4 Interpret the TB infection test result	TB.E3.4.DE.1	TB infection test result	Records the result of the TB infection test
TB.E4.2. Assess medication history	TB.E4.2.DE.1	Medication affecting TPT	The medication history is used to guide the choice of TPT regimen or determine the need for modification of the treatment of comorbid conditions. Certain drug classes such as ARV drugs, opioids and antimalarials often affect TPT
TB.E4.7. Determine TPT eligibility	TB.E4.7.DE.1	Eligible for TPT	Client is eligible for TPT according to national guidelines
TB.E6 Determine the TPT regimen	TB.E6.DE.1	TPT regimen	The TPT regimen is proposed to the client or taken by the client
TB.E9. Initiate TPT and develop an adherence plan	TB.E9.DE.3	TPT status	Indicates the current status of TPT
TB.E14. Report TPT completion	TB.E14.DE.1	TPT completion date	The date on which the client completed TPT

Activity ID and name	Data element ID	Data element name	Description and definition
Business process TB.F: referral			
TB.F6. Provide information to the receiving facility	TB.F6.DE.1	Client transferred	Indicates if the client was transferred “in” or “out”. The client permanently changes facilities to continue TB care. The transferring facility can consider the record as closed on its side
	TB.F6.DE.12	Source facility ID	Unique code of the facility from where the client moved
	TB.F6.DE.13	Destination facility ID	Unique code of the facility to whose care the client moved
	TB.F6.DE.14	Destination facility address	Address of the facility to whose care the client moved
	TB.F6.DE.15	Referral date	The date the referral was made
	TB.F6.DE.16	Reason for the referral	Indicates the reason why the client is referred to another health-care facility. The client is expected to return to the referring facility to continue further TB diagnosis or treatment or care
	TB.F6.DE.29	Referral notes	Any additional relevant details of clinical significance for the receiving facility to provide quality care
	TB.F6.DE.30	Transfer notes	Any additional relevant details of clinical significance for the receiving facility to provide quality care, in case of transfer
	TB.F6.DE.31	Client history summary	With interoperable systems, the provider receiving the referral or transfer should be able to access the client’s health record digitally. However, in the absence of this, the receiving provider should receive a summary of the client’s health records that include the client’s history, reported issues and concerns, and any other relevant clinical information the referring health-care provider has already obtained

ARV: antiretroviral; BMI: body mass index; DR-TB: drug-resistant TB; DS-TB: drug-susceptible TB; TB: tuberculosis; TPT: tuberculosis preventive treatment.

5.2 List of calculated data elements

The previous section outlines the core data elements that should be included within digital systems to facilitate the decision-support logic or indicators. There are additional derived data elements that are based on calculations from core data elements and these are shown in [Table 8](#).

Table 8 Calculated data elements

Calculated data element label	Core data elements used for calculation (i.e. the variables)	Calculation
BMI	<ul style="list-style-type: none"> » Body weight » Body height 	Body weight (kg)/([Body height (cm)]/100) ²
Age	<ul style="list-style-type: none"> » Date of birth 	(TODAY – “Date of birth”)/365.25
z-score	<ul style="list-style-type: none"> » Body weight » Body height » Age 	$z = (\text{raw score} - \text{population mean}) / \text{standard deviation}$ Use WHO chart tables for sex (49)
Children with severe acute malnutrition	<ul style="list-style-type: none"> » Body weight » Body height » Age » Mid-upper-arm circumference 	Defined as weight-for-height z-score below –3 OR Mid-upper-arm circumference below 115 mm
Underweight	<ul style="list-style-type: none"> » Body weight » Body height » Age 	Adults and adolescents: BMI <18.5 Children aged under 10: weight-for-age z-score below –2
Age group	<ul style="list-style-type: none"> » Age 	<ul style="list-style-type: none"> » Infant: aged under 1 year (12 months) » Child: aged under 10 years <ul style="list-style-type: none"> – Young child: aged under 5 years » Adolescent: aged 10–19 years (inclusive) <ul style="list-style-type: none"> – Young adolescent: aged 10–14 years – Older adolescent: aged 15–19 years » Adult: aged 20 years or older

BMI: body mass index.

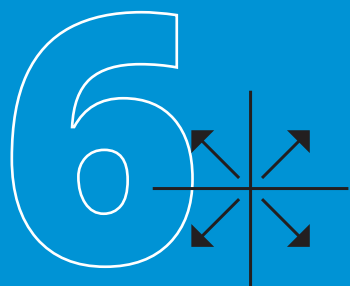
5.3 Additional considerations for adapting the data dictionary

Some settings may require the inclusion of additional data elements into the full data set or changes to response options based on contextual differences. Additionally, the transition from paper-based forms to digital systems may require some reflection on whether data elements currently on the paper forms should be incorporated into the digital system. [Table 9](#) is an initial list of considerations anticipated for each implementation to review and customize based on the national guidelines and local context. [Annex 2](#) provides further guidance for adapting the data dictionary.

Table 9 Characteristics for local customization and configuration

Points of customization and configuration	Description
Unique identifier	The unique identifier of the client can be based on a national unique ID, a national health ID, biometrics, a system-generated unique identifier or something else.
National ID	The format of the national ID varies from country to country.
Facility identifier	The unique identifier of the facility. A reference to a facility registry or a reporting system (e.g. DHIS2, formerly District Health Information Software) should be included where possible.
Facility name	The name of the different health-care facilities based on a facility registry or a reporting system (e.g. DHIS2) should be included where possible.
Ownership	This denotes whether the facility is public or private, where relevant.
Type of health-care facility	Type of facility, which is based on country terminology (e.g. health centre, health post, dispensary, hospital).
Global positioning system coordinates	Latitude and longitude coordinates can be included, if relevant for mapping purposes. This can be helpful especially in the context of community health workers who could be given TB tasks based on their catchment area and client's visit history.
Administrative areas	Administrative areas can be based on geographical location, catchment area or another mechanism the country uses for managing health-care facilities.
Catchment population	If known, the catchment population would be useful to include in the automated calculation of indicators.
Laboratory tests available	Whether or not certain laboratory tests are available at the health-care facility could impact the health worker's workflow and the client's TB service experience (e.g. haemoglobin, LFT and HIV screening tests, molecular WHO-recommended rapid diagnostic tests for TB, other rapid diagnostic tests).

LFT: liver function test; TB: tuberculosis; WHO: World Health Organization.



Decision-support logic

The decision-support logic component of the DAK provides the decision logics and algorithms, and the scheduling of services, in accordance with WHO guidelines. In this DAK, the decision logics and algorithms deconstruct the recommendations within the TB guidelines and guidance into a format that clearly labels the inputs and outputs that would be operationalized in a digital decision-support system.

6.1 Overview

Table 10 provides an overview of the decision-support tables and algorithms for the different TB module business processes. The structure of the decision-support tables is based on an adaptation of the Decision Model and Notation (DMN), an industry standard for modelling and executing decision logics (50). These decision-support tables detail the business rules, data inputs and outputs to support the TB module business processes.

