Process Design Table

Step	Description	Key Attributes	Descriptions	Feedback on Step description		Feedback on Attribute description		Any other comments Any questions?	Questions (one question, or up to 3 if necessary)	Answers
				Does the step exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?	Does the attribute exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?			
1. Is there a functioning TB Recording and reporting system in place?	Assess whether the current TB recording system consistently applies WHO-recommended case definitions and recording standards across all facilities. Identify any gaps in functionality and ensure that both WHO and national TB guidelines are followed.	Case definitions	Ensure that the system records patient types such as bacteriologically confirmed, clinically diagnosed, pulmonary (PTB), extra pulmonary (EPTB), new, relapse, and other patients as per WHO standards.	Yes	The step relates to the existing one. Currently there is a functioning system at the facility that uses register. The system follows the WHO standards and National guidelines	Yes	The case definitions are defines in the forms and the registers.	The current system uses registers that have clear case definitions and related procedures	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?	We have a paper based system which has a 100% coverage and comply with WHO and national guidelines. Quarterly supervisions and DQA (Data Quality Assessments) are done to evaluate compliance.
		Recording and reporting standards	WHO sets standards for case definitions and data reporting formats. Verify whether these standards are being followed consistently across health facilities.			Yes	The registers and forms that are used follow the WHO reporting standards and they are the same type across the country	In the national guidelines, it is recommended that all facilities follow the same reporting and reporting standards		
		National guidelines in place	Ensure compliance with national TB and Leprosy guidelines, published in 2024, that are aligned with WHO's global standards.			Yes	There are National guidelines in place that are reviewed every 5 years. These guidelines are used in all facilities across Malawi	National Guidelines are in place and they are reviewed every 5 years.	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 notified TB cases are recorded in compliance with WHO and national TB guidelines. Reviews are conducted quarterly.
		Staff capacity in TB	Ensure that healthcare workers handling TB recording and reporting are well-trained to avoid errors in data capture and management.			Yes	TB Officers (TBO) and Lab officers are trained in TB report and recording.	Trainings are done but not covering all the health workers	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?	Roughly 70% TB staff trained in data reporting procedures and mentorship done during quarterly supervisions. Refresher trainings are supposed to be done quarterly but these depends on funding availability

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	This relates to the technical working group (TWG) in the existing setup. This group provides the overall oversight and decision making regarding TB	Yes	In the existing system, users include TBO, Lab officers, Nurses and Clinicians. Beneficiaries are the patients	TBO, Lab officers, Nurses and Clinicians. Beneficiaries are the 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?	Yes, stakeholders include WHO, Ministry of Health (National TB Program (NTP), Central Monitoring and Evaluation Division (CMED), Department of HIV Aids (DHA), Hospitals) e-Government) NTP overall seer and CMED managing data. Not sure on the frequency.
		TB care providers	Frontline health workers responsible for entering patient data, managing cases, and following up with patients			Yes	This will fit. The existing TB care providers include volunteers, TBO, Nurses and Clinicians	The existing TB care providers include volunteers, TBO, Nurses and Clinicians		
		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.			Yes	The attribute relates in the same way. Ministry of Health Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding	The National TB control Program is a department within Ministry of Health.		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure			Yes	This attribute relates in the same way. IT Experts handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure	IT Experts have the same roles for the existing systems like DHIS 2 and HIV system		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.			Yes	This relates to the existing attribute. It is in the same way.	District managers are responsible for facilities within the districts.		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations			Yes	NTP is available and it control and it oversees TB activities under ministry of health.	The owners of TB program and they guide the entire TB program		
		Laboratory networks	Feed lab test results into the system, ensuring timely diagnosis and data accuracy.			Yes	This relates to the current system. They play the same role	The various laboratory networks across the country provides the vital testing role for the program.		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.			No	Currently not related to any	Not related		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.			Yes	WHO, World Bank, USAID, Global Fund and CSO's	WHO, World Bank, USAID, Global Fund		

