Process Design Table – Appendix D

Step	Description	Key Attributes	Descriptions	Feedback on Step description		Feedback on Attribute description		Any other comments	Questions	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?	Any questions?	(one question, or up to 3 if necessary)	
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 TB recording and reporting system in place at the facility that applies WHO recommended case definitions and recording standards. This system complies to the National Guidelines	Yes	The system records all patient types including bacteriologically confirmed, clinically diagnosed, pulmonary (PTB), extra pulmonary (EPTB), new, relapse, and other patients as per WHO standards	All patients are recorded in the system	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?	95% of the facilities have a fully functional TB recording system
		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 system follows the WHO set standards for case definitions and data reporting formats	The system follow the WHO standards for case definitions		
		National guidelines in place	Ensure compliance with national TB and Leprosy guidelines, published in 2024, that are aligned with WHO's global standards.			Yes	The system complies with the national guidelines of 2024	The system complies with the national guidelines	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)?	100% of the TB cases are recorded in compliance with the WHO and National guidelines
		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	All health workers are trained in TB before handling TB recording and reporting are well-trained to avoid errors in data capture and management	All TB health workers are trained in TB recording	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?	100% of TB health workers are trained in TB recording and reporting. The is mentorship that happen every quarter
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 multi-stakeholder steering committee, the technical TB working group that has representatives from donors, health institutions, academia, NGO's and IT that oversee TB in Malawi	Yes	For the system success, there are TB Officers, Clinicians, Nurses, Lab Officers that use the system. The Patient is the main beneficiary for the system.	TBO, Clinicians, Nurses, Lab Officers and Patients	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?	There is a technical working group from various stakeholders that manages the system design and implementation WHO, CDC, Ministry of Health. Their role is reviewed once every 5 years

		TB care providers	Frontline health workers responsible for entering patient data, managing cases, and following up with patients			Yes	TB care providers include volunteers, Nurses, Clinicians, Lab Officers and TBO'S	Volunteers, Nurses, Clinicians, Lab Officers and TBO'S		
		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.			Yes	The Ministry of Health has the National TB Control Program and it Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.	The ministry of health sets policy and controls oversees the TB activities		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure			Yes	Government and partner IT experts handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure	IT experts are at the center for system management for TB		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.			Yes	District managers oversee health activities in the district including TB. They are responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts	No		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations			Yes	This is a department in the Ministry of health establish to oversee TB. It 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	Lab provide tests for TB	Various Laboratories test TB samples and provide results to the TBO's		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.			No	There are no legal experts currently	Legal experts are required to ensure compliance		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.			Yes	Various external agencies like WHO, CDC, USAID, Global Fund, Stop TB provide support	Stakeholders and donors provide funding support and guidance for TB control		
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 current reporting and recording system aims to improve surveillance, improve resource management and improve patient care in compliance with the national guidelines	Yes	The system records data that eventually enhances case detection and data from the system enables users to monitor trends thus improving surveillance	The electronic system should enhance case detection, monitor trends, and provide real-time data for informed decision-making and public health interventions	What are the primary objectives of the TB recording and reporting system at your facility?	Improve surveillance, improve resource management and improve patient care
		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 system should be able to tract resources allocated so that they can be well managed	Patient drugs, lab reagents and other resources must be well managed by the systems	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 system is effective in meeting its objectives. However there is room for improvement if this can be done in real time.

		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	The patient treatment is managed using treatment cards that ensures improvement of patient outcomes by ensuring timely follow-up, tracking adherence to treatment, and ensuring no patients are lost to follow-up	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 us patient treatment progress and in the past 6 months we were able to track defaulters easily
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	Following the National Guidelines, the key system users include Clinicians, TB Officers, Nurses, Lab Officers, Data Entry Clerks and Monitoring and Evaluation (M&E)	Yes	Clinicians, TB Officers, Nurses, Lab Officers are responsible for inputting patient data	No	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? Who will be entering data, using data, or receiving reports from the system? How does the system support different types of users in their roles (e.g., data entry, case management, reporting)?	Clinicians, TB Officers, Nurses, Lab Officers. They access the system daily to record data. Clinicians, TB Officers, Nurses, Lab Officers will be entering data. M&E, managers and stakeholders will be using the data and receive the reports The system support various roles depending on the user function at the facility
		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	Clinicians, TB Officers, Nurses, Lab Officers use the data directly	Clinicians, TB Officers, Nurses, Lab Officers use the data directly		
		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, and program coordinators who use system-generated reports to make policy decisions and allocate resources	Policymakers, district managers, and program coordinators who use system-generated reports to make policy decisions and allocate resources		
		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	M&E are responsible for for extracting data to identify trends and produce reports for TB surveillance and program performance evaluation	M&E		
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 system covers all diagnosed TB cases	Yes	All diagnosed TB patients, including new and relapse cases, are covered by the system for accurate reporting.	All diagnosed cases are covered	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?	All TB diagnosed cases are covered and this is in compliance 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	All diagnosed cases are covered	All diagnosed cases are covered	Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system?	All diagnosed cases are covered
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			No	All diagnosed cases are covered	All diagnosed cases are covered		

