

Process Design Table – Appendix G

Step	Description	Key Attributes	Descriptions	Feedback on Step description		Feedback on Attribute description		Any other comments	Questions (one question, or up to 3 if necessary)	Answers
				Does the step exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?	Does the attribute exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?			
1. Is there a functioning TB Recording and reporting system in place?	Assess whether the current TB recording system consistently applies WHO-recommended case definitions and recording standards across all facilities. Identify any gaps in functionality and ensure that both WHO and national TB guidelines are followed.	Case definitions	Ensure that the system records patient types such as bacteriologically confirmed, clinically diagnosed, pulmonary (PTB), extra pulmonary (EPTB), new, relapse, and other patients as per WHO standards.	Yes	There is a functioning TB and recording system in place. The system utilizes paper registers and forms that are used at the OPD, Lab, TB office and Ward. The forms are used at the community and TB Office. There are also TB treatment cards used to track patient treatment. All this ensures that the TB recording system follows the WHO and National guidelines	Yes	The guidelines provide clear case definitions in line with the WHO standards	The forms and registers have sections that define cases and the patients are categorized accordingly	What percentage of health facilities in your jurisdiction have a fully functional TB recording and reporting system that complies with WHO standards, and how often (e.g., annually) are these systems evaluated for compliance?	100% .quarterly supervision is used to evaluate compliance
		Recording and reporting standards	WHO sets standards for case definitions and data reporting formats. Verify whether these standards are being followed consistently across health facilities.			Yes	The forms and registers are reviewed and updated accordingly in line with the WHO and national guidelines			
		National guidelines in place	Ensure compliance with national TB and Leprosy guidelines, published in 2024, that are aligned with WHO's global standards.			Yes	There are national Guidelines for TB and Leprosy published in 2024, they are aligned to WHO's global standards.		What percentage of TB cases in your facility are recorded in compliance with WHO and national TB guidelines, and how often are compliance reviews conducted (e.g., quarterly)?	
		Staff capacity in TB	Ensure that healthcare workers handling TB recording and reporting are well-trained to avoid errors in data capture and management.			Yes	Health workers are trained before assigned the TB roles.		What percentage of TB staff are currently trained in data reporting procedures, and how often (e.g., every 6 months) are refresher training sessions conducted?	
2. Who needs to provide overall oversight and participate in decision making related to the adoption, design and implementation of an electronic and reporting system for TB?	Assemble a multi-stakeholder steering committee, including representatives from health facilities, government, and IT. Ensure all stakeholders are fully briefed on system objectives, available resources, TB treatment workflows, and relevant information-system regulations.	Users and beneficiaries	These stakeholders are critical to the system's success, ensuring proper use and benefit distribution, especially among TB care providers and policy-makers	Yes	There is a Technical Working Group (TWG) comprised of various stakeholders from Government, WHO, USAID, CDC and other donors, NGO's, academia and churches that provide oversight for TB	Yes	Users include TB officers, Volunteers, Nurses, Clinicians, Monitoring and Evaluation, Lab. The beneficiary is the patient	No	Are there key stakeholders or a steering committee that manages the system's design and implementation? Who are the designated stakeholders responsible for overseeing the TB recording system, and how frequently (e.g., annually) are their roles reviewed for clarity and accountability?	YES, NTLEP , Digital health , partners (GF,USAID,CDC ,EGPAF ,

		TB care providers	Frontline health workers responsible for entering patient data, managing cases, and following up with patients			Yes	These include TBO, Nurses, Volunteers, Clinicians and Lab	No		
		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.			Yes	The Ministry of Health sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.	The ministry controls the health activities for Malawi		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure			Yes	The IT experts operate under the Malawi e-government. They handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure	National TB Program is assigned in-house IT experts from e-government to support various systems		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.			Yes	District managers oversees TB activities in their respective district. They have a network of TB officers in different facilities	No		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations			Yes	The National TB Control Program oversee the TB activities across Malawi. Ensures alignment of the system with the country's TB control strategy and WHO's recommendations	No		
		Laboratory networks	Feed lab test results into the system, ensuring timely diagnosis and data accuracy.			Yes	There are various Laboratory networks across the country that offer various tests. The labs are critical for TB operations to provide tests and results.	Labs offer various tests. Other labs refer samples to advanced labs for services		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.			No	There are no legal experts that ensure compliance	No		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.			Yes	Organizations include CDC, who, Global Fund, WHO provide support, funding, or guidance for TB control initiatives	More organisations are stepping in to provide support		
3. Establish the primary objectives of building an electronic recording and reporting system for TB care and control	Establish clear objectives for the electronic system, with a focus on defining its design, content, and complexity.	Improve surveillance and public health	Enhance case detection, monitor trends, and provide real-time data for informed decision-making and public health interventions.	Yes	The National Guidelines provide clear guidelines that include Improving surveillance and public health, Improving Programme and resource management and Improving clinical care of individual patients	Yes	The current recording and reporting system enhance case detection, monitor trends for informed decision-making and public health interventions	No	What are the primary objectives of the TB recording and reporting system at your facility?	The primary objective is to improve patient clinical care, improve resource management and overall improve surveillance so that decisions can be made easily
		Improving Programme and resource management	Optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data.			Yes	The current reporting and recording system help optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data	No	How effectively is the TB recording system meeting its objectives of improving surveillance, resource management, and clinical care, and what measurable outcomes can demonstrate this success in the past year?	The current TB recording system uses paper register and forms that are consolidated quarterly, with this in mind, the system is not effective in meeting its objectives

