Process Design Table

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	This will fit in the existing step. The current system follows the WHO standards and National guidelines that have the case definitions, reporting and recording standards defined	yes	The case definitions are outlined in in the guidelines and they are currently being used.	The case definitions are outlined in in the guidelines and they are currently being used.	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?	All TB Registration sites. They are evaluated twice a year
		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	This relates to the current standards defined in the WHO Standards and National guidelines	The current system uses the recording and reporting standards defined by 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	The existing steps uses National Guidelines	National Guidelines are in place, the latest version is 2024 and follows WHO 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)?	All diagnosed cases
		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	There are trainings for TBO	Before establishing TB sites, trainings are done and there is continuous capacity building	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?	Trainings are ongoing on needs basis. Mentoring is on quarterly basis (depending on supervision findings)
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	Currently we have a Technical Working Group (TWG) that oversees TB Efforts. This group is a multi-stakeholder group that provides overall oversight for TB	Yes	Users and beneficiaries are clearly defined in the guidelines	The National Guidelines clearly defines users for the system that includes TB Officers (TBO) Nurses, Clinicians, Laboratory Staff, Data Officers, Monitoring and Evaluation, District managers. Beneficiaries are the patients and NTP high level that use the data	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 TB Technical Work Group that oversee the TB TECHNICAL functions NTP, Donors and implementing (partners), Ministry of health, Academia, Civil Society (represent community)
		TB care providers	Frontline health workers responsible for entering patient			Yes	These are described in the guidelines and currently used	TB Care providers include Volunteers,		

		Stakeholder	Role		Relation		Current		Question	Answer
			data, managing cases, and following up with patients					TBOs, Lab, Nurses and clinicians.		
		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.			Yes	Ministry of health provides overall oversight currently	NTP sits within the ministry of Health and according to the guidelines, the ministry controls everything		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure			Yes	Currently we have an IT team that help in other systems like DHIS 2.	The guidelines recommend that as part of the stakeholders, IT experts must provide guidance in the use and development of systems		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.			Yes	They currently provider an oversight role in their districts	District Managers have several facilities under their watch and currently they control those facilities by doing supervisions and ensuring that the guidelines are followed.		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations			Yes	Provides overall oversight for TB currently	NTP is a department within the Ministry of Health that provides oversight for TB. They develop guidelines and ensure that WHO standards are followed		
		Laboratory networks	Feed lab test results into the system, ensuring timely diagnosis and data accuracy.			Yes	All tests are currently done by the vast networks of labs	Laboratories are the engine for the program. They provide the crucial tests required		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.			No	no	Currently we do not have legal experts directly involved		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.			Yes	CSO's WHO, USAID, CDC and other donors	Currently NTP CSO's WHO, USAID, CDC and other donors		
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 objectives of the TB recording system relate with the step and all the objectives outlines here. Mainly NTP wants to improve surveillance, improve resource management and improve patients care	Yes	The step fits in the current system, the records are used to improve surveillance	Data gathered during supervisions is analyzed and used to make decisions to improve surveillance	What are the primary objectives of the TB recording and reporting system at your facility?	Improving clinical care of individual patients. Acquisition of data quickly
		Improving Programme and resource management,	Optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data.			yes	The step fits in the current system, the records are used to improve program and resource management	Data gathered during supervisions is analyzed and used to make decisions to improve program and resource management.	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 system is meeting its objectives. Suboptimal performance in DR – TB, Childhood (surveillance) Same above information used to justify additional resources (resource management) Adverse Drug reaction data was used to switch Tb preventive therapy (from H to 3HP)

		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 step fits in the current system, the records are used to improve patients care	The program uses supervision data to make decisions on the program and individual patients	How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement?	
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 National guidelines defines users and beneficiaries of the current system. This relates well to the step	yes	The guidelines clearly describe the people using the forms and the registers	Currently, the program uses registers and forms and the guidelines describe TBO's, Nurses, Clinicians and Lab officers	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, LAB, Public Health, HAS'S. Access the system daily Clinicians, LAB, Public Health, HAS'S. Access the system daily Follow up of patients, how well the treatment is going and decision on changes. Contact investigation and actions. Project the needs in the lab
		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	This step fits with the current system. The guidelines describe this step	Currently, TBO's, Nurses, Clinicians and Lab officers use data in real-time to make decisions		
		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	This step fits in the current step. Supervisions collect data that is analyzed and produce reports which M&E, Managers, NTP use to make decisions	Currently NTP, Monitoring and Evaluation, District Managers Vies the reports		
		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	This step fits in the current system. Data is extracted by the Monitoring and Evaluation (M&E) team	Currently this is done by the M&E Team		
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	In the current system, this step covers all TB Diagnosed patients	yes	All diagnosed patients are covered	Currently 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?	Yes.
		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 patients are covered	Currently all diagnosed cases are covered	Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system?	All key and vulnerable populations as per WHO are covered.
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			Yes	This step relates to the current	The system is currently only in TB Registration sites		
		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 current system data is used in other systems like DHIS 2, EMR, HIV system	The current system data is used in other systems like DHIS 2, EMR, HIV system	Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	Yes. Integrated with OPD, Lab, HIV