# / Question	Guidance	Element	Element description							
		Links to different systems	Specifies the integration of other health systems to track different TB patient sub-groups (e.g., HIV co-infected)			Yes	The recording and reporting system is linked to HIV system, TB EMAR and DHIS 2		Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	Yes. Data from the TB system is integrated in the HIV system, DHIS 2 and TB EMR
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 system the system will include all geographic areas and facility types (e.g., urban, rural, remote, public, private)	Yes	The system should be implemented across all TB diagnostic and care facilities, whether public, private, or specialized	The system should be implemented across all TB diagnostic and care facilities, whether public, private, or specialized	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?	Yes. The system covers 100% of facilities across the country
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	The system is implemented in all geographic areas	No	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	Yes, all types of facilities are covered
		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	The system is implemented in all types of facilities	All types of facilities	Are there specific facility types (e.g., public health centers, private clinics) that are excluded from the system's coverage?	No. All types of facilities are covered
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	Patients are registered at the TB Office/OPD or Ward. They are then referred to the lab for sample collection and testing. They are then referred to the TB Office for results and registration in the TB treatment register where treatment is managed using treatment cards. Data from facilities is collected quarterly to National TB control program where it is consolidated for reporting by M&E	Yes	The current relevant systems to be integrated include HIV system, DHIS 2, TB EMR	HIV system, DHIS 2, TB EMR	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	The system is intended to be integrated
		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 HIV System, DHIS 2, TB EMR	Integrate with HIV System, DHIS 2, TB EMR	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	Benefits include data consistency, reduction in workload, reduced patient redundancy and accurate reporting
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	Ensure that the system data is formatted correctly as required by other systems	Ensure correct data format		
		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 implement any security measures	For the proposed system, Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.	What challenges might arise during system integration (e.g., data compatibility, security, training)?	Data compatibility, security concerns
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	Retain elements of the current system to ensure no data loss during migration	No	This is not legally required	Not legally required	What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system?	The registers and the treatment cared must be retained because they contain rich information about the patient
		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	For patient well-being, ensure that paper based records are kept for history and references	No	Do you believe that some data should remain paper-based for a certain period after the electronic system is implemented? Why or why not?	Yes. The information contain patient history and they are important in managing patients.
		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	Gradually move from paper to digital systems, allowing time for healthcare providers to adjust to the new technology while minimizing disruptions to TB care	Gradually move from paper to digital systems, allowing time for healthcare providers to adjust to the new technology while minimizing disruptions to TB care	How do you currently ensure that essential paper records are preserved?	The records are safely stored in lockable offices

# / Question	Description	Data category	Explanation	Fit	Comment	Y/N	Current status	Gap	Interview questions	Responses
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 step fit. Data entry is done on each patient and it is later aggregated for analysis purposes.	Yes	There are unique identifiers that are called TB number for each patient	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?	The unit of recording is patient level and this is reviewed every 5 years No. Recording at patient levels enables the program to have detailed information on TB. This data can still be aggregated Using aggregated data will ease workload while diluting value of the data
		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 is corrected from all facilities and aggregated during quarterly supervisions	No		
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 data collection tools has essential data variables for reporting, management and surveillance	Yes	The current tools collect essential data such as patient demographics, case type, and treatment progress to monitor TB cases and evaluate program effectiveness	The current tools collect 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?	patient demographics, case type, treatment progress, location, occupation, tests types. This is updated every 5 years These are defined by the national guidelines that follow the WHO standards GIS data to determine hotspots
		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	The current tools track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.	Patient management data items are adequately collected		
		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	The current tools record data fields that track the workflow of health workers, ensuring that patients receive care at every step of the TB care continuum			
		system administration data items	Data related to the management of the system itself, such as user access logs and system performance metrics.			No	The current system uses paper registers and this does not apply	For the new system, this data must be captured		
		System monitoring and audit data items	Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies.			No	The current system uses paper registers and this does not apply	For the new system, this data must be captured		