		Improving clinical care of individual patients	Improve patient outcomes by ensuring timely follow-up, tracking adherence to treatment, and ensuring no patients are lost to follow-up.			Yes	There are TB treatment cards used currently that track treatment and help improving clinical care of individual patients	No	How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement?	The system is able to show treatment success rates, number of patients diagnosed and put on treatment, lost to follow-up and case detection rates. This data is consolidated once every quarter and the program is able to tell trends.
4. Identify Users and Beneficiaries of the system	Determine user roles and identify key system users, such as clinicians, lab technicians, and policymakers, to guide both the planning and implementation phases.	Who will be entering data	Health workers, clinicians, lab technicians, and surveillance officers responsible for inputting patient records, lab results, and treatment plans.	Yes	The current recording and reporting system identify TB Officers, Clinicians, Nurses, Volunteers, Lab, M&E and TB managers as key users of the system	Yes	According to the current system and the guidelines, the ones entering data include TB Officers, Clinicians, Nurses, Volunteers and Lab	The system has various registers in various departments that record patient details these include the Lab, TB Office, Wards and OPD	Who are the primary users (e.g., clinicians, lab technicians) of the TB system, and how often (e.g., daily, weekly) do they access the system to record or review data?	Clinicians, lab personnel and program staffs, Volunteers, TB Officers and Nurses
		Who will be using data directly while interacting with the system	Health workers and clinicians use real-time data for decision-making and managing patient care.			Yes	TB Officers, Nurses, Clinicians and Laboratory	Health workers and clinicians use real-time data for decision-making and managing patient care	Who will be entering data, using data, or receiving reports from the system?	Patient management and M&E
		Who will be viewing or receiving reports	Policymakers, district managers, and program coordinators who use system-generated reports to make policy decisions and allocate resources			Yes	Policymakers, district managers, M&E and program coordinators will be viewing and receiving reports	Supervision visits collect and consolidate data from all facilities, M&E will generate reports from the data for the program	How does the system support different types of users in their roles (e.g., data entry, case management, reporting)?	The system has registers for particular roles like TB Officers, Lab Clinicians that capture information relevant to the role
		Who will be extracting data for analysis	Health analysts and IT experts responsible for extracting data to identify trends and produce reports for TB surveillance and program performance evaluation.			Yes	Monitoring and Evaluation (M&E) extract data to identify trends and produce reports for TB surveillance and program performance evaluation	No		
5. Determine which Patient the system will coverage	Clarify which patient groups will be included in the system, such as TB patients, including MDR and latent cases, and establish a rationale for their inclusion. This will inform the choice of different aspects and workflows in the system design.	All diagnosed TB patients	Ensure that all diagnosed TB patients, including new and relapse cases, are covered by the system for accurate reporting.	Yes	The current WHO standards and TB Guidelines have tools covering all patient groups including MDR and latent cases	Yes	The current electronic and reporting system has registers for all diagnosed TB patients, including new and relapse cases, are covered by the system for accurate reporting		Does the TB recording system cover all diagnosed patient types, including MDR-TB and latent TB, and how often is coverage updated to include new patient groups?	Yes, there are different registers for different patient groups. These are updated together regularly together with the National guidelines
		only MDR-TB patients	Initially, the system may focus on MDR-TB patients as a priority group before expanding to other patient categories.			No	The system should focus on all the patient groups	No	Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system?	All patient subgroups are covered by the system
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			No	The system should focus on all the patient groups just like the current system	No		