Table 10 Overview of the decision-support tables for the TB module

Activity ID and name	Decision-support table ID	Decision-support table description	Reference/source
TB.B4. Determine the screening algorithm	TB.B4.DT	Determine the screening algorithm	<i>WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)</i>
TB.B7. Evaluate the screening results	TB.B7.DT	Evaluate the screening results	<i>WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)</i>
TB.E3.1. Determine whether TB infection testing is relevant	TB.E3.1.DT	Determine whether TB infection testing is relevant	<i>WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (22)</i> <i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)</i> <i>WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31)</i>
TB.E4.7. Determine TPT eligibility	TB.E4.7.DT	Determine TPT eligibility	<i>WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)</i> <i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)</i>
TB.E6. Determine the TPT regimen	TB.E6.DT	Determine TPT regimen	<i>WHO consolidated guidelines on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (18)</i> <i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)</i>

Activity ID and name	Decision-support table ID	Decision-support table description	Reference/source
TB.E8. Determine the dosages of medicines for TPT	TB.E8.DT	Determine the dosages of medicines for TPT	<i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29)</i>
TB.C7. Determine the diagnostic tests for the initial testing	TB.C7.DT	Determine the diagnostic test(s)	<i>WHO operational handbook on tuberculosis – Module 3: diagnosis (rapid diagnostics for tuberculosis detection, 2021 update) (32)</i> <i>WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, 2nd ed (51)</i>
TB.C12. Interpret the test(s) results	TB.C12.DT	Interpret the TB “Initial testing” results	<i>WHO operational handbook on tuberculosis – Module 3: diagnosis: (rapid diagnostics for tuberculosis detection, 2021 update) (32)</i>
TB.C16.1 Interpret RIF susceptibility test results	TB.C16.1.DT	Interpret the RIF susceptibility test results	<i>WHO operational handbook on tuberculosis – Module 3: diagnosis: (rapid diagnostics for tuberculosis detection, 2021 update) (32)</i>
TB.C16.4 Interpret RIF susceptibility test results for the retest	TB.C16.4.DT	Interpret the RIF susceptibility test results for the retest	<i>WHO operational handbook on tuberculosis – Module 3: diagnosis: (rapid diagnostics for tuberculosis detection, 2021 update) (32)</i>
TB.C20. Interpret the follow-on test(s) results	TB.C20.DT	Interpret the “Follow-on testing” results	<i>WHO operational handbook on tuberculosis – Module 3: diagnosis: (rapid diagnostics for tuberculosis detection, 2021 update) (32)</i>
TB.C24 Make a diagnostic decision	TB.C24.DT	Treatment decision algorithm for children	<i>WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents (37)</i>
TB.D9. Determine the regimen designed to treat rifampicin-susceptible TB	TB.D9.DT	Determine the regimen designed to treat rifampicin-susceptible TB	<i>WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update) (34)</i> <i>WHO operational handbook on tuberculosis – Module 4: drug-susceptible tuberculosis treatment (35)</i> <i>WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents (37)</i>
TB.D10. Determine the regimen designed to treat rifampicin-resistant TB	TB.D10.DT	Determine the regimen designed to treat rifampicin-resistant TB	<i>WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update) (34)</i> <i>WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents (37)</i>
TB.D11. Determine the dosages of medicines for TB treatment	TB.D11.DT	Determine the dosages of medicines for TB treatment	<i>WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update) (34)</i> <i>WHO operational handbook on tuberculosis – Module 4: drug-susceptible tuberculosis treatment (35)</i> <i>WHO operational handbook on tuberculosis – Module 5: management of tuberculosis in children and adolescents (37)</i>

6.2 Decision-support tables

Each of the decision logics listed in the overview table is elaborated in the decision-support implementation tool found [here](#). These decision-support tables include the components described in [Table 11](#). [Table 12](#) is an example of a decision-support logic table for determining if a TB infection test is relevant.

Note that the decision-support logic here is translated directly from WHO guidelines and guidance documents, and has been reviewed by the panel of experts that has created these guidelines. We do not anticipate the decision-support logic to change much because the logic has been created and reviewed by clinical experts. However, some level of adaptation may be needed depending on changes to the workflow or changes to the data dictionary.

Any changes to the decision-support logic should be considered carefully because an embedded decision-support system can greatly affect quality of care at the point of care. As helpful as decision-support logic can be to the health worker, an incorrect decision-support logic can also be detrimental. Thus, any new decision-support logic should be carefully reviewed and agreed on by in-country clinical experts.

Table 11 Components of the decision-support tables

Decision ID	The ID of the decision. The decision ID should correspond to the ID in the overview table (e.g. TB.B4.DT , TB.C7.DT .)						
Business rule	The description of the decision that needs to be made based on IF/THEN statements with the appropriate data element name for the variables. The rule should demonstrate the relationship between the input variables and the expected outputs and actions within the decision-support logic.						
Trigger	The event that would indicate when this decision-support logic should appear within the workflow, such as the activity that would trigger this decision to be made.						
Hit policy indicator	Displays the hit policy selected for the table. The hit policy determines the output of a decision table from the output cells of matched rules. A rule is matched when all of its condition cells match the inputs of the decision table. First (F): The first hit by rule order is returned (and evaluation can halt). Rule order (R): returns all hits in rule order.						
R or F	Input expression 1	Input expression 2	Output type	Action	Guidance	Annotation(s)	Reference(s)
Rule ID: “Process ID”: “activity number”. “DT”: “Rule number” E.g. TB.B4.DT.01	Input entry: the value of the input expression; the data type of the input entry cells is determined by the data type of the input expression.	If there are multiple input entries in the same row (such as here), these different inputs are considered as “AND”, that is, conditions that need to be in place at the same time.	Select an output type that best describes the type of action detailed in the next column. For additional guidance, please refer to the ReadMe section that describes each option in detail. If there are multiple outputs that apply for the given rule, then select “Plan Definition”.	A specific action detailing the output type; the action will always start with a verb . The action will trigger the system to perform a decision-support outcome.	Pop-up alert messages for the health worker; these should include the written content that would appear in the pop-up messages notifying the health worker of the appropriate next steps.	This column should be used for any other notes, annotations or communication messages within the team. This should include any additional information that does not fit into the other columns. Please note, this message will not appear as a pop-up message. While noting down the annotations, please note the correct audience for the annotation (i.e. Who is this message for?).	Add the reference to the appropriate guidance document.
Rule ID: “Process ID”: “activity number”. “DT”. “Rule number” E.g. TB.B4.DT.02	Inputs placed in different rows are considered as “OR” conditions that can be considered independently of the inputs in other rows.						

Table 12 Example decision-support logic table for determining if a TB infection test is relevant

Decision ID	TB.E3.1.DT						
Business rule	The results of the screening activities and the risk group to which the client belongs are used to determine if a TB infection test is relevant						
Trigger	TB.E3.1. Determine whether TB infection testing is relevant						
Hit policy indicator	Rule order						
R	Risk group	Age	Output type	Action	Guidance	Annotations	Reference(s)
TB.E3.1.DT.01	“Risk group” in “PLHIV”	–	ActivityDefinition	“Assess for TPT eligibility”	TB infection test is optional. WHO recommends that testing for TB infection should not be a requirement for initiating TB preventive treatment (TPT) among people living with HIV	People living with HIV who are on antiretroviral therapy (ART) benefit from TPT regardless of whether they test positive or negative for TB infection. People living with HIV who are not on ART and who test positive for TB infection are shown to benefit more from TPT than those with a negative test. However, WHO recommends that testing for TB infection should not be a requirement for initiating TPT among people living with HIV	<i>WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (22)</i> <i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29):</i> Chapter 4. Testing for TB infection
TB.E3.1.DT.02	“Risk group” in “Contacts” and not (“Risk group” in “PLHIV”)	“Age” ≥5 ‘year’	ActivityDefinition	“Test for TB infection”	TB infection test is recommended. Test the client for TB infection using TST, IGRA or TBST	The use of TB infection tests limits unnecessary treatment of uninfected individuals (such as settings with low prevalence of TB infection). Availability of a positive test for TB infection among HIV-negative contacts may reassure clinicians and health workers that TB infection is likely and to start TPT	
TB.E3.1.DT.03		“Age” <5 ‘year’	ActivityDefinition	“Assess for TPT eligibility”	TB infection test is optional. The benefits of TPT (even without testing) clearly outweigh the risks	WHO recommends that testing for TB infection should not be a requirement for initiating TPT among child contacts below 5 years of age, particularly in countries with high TB incidence, given that the benefits of treatment (even without testing) clearly outweigh the risks	