# / Question	Description	Element	Element Description	Fits?	Comment	Y/N	Current System	Improvement / New System	Question	Answer
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 step fits. The key data entry points are including TB Office, OPD, Wards and Lab. Patients are registered at the TB office or OPD or Wards where demographics and vital signs are collected. The patient then referred to the lab for sample collection and testing. The patient then moves to the TB Office for test results, registration in the TB register and treatment administration.	Yes	The key data entry points are including TB Office, OPD, Wards and Lab. Patients are registered at the TB office or OPD or Wards where demographics and vital signs are collected. The patient then referred to the lab for sample collection and testing. The patient then moves to the TB Office for test results, registration in the TB register and treatment administration	The key data entry points are including TB Office, OPD, Wards and Lab.	Who will be entering data into the TB recording and reporting system?	These include Nurses, Lab Officers, TB Officers and Clinicians
		Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			Yes	At each data entry point, staff only enter data vital to the service they are giving.	To improve this, it would be better to have a single data entry point for patient demographics in the electronic system	Are there any bottlenecks or challenges in the data entry process?	Same data is entered multiple times in the different registers, this increase workload.
		Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	Data is collected at the local health centers and during quarterly supervisions, data is corrected at district level and passed to national level for consolidating and reporting	No	How does data flow from the point of data collection to reporting?	Data is collected at the local health centers then consolidated at the district levels then finally at the national level where reporting is done.
		Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			No	The current system does not transmit data in real time because it uses papers	The data is transmitted manually to the central point and this is done quarterly	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?	
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 are done monthly to ensure data quality	No	This is not applicable to the current paper system	In the new system, Implement validation protocols to ensure data accuracy and completeness during entry	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?	Data quality audits done monthly to ensure data quality. Reviewed every 5 years
		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 applicable to the current paper system	In the new system, set up alerts that Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries		

		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			No	This is not applicable to the current paper system	In the new system, Use automated algorithms to flag errors, anomalies, or missing data for review and correction.		
		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	There are monthly Data Quality Audits to identify gaps and ensure data integrity	For the new system implement the automated audits		
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			Yes	NTP conducts supervisions quarterly to ensure compliance	Continue 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	This step does not relate to any in the current system	No	This is not applicable to the current paper system	For the new system, ensure the system allows for feedback loops that engage data-entry users actively, 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?	Currently none
									What challenges do users face in receiving and acting on feedback from the system?	Currently none
		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			No	This is not applicable to the current paper system	For the new system, build 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	case notifications, treatment outcomes and other reports are generated from the system.	Yes	Once data is consolidated and aggregated, various charts are developed by the M&E team manually	The new system must be able to Create visual outputs such as charts, graphs, and maps for TB case trends, outbreaks, and treatment outcomes 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?	Standards reports include TB case notifications, treatment outcomes. They are produces monthly and distributed to stakeholders
									What additional analyses do you believe are necessary for effective TB management but are currently not available?	GIS analysis, Statistical analyses and dashboards
									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?	0% delay.

		Reports	Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.			Yes	Data from the current system is used manually to generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels	The new system should be able to produce reports automatically		
		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 include statistical tools, these are done manually	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.	No	The current system does not have this step. But there is a need to 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.	No	This does not relate with the current paper based system.	For the new system, set up system language options based on users' preferences and comfort. Ensure that technical language is minimized for 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?	They receive trainings before assigned their roles and whenever there are changes in the recording tools. There are also quarterly mentorships Currently no. But there is a need to develop dashboards, statistical charts and automated reports for the new system Common data entry platforms to reduce duplication will improve 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 and this is not applicable	When designing the new system, 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.							

# / Question	Description	Component	Component Detail	Y/N	Current System Explanation	Y/N	Current System Note	New System	Question	Response
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.	No	This does not apply to the current paper based system. However, there is a need to ensure that users are trained 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.	No	This does not apply to the current system	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? 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?	Currently none. But it is important to encrypt all data. This must BE tested during DQA Missing or theft of registers but it is not commomg
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			No	This does not apply to the current system	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 to the current system	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 to the current system	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	The current setup has secure physical locations for servers and backups to protect against theft or damage	Ensure secure physical locations for servers and backups to protect against theft or damage.		
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	User roles and training plans are planned prior to setting up TB testing sites.	Yes	User roles include Clinicians, Nurses, TB Officers, Districts Managers, Data Entry Clerks, IT and M&E		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?	The roles are clearly defines in the National Guidelines and are reviewed every 5 years
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			Yes	The trainings and mentorship are continuous to ensure staff turnover contigency		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?	100% of staff are currently trained for data entry. None is trained for system maintenance since we are using a manual system. Staff capacity is assessed quarterly Staff turnover is a challenge