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 objectives relate to the existing paper system that include Improve surveillance and public health, Improving Programme and resource management, Improving clinical care of individual patients	Yes	The current recording system is helping in improving surveillance and public health	Reports from the current reporting and recording system help in Improving surveillance and public health	What are the primary objectives of the TB recording and reporting system at your facility?	Enhance case detection, monitor trends, and provide real-time data for informed decision-making and public health interventions
		Improving Programme and resource management,	Optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data.			Yes	The attribute relates to the existing system in improving program and resource management	Reports from the current reporting and recording system help in Improving Programme 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 current system is not meeting its objectives because its paper based and hence we cannot provide real time data for decision making , it is difficult to optimize resources and monitoring of patients
		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 attribute relates to the existing system	Reports from the current reporting and recording system help in Improving clinical care of individual patients	How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement?	Current system is a paper based which delays in providing real time data which also affects decision making. Data is consolidated every quarter meaning the current issues were for the past three months
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	This relates to the existing system. TBO's, Lab, Nurses, Clinicians are the users. Patients are the beneficiaries	Yes	The attribute relates to the existing system. TBO's, nurses, clinicians and data entry officers enter data.	Volunteers, Health Surveillance Assistants, Clinicians and lab	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)?	Volunteers, Health Surveillance Assistants, Clinicians, administrators and lab. Access the system daily. Volunteers, Health Surveillance Assistants, Clinicians and lab enter data and reports are received by Administrators, NTP, CMED. We wish all the users to have different interface to support their roles
		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, Nurses, TBO's, Data entry clerks	Clinicians, HSA and Lab		
		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	TBO, Lab, Clinicians, NTP,	HSA, Lab, Clinicians, NTP, Administrators and CMED		
		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	NTP, M&E	Administrators, M&E and NTP		

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 step relates to the current practice. All patients are covered in the current recording and reporting system	Yes	All patients are covered in the current system	We currently cover all patients	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, the current paper based system covers all the patient types. The coverage is updated whenever there are new 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	No	We support all type of diagnosed TB patients	Are there patient subgroups (e.g., MDR TB, HIV co-infected) not currently covered by the system?	No, all patients sub groups are covered.
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			No	All patients are covered	All patients are covered		
		Links to different systems	Specifies the integration of other health systems to track different TB patient sub-groups (e.g., HIV co-infected)			Yes	Yes. In the existing system, there is a manual link to DHIS 2 and HIV system	HIV system integration is important to manage TB /HIV coinfection. Other TB platforms integration is also important like DHIS 2	Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	Currently no but it's our wish to have it integrated
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. The existing system covers all locations and providers that are TB diagnostic sites	Yes	All locations that have TB diagnostic sites are covered	The existing system covered all geographic areas and facility types	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 it covers and evaluated quarterly
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	All geographic locations that have TB diagnostic sites are covered	All geographic locations that have TB diagnostic sites are covered	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	Yes it covers all types of facilities
		Type of facility	Consider the range of facility types (public, private, military, prison, etc.) to ensure that the system is adaptable to different settings.			Yes	The existing system covers all types of facilities	The existing system covers 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
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 will be an integrated system. The existing system shares data with HIV system and DHIS 2	Yes	The attribute relates to the existing system, currently data is shared with HIV and DHIS 2.	The main systems include HIV system and DHIS 2	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	We intended to integrate with other systems like HIV systems to manage co-infected patients and improve efficiency
		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. There is data sharing between the existing system with HIV System and DHIS 2.	There is a need to integrate with HIV and DHIS 2 when developing the TB electronic reporting and recording system	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	Easy patient managements and avoid duplication entries of the same patients
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	The attribute relates to the existing system. When data is extracted from the existing system it is formatted in a way that it work with the other systems	Ensure that the data on all systems is compatible.		

		Security Requirements	Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.			Yes	The attribute relates to the existing system, access and physical control is used	The current system is paper based and the security requirements are mainly physical control. But for the electronic system there is a need to develop 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 formats, resistance from different partners and staff and system compatibilities.
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	The step relates to the existing system. It has been a practice that when National guidelines are reviewed, the registers are reviewed also and make changes accordingly. Elements of the previous registers are retained.	No	This is not related	This is not related	What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system?	Registers, Lab result forms, Treatment Cards and appointment cards
		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	Retaining paper based elements ensures that records from the past are available.	This is important for patient history and system backup	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 , In terms of system failure might act as backup, Legal requirement and to ensure data quality
		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	To implement the system well, it is important to do a phased transition to ensure that the new system is working accordingly	Plan for phased transition to ensure that the new system is meeting all requirements and working accordingly	How do you currently ensure that essential paper records are preserved?	Stored in locked cabinets in self room and accessible by authorised users
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	This step relates. The basic unit for the existing system should be the same as the electronic system which is unique patient data	Yes	The attribute relates. The current basic unit is the unique patient data	The unique patient data is the basic unit for recording data currently.	Is the unit of data entry at your facility (patient 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 is patient which is appropriate for accurate reporting. This reviewed during the quarterly supervision visits. Recording the patient level data is advantages because it helps in easy management of individual cases, also aggregated data can be derived from the individual patient data. Improved efficiency ,easy patient management, Improved resource allocations
		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	In the existing system, data is only aggregated during reporting for use in other systems like DHIS	In the existing system, data is only aggregated during reporting for use in other systems like DHIS		