TB.E3.1.DT.04	“Risk group” in “Other risk group” and not (“Risk group” in “PLHIV, Contacts”)	–	ActivityDefinition	“Test for TB infection”	TB infection test is recommended. Test the client for TB infection using TST, IGRA or TBST	For individuals or populations with a higher risk of harms due to TPT or (relatively) lower risk of progression to TB disease, confirmation of TB infection may be preferred. Availability of a positive test for TB infection among individuals in other clinical risk groups (clients initiating anti-tumour necrosis factor treatment, receiving dialysis, preparing for organ or haematological transplantation) may reassure clinicians and health workers that TB infection is likely and to start TPT	<p><i>WHO consolidated guidelines on tuberculosis – Module 3: diagnosis (tests for tuberculosis infection) (22)</i></p> <p><i>WHO operational handbook on tuberculosis – Module 1: prevention (tuberculosis preventive treatment) (29):</i> Chapter 4. Testing for TB infection</p> <p><i>WHO operational handbook on tuberculosis – Module 2: screening (systematic screening for tuberculosis disease) (31):</i> Chapter 3. Screening tools and algorithms</p>
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ART: antiretroviral therapy; IGRA: interferon-gamma release assay; PLHIV: people living with HIV; TB: tuberculosis; TBST: *Mycobacterium tuberculosis* antigen-based skin tests; TPT: tuberculosis preventive treatment; TST: tuberculin skin test; WHO: World Health Organization.

For all the decision-support tables that are available for the TB DAK, please refer to the [decision-support implementation tool](#).

6.3 Decision trees

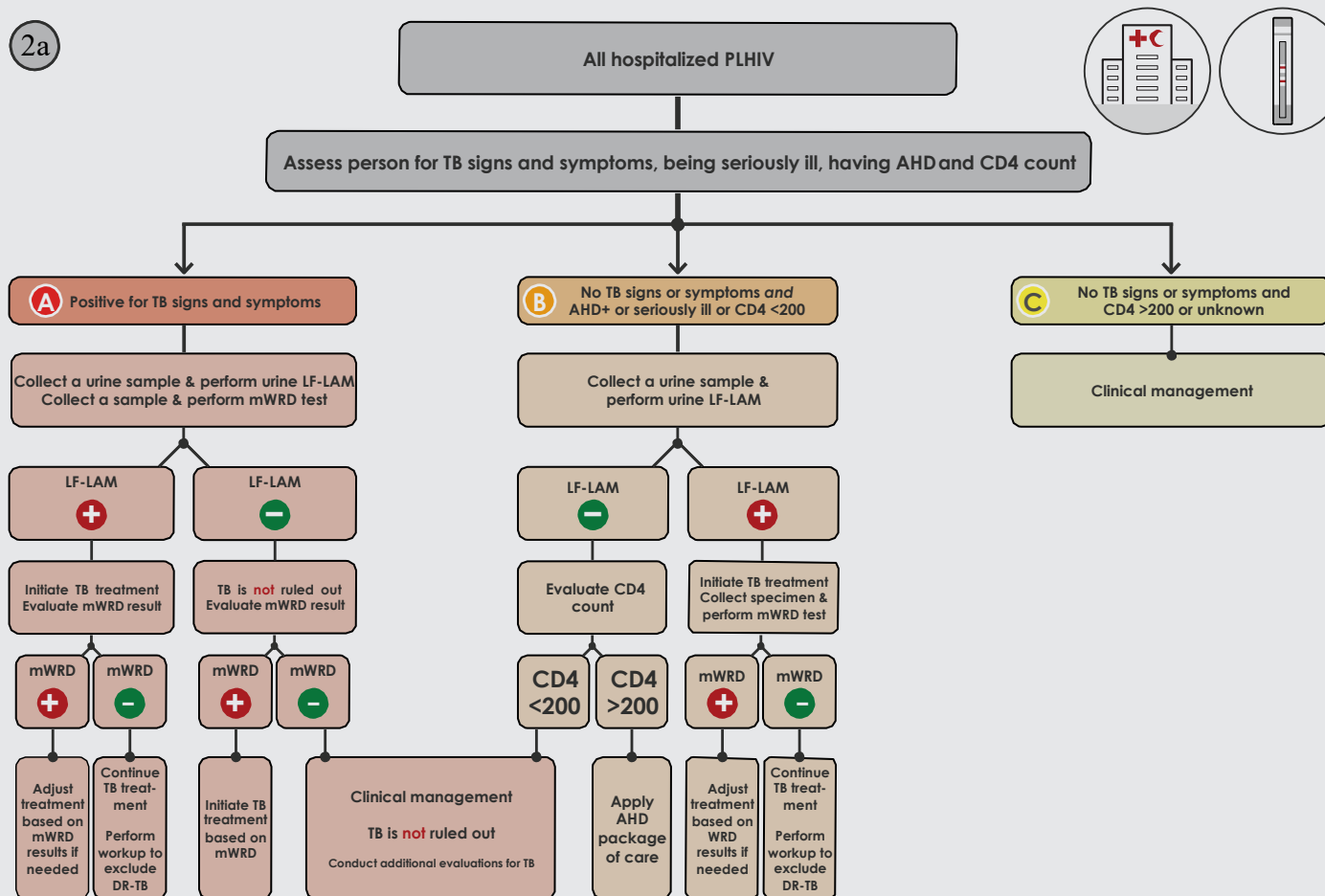
Decision trees are a graphical depiction of your decision-support logic ([Fig. 12](#)). Although the decision-support tables, linked to specific activities in the workflow, should be comprehensive in covering all the logic that will need to be included in the system, sometimes a visual depiction of the decision logic in a decision tree form can be helpful. Depending on the complexity of the care pathway algorithm, this decision tree can be too overwhelming and unhelpful. However, less complex decisions can easily also be depicted in graphical form, which may prove helpful if included.

EXAMPLE DECISION TREE

Decision trees may be used to supplement the structured format of the decision-support tables and can help in visualizing different pathways. The addition of decision trees may be especially useful for decision points that consist of multiple inputs and outputs. An example of a decision tree is given in [Fig. 12](#). Each box represents a single decision that needs to be made. The tree depicts how the outputs of one decision will serve as inputs to another decision that will need to be made.

Fig. 12

Algorithm 2a: LF-LAM to aid in the diagnosis of TB among PLHIV in inpatient settings



AHD: advanced HIV disease; DR-TB: drug-resistant TB; LF-LAM: lateral flow urine lipoarabinomannan [assay]; mWRD: molecular WHO-recommended rapid diagnostic test; PLHIV: people living with HIV; TB: tuberculosis.

Source: WHO (32).

6.4 Scheduling logic overview

In addition to specific decision-support logic that needs to be detailed, there is also a scheduling logic that can be used to facilitate the digital tracking of clients. For example, it will be important for the health worker to know when the client's next visit is due based on the recommendations for follow-up. The follow-up schedules (examples) developed for TB DAK are meant to be used for clients with confirmed TB disease and are based on the client's TB treatment regimen and recommended monitoring examinations for that regimen. The overview of the follow-up schedules is provided in [Table 13](#) and the corresponding logic is elaborated in the [decision-support implementation tool](#).