# / Question	Guidance	Attribute	Attribute Description		Step Relation		Response	Current System	Question	Answer
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 step relates to the current system. The system covers all locations that are TB Diagnostic sites regardless of location and type	yes	Yes the system is in TB Diagnostic sites in all locations and all providers	The current system is used in public, mission, private and military sites	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?	100%
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	The attribute relates to the current system. The system is in all geographical locations	The current system is in use in TB diagnostic sites in urban, rural and remote sites	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	yes
		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 in type of facilities	The current system is used in public, mission, private and military sites	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 step relates to the existing system. The system is an integrated system and data is shared with EMR's, DHIS 2 and HIV system	yes	This step fits. There are systems like DHIS 2, EMRS and HIV systems	Mapped systems include DHIS 2, EMR and HIV system	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	Integrate with all systems
		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	The attribute relates to the existing system. Data from the current paper system is used in DHIS 2, EMR and HIV System.	The current system shared data with DHIS 2, EMR and HIV system	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	Data sharing, Facilitate other treatment and other diagnosis. Reduce duplication.
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	The current system use individual data that is aggregated to ensure compatibility with DHIS 2	The current system use individual data that is aggregated to ensure compatibility with DHIS 2		
		Security Requirements	Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.			No	Currently no	This must be considered	What challenges might arise during system integration (e.g., data compatibility, security, training)?	Data compatibility, Unique identifiers, data security, data ownership, definitions and standards. Sustainability of systems.
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	This step relates to the current system. Currently the papers are retained for a 7-year period before discarding them	yes	Patient records are important legal requirement	Patient records are kept for future references. This is a legal requirement	What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system?	All the elements of the current system should be maintained because Malawi still has a low electrification and computer penetrations and internet coverage.
		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	Currently to manage patients well, paper records are kept for future reference	Currently to manage patients well, paper records are kept for future reference	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.
		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	Paper based records are kept to manage transitions	Paper based records are kept to manage transitions	How do you currently ensure that essential paper records are preserved?	Lock and key in the cabinets
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	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 system follows the 2024 guidelines which require us to record unique patient data. This data can be	yes	The current system use unique data	The current paper based system follow the WHO standards and national guidelines that	Is the unit of data entry at your facility (patient, case, or group) appropriate for accurate reporting, and how often is this reviewed	Unique

Step	Description	Sub-item	Sub-item description	Fit	Comment	Rel	Attribute relation	Current system	Question	Answer
	level, and ensure consistency across the system.				aggregated and used in other systems			require recording unique data	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?	No More information in unique data. Aggregated data has no risk to patient 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	During supervisions, data is collected and aggregated to be used in DHIS 2	Data from the current system is aggregated and used in 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	This step fits. Currently the data captured is driven by National guidelines.	yes	The attribute relates with the current system, patient demographics, case type, and treatment progress data are collected to monitor TB cases and evaluate program effectiveness.	The current system, patient demographics, case type, and treatment progress data are collected to monitor TB cases and evaluate program effectiveness	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, Signs and symptoms, Sample type, Test Technique and result. Treatment, Outcome. Location. Occupation, Risk factors Yes All is collected.
		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	The attribute relates. Currently the system Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care	Currently the system Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care		
		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 attribute relates to the current system work flow	The data collected currently follows a particular flow from the TBO where registration is done, Lab for testing and TBO for patient management		
		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 is a requirement for the electronic 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	Currently no	This is a requirement for the electronic system		
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	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 relates to the current system that follows the national guidelines where data entry is clearly defined	Yes	It related. Data is entered at the TBO, Wards, OPD and Labs	The current system has registers at the TBO, Wards, OPD and Labs where data is entered	Who will be entering data into the TB recording and reporting system?	TBO, Clerical staff, Data entry Clerks, Volunteers

