Process Design Table – Appendix E

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	All the steps are available in the current system and it follows the WHO standards	yes	Case definitions are clearly outlined in the guidelines	Case definitions are defined in the guidelines	What percentage of health facilities in your jurisdiction have a fully functional TB recording and reporting system that complies with WHO standards, and how often (e.g., annually) are these systems evaluated for compliance?	100 percent of facilities that are treatment centers (presumptive register, facility, contact, TPT, Lab forms, Medicine, ordering medicine). Every Quarter
		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	Yes, the recording and reporting standards follow WHO set standards	The recording and reporting tools follow the WHO 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	The national guidelines are aligned to the WHO standards	We are currently using the 2024 National Guidelines	What percentage of TB cases in your facility are recorded in compliance with WHO and national TB guidelines, and how often are compliance reviews conducted (e.g., quarterly)?	100 percent. All TB diagnosed cases are recorded in the registers in line with guidelines
		Staff capacity in TB	Ensure that healthcare workers handling TB recording and reporting are well-trained to avoid errors in data capture and management.			yes	Officers working in the TB office are strained on TB	All staff working at this facility are trained in TB management	What percentage of TB staff are currently trained in data reporting procedures, and how often (e.g., every 6 months) are refresher training sessions conducted?	100% trained. Refresher trainings may happen after 2 to 3 years. Quarterly supervisions do onsite mentoring
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	The step relates to the current Technical Group that comprises of various stakeholders who oversee the work in TB	Yes	TBO, Clinicians, Lab, Monitoring and Evaluation, NTP are the main users. Patients and the ministry are the beneficiaries	This is clearly outlines in the National Guidelines	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?	NTP, Partners, Facility mangers, Volunteers, DHO, Labs, IT, Data Officers NTP, WHO and CSO's. Their roles are reviewed in the guidelines every 5 years
		TB care providers	Frontline health workers responsible for entering patient data, managing cases, and following up with patients			Yes	They include Clinicians, TBO's, Nurses and Volunteers.	These are as outlines in the guidelines		

		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.			YES	The Ministry of Health providers oversight for all disease programs including TB	The Ministry of health set policies and oversight for health.		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure			Yes	We have the e-government and digital health that has IT experts who develop health systems and provide IT infrastructure.	IT experts are part of the stakeholders for TB according to the TB guidelines		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.			Yes	Called Director of Health Services in the current setup, they oversee the ministry of health roles in the district	They DHS manages a network of health facilities in their district.		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations			Yes	NTP provides the overall oversight of TB and Leprosy in Malawi	NTP sits in the Ministry of health. Oversee all TB work		
		Laboratory networks	Feed lab test results into the system, ensuring timely diagnosis and data accuracy.			Yes	Various networks of Laboratories across the country that carryout different tests including TB	All hospitals have laboratories that vary in size and test types depending on the hospital type.		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.			No	No	none		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.			Yes	Various stakeholders that include WHO, CDC, NGO's and churches	WHO, CDC, NGO'S, Churches, Universities		
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	According to the National Guidelines, the objectives include improving surveillance, improving resource management and improving patient management	Yes	The step relates exactly to the current objective	Data collected in facilities is analyzed and used to come up with innovations to improve surveillance	What are the primary objectives of the TB recording and reporting system at your facility?	Improve surveillance and public health, Improving Programme and resource management, Improving clinical care of individual patients, Data Management, Stability,
		Improving Programme and resource management,	Optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data.			Yes	This relates to the current step	The data collected, once analyzed is used to improve Programme and resource management , like managing drugs and laboratory chemicals	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 effectively meeting the objectives. Treatment success rates, treatments outcomes, drug levels.
		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	Currently information from the system is used to improve care of individual patients	Data collected from all facilities is analyzed and the information is used to help improve individual patients' care	How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement?	Treatment for patients can be tracked in the current system and decisions are able to be made. Drug stock levels. Rate of cases can be tracked that trigger special efforts.