Table 13 Overview of scheduling logic

Schedule	Scheduling logic ID	Scheduling logic description	Reference/source
Monitoring examinations schedules	TB.D14.S	Scheduling logic for TB monitoring examinations	<i>WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update) (34)</i> <i>WHO operational handbook on tuberculosis – Module 4: drug-susceptible tuberculosis treatment (35)</i>

6.5 Scheduling logic

Scheduling logic, as shown in [Table 14](#), is at a much higher level than the decision-support logic; it describes how services overall should be scheduled based on recommendations rather than specific decisions that need to be made at the point of care. For example, the scheduling logic developed in the [decision-support implementation tool](#) would include the recommended follow-up schedule based on the treatment regimen and the recommended monitoring examinations for that regimen. Clinical visits should coincide with bacteriological and clinical laboratory examination schedules to limit time and transportation constraints for the client. This should be included in the DAK in a spreadsheet.

Table 14 Scheduling logic

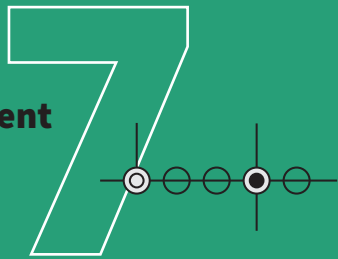
Columns ^a	Description ^b	Example: Monitoring schedule for clients receiving the 9-month all-oral MDR/RR-TB regimen
Service name	What is the short name of the service? This can also be used as the service schedule label in your digital client record system.	Monthly sputum smear test
Service description	What is the longer description of the service? In 1 or 2 sentences, describe the service and when it is given.	Sputum smear microscopy test performed on a monthly basis
Trigger event	What event signals the start of the service schedule?	"TB treatment regimen" in "4-6 Bdq _(6m) -Lfx/Mfx-Cfz-Z-E-Hh-Eto / 5 Lfx/Mfx-Cfz-Z-E, 4-6 Bdq _(6m) -Lzd _(2m) -Lfx/Mfx-Cfz-Z-E-Hh / 5 Lfx/Mfx-Cfz-Z-E" and "TB treatment is started" = TRUE
Trigger date	What is the date of the signalling event that will be used to determine a service's due date?	IF "Month of treatment" = 0 THEN "TB treatment start date" + 3 'week' ELSE last "Trigger date" + 1 'month' (for every treatment month)
Create condition	Are there any conditions that specify when a service should be given? If yes, write the condition here. If no, write "N/A".	Response to treatment is monitored by monthly sputum smear microscopy and culture
Due date	How is the due date of the service calculated? Write the formula here using the trigger date.	"Trigger date" + 1 week
Overdue	Is the service overdue? If yes, write the formula that defines the overdue date. If no, write "N/A".	"Due date" + 1 day
Expiration	Does the service expire? If yes, write the formula that defines the expiration date. If no, write "No expiration date".	"Due date" + 1 week
Completion	How does the health worker complete the service?	"Monitoring examinations" = 'Follow-up microscopy – sputum acid-fast bacilli (AFB)' and ("Date of monitoring examination" is between "Due date" – 1 'week' and "Due date" + 1 'week')
Potential risks and alternative schedules	What are the potential risks to client safety if the service is not delivered according to the recommended schedule? What are the possible alternative service schedules?	Not following the schedule for sputum smear microscopy and culture tests might represent a missed opportunity in detecting treatment failure in a timely manner Delayed detection of failure can increase transmission and increase the probability of acquisition of resistance to the client's strain, making it harder to cure the client after failure
Comments	Any narrative or additional comments that need to be added by the implementation team should be written here.	–
References	If there are any national or global guidelines (e.g. WHO guidelines) that dictate the health service schedule noted here, then they should be noted. If any guidelines or recommendations change, having a clear reference listed would help in updating or restructuring your service schedule.	<i>WHO operational handbook on tuberculosis – Module 4: treatment (drug-resistant tuberculosis treatment, 2022 update)</i> (34): » Chapter 5. The 9-month all-oral regimen » Table 5.1. Example of a monitoring schedule for patients receiving the 9-month all-oral MDR/RR-TB regimen » Web Annex 1. Tuberculosis medicines – information sheets

MDR: multidrug resistance; N/A: not applicable; RR-TB: rifampicin-resistant tuberculosis; WHO: World Health Organization.

^a Each of these should be a separate column in Excel, corresponding with each discrete service.

^b Description of what to note in each column for each discrete service.

Component



Indicators and performance metrics

This section details indicators and performance metrics that would be aggregated from the core data elements identified in **Component 5**. The list in **Table 15** is a selection of indicators from the **indicators and performance metrics implementation tool** for demonstration purposes and is non-exhaustive. These indicators can be aggregated for decision-making, performance metrics, and subnational and national reporting based on data collected from individual-level, routine health systems. The indicators can be aggregated automatically from the digital tracking tool to populate a digital HMIS, such as the DHIS2. The complete list of indicators and associated details are available [here](#).

Table 15 Indicators and performance metrics

Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
Business process B: screening						
TB.IND.1	Percentage of clients who were screened for TB out of those eligible	Percentage of clients screened for TB out of those eligible for screening following provider-initiated TB screening programme	COUNT of clients where “Date of TB screening result” is within the reporting period	Estimated number of clients eligible for screening following provider-initiated TB screening programme in the reporting period		<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
TB.IND.2	Percentage of clients diagnosed with TB out of those who were screened	The proportion of clients diagnosed with TB among those screened for TB following provider-initiated TB screening programme	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND “TB screening result” = “Screen positive for TB” AND “Date of TB screening result” is within the reporting period	COUNT of clients where “Date of TB screening result” is within the reporting period		<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
TB.IND.3	Percentage of clients diagnosed with TB infection out of those screened	Of all the clients screened, the proportion of clients diagnosed with TB infection	COUNT of clients where “TB infection test result” = “Positive” AND (“Date of TB infection test” AND “Date of TB screening result” is within the reporting period)	COUNT of clients where “Date of TB screening result” is within the reporting period		<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
Business process C: diagnosis						
TB.IND.8	Notifications: number of notifications of people diagnosed with a new episode of TB. This includes both drug-susceptible and drug-resistant TB	Number of new, recurrent or unknown previous TB treatment history case of TB (i.e. any case apart from a re-registered cases)	COUNT of clients where (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	N/A	Sex: male, female, intersex, unknown or unspecified Age group (in years): 0–4, 5–9, 10–14, 15–19, 20–24, 25–34, 35–44, 45–54, 55–64, 65+ Geographical area: administrative unit (reporting entities such as provinces, regions and districts as opposed to individual health-care facilities, which are too small a unit for meaningful analysis) Type of TB: pulmonary bacteriologically confirmed, pulmonary clinically diagnosed, extrapulmonary Treatment history: new, recurrent, unknown	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
TB.IND.9	Notification rate: number of people diagnosed with a new episode of TB per 100 000 population	Number of people diagnosed with a new episode of TB (all forms) per 100 000 population	COUNT of clients where (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	Total population in the specified area during the reporting period	Sex: male, female, intersex, unknown or unspecified Age group (in years): 0–4, 5–9, 10–14, 15–19, 20–24, 25–34, 35–44, 45–54, 55–64, 65+ Geographical area: administrative unit	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
TB.IND.11	Bacteriological confirmation: percentage of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed	Percentage of people diagnosed with a new episode of pulmonary TB for whom biological specimen are positive by a WHO-recommended rapid diagnostics, culture or smear microscopy	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	Geographical area: administrative unit	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
TB.IND.15	Documentation of HIV status: percentage of people diagnosed with a new episode of TB whose HIV status was documented	Percentage of people diagnosed with a new episode of TB who were tested for HIV at the time of diagnosis or with known HIV status at the time of TB diagnosis	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “HIV status” != “Unknown” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “HIV status” != “Unknown” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	Geographical area: administrative unit	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
TB.IND.18	Testing for RR-TB: percentage of people diagnosed with bacteriologically confirmed pulmonary TB who were tested for rifampicin susceptibility	Percentage of people with a documented susceptibility test result (susceptible or resistant) for rifampicin among those diagnosed with bacteriologically confirmed pulmonary TB	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Re-registered”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND (“Rifampicin susceptibility test result” = “Susceptible” OR “Resistant”) AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Re-registered”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	Geographical area: administrative unit Treatment history: new (“TB treatment history” = “New”), previously treated (“TB treatment history” = “Recurrent” OR “Re-registered”), unknown (“TB treatment history” = “Unknown”)	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