		Links to different systems	Specifies the integration of other health systems to track different TB patient sub-groups (e.g., HIV co-infected)			Yes	Data from the current manual system once consolidated is also used in the DHIS 2 and HIV system, this shows the need for system integration	Data is formatted for use in other systems	Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	With HIV , TB EMR and DHIS 2.
6. Which locations the system cover	Assess whether the system will include all geographic areas and facility types (e.g., urban, rural, remote, public, private) or a subset. Plan accordingly to ensure comprehensive TB surveillance, with particular emphasis on including high-risk areas.	All locations and all providers of TB diagnostic and care service	The system should be implemented across all TB diagnostic and care facilities, whether public, private, or specialized (e.g., military hospitals, refugee camps	Yes	The current reporting and recording system included all geographical areas and facility types. This is according to the National Guidelines	Yes	The system should be implemented across all TB diagnostic and care facilities, whether public, private, or specialized (e.g., military hospitals, refugee camps	This is according to the guidelines to ensure compliance.	Does the TB recording system cover 100% of urban, rural, and remote areas in your jurisdiction, and how frequently (e.g., biannually) is this coverage evaluated?	The paper based system it coverage all TB registration faculties.
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	All geographical locations must be covered	This is according to the guidelines to ensure compliance.	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	Paper based system covers all types of health facilities.
		Type of facility	Consider the range of facility types (public, private, military, prison, etc.) to ensure that the system is adaptable to different settings.			Yes	All types of facilities must be covered	This is according to the guidelines to ensure compliance.	Are there specific facility types (e.g., public health centers, private clinics) that are excluded from the system's coverage?	No
7. Will the system be a stand-alone system or will it be integrated with other electronic systems	Map the entire data flow process from patient intake at clinics and labs to central reporting, identifying all data entry points and ensuring smooth, real-time data transfer. Additionally, determine whether the system will be standalone or integrated with existing health information systems (e.g., HIV, pharmacy, lab management) and map the necessary integration points.	Mapping all existing paper and electronic systems	Identify current systems (e.g., HIV, lab management) that need to be integrated with the TB system for consistent and unified reporting.	Yes	The current reporting and reporting system identified TB Office or OPD as a patient intake point where patients are registered in the registers. The patient is then referred to the laboratory where samples are taken and results are registered in the laboratory register. The patient is then referred to the TB Office where they are registered as patients and assigned treatment cards for treatment tracking and FollowUp	Yes	The current systems need to be integrated and these include the HIV system, DHIS 2, TB EMR and E-Health System. This will ensure consistent reporting	All systems capturing TB data or requiring TB data must be integrated to ensure data consistency.	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	The plan to integrate all systems to ensure consistency
		Integrate with existing systems e.g. DHIS2 or HIV System	Integrate with national health information systems (e.g., DHIS2, HIV program) to avoid data duplication and streamline reporting processes.			Yes	Integrate with national health information systems HIV system that include DHIS 2, TB EMR and E-Health System to avoid data duplication and streamline reporting processes	Integrate with all necessary systems	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	The aggregated data is already integrated to DHIS 2. Patient level EMR is underdevelopment.
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	Data is collected according to the WHO standards and is formatted accordingly to ensure smooth integration	For the electronic system this must be ensured		
		Security Requirements	Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.			No	The current system does not have this feature	This is a very important feature to ensure system security and must be implemented	What challenges might arise during system integration (e.g., data compatibility, security, training)?	The anticipated challenges include different data formats that may not be compatible, standard security requirements for the systems, willingness to share data from various players.
8. What elements of paper-based recording and reporting should be maintained	Retain critical paper records as necessary while planning for digital migration. Identify essential paper-based records (e.g., patient history, treatment plans) for transition to the electronic system, and implement a phased transition plan to ensure no data loss during the migration process.	Legal requirements	Certain legal obligations may require retaining paper-based records for a specific period before fully transitioning to a digital system.	Yes	Paper records are retained for 7 years following the guidelines. While transitioning to the electronic system, it is important to retain all the paper records to ensure smooth migration	Yes	The guidelines recommend retaining the paper records for 7 years.	This will ensure compliance.	What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system?	
		Patient well being	Ensure that critical paper-based records (e.g., patient history) are maintained for proper follow-up and patient care, especially during the transition phase.			Yes	Patient history and treatment tracking is important when managing the patient and retaining the records will ensure good patient well-being	This will ensure good patient well being	Do you believe that some data should remain paper-based for a certain period after the electronic system is implemented? Why or why not?	In the near future , all facilities are not expected to be managing their data electronically