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	We follow the National guidelines that identify TBO's, Nurses, Clinicians and Lab as users of the system. Patients are the beneficiaries	Yes	Different groups enter data according to their roles, Nurses, TBO's, Clinicians and Lab	According to the guidelines, there are different registers used by Nurses, clinicians and Lab. These are clearly identified as users	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)?	TB Officers, Nurses, Clinicians, Volunteers, Lab, NTP. They access the system daily to enter data TB Officers, Nurses, Clinicians, Volunteers, Lab Each group has its own registers and interfaces depending on 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	According to the guidelines, TBO's, Nurses, Clinicians and Lab are the ones that directly interact with the data	According to the guidelines, TBO's, Nurses, Clinicians and Lab are the ones that directly interact with the data		
		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	The step fits. The current reporting is done at the facility, district and National levels.	Currently TBO''s, clinicians, District Managers, Monitoring and Evaluation view 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	The step fits and is guided by the guidelines. The M&E extracts the data	M&E extract the data		
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	This step relates. The current system covers all patients	Yes	In the guidelines, all diagnosed patients are covered	In the current system all diagnosed patients are covered	Does the TB recording system cover all diagnosed patient types, including MDR-TB and latent TB, and how often is coverage updated to include new patient groups?	All TB diagnosed cases are entered in the system
		only MDR-TB patients	Initially, the system may focus on MDR-TB patients as a priority group before expanding to other patient categories.			Yes	In the guidelines, all diagnosed patients are covered	In the current system all diagnosed patients are covered	Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system?	None. The system support all patients
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			Yes	In the guidelines, all diagnosed patients are covered	In the current system all diagnosed 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	In the guidelines, all relevant systems are supposed to be diagnosed	Data from the TB system is shared with DHIS 2 system and HIV system	Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	Yes. DHIS2, HIV, EMR, E-HEALTH.
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	According to the guidelines, the system is supposed to cover all areas	Yes	The step relates to the current system, it covers all locations according to the guidelines	All locations are covered	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% Sites covered. Evaluated quarterly
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	The current system covers all geographic locations according to the guidelines	All geographic locations are covered	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	Yes all facility types are covered.

		Type of facility	Consider the range of facility types (public, private, military, prison, etc.) to ensure that the system is adaptable to different settings.			Yes	The system is in all types of facilities according to the guidelines	All types of facilities are covered	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	This step relates to the current practice. The current system integrates its data with DHIS 2 and HIV system	Yes	This relates with the current system, it mapped EMR, HIV system, DHIS 2 and the manual TB system	EMR, HIV system, DHIS 2 and the manual TB system	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	Integrated system is required because patients come from different systems like HIV as well.
		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	This relates. Data from the Paper-based TB system is integrated with DHIS 2 and HIV system	Data is integrated with DHIS 2 and HIV system	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	Time management for health workers. Patients assisted effectively. Duplication of data is reduced
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	The step relates. The paper system collect patient level data that must be aggregated to integrate with DHIS 2 to ensure compatibility	To ensure compatibility data is formatted accordingly		
		Security Requirements	Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.			No	No	No	What challenges might arise during system integration (e.g., data compatibility, security, training)?	Patient identification, data compatibility
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 record retention policy stipulated in the guidelines.	Yes	Legally it is required to retain records for 7 years before destroying them	It 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 must be retained for redundancy.
		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	The step relates to the guidelines. Patient records and history are important for patient well-being for reference	It is a requirement for to retain critical paper based records for patient well being	Do you believe that some data should remain paper-based for a certain period after the electronic system is implemented? Why or why not?	Yes. Redundancy and backup
		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.			No	It will be important to do phased transition	It will be important to do phased transition	How do you currently ensure that essential paper records are preserved?	Stored in lockable cabinets, and stores.
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 to the current system where the unit of recording patient data is Unique patient data	Yes	The attribute relates to the current system where data is recorded at the patient level	Unique Patient data is used	Is the unit of data entry at your facility (patient, case, or group) appropriate for accurate reporting, and how often is this reviewed to ensure optimal data management? Do you believe that recording data at a different unit level (patient vs. case vs. group of cases) would improve data management? Why or why not? What benefits do you foresee in using an alternative unit for recording data?	Patient level data, reviewed with the guidelines. This is reviewed every quarter Yes. It helps in tracking detailed information about the patient like treatment failures and successes. At patient level we will have