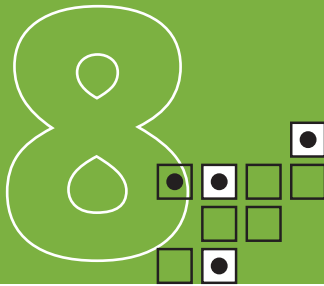
Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
TB.IND.27	RR-TB: percentage of people tested for RR-TB who were resistant to rifampicin	Percentage of people resistant to rifampicin (RR-TB) among those diagnosed with bacteriologically confirmed pulmonary TB with a documented susceptibility test result (susceptible or resistant) for rifampicin	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Re-registered”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Rifampicin susceptibility test result” = “Resistant” AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Re-registered”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND (“Rifampicin susceptibility test result” = “Susceptible” OR “Resistant”) AND “Client transferred” != “In” AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True”	Geographical area: administrative unit Treatment history: new (“TB treatment history” = “New”), previously treated (“TB treatment history” = “Recurrent” OR “Re-registered”), unknown (“TB treatment history” = “Unknown”)	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
Business process D: TB treatment						
TB.IND.32	Treatment initiation: percentage of people diagnosed with TB and registered as a TB case who were started on TB treatment	Percentage of people who were started on TB treatment among all people diagnosed with TB and registered as a TB case	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND “TB treatment started” = “True” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown” OR “Re-registered”) AND (“Site of TB disease” = “Pulmonary” OR “Extrapulmonary”) AND (“Method of diagnosis” = “Bacteriologically confirmed” OR “Clinically diagnosed”) AND “Date of TB diagnosis” AND “Date TB treatment started” are within the reporting period AND “Case de-notified” != “True” (exclude those who did not start treatment or transferred out before start of treatment, add any people transferred in before start of treatment)	COUNT of clients where “TB diagnosis result” = “Diagnosed TB” AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown” OR “Re-registered”) AND (“Site of TB disease” = “Pulmonary” OR “Extrapulmonary”) AND (“Method of diagnosis” = “Bacteriologically confirmed” OR “Clinically diagnosed”) AND “Date of TB diagnosis” is within the reporting period AND “Case de-notified” != “True” (add people transferred in to start treatment at this facility and exclude people transferred out to start treatment in another facility)	Geographical area: administrative unit Regimen type: » Regimen designed to treat rifampicin-susceptible TB (irrespective of HIV-status) » Regimen designed to treat rifampicin-susceptible TB (people living with HIV) » Short (≤12 month) regimen designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB) » Long (>12 month and ≤24 month) regimen designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
TB.IND.35	Treatment outcome: percentage of TB patients who were cured out of those who started TB treatment	Percentage of TB patients who started TB treatment who were cured	COUNT of clients where “Date of TB diagnosis” is 12 months earlier than the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown” OR “Re-registered”) AND (“Site of TB disease” = “Pulmonary” OR “Extrapulmonary”) AND “Method of diagnosis” = “Bacteriologically confirmed” AND “TB treatment started” = “True” AND “Treatment outcome” = “Cured” AND “Case de-notified” != “True” (add people transferred in to continue TB treatment after starting at another facility and remove people that were transferred out to continue TB treatment in another facility after starting at this facility)	COUNT of clients where “Date of TB diagnosis” 12 months earlier than the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown” OR “Re-registered”) AND (“Site of TB disease” = “Pulmonary” OR “Extrapulmonary”) AND (“Method of diagnosis” = “Bacteriologically confirmed” OR “Clinically diagnosed”) AND “TB treatment started” = “True” AND “Case de-notified” != “True” (add people transferred in to continue TB treatment after starting at another facility and remove people that were transferred out to continue TB treatment in another facility after starting at this facility)	Geographical area: administrative unit Regimen type: » Regimen designed to treat rifampicin-susceptible TB (irrespective of HIV-status) » Regimen designed to treat rifampicin-susceptible TB (people living with HIV) » Short (≤12 month) regimen designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB) » Long (>12 month and ≤24 month) regimen designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
Business process E: TPT						
TB.IND.49	Contact investigation coverage: percentage of household contacts (or all close contacts) who were evaluated for TB (disease or infection) <i>(This indicator can be constructed for one or more subpopulations considered at particularly high risk of TB disease or infection; the example provided here is for a household contact)</i>	Percentage of household contacts of people with a new episode of bacteriologically confirmed pulmonary TB notified in the reporting period who were evaluated for TB (disease or infection)	COUNT of clients where “TB screening result” is not null AND “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” is within the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”]	COUNT of clients where “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” is within the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”]		<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

Indicator ID	Indicator name	Definition	Numerator computation	Denominator computation	Disaggregation	References
TB.IND.50	<p>Initiation of TPT among contacts: percentage of household contacts (or all close contacts) who were started on TPT, out of those eligible</p> <p><i>(This indicator can be constructed for one or more subpopulations considered at particularly high risk of TB disease or infection; the example provided here is for household contacts of all ages)</i></p>	Percentage of household contacts (all ages) of people with bacteriologically confirmed pulmonary TB notified in the reporting period who were eligible for TPT and who were started on TPT in the reporting period	COUNT of clients where “TPT started” = “True” AND “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” is within the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”]	COUNT of clients where “Eligible for TPT” = “True” AND “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” is within the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”]	Age group: <5 years	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>
TB.IND.51	<p>Completion rate for TPT among contacts: percentage of household contacts (or all close contacts) who completed TPT</p> <p><i>(This indicator can be constructed for one or more subpopulations considered at particularly high risk of TB disease or infection; the example provided here is for a household contact)</i></p>	Percentage of household contacts of people with bacteriologically confirmed pulmonary TB who completed their course of TPT during the reporting period among those who started TPT and were due to finish their treatment course during the reporting period	COUNT of clients where “TPT started” = “True” AND “Date TB preventive treatment started” is 12 months before the reporting period AND “TPT status” = “Completed” AND “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” is 12 months before the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”] (add people transferred in to continue TPT after starting at another facility and exclude people transferred out to continue TPT in another facility after starting at this facility)	COUNT of clients where “Date TB preventive treatment started” is in the previous calendar year AND “Index case ID” is not null AND the linked index case has: [“Date of TB diagnosis” 12 months before the reporting period AND (“TB treatment history” = “New” OR “Recurrent” OR “Unknown”) AND “Site of TB disease” = “Pulmonary” AND “Method of diagnosis” = “Bacteriologically confirmed” AND “Case de-notified” != “True”] (add people transferred in to continue TPT after starting at another facility and exclude people transferred out to continue TPT in another facility after starting at this facility)	Age group: <5 and ≥5 years	<i>WHO consolidated guidance on tuberculosis data generation and use – Module 1: tuberculosis surveillance (15)</i>

For the full list of indicators defined for the TB DAK, please refer to the [indicators and performance metrics implementation tool](#).

Component



High-level functional and non-functional requirements

This section provides an overview of illustrative functional and non-functional requirements that may be considered to kick-start the process of designing or adapting the DTDS system. Functional requirements describe the capabilities the system must have to meet the end users' needs and achieve tasks within the business processes. Non-functional requirements provide the general attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include the ability to work offline, multiple language settings and password protection.