		Phased transition.	Gradually move from paper to digital systems, allowing time for healthcare providers to adjust to the new technology while minimizing disruptions to TB care.			Yes	As good practice, a phased transition will ensure that the system is functioning well, allowing time for healthcare providers to adjust to the new technology while minimizing disruptions to TB care.	No	How do you currently ensure that essential paper records are preserved?	Printing hard cover registers,
9. Is the basic unit of recording clinical data a patient, a case or a group of cases?	Decide on the data entry units for clinical data, determining whether it will be recorded at the patient, case, or group level, and ensure consistency across the system.	Unique Patient Data (Unique personal identifiers)	Each patient should have a unique identifier to ensure accurate tracking and reporting of their health status, avoiding duplication of records	Yes	The current electronic and reporting system use the unique patient data or patient level data.	Yes	The electronic and reporting system assign each patient a TB number that uniquely identifies them to help avoiding duplication.	No	Is the unit of data entry at your facility (patient, case, or group) appropriate for accurate reporting, and how often is this reviewed to ensure optimal data management? Do you believe that recording data at a different unit level (patient vs. case vs. group of cases) would improve data management? Why or why not? What benefits do you foresee in using an alternative unit for recording data?	Patient data is registered uniquely to strengthen patient management. This is reviewed alongside the national guidelines No. Recording at the patient level ensures that patients are managed well. This unit is also flexible that it can be aggregated Easy reporting and data consolidating.
		Aggregated Data (sub-national or local patient identifiers)	Data can also be aggregated at the local level (district, facility) for broader analysis without losing patient-specific information.			Yes	Data from facilities is consolidated and aggregated at different levels.	Aggregated data is used for reporting and use in other systems like DHIS 2		
10. Determine what data items that needs to be captured	Develop and maintain an updated data dictionary that identifies essential data variables for reporting, management, and surveillance, ensuring alignment with WHO guidelines and reporting requirements.	Programme management and TB surveillance data	Collect essential data such as patient demographics, case type, and treatment progress to monitor TB cases and evaluate program effectiveness.	Yes	The current recording and reporting system identifies various types of essential data that include name of health facility, point of registration, patient's name, age, gender, location, district, phone number, reasons for diagnosis, HIV status, Treatment history and examination requested. This ensures alignment with WHO guidelines for reporting	Yes	The current system collects include name of health facility, point of registration, patient's name, age, gender, location, district, phone number, reasons for diagnosis, HIV status, Treatment history and examination requested that help monitor TB cases and eventually help program effectiveness	Registers and forms have clear Programme management and TB surveillance data	What essential data variables are captured by the TB system according to WHO guidelines, and how frequently is the data dictionary updated to reflect any changes? How do these data items align with WHO guidelines or national TB reporting standards? Are there additional data items that you believe should be included to improve patient care or program management?	Name of health facility, point of registration, patient's name, age, gender, location, district, phone number, reasons for diagnosis, HIV status, Treatment history and examination requested These are defined by the WHO standards and adopted by the National Guidelines. These is need to include GIS data to predict TB hotspots easily
		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	The current system has TB Treatment Cards that track patient's treatment and FollowUp at every stage	No		
		Work flow management	Data fields that track the workflow of health workers, ensuring that patients receive care at every step of the TB care continuum.			Yes	Each station that the patient go through has a register that records care that the patient received showing work flow	OPD, TB Office and Lab all have registers		
		system administration data items	Data related to the management of the system itself, such as user access logs and system performance metrics.			No	Currently no	This must be implemented in the new system		

		System monitoring and audit data items	Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies.			No	Not in the current system	This must be implemented		
11. Identify who enters data, where and when will data be entered, and how do data flow within the system	Develop a data flow diagram that identifies where and when data will be entered and how it will flow through the system, mapping the entire process from clinics and labs to central reporting.	Data entry points	Describe all the situations where data is entered, such as clinics, labs, and hospitals. Map data entry by healthcare staff (e.g., clinicians, lab technicians).	Yes	The Guidelines described a workflow from registration to treatment completion. A patient is registered either at TB Office or OPD or ward in the TB registration register. They are then referred to the Laboratory for sample collection and registration and testing. They are then referred to the TB Office for registration in the TB patient register and enrolled in TB treatment register for TB treatment register.	Yes	Data is entered at the Health Facilities, Clinics and Hospitals. A patient is registered either at TB Office or OPD or ward in the TB registration register. They are then referred to the Laboratory for sample collection and registration and testing. They are then referred to the TB Office for registration in the TB patient register and enrolled in TB treatment register for TB treatment register.	TB Officers, Clinicians, Nurses and Laboratory Technicians enter the data in various data entry points.	Who will be entering data into the TB recording and reporting system?	DHIS 2 entered at district level for all district facilities. For central hospitals , it is entered at Central hospital level. For the TB reporting and recording system, TB Officers, Clinicians, Nurses and Laboratory Technicians
		Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			Yes	Currently there is duplication data entry at all points and this increase workload.	It will be good to have one patient registration sites and the other sites should just update their tasks	Are there any bottlenecks or challenges in the data entry process?	Timeliness
		Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	A patient is registered either at TB Office or OPD or ward in the TB registration register. They are then referred to the Laboratory for sample collection and registration and testing. They are then referred to the TB Office for registration in the TB patient register and enrolled in TB treatment register for TB treatment register.		How does data flow from the point of data collection to reporting?	Paper based reports are compiled and collected from health facilities once every quarter by a supervision team. The team then consolidates all the data collected and process the reports.
		Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			Yes	Data is recorded in real time. But since the current system is paper based, transmission is not in real time	Real time data transmission is required	What percentage of TB data is entered in real-time, and what is the average delay (in hours or days) between data collection and system entry over the past 3 months? What is the typical turnaround time from data collection to reporting?	DHIS quarterly entered and reporting rate is at 90% and above Reporting is done once the quarterly supervisions are done.