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 relates to the current system. Data items that are captured are guided by the WHO standards	Yes	The attribute relates to the existing system.	Essential program management and surveillance data is currently collected	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, Contacts, TB case type, treatment progress and outcomes, diagnostics, Lab test and results These are derived from WHO and national TB guidelines GIS data,
		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	The existing system captures individual patient data and it is able to track individual patient treatment adherence and outcomes	The current system captures data enough to manage patients		
		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	There is workflow management in the existing system. Different registers to track workflow	This must be adopted and implemented in the new system		
		system administration data items	Data related to the management of the system itself, such as user access logs and system performance metrics.			Yes	The current system does not have this	This must be developed and implemented		
		System monitoring and audit data items	Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies.			Yes	The current system does not have this	This must be developed and implemented		
11. **Identify who enters data, where and when will data be entered, and how do data flow within the system**	Develop a data flow diagram that identifies where and when data will be entered and how it will flow through the system, mapping the entire process from clinics and labs to central reporting.	Data entry points	Describe all the situations where data is entered, such as clinics, labs, and hospitals. Map data entry by healthcare staff (e.g., clinicians, lab technicians).	Yes	The step relates. Data is entered at TBO, OPD, Wards, Labs. Data is entered by Data officers, TBO, Clinicians, Nurses and Lab	Yes	Yes. TBO, Wards, OPD and Lab	Data entry points include TBO, Wards, OPD and Lab	Who will be entering data into the TB recording and reporting system?	Volunteers, HAS, Lab personnel and Clinicians
		Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			No	This does not relate	This does not relate	Are there any bottlenecks or challenges in the data entry process?	So far no any bottlenecks identified
		Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	The step relates. The data currently flow from community level to health facility to district office and to the national level	The data currently flow from community level to health facility to district office and to the national level	How does data flow from the point of data collection to reporting?	From community to health facility to National level

		Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			Yes	The step relates. Currently the TBO's, Clinicians, Nurses and lab	Currently the TBO's, Clinicians, Nurses and lab	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?	Currently is only GenXpert which has real time data capturing and reporting. Within 24 hours turnaround time for GenXpert
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	There are data quality check currently that include supervision and data quality audits (DQA)	No	The step does not relate.	This attribute needs to be developed	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?	The system uses barcode as a unique identifier to avoid duplicates, doesn't accept empty forms. So far no audit has been done.
		System generated alerts	Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries.			No	The current system does not have this attribute	This feature needs to be developed and implemented		
		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			Yes	The current system does not have this attribute	This feature needs to be developed and implemented		
		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	The attribute relates. The existing system has DQA monthly	The existing system has DQA		
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			No	No	This must be developed and implemented		
13. **How is feedback provided to the system?**	Design interactive user interfaces that provide real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies.	Engaging users	Ensure the system allows for feedback loops that engage data-entry users actively, making data entry an interactive process.	No	The existing system uses register books and forms therefore the step does not exist	No	The existing system does not engage users It is paper based	The electronic recording and reporting system will need to be engaging users	What percentage of users receive real-time notifications for incomplete data entries, and how frequently (e.g., quarterly) are feedback loops evaluated to improve system accuracy? What challenges do users face in receiving and acting on feedback from the system?	during data entries the system notifies users about any errors in real time. So far no any challenges identified.