Table 16 highlights some key functional requirements for executing the business processes listed in **Component 4** of this document; the complete set of functional requirements can be accessed [here](#). **Table 17** provides non-functional requirements as general characteristics of the overall system. Please note that these are not exhaustive lists and should be modified according to the context and user persona needs.

8.1 Functional requirements

Table 16 Functional requirements

Requirement ID	Activity ID and description	As a ...	I want ...	So that ...
Business process A: registration				
TB.FXNREQ.001	TB.A5. Search for the client record	Health worker or data entry clerk or medical office receptionist	To search to see whether client is already in the system (using at least two identifiers)	I can check whether this is a new or existing client
TB.FXNREQ.007	TB.A7. Create a new client record	Health worker or data entry clerk or medical office receptionist	To be able to enter identification information	I can enter new client information
TB.FXNREQ.012	TB.A9. Validate the client details	Health worker or data entry clerk or medical office receptionist	To display client information for validation (and be able to edit it)	I can ensure information has been checked before submission
TB.FXNREQ.016	TB.A9. Validate the client details	Health worker or data entry clerk or medical office receptionist	To be able to confirm the client's identity	I can be sure it is the right person
TB.FXNREQ.020	TB.A9. Check in the client	Health worker or data entry clerk or medical office receptionist	Provide a list or roster of all clients due to arrive	I know which clients to follow up or are due for services

Requirement ID	Activity ID and description	As a ...	I want ...	So that ...
Business process B: screening				
TB.FXNREQ.021	TB.B1. Provide pre-screening information and ask for consent	Health worker (e.g. nurse)	To have available general pre-screening information about potential risks and benefits, screening tools and procedure to share with clients during counselling activities	I can better answer the client's questions and better prepare them for screening activities
TB.FXNREQ.022	TB.B1. Provide pre-screening information and ask for consent	Health worker (e.g. nurse)	The system to prompt the health worker to get informed consent from the client before proceeding with screening	I can ensure that ethical principles for screening for infectious diseases are followed and that the clients' rights are protected
TB.FXNREQ.023	TB.B3. Assess medical history and risk factors	Health worker (e.g. nurse)	To be able to capture or update client information related to medical history and risk factors for TB	I make sure that new relevant information is not missed
TB.FXNREQ.024	TB.B4. Determine the screening algorithm	Health worker (e.g. nurse)	To have available general information about screening algorithms	I have a quick reference to help me choose the most appropriate screening algorithm for a client or group of clients
TB.FXNREQ.025	TB.B5. Perform the TB screening	Health worker (e.g. nurse)	To be able to send referral letters via appropriate digital tools (e.g. email, digital health portal)	I can speed up the referral process and check-in at the accommodating health-care facility
Business process C: diagnosis				
TB.FXNREQ.026	TB.C1. Carry out clinical examination	Health worker (e.g. nurse)	The system to use the data entered for a client to generate statistics, graphs, pop-ups (on demand or ad hoc)	I can take better clinical decisions
TB.FXNREQ.027	TB.C2. Assess medical history and risk factors	Health worker (e.g. nurse)	To be able to route the consultation via different health workers and save in the system the information already entered during the consultation even if the consultation is not yet complete, enabling other health workers to see the information already entered and to be able to add or edit information as it becomes available	I do not have to start a new consultation for every health worker that the client is involved with
TB.FXNREQ.028	TB.C4 Assess history of prior TB treatment	Health worker (e.g. nurse)	To be able to check client's medical history	I can use this information for investigations or treatment recommendations
TB.FXNREQ.029	TB.C12. Interpret test(s) results TB.C20. Interpret the follow-on test(s) results	Health worker (e.g. nurse)	The system to be capable to receive diagnosis test results from laboratories or other test centres	I can take the appropriate actions more quickly

Requirement ID	Activity ID and description	As a ...	I want ...	So that ...
Business process D: TB treatment				
TB.FXNREQ.030	TB.D9. Determine the regimen designed to treat rifampicin-susceptible TB TB.D10. Determine the regimen designed to treat rifampicin-resistant TB	Health worker (e.g. nurse)	The system to propose TB treatment regimens based on predefined criteria and on the information available in the system	I can select the appropriate treatment regimen for the client
TB.FXNREQ.032	TB.D13. Initiate the treatment and discuss the adherence	Health worker (e.g. nurse)	The system to automatically calculate the expected TB treatment completion date	I do not have to calculate this myself
TB.FXNREQ.033	TB.D14. Develop monitoring examinations and a schedule of follow-up visits	Health worker (e.g. nurse)	To have the system automatically calculate a date when the client should return for care, based on treatment regimen, clinical condition and monitoring examinations	I do not have to calculate this myself
TB.FXNREQ.035	TB.D19. Manage TB treatment interruptions	Health worker (e.g. nurse)	The system to be able to exchange information with digital adherence technologies to automatically record and calculate information related to treatment progress or interruptions	I do not have to calculate this myself and fill in the information manually
TB.FXNREQ.036	TB.D24. Report the outcome(s)	Health worker (e.g. nurse)	The system to trigger an alert to assign treatment outcome in case the expected TB treatment completion date is reached and there is no treatment outcome assigned	Alignment between the number of cases notified and number of treatment outcome cohort (all notified cases have assigned treatment outcomes) is ensured
Business process E: TPT				
TB.FXNREQ.037	TB.E1. Offer TB prevention counselling	Health worker (e.g. nurse)	To be prompted to provide counselling on TPT	I can ensure that the client is educated on TPT before offering any TPT-related service
TB.FXNREQ.038	TB.E2. Make an informed decision	Health information officer	The system to prompt the health worker to get informed consent from the client before proceeding with the TPT evaluation	I can ensure that client rights are protected
TB.FXNREQ.040	TB.E4.7. Determine TPT eligibility	Health worker (e.g. nurse)	To have questions that guide me in TPT eligibility assessment	I can better evaluate client TPT eligibility
TB.FXNREQ.042	TB.E9. Initiate TPT and develop an adherence plan	Health worker (e.g. nurse)	To have available general information about TPT adherence	I can better prepare the TPT adherence plan
TB.FXNREQ.043	TB.E13. Schedule the follow-up visit	Health worker (e.g. nurse)	To be able to indicate if the client agrees to receive notifications and their preferred communication channel (including sending reminders for the next follow-up visit)	I can send communications via the client's preferred communication channel

Requirement ID	Activity ID and description	As a ...	I want ...	So that ...
Business process F: referral				
TB.FXNREQ.044	TB.F2.1. Stabilize the client and give pre-referral treatment	Health worker (e.g. nurse)	To be able to bypass the standard flow at any point if danger signs are present or emergency care is needed; urgent cases should be flagged and seen promptly	The client can be referred, if needed
TB.FXNREQ.045	TB.F3. Identify and discuss referral location options	Health worker (e.g. nurse)	To be able to find out in the system where the required service may be available	I can refer my client to another facility to receive the appropriate services
TB.FXNREQ.047	TB.F4. Contact referral facility	Health worker (e.g. nurse)	To have a list of the contact information for referral facilities	I can easily contact the facility when making the referral arrangements
TB.FXNREQ.048	TB.F6. Provide information to the receiving facility	Health worker (e.g. nurse)	To indicate in the system the referral reason	I can identify ways to improve the TB care process at my health-care facility
TB.FXNREQ.050	TB.F8. Check whether the client can be accommodated	Health worker (e.g. nurse)	To be able to check if the supplies and skills needed to accommodate a referred client are available at my facility	I can validate to the referring facility (or directly to the client) where the client can be accommodated
Business process G: aggregate reporting and data use				
TB.FXNREQ.052	TB.G4. Generate aggregate reports	Health worker or data entry clerk	To produce a range of prepared reports	I do not need to create the reports manually for reporting purposes
TB.FXNREQ.053	TB.G7. Analyse and interpret the reports	Health worker (e.g. nurse)	To view a range of standardized visualizations (e.g. charts, tables, maps)	I am able to use data collected at the facility for service delivery and informing programmatic actions with the aim of improving the quality of care for clients with TB

For the full list of functional requirements defined for the TB DAK, please refer to [functional and non-functional requirements implementation tool](#).