12. What data quality assurance processes are required?	Set up data validation protocols, regular audits, and error-checking processes. Implement detailed validation checks that specify the people involved, their responsibilities, the timing of checks, the procedures followed, and the handling of records at each stage.	Data checks at the point of entry.	Implement validation protocols to ensure data accuracy and completeness during entry.	Yes	Data Quality Audits (DQA) is done regularly to ensure quality. Data is validated during these audits and errors are collected.	Yes	When entering data in the registers and forms, the data is checked in the current system	Need to enhance this in the electronic system	What data quality assurance protocols (e.g., audits, validation checks) are currently in place, and how often are they reviewed to ensure data accuracy and completeness? What percentage of data quality issues are flagged during audits, and how often (e.g., monthly) are these challenges addressed and resolved?	There are validation checks in DHIS 2 , Data quality assessments are conducted quarterly
		System generated alerts	Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries.			No	This is not in the current system	Need to implement this		
		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			No	This is not in the current system	Need to implement this		
		Regular audits.	Conduct regular data quality audits to identify gaps and ensure data integrity. Use manual checks and automated validation to clean the data.			Yes	Data Quality Audits (DQA) is done monthly to ensure quality	Continue this in the new system		
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			Yes	Supervision visits are done by the program team to ensure compliance	Continue this in the new system		
13. How is feedback provided to the system?	Design interactive user interfaces that provide real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies.	Engaging users	Ensure the system allows for feedback loops that engage data-entry users actively, making data entry an interactive process.	No	The current system uses paper forms and registers and this is not implemented	No	The current system is paper based	This is recommended. The interfaces designed should be able to engage users for feedback making data entry an interactive process	What percentage of users receive real-time notifications for incomplete data entries, and how frequently (e.g., quarterly) are feedback loops evaluated to improve system accuracy? What challenges do users face in receiving and acting on feedback from the system?	Currently 0% because the system is paper based This is not applicable
		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			No	The current system does not give real-time feedback	When building the new system, consider building feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.		

14. What standard outputs, reports and other analyses are required?	Identify standard outputs for each user group, including data visualizations and statistical tools, and define standard reports for stakeholders (e.g., case notifications, treatment outcomes). Specify the audience for each output or report, ensuring that visual displays such as graphs, maps of spatial and temporal trends, and potential outbreaks can be generated within the system or through external software (e.g., statistical, visualization, or GIS packages).	Data visualization	Create visual outputs such as charts, graphs, and maps for TB case trends, outbreaks, and treatment outcomes to support decision-making.	Yes	The current system, data is consolidated during the supervision visits and various reports are generated. Various visualizations, charts and statistical analyses are done outside the system	No	The current system does not produce data visualizations. These are done outside the system	The new system must implement visual outputs for data to support decision making	What standard reports (e.g., case notifications, treatment outcomes) are generated by the system, and how frequently are they produced and distributed to stakeholders? What additional analyses do you believe are necessary for effective TB management but are currently not available? What percentage of standard TB reports (e.g., case notifications, treatment outcomes) were delayed in the past year, and how often have these delays affected decision-making processes?	Quarterly produced < reporting rate monitored at national level through DHIS 2
		Reports	Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.			Yes	The consolidated data is used to generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.	This must be enhanced in the new system		
		Statistical Analysis	Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software.			No	The current system does not produce statistical analyses	The new system should include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software		
15. What are the data entry screen or interface requirements?	Consult with stakeholders to design user-friendly data entry screens and interfaces that are intuitive and familiar, ensuring they meet the needs of all users.	System language	Set up system language options based on users' preferences and comfort. Ensure that technical language is minimized for ease of use.	Yes	This relates to the current designs for the forms and registers that were designed in consultation with WHO standards and various input from stakeholders	Yes	The current registers and forms are in English and Chichewa based on the user's [references	It will be good to consider maintaining the languages for the new system to ensure ease of use	How often do users receive formal training on the TB recording system, and what percentage of staff have completed training in the past 12 months? What specific tools (e.g., software, dashboards) are used to generate reports, and how are they shared with relevant stakeholders? What specific features in a new TB recording system would improve your workflow and patient care, and by when should these features be implemented to optimize care delivery?	Not regular for dhis 2 For EMR : is being developed , initial trainings are being implemented. Statistical Software like SPSS, and Excel are used to generate reports and various charts Dashboards, GIS, SMS's will help improve patient care. Single data entry interfaces will help improve patient workflow