		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			No	The existing system does not engage users It is paper based	The electronic recording and reporting system will need to provide real-time feedback		
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 existing system, there are standard reports and the analyses are done out of the system by the M&E team	No	There are currently no data visualizations done in the existing system	This feature needs to be developed 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 findings, TB/HIV, Treatment Outcome, Case Detection Effort, Community TB etc, Produced quarterly, bi-annual Dashboard, GIS, Trend analysis, Turnaround time. Reports are compiled quarterly meaning that the current reports are showing issues of the last three months this affect decision making because it is not easy to notice and act on issues in real time.
		Reports	Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.			Yes	This attribute relates to the existing system. There are case notifications, treatment outcomes	This needs to be developed and implemented in the electronic system		
		Statistical Analysis	Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software.			No	The current system does not do any statistical analysis	This feature needs to be developed and implemented in the electronic system		

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	This step does not relate to the existing system because it is paper-based. But it is an important step in the electronic system	Yes	This can be related to the language that is used in the registers in the existing system	The electronic system should maintain English as a system language as it is the one used across the country	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?	75% of the users have received formal training and the past 12months there has been no training Dashboards, GIS, SMS, system alerts, CSV, Excel extracts. They can be shared through emails, cloud platforms and in printed format. Single data entry interface, unique identifier, linkage with other systems e.g. HIV, GIS and data analytics.
		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 to the existing paper based system	There is a need to carefully prepare for logical screen layout		
		Use date or time formats	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.			No	This does not relate to the existing paper based system	This needs to be planned and implemented properly		
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 security measures implemented by the existing system. This include authorised access to the TB registers and secure storage of the registers	No	This attribute does not relate to the current system	This needs to be designed and implemented	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 we are using paper based system therefore no encryption is done. Registers are stored in a secure locked place accessible to authorised users. There are not tested for vulnerability. Fire, flooding and theft. Audits are not done.
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			No	This attribute does not relate to the current system	This needs to be designed and implemented		
		Data Anonymization	Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.			No	This attribute does not relate to the current system	This needs to be designed and implemented		
		Encryption	Encrypt data during transmission and storage to prevent unauthorized access and ensure data security.			No	This attribute does not relate to the current system	This needs to be designed and implemented		

		Physical Security	Ensure secure physical locations for servers and backups to protect against theft or damage.			Yes	This attribute related to the current security measures where registers are securely stored in locked cabinets in lockable rooms	The servers and IT equipment must be safely kept in lockable rooms.		
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	This relates to an existing step that has users with different roles. There is a plan for trainings when setting up sites and supervisions	Yes	The attribute relates to the current system. There are different registers that eventually defines different user roles	This needs to be implemented in the electronic system	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?	Currently no
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			No	Currently we don't have a staff turnover contingency plan	There is a need to develop one	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?	Currently no trainings have been done since we are using paper based system. Transfers done to already trained personnel, understaffing, Computer literacy.
		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	This relates to the current system. There are trainings done during setup of diagnostic sites and there are mentorship trainings done during quarterly supervisions	When implementing and using the electronic system, there will be a need to conduct regular trainings for users		
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 step relates to the current training and technical support that happens during quarterly visits	No	The current system does not have helpdesk services	This needs to be developed 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?	Currently we are using paper based system hence no issues or challenges Within end of business day
		Technical assistance	Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.			Yes	The current system does not have helpdesk services	This needs to be developed and implemented	Are there "how-to" guides or standard operating procedures (SOPs) available for users?	Yes, there are job aids
		Training	Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system.			Yes	This relates to the existing system. New staff are trained. When establishing diagnostic sites there are also trainings. During supervisions there are also trainings	New staff are trained. When establishing diagnostic sites there are also trainings. During supervisions there are also trainings		