8.2 Non-functional requirements

Table 17 Non-functional requirements

Requirement ID	Category	Non-functional requirement
TB.NFXNREQ.001	Security – confidentiality	Provide password-protected access for authorized users.
TB.NFXNREQ.002	Security – confidentiality	Provide a means to ensure confidentiality and privacy of personal health information.
TB.NFXNREQ.003	Security – confidentiality	Provide the ability for allowed users to view confidential data.
TB.NFXNREQ.007	Security – confidentiality	Provide encrypted communication between components.
TB.NFXNREQ.008	Security – confidentiality	Provide secure data transmission methods to prevent others from seeing data sent from one computer to another by using data encryption and private networks across public networks.

Requirement ID	Category	Non-functional requirement
TB.NFXNREQ.009	Security – authentication	Notify the user to change their password the first time they log in.
TB.NFXNREQ.010	Security – authentication	Adhere to complex password requirements.
TB.NFXNREQ.014	Security – authentication	Lock a user out after a specified number of wrong password attempts.
TB.NFXNREQ.015	Security – authentication	Notify a user if their account is locked due to wrong password attempts.
TB.NFXNREQ.016	Security – authentication	Provide role-based access to the system: users of the system get access on a need-to-know and need-to-use basis.
TB.NFXNREQ.017	Security – audit trail and logs	Log system logins and logouts.
TB.NFXNREQ.018	Security – audit trail and logs	Record all authentication violations.
TB.NFXNREQ.024	Security – audit trail and logs	Log all data and system errors.
TB.NFXNREQ.025	Security – user management	Allow user with permission to create a new user and temporary password.
TB.NFXNREQ.026	Security – user management	Provide role-based access.
TB.NFXNREQ.027	Security – user management	Allow roles to be associated with specific geographical areas or health-care facilities.
TB.NFXNREQ.028	Security – user management	Allow cascading user management and assignment of roles.
TB.NFXNREQ.033	Security – user management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing and auditing.
TB.NFXNREQ.034	System requirements – general	Provide a unique version number for each revision.
TB.NFXNREQ.035	System requirements – general	Enable earlier versions of a record to be recoverable.
TB.NFXNREQ.042	System requirements – general	Show the number of records that are not yet synchronized.
TB.NFXNREQ.043	System requirements – general	Have the ability to easily back up information.
TB.NFXNREQ.044	System requirements – general	Warn user if no valid backup for more than a predefined number of days.
TB.NFXNREQ.045	System requirements – general	Must have the ability to store images and other unstructured data.
TB.NFXNREQ.046	System requirements – scalability	Scalable to accommodate new demands.
TB.NFXNREQ.047	System requirements – scalability	Be able to accommodate at least [x number of] ^a health-care facilities.
TB.NFXNREQ.048	System requirements – scalability	Be able to accommodate at least [x number of] ^a concurrent users.
TB.NFXNREQ.049	System requirements – usability	Be user-friendly for people with low computer literacy.
TB.NFXNREQ.057	System requirements – usability	Provide guidance to users to better support clinical guidelines and best clinical practices.
TB.NFXNREQ.058	System requirements – usability	Be reliable and robust (minimize the number of system crashes).
TB.NFXNREQ.059	System requirements – usability	Adjust display to fit small screens (e.g. mobile phones).
TB.NFXNREQ.060	System requirements – configuration	Configure the system centrally.
TB.NFXNREQ.061	System requirements – configuration	Configure business rules in line with guidelines and standard operating procedures.
TB.NFXNREQ.062	System requirements – configuration	Configure error messages.
TB.NFXNREQ.063	System requirements – configuration	Configure workflows and business rules to accommodate differences between facilities.
TB.NFXNREQ.064	System requirements – interoperability	Communicate with external systems through mediators.

Requirement ID	Category	Non-functional requirement
TB.NFXNREQ.065	System requirements – interoperability	Provide access to data through application programming interfaces.
TB.NFXNREQ.066	System requirements – interoperability	Be interoperable with external systems through mediators.
TB.NFXNREQ.067	System requirements – interoperability	Link with insurance systems to verify eligibility and submit claims.
TB.NFXNREQ.068	System requirements – interoperability	Exchange data with other approved systems.
TB.NFXNREQ.069	System requirements – interoperability	Accept data from multiple input methods including paper and geocoding (GPS).

GPS: Global Positioning System.

^aThis is dependent on each country being able to determine the scale of the system and system deployment.

For the full set of non-functional requirements defined for the TB DAK, please refer to [functional and non-functional requirements implementation tool](#).

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Annexes



Annex 1. Examples of detailed personas

Awe, Nurse, 42-year-old man

My tasks

- » Clinical tasks (80%):
 - TB consultations;
 - provide diagnostic services for TB; and
 - provide treatment services for TB, that is, treatment initiation and monitoring.
- » Other tasks (20%):
 - filling in TB registers;
 - providing TB reports to the district; and
 - TB medication logistics in the clinic.

There are many forms to fill in, some of which collect similar information.

My workplace

- » A rural clinic that provides both diagnostic and treatment services for TB.
- » I am the only one responsible for the clinical management of patients with TB in this clinic.
- » I provide TB services to around 15 patients per day, on average.
- » The health-care facility was recently equipped with a computer and a new digital system.
- » The internet connection is very slow and sometimes does not work.

My typical day

- » 08:00 Arrive at work, check the agenda and check the stock.
- » 09:00 Check clients who have arrived and start clinical tasks.
- » 12:00 Lunch break.
- » 13:00 Resume the work on the clinical tasks.
- » 14:00 Community health worker calls and alerts that there is a man with symptoms of TB and asks if the man could be brought urgently to the clinic for a consultation. The man is seen in the following 30 min.
- » 15:30 Closing and completing the missing information in the register.

Challenges encountered working on TB services

PAPERWORK

- » It is time-consuming to fill in the necessary information (treatment initiation, dispensing of medication, laboratory results) on the forms provided by the district health authority.
- » It is difficult to manually find the names of the clients in the register.

NEW WAY OF WORKING

- » A new computer was brought to the clinic. Awe finds it difficult to use the computer instead of relying on the paper register. He is not sure why he needs to change his way of working. He is also not sure why he needs to collect all this information on his clients.

STOCK-OUT

- » Sometimes there is not enough medication at the clinic

Ina, District Health Information Officer, 36-year-old woman

My tasks

- » Administrative tasks (80%):
 - undertaking data management and analysis;
 - supervising the health-care facilities within the district; and
 - generating updates regarding the epidemiological situation in the district and reporting these data to higher administrative levels.
- » Other tasks (20%):
 - contributing to the development of financial reports; and
 - undertaking medical ad-hoc tasks.

Ina is motivated in her job and has the right intentions; however, she feels overwhelmed by the data.

My workplace

- » A district health clinic of a large rural district in Nigeria.
- » My primary focus is TB, leprosy, HIV, sexually transmitted infections and vaccine-preventable diseases.
- » My preferred software for data management and analysis (and other monitoring and evaluation [M&E] activities) is Excel.

Needs and goals

- » Ina is interested in understanding the TB epidemic in the district and how it is changing over time.
- » She would like to know if the district is close to reaching its targets.
- » She would like to understand if there are areas that need more support and use this information to advocate for additional resources.
- » She would like a better way to manage the collected data to keep it better organized, but she is not sure if it is possible, especially with her level of training.
- » One day, she hopes to take formal classes in epidemiology to improve her skills, but due to the demanding nature of her job, she does not have the time.