		Screen layout.	Ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers.			No	The current system is paper based	The design for the new system must ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers		
		Use date or time formats	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.			No	The current system is paper based	The design for the new system must implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.		
16. How will Data Confidentiality and Security be ensured?	Train users on data confidentiality and the importance of compliance with data protection laws. Implement robust security measures, including encryption, access control, secure data transmission, and physical security. Ensure users formally commit to these standards by signing a document outlining their responsibilities regarding data handling.	Access control Mechanisms	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.	Yes	This relates to the current practice where users are trained on securing patient data to ensure confidentiality	Yes	This relate to the current practice where only authorised users access particular registers and patient data	For the new system implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.	What percentage of TB data is encrypted, and how frequently (e.g., quarterly) are security measures such as access control and encryption tested for potential vulnerabilities?	100% of the patient data must be encrypted and must be tested together with the DQA
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			No	This does not apply	For the new system, Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts		
		Data Anonymization	Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.			No	This does not apply	For the new system, Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.		
		Encryption	Encrypt data during transmission and storage to prevent unauthorized access and ensure data security.			No	This does not apply	For the new system, encrypt data during transmission and storage to prevent unauthorized access and ensure data security.		
		Physical Security	Ensure secure physical locations for servers and backups to protect against theft or damage.			Yes	There are secure physical locations for servers and registers	There are secure physical locations for servers and registers		
									What are the most common security risks encountered in the past year, and how frequently (e.g., monthly) are data security protocols updated or audited to address these risks?	Missing registers is the main challenge. Security protocols are update whenever the guidelines are updated.

17. What staffing is required?	Plan for user roles and training to ensure sustainability, while defining staffing needs for the effective operation and management of the system. Develop a comprehensive staffing plan that outlines required roles and responsibilities.	User Roles	Identify necessary roles (clinicians, IT personnel, lab staff) required to operate the system at various levels (local, district, national).	Yes	In the current setup, there is a clear plan for the user roles that include TB Officers, TB Nurses, Clinicians, Lab Officers. There is a proper plan for training for the staff according to the national guidelines.	Yes	The current system identified necessary roles that include TB Officers, Nurses, Clinicians and Lab Officers at the facility level. There are district managers at the district level and M&E and managers at the national level.		Are all roles and responsibilities for TB system users (e.g., data entry, analysis, reporting) clearly defined and reviewed at least once per year to ensure clarity and accountability?	Yes, (for DHIS 2 and the paper based system). This is in line with the National Guidelines
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			No	In the current system there is no contingency plan for staff turnover	To implement the electronic system, plan for staff turnover	What percentage of staff are trained for data entry and system maintenance, and how frequently (e.g., annually) is staffing capacity assessed to ensure adequate coverage? What challenges do you face regarding staff capacity or turnover?	This does not apply to the current system. There is high staff turnover due to staff looking for greener pastures
		Training	Regular training ensures that all users understand how to use the system and are aware of best practices for data entry and reporting.			Yes	Users are trained before assigned the TB role. They are trained at various intervals whenever there are changes in the guidelines. There are also trainings during supervisions	Maintain the current training schedules according to the guidelines		
18. What user Support is needed?	Establish clear response times and support mechanisms for user issues, including providing "how-to" guides or easy-to-follow standard operating procedures (SOPs), help desk or hotline services with defined response times, and a web-based discussion forum. Facilitate sharing of experiences and learning from users in other countries that have transitioned from paper-based to electronic recording and reporting.	Helpdesk services	Provide a dedicated helpdesk with clearly defined response times for addressing user issues and system troubleshooting	No	This step does not relate to any steps in the current setup.	No	Currently there is no helpdesk service	For the proposed system, provide a dedicated helpdesk with clearly defined response times for addressing user issues and system troubleshooting	What kind of technical support is available to users when there are system issues or data-related challenges? What percentage of technical support requests are resolved within the agreed service level timeframe, and what is the average resolution time (in hours or days) for the past 6 months?	For the other systems like HIV and DHIS 2, there are district and national support teams for the systems Currently the requests are resolved within 2 days.
		Technical assistance	Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.			No	The current paper based system does not have this.	Plan for technical assistance for the the new system	Are there "how-to" guides or standard operating procedures (SOPs) available for users?	For the current systems, there are how to guides
		Training	Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system.			Yes	There are ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system	Maintain the training plan		
19. What technical support is needed?	Plan for system administration, hardware maintenance, and bug fixes, while determining the technical support needed for the system's infrastructure and ongoing software maintenance.	System administration	Assign a dedicated team to manage day-to-day system operations, perform regular data backups, and handle system maintenance tasks (e.g., software updates, bug fixes) to ensure smooth system functionality.	No	The step does not have this step.	No	There is no system administration for the current paper based system	For the new system, assign a dedicated team to manage day-to-day system operations, perform regular data backups, and handle system maintenance tasks (e.g., software updates, bug fixes) to ensure smooth system functionality.	What specific technical support (e.g., helpdesk, software updates) is available to maintain the TB system, and how frequently are maintenance and bug fixes implemented? How often do technical issues affect your ability to use the system effectively?	Currently for the TB system, this does not apply This does not apply to the current system