system, mapping the entire process from clinics and labs to central reporting.	Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			Yes	Health workers handle other tasks and it is important to assess the workload	The current system is handled by health workers that work on other programs as well	Are there any bottlenecks or challenges in the data entry process?	Completeness is a challenge. Training for people who know what they are doing. Data usage at local level	
	Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	The current system has a clear data flow from the guidelines	The current system follows the TB Guidelines. Data flow from the Community, TBO, Labs and TBO	How does data flow from the point of data collection to reporting?	Community Registers and forms TO TBO Presumptive Register To Lab Register TO TBO TB Register, Contact tracing, Register Treatment TO Reports (Districts, Zone, NTP)	
	Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			No	This does not relate currently	Implement and design	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?	100%	
								What is the typical turnaround time from data collection to reporting?	Maximum 4 DAYS	
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	This relates to the current setup. There are data quality audits (DQA) that are taken by the program to ensure data quality	Yes	This relates to the DQA in the current setup	The program does monthly DQA to ensure data quality.	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?	Data Quality Audits, External Quality Assurance Lab, Reviewed Quarterly	
									What percentage of data quality issues are flagged during audits, and how often (e.g., monthly) are these challenges addressed and resolved?	About 30%	
		System generated alerts	Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries.			No	Not in the current system	The current paper-based system does not have this. This must be implemented in the electronic system			
		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			No	Not in the current system	The current paper-based system does not have this. This must be implemented in the electronic system			
		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	This currently relates to the DQA	The program currently do monthly DQA to ensure data quality			
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			Yes	Quarterly supervisions	The current system, the program does monthly DQA and quarterly support visits to facilities			
13.	Design interactive user interfaces that provide	Engaging users	Ensure the system allows for feedback loops that engage data-	Yes		No	Currently no	The current paper bases system does	What percentage of users receive real-time		

How is feedback provided to the system?	real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies.		entry users actively, making data entry an interactive process.		This step relates to the feedback that users receive from the DQA and supervisors			not engage users. This must be designed and implemented	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?	
		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			No	There is no real-time feedback	The current paper bases system does not engage users. This must be designed and implemented		
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	This step relates to the current system. The supervisions collect data that is then used to develop different reports	No	In the current system there are no data visualization	The current paper bases system does not any data visualization. This must be designed and implemented	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?	Case Finding Report, Treatment Outcome Report, Quarterly Facility Report. Monthly basis. Print and distribute. Graphs, Dashboards, GIS, 7.3%
		Reports	Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.			Yes	In the current paper-based report, reports are consolidated every quarter.	In the current paper based system, the following reports are produced, Case Finding Report, Treatment Outcome Report, Quarterly Facility Report		
		Statistical Analysis	Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software.			No	In the current system there are no statistical analysis	This needs to be designed and implemented		

# / Question	Description	Component	Design action	Y/N	Notes	Y/N	Register notes	Paper-based notes	Questions	Answers
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 paper based system does not have this therefore it is not related	Yes	The registers use the official language which is English.	The paper-based system uses English in the registers and forms	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?	On opening a TB registration site. Training every year. Mentoring Quarterly Online Scan form, SMS, Alerts
		Screen layout.	Ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers.			No	This does not relate	This must be designed and implemented		
		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 does not relate	This must be designed		
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 step relates to the current data security features currently in use mainly the physical mechanisms and role based mechanisms	Yes	Currently registers are accessed by authorised health workers	The registers have different functions and they are accessed by authorised personnel	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?	
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			No	The current system does not relate	The paper-based system does not have this. This must be designed in the electronic system		
		Data Anonymization	Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.			No	The current system does not relate	The paper-based system does not have this. This must be designed in the electronic system		
		Encryption	Encrypt data during transmission and storage to prevent unauthorized access and ensure data security.			No	The current system does not relate	The paper-based system does not have this. This must be designed in the electronic system		
		Physical Security	Ensure secure physical locations for servers and backups to protect against theft or damage.			Yes	In the current setup, registers are stored in lockable cabinets	The paper-based registers are stored safely in lockable cabined in safe rooms.		

# / Question	Plan	Element	Step Description	Y/N	Relation to Existing	Y/N	Current System	Current System Detail	Questions	
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	The existing system relates with this, currently the guidelines defined the staffing requirements for a TB testing site	Yes	The user roles are defines and this relates	The current system follow the national guidelines that clearly defined the different user roles including TBO, Clinicians, Nurses, Data Entry Clerks, Labs 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?	
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			Yes	This relates to the current setup	In the current setup, for a site to be a diagnostic site, there must be a plan according to the guidelines.	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?	
		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	Currently all TB staff are trained	Currently, all staff are trained. Quarterly there are mentorships as well.		
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	Yes	This relates with the existing system. There are monthly and quarterly supports visits in place	No	The current system does not have helpdesk	Currently there is no helpdesk function. This needs to be designed and implemented	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.			Yes	The current system get technical assistance from NTP and district teams	The current paper based system get assistance through district monthly visits and quarterly visits.	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	Trainings are done and mentorship is also done	Trainings are done and mentorship is also done		
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 step is not related to any existing steps. The current system does not have this step	No	This does not exist in the current system	The electronic recording system will need this to be designed and implemented	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?	
		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			No	This does not exist in the current system	The electronic recording system will need this to be designed and implemented	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?	