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 does not exist in the existing system.	No	The current system uses registers hence no system administrators	Need to plan and implement levels of system support	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?	Helpdesk at NTP, Issues are reported to the technical team. Not quite often but mostly affected by power outages network failure
		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			No	The current system is paper based therefore does not require hardware maintenance	Make plans and implement	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?	Though not often but sometimes we are affected by barcode printer failures, software crashes which requires central team to fix.
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			Yes	The current system is paper based therefore does not require fixing software and bugs	Make plans and implement		
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 is not related to any existing steps	No	The current system does not have this attribute	There is a need to plan for this and implement	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?	The system is not in place hence no downtime Real time management
		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 does not have this attribute	There is a need to plan for this and implement	Are service level agreements in place to ensure consistent system availability?	Yes
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			No	The current system does not have this attribute	There is a need to plan for this and implement		
21. **What funding is required for both start-up and routine operations**	Plan for ongoing costs, including hardware, software, staffing, and services, while ensuring a long-term budget strategy that maintains the system's sustainability beyond the initial implementation phase.	capital costs	Estimate the initial investment required for system infrastructure, including hardware, software, and training	No	This step does not relate to any existing step	No	The current system does not have this attribute	There is a need to plan for this and implement	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
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			No	The current system does not have this attribute	There is a need to plan for this and implement		
		Software development, maintenance and licenses	Include ongoing costs for software updates, licenses, and feature enhancements			No	The current system does not have this attribute	There is a need to plan for this and implement	How sustainable is the system beyond the initial implementation phase?	
		Staffing and Project management	Ensure funding for staff salaries and project managers to maintain system functionality.			No	The current system does not have this attribute	There is a need to plan for this and implement		

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 step somehow relates to the existing data retention policies that are available	Yes	The attribute relates with the TB data retention policy which is 7 years	TB data is stored for 7 years, after which it can be archived	What is the current data retention policy for TB patient records, and how often is this policy reviewed for compliance with national regulations?	5 years plan
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			Yes	This attribute relate to who can access archived data at the archiving site. This is authorised staff	Archived data can be accessed by authorised members after getting approval	How is secure access to archived data ensured?	
		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			Yes	This attribute related to the current archiving processes. When data is stored for 7 years, it is moved to archive	Data is moved to archive after 7 years.	How long do you believe electronic data should be retained to support patient care and public health initiatives?	5 years
23. **How is the electronic recording and reporting software made available to users?**	Determine how users will access the system based on connectivity and infrastructure needs, and plan the technical infrastructure, including servers, software, and hardware, to support this access.	User access methods	Determine how users will access the system based on internet availability, considering both online and offline functionality.	No	This step does not relate to any step in the current system	No	The current system does not have this attribute	There is a need to plan for this and implement	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity?	The system can be accessed through an apk which can be accessed offline and web-based which can accessed online
		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	The current system does not have this attribute	There is a need to plan for this and implement	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Computers, smartphones, and internet routers
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 step does not relate to any step in the current system	No	The current system does not have this attribute	There is a need to plan for this and implement	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?	Smartphones, tablets and computers
		Usability and security	Ensure that devices are user-friendly and secure, with appropriate measures to protect data and ensure that users can operate them with varying levels of digital literacy.			No	The current system does not have this attribute	There is a need to plan for this and implement	Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	No, all computers are latest versions
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.	Yes	This step does not relate to any step in the current system	No	The current system does not have this attribute	There is a need to plan for this and implement	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	SQL
		Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			No	The current system does not have this attribute	There is a need to plan for this and implement	How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)? Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission?	Currently the system is not integrated with any external system but it's our wish to integrate it

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	There are data ownership requirements for Malawi. This step relates to that.	N0	This step does not relate to the existing steps.	This needs to be decided	Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users? How will the server location affect system uptime, data access, and security, especially in rural or remote areas?	Servers will be located at Central Point such as NTP The server will be centrally positioned hence easy to be used by responsible personnel
		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 collected in health facilities belong to government according to the laws and guidelines	All data in the electronic recording and reporting system will belong to 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?	NPT, Ministry of Health
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	This step does not relate to the existing system because it is a paper based system	No	The current system does not require any Local area network , internet or mobile network	There is a need to establish Local Area Network and internet and also mobile data for the electronic recording and reporting system	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?	GWAN The system is a real time model where data once captured can be accessed at all levels in real time
		Network Reliability	Ensure that the network infrastructure is reliable and has contingency plans in place for potential outages, particularly in rural areas where connectivity may be less stable.			No	This does not relate to the current system	There is a need to ensure network reliability when implementing the electronic recording system.	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	The system was using a central billing payment system, resulting in internet downtime when payment has not been made
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	The step relates to the existing step. Health facilities have reliable power sources from the national grid.	Yes	This relates to the existing system. The current sites have power available	Health facilities have reliable power sources	What backup power options are available at your facility to ensure continuous system operation?	Solar, and Genset.
		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 current sites have backup power available therefore the attribute relates to the existing system	Health facilities have backup solar power	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, there is a reliable UPS and Backup Generator system.