		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			No	The current system does not use any hardware	For the new system, Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.	What specific hardware or software issues are most common, and how often do these issues disrupt TB data entry or reporting in a typical month?	This does not apply to the current system
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			No	The current system, this does not apply	For the new system plan to have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.		
20. What level of service availability, response times and contingency planning is required?	Establish business continuity plans and service level agreements that address system downtime and ensure continuity of operations through effective contingency planning.	Response times	Set acceptable response times for system issues, ensuring quick resolution to minimize downtime.	No	This step does not relate to any steps in the current system	No	This does not relate	For the new system, set acceptable response times for system issues, ensuring quick resolution to minimize downtime	How often does system downtime affect TB data reporting, and that is the expected response time to resolve such issues to minimize disruption?	This does not apply to the current system
		Service level agreements	Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.			No	We do not have service level agreements in the current system	This must be planned and implemented in the proposed system	Are service level agreements in place to ensure consistent system availability?	This must be established for the new system
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			No	There is no business continuity plan in the current system	For the proposed system, create contingency plans for system failures, including backup servers and recovery procedures		
21. What funding is required for both start-up and routine operations	Plan for ongoing costs, including hardware, software, staffing, and services, while ensuring a long-term budget strategy that maintains the system's sustainability beyond the initial implementation phase.	capital costs	Estimate the initial investment required for system infrastructure, including hardware, software, and training	No	This step does not relate to any current steps	No	This step does not relate to any attribute	For the new system, Estimate the initial investment required for system infrastructure, including hardware, software, and training	Is there a sustainable funding plan in place for the TB recording system, and how often is funding reviewed to ensure continuity of operations?	Yes. There is a funding plan that is used to run the current system. It is reviewed annually during the national budget
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			No	This step does not relate to any attribute	For the new system, develop a budget for regular hardware replacements to prevent system failures caused by outdated technology.		
		Software development, maintenance and licenses	Include ongoing costs for software updates, licenses, and feature enhancements			No	This step does not relate to any attribute	For the proposed systems, Include ongoing costs for software updates, licenses, and feature enhancements	How sustainable is the system beyond the initial implementation phase?	The system must be planned beyond implementation phase
		Staffing and Project management	Ensure funding for staff salaries and project managers to maintain system functionality.			No	This step does not relate to any attribute	For the new system, plan funding for staff salaries and project managers to maintain system functionality		

22. How long will electronic data be retained and will they be archived?	Establish data retention policies that define retention periods, secure archiving processes, and retrieval mechanisms, ensuring secure access to archived data.	Retention policy	Define how long TB data will be retained in the system, ensuring compliance with national data storage	Yes	There are data retention policies that define retention periods, secure archiving processes, and retrieval mechanisms, ensuring secure access to archived data	Yes	According to the National guidelines, TB data is retained for 7 years	This must be maintained in the new system to ensure compliance	What is the current data retention policy for TB patient records, and how often is this policy reviewed for compliance with national regulations?	the current plans recommends data to be retained for 7 years in compliance with the national guidelines. This is reviewed every 5 years
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			Yes	Currently, archived data can only be accessed by authorised staff in compliance with the national guidelines	For the new system, Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive	How is secure access to archived data ensured?	Implement role based access methods .
		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			No	The current system simply archive data in the secure physical locations	For the new system, Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data	How long do you believe electronic data should be retained to support patient care and public health initiatives?	Data must be retained for 7 years.
23. How is the electronic recording and reporting software made available to users?	Determine how users will access the system based on connectivity and infrastructure needs, and plan the technical infrastructure, including servers, software, and hardware, to support this access.	User access methods	Determine how users will access the system based on internet availability, considering both online and offline functionality.	No	This step does not relate to the current system	No	The current paper based system does not have this	This must be considered in the new system. Relate with the implementation for the existing systems that use both online and offline access methods	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity?	The existing systems that include DHIS 2 and HIV system have both offline and online access to ensure that unstable connectivity does not affect data entry
		Connectivity infrastructure	Ensure that necessary network infrastructure (e.g., LAN, internet, mobile networks) is in place to facilitate reliable access to the system across various healthcare settings.			Yes	There is Local area network in place mobile network and internet coverage.	There is Local area network in place mobile network and internet coverage	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Tablets, printers, computers, servers, networks
24. Device Requirements	Identify the devices users will need to access the system, ensuring compatibility, usability, and security for long-term use.	Device Requirements	Identify the types of devices (e.g., computers, tablets) that will be needed to access the system and ensure they are available across different healthcare facilities.	No	This does not relate to any current step	No	The current system does not require any devices.	For the new system consider tablets, smartphones and computers to access the system	What devices (e.g., tablets, computers) are currently used for TB data management, and are there plans to upgrade or replace outdated devices within the next fiscal year?	Tablets, computers, smartphones
		Usability and security	Ensure that devices are user-friendly and secure, with appropriate measures to protect data and ensure that users can operate them with varying levels of digital literacy.			No	The current system is paper based	For the new system, ensure that devices are user-friendly and secure, with appropriate measures to protect data and ensure that users can operate them with varying levels of digital literacy.	Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	Yes, some computers are old. Need for more servers to host new systems
25. What database software is required	Assess database functionality and compatibility with system requirements to determine the appropriate database	Functionality	Choose database software (e.g., SQL, NoSQL) that meets system needs for scalability, security, and integration with other health data systems.	No	The current system is paper based and this does not relate	Yes	The step does not relate to the current system	For the new system, to ensure integration, there is need to use similar database software SQL that is used for the HIV system and DHIS 2	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	SQL database will suit the system since it is proven in the health sector.