Question	Objective	Attribute	Description	Step Y/N	Step comment	Attr Y/N	Attribute comment	Current system	Question	Answer
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			No	This does not exist in the current system	The electronic recording system will need this to be designed and implemented		
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	The current system is paper-based therefore it does not relate to this step.	No	The current system is paper-based therefore it does not relate to this step.	The electronic recording system will need this to be designed and implemented	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?	
		Service level agreements	Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.			No	The current system is paper-based therefore it does not relate to this step.	The electronic recording system will need this to be designed and implemented	Are service level agreements in place to ensure consistent system availability?	
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			No	The current system is paper-based therefore it does not relate to this step.	The electronic recording system will need this to be designed and implemented		
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	Yes	This step related to the current system where there is a budget for the registers used	No	We currently do not have the estimate for the capital costs	There is a paper-based system which cannot give a clear estimate of the capital cost. There is a need to develop	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. Government funding is not consistent therefore not sustainable
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			No	The current system uses paper registers	There is a need to develop this		
		Software development, maintenance and licenses	Include ongoing costs for software updates, licenses, and feature enhancements			No	The current system uses paper registers	There is a need to develop this	How sustainable is the system beyond the initial implementation phase?	Depends on the system implemented. It will be sustainable if it is local
		Staffing and Project management	Ensure funding for staff salaries and project managers to maintain system functionality.			No	The current system uses paper registers	There is a need to develop this		
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	The step relates to the data retention that is followed by the current system	Yes	It relates with the existing system which follows the guidelines.	The current system retains data for 7 years in line with the TB National Guidelines	What is the current data retention policy for TB patient records, and how often is this policy reviewed for compliance with national regulations?	7 years before archiving. Reviewed every 7 years
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			Yes	The current system follows the TB Guidelines	Currently, data is archived in lockable cabinets that are in a lockable store room	How is secure access to archived data ensured?	Archived data is stored in locked cabined in locked stores room.
		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			Yes	The existing system follow the TB guidelines	The existing system follow the TB guidelines on data archiving. Data is archived after 7 years.	How long do you believe electronic data should be retained to support patient care and public health initiatives?	Same as the paper based system which is 7 years according to the guidelines.
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	User access methods	Determine how users will access the system based on internet availability, considering both online and offline functionality.	No	The step does not exist currently. The program uses a paper based system	No	This attribute does not exist	Currently the system is paper based	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to	It will be good to access it both online and offline because if there are network challenges users can

	infrastructure, including servers, software, and hardware, to support this access.								unstable network connectivity?	still use the system offline.
		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.			No	This attribute does not exist	Currently the system is paper based	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Computers, phones, tablets, phones, servers, printers and scanners.
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	The step does not exist currently. The program uses a paper based system	No	This attribute does not exist	Currently the system is paper based	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?	Computers, phones, tablets, phones, servers, printers and scanners. There are plans to add more
		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	This attribute does not exist	Currently the system is paper based	Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	Some hardware is relatively old. There is also insufficient hardware.
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 step does not exist currently. The program uses a paper based system	No	This attribute does not exist	Currently the system is paper based	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	It will be good to align with the existing systems so SQL.
		Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			No	This attribute does not exist	Currently the system is paper based	How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)?	By choosing similar database, we ensure interoperability therefore ease integration
									Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission?	Yes, TB data is entered in real time, and real time support is also necessary
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.	No	The current system is paper based and this step does not exist	No	The current system does not use servers	The requirements in the guidelines recommend that government must host health data	Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users?	According to the country laws, the servers must be hosted in country.
									How will the server location affect system uptime, data access, and security, especially in rural or remote areas?	If servers are located remotely, network downtimes affect accessibility in local sites.
		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	All data belongs to government	The owner of health data is Malawi Government according to the National guidelines	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?	NTP is the owner of the data stored on TB system servers. The guidelines are reviewed every 5 years
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 current system is paper based and this step does not exist	No	The current system does not use LAN.	The existing system is paper based. LAN needs to be designed and implemented. Other areas have LAN because there are systems like HIV	What communications networks are in place to support the TB system, and how often is network reliability evaluated, especially in rural areas?	Government Wide Network, Mobile networks
									How efficiently is TB data transmitted from rural to	Data is transmitted through mobile

Question	Plan	Attribute	Attribute Description						Question	Answer
									urban healthcare facilities, and what percentage of data is successfully transmitted without delay each month?	networks from remote sites and this is very successful
		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	This does not exist	This needs to be defined and implemented	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	Network downtimes do not occur frequently.
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.	No	The current system is paper based and this step does not exist	Yes	Most facilities have power and the attribute relates.	The current system does not require power availability. However all TB diagnostic sites have 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	Most facilities have power backup	Most TB diagnostic sites have power backup	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?	Yes. This is supported by generator and solar