						Yes/No	Current system	Proposed system	Questions	Answers
		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	There are regular trainings and mentorship in the current system	Ensure continuous trainings and mentorship for the new system		
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	For the current system, there is no dedicated helpdesk	For the proposed system, there is a need to have a 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?	
		Technical assistance	Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.			No	This is not available in the current system	For the new system, offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.	Are there "how-to" guides or standard operating procedures (SOPs) available for users?	
		Training	Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system.			Yes	There are currently trainings sessions for new staff and refresher for existing staff	Maintain this practice		
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	This does not apply to the current 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?	None at the moment. This must be established Currently no
		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			No	This does not apply to the current 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?	Currently none
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			No	This does not apply to the current system	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. However there is a need to establish business continuity plans and service level agreements that address system downtime and ensure continuity of operations through effective contingency planning to implement a new system	No	This does not apply currently	For the electronic 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? What are the acceptable response times for system issues to be resolved?	This does not apply currently. The system must be up 99.99% of the time. Response time must be within 24 hours

		Service level agreements	Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.			No	This does not apply currently	For the electronic system, Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.	Are service level agreements in place to ensure consistent system availability?	No. there is a need to develop service level agreements to ensure quality service
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			No	This does not apply currently	For the new 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	The current system does not require most of these attributes. However to implement the electronic system, it is important to plan for ongoing costs.	No	This does not apply currently	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?	No. There is a need to develop a sustainable funding plan
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			No	This does not apply currently	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 does not apply currently	Include ongoing costs for software updates, licenses, and feature enhancements	How sustainable is the system beyond the initial implementation phase?	The system must be developed with minimal needs to work in low funding environment for it to be sustainable
		Staffing and Project management	Ensure 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	This relates to the current data retention policies that define retention periods, secure archiving processes, and retrieval mechanisms, ensuring secure access to archived data	Yes	According to the guidelines, data is retained for 7 years	Maintain the current practice that follow the guidelines	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 policy requires data to be retained for 7 years. This is reviewed every 5 years
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			No	This does not currently apply	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?	Currently no
		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			No	This does not apply currently	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?	Follow the guidelines, I believe 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.	Yes	This relates to the current step in how the users are accessing current systems based on the connectivity infrastructure	Yes	The current system is paper based. However, at the facility there are other systems that use electronic system, adopting the same methods for the TB system will be good. Consider both online and offline	Both online and offline	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity?	Currently the system is paper based. However the other systems use online and offline access to ensure availability

		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	Network infrastructure is in place for the other systems	Use the existing infrastructure	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Computers, servers and networks are in place
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.	Yes	This relates to the devices that are currently used at the facility in other systems	Yes	Currently the systems use Tablets and computers are used	Adopt device types for the current systems to reduce capital costs	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?	The current system does not require any devices. However the other systems are using computers and tablets to access the systems.
		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.						Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	Some computers are aging and there is a need to increase servers
25. What database software is required	Assess database functionality and compatibility with system requirements to determine the appropriate database software needed based on system needs.	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 uses paper based tools however there is a need to assess databases for the new system	No	The current system is paper bases.	To ensure integration and interoperability and functionality there is a need to choose databases that will provide functionality and integration features. Current systems use SQL	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	SQL will meet the system needs
		Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			No	The attribute does not relate. However adopting the databases currently used will ensure compatibility	Adopt the databases used by the existing system to ensure compatibility	How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)?	It will be easy to integrate since we are adopting it from the existing systems
									Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission?	Yes.
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 recommendations that servers be located within the country	Yes	It is recommended in the guidelines that servers hosting health data be hosted within Malawi	Comply with the guidelines	Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users?	Servers should be located within Malawi at the Ministry of Health datacenter. Local servers must be hosted within the local facilities as in the current setup
									How will the server location affect system uptime, data access, and security, especially in rural or remote areas?	Implementing local servers ensure that the system is available all the time unlike implementing only the national servers
		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	The National Guidelines state that 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?	The ministry of health is responsible for the data on TB servers.

# / Question	Plan	Item	Implementation		Comment		Status	Use	Question	Answer
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.	Yes	User the existing infrastructure to run the planned system	Yes	There is LAN Government Wide Network and Mobile network available at the facility	User the existing infrastructure	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?	LAN, GWAN and mobile network coverage. Currently not evaluated This is not applicable currently
		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.			Yes	The existing infrastructure is being used effectively by the existing systems	Use the existing infrastructure	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	This is not applicable currently
28. **What are the electrical power Needs?**	Plan for power availability and backup systems to ensure continuous operation, ensuring reliable power sources for both urban and rural areas, including backup options.	Power availability	Ensure that health facilities have reliable power sources for system operations, including alternative backup options in case of outages.	Yes	This relate to the current power options available for the other existing systems	Yes	Power is available at the facility and has solar power for backup. This is being used by the existing systems	Use the existing power	What backup power options are available at your facility to ensure continuous system operation?	Solar power backup and generator
		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	The facility has a generator and solar power backup to ensure system availability		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?	The facility has generator and solar power backup