	software needed based on system needs.	Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			No	The current system is paper based	For easy integration, adopt SQL which is used in DHIS 2 AND HIV system	How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)? Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission?	The chosen database will have to share data periodically with the existing systems The database will require real-time data updates
26. Where will the servers be located?	Assess server locations to ensure legal compliance and data accessibility, and decide on server placement based on legal requirements and data ownership considerations.	Data hosting legal requirements	Ensure that server locations comply with national data-hosting laws and provide easy access to data for authorized users.	Yes	This relates to the current guidelines that require servers be hosted in country.	Yes	The national guidelines recommend that data hosting is within country to ensure compliance.	Data must be hosted within country for compliance	Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users? How will the server location affect system uptime, data access, and security, especially in rural or remote areas?	The servers must be located within the country. One layer at the ministry data center, another for the local health centers Local servers will allow data to be accessed locally anytime
		Data Ownership	Establish clear ownership of the data stored on the servers, ensuring that access rights and responsibilities are defined for all stakeholders involved in data management.			Yes	This national guidelines recommends that all the data is owned by government	Data is owned by government	Who is responsible for the ownership and management of data stored on TB system servers, and how often is this ownership reviewed to ensure compliance with legal standards?	Government of Malawi is responsible for the data ownership and management
27. What communications networks are needed	Plan for network infrastructure by considering LAN, internet, and mobile options, and identify suitable communication networks for effective data transmission.	Local area network, Internet and Mobile network	Implement reliable network infrastructure (LAN, mobile, internet) to ensure seamless data transmission from rural to urban healthcare facilities and support effective communication among healthcare providers.	No	The step does not relate	No	The paper based system does not use local area network	For the new system, Implement reliable network infrastructure (LAN, mobile, internet) to ensure seamless data transmission from rural to urban healthcare facilities and support effective communication among healthcare providers	What communications networks are in place to support the TB system, and how often is network reliability evaluated, especially in rural areas? How efficiently is TB data transmitted from rural to urban healthcare facilities, and what percentage of data is successfully transmitted without delay each month?	There is LAN, Government Wide Area Network and Mobile networks that support the existing systems. Currently, TB data is manually collected every quarter. But it is recommended that this can be transmitted in real time
		Network Reliability	Ensure that the network infrastructure is reliable and has contingency plans in place for potential outages, particularly in rural areas where connectivity may be less stable.			No	The current system did not require network to function	For the new system, Ensure that the network infrastructure is reliable and has contingency plans in place for potential outages, particularly in rural areas where connectivity may be less stable	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	Currently, TB data is b=not affected as it is a manual system
28. What are the electrical power Needs?	Plan for power availability and backup systems to ensure continuous operation, ensuring reliable power	Power availability	Ensure that health facilities have reliable power sources for system operations, including alternative backup options in case of outages.	Yes	There is power availability and backup power at the health facilities to ensure continuous operations	Yes	There is power at the facility and the existing system rely on that power	Health facilities have power and backup solar power	What backup power options are available at your facility to ensure continuous system operation?	Solar Power

	sources for both urban and rural areas, including backup options.	Backup power	Install uninterruptible power supplies (UPS) and generators in health facilities to ensure that systems remain operational during power outages, safeguarding data integrity and availability			Yes	There is solar power backup to support systems at the facility	There is solar power backup to support systems at the facility	Does your facility have reliable uninterruptible power supplies (UPS) or backup generators, and how often have these systems been activated to maintain functionality during power outages?	During power outages, the facility depends on solar power
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