Challenges encountered working on TB M&E

WORKLOAD

- » Ina and other team members visit the health-care facilities in the district to supervise their performance. They have a quick look at the registers and other TB data collection tools; however, not much time is spent on this task because they have many health-care facilities to cover.

LACK OF SUPPORT

- » Ina was shown how to do some analyses in Excel from the person she replaced in this role, but she does not have an analytical plan to follow. While she finds it useful, she does not enjoy doing the analysis – it takes a very long time and she does not have much support for it.

LACK OF HARDWARE

- » She has access to one laptop and finds it very hard to navigate through all the sheets on such a small screen. She sometimes loses track of where she is and worries that she is introducing errors.

Annex 2. Guidance for adapting the data dictionary

When adapting the data dictionary, data elements may need to be modified or added because of the structure of existing paper registers or local reporting requirements. If starting from paper-based registers and forms, you can find additional guidance in the *Digital transformation handbook for primary health care (1)*; [Table A2.1](#) contains an overview of data mapping that can be used when adjusting the data dictionary. When amending the wording of data elements, it is important to ensure that the standard terminology codes still reflect the data element as originally intended.

Table A2.1 Overview of data mapping for data dictionary adaptation

What to note	Description
Activity ID	The ID number of the task in the workflow in which the data element is collected. This will denote the point in time at which this data element is collected. This should align with the Activity ID that is provided in Form Mapping.
Data element code	Each data element should have an identification number or code that is unique across the entire project. Use existing serial or identification numbers when available. If no identifiers exist, fields should be enumerated in a logical format.
Form ID and form data element label	The Form ID should be from the ID listed. List the Form ID in which the data element appears. This is important to ensure that the design of the digital system has taken into account all the required paper forms and data elements on those paper forms. Also list the label of the data element as written on the original form (or translated as closely as possible). This will be key in keeping track of which data elements from the original paper forms are duplicated. Note that duplicate data fields can be included purposely (client identifiers, such as name, date of birth, village, ID number, would be included in multiple data instruments to identify an individual client).
Data element label	The label of the data element written in a way in which the end users can easily understand, for example, “educational level”, “weight”, “height”, “reasons for coming into the facility”, “which medication(s) is your client taking?” The data element label in this column is what will be used in the digital form. The digital register should not simply replace the paper registers; it should also streamline processes and link duplicated data elements; thus, the data element label listed here should be what will be used in the digital system.

Data element name	The shorthand name for the data element (e.g. “educ_level” for “educational level”, “weight_kg” for “weight” and “height_m” for “height”). This will be key when coding the system and determining the calculations required. This data element name is what will reconcile any duplicate data elements in the digital system.
Description and definition	The description of the data field, including any units that define the field (e.g. “weight in kilograms [kg]”). Provide a clear explanation of what this data point is requesting, assuming the reader has never seen the form. Be sure to use consistent and easy-to-understand terminology across all forms. This is particularly important if the data element name differs across forms but requires the same input.
Data type	The data type should be aligned with data types outlined by fast health interoperability resources (FHIR) standards (2). Some common data types are: <ul style="list-style-type: none"> » Boolean (e.g. true/false, yes/no); » string (a sequence of Unicode characters, e.g. name); » date (e.g. date of birth); » time (e.g. time of an appointment); » ID (e.g. unique identifier assigned to the client); » integer (a whole number, e.g. the number of previous appointments); » decimal (rational numbers that have a decimal representation, e.g. the exact duration of time, location coordinates, all percentages); » codable concept (a value that is usually supplied by providing a reference to one or more data points, e.g. body mass index [BMI], contraceptive prevalence rate); » signature (an electronic representation of a signature that is either cryptographic or a graphical image that represents a signature or a signature process, e.g. supervisor’s approval); » attachment (additional data content defined in other formats, e.g. images). <p>Note that if there are multiple-choice data fields, the “parent” data field should be labelled “Multiple choice – Select one” or “Multiple choice – Select all that apply”. Then each individual option should be listed in the “Input” options column and be classified with one of the data types listed above.</p> <p>Although the list above should be sufficient to relay this information to a health informatics specialist or technology vendor, there are many more data codes that can be applied to achieve a more precise classification. For other possible data types, please refer to the HL7 FHIR data types (2).</p>

Input options	For multiple-choice fields only; otherwise leave this column blank. Write the list of responses from which the health worker may select. Each of these input options should be in a separate row and should be labelled with the data type “Codes”.
Calculation	If a calculation is needed to define the data element, write the formula here. Leave this column blank if no calculation is needed. Use standard mathematical symbols and the data element label of the data element names included in the formula (e.g. for the BMI calculation: “weight_kg / ([height_m] ²)”.
Validation required	Yes or No to indicate whether there needs to be some form of validation given the constraints provided by a range of acceptable responses.
Validation condition	With digital systems, it is possible to incorporate data entry validation to ensure that the data entered into the field are accurate at the time of data entry. For example, if a health worker accidentally enters the height of an individual as 1650 cm instead of 165 cm, the system should notify the health worker that an erroneous height has been entered. This feature will help increase the fidelity of data entry. This should contain the range of acceptable responses, if validation is required (e.g. for a phone number, only 10 digits allowed; for a birthday, only past dates are allowed).
Editable	Yes or No to indicate whether the end user, or health worker, would be able to edit the field after it has been input to the system.
Required	Note whether or not this field is: » required – R; » optional – O; » conditional on answers from other data fields – C.
Reason for required data	If this field is required (R), state the reason here whether for: » accountability for national-level reporting; » service delivery or clinical decision-making; » client identification. The digital system should not simply replace your paper registers, but it should also streamline processes; thus, it is important to understand why a certain data field is actually required and seek opportunities to optimize data flows. Given the high volume of data collection required of health-service providers, it might be better to remove a data entry field if it serves no real purpose for the clinician, public health reporting or any other identified purpose.

Explain conditionality	If the field is conditional on inputs from other data elements, denote what the conditionality is here. A conditional data element will be interpreted as R for implementation to support the field for interoperability purposes. The health worker should fill in a value if the information is available, otherwise the data element may be left empty.
Linked to an aggregate indicator	Aggregate indicators should be called out and specified. If this data element is linked to an aggregate indicator, then indicate the IDs of the linked indicators, if known. If there is linkage to indicators for which the IDs are not known, indicate Yes here. If there is no link with aggregate indicators, indicate No.
Annotations	If there is an issue or inconsistency in how a data field is defined, make a note of the issue here. Irregularities and inconsistencies will need to be resolved at a later stage through a process of team discussion and triangulation. This column should also be used for any other notes, annotations or communication messages within the team.
Mapping to code systems (standardized terminologies and classifications) (3)	Depending on which systems you plan on interoperating with, other columns will most likely need to be added to map to the concepts used in the other system (e.g. International Classification of Diseases [ICD], Systematized Nomenclature of Medicine [SNOMED]). Dedicated columns should be used for each concept dictionary.

ANNEX REFERENCES

1. Digital transformation handbook for primary health care: optimizing person-centred point of service systems. Geneva: World Health Organization; in press.
2. HL7 FHIR Release 5 [website]. 2.1.28.0 Data types. Ann Arbor (MI): Health Level 7 International; 2023 (<http://hl7.org/fhir/datatypes.html>, accessed 19 August 2023).
3. International Statistical Classification of Diseases and Related Health Problems (ICD). Geneva: World Health Organization; 2023 (<https://www.who.int/standards/classifications/classification-of-diseases>, accessed 19 August 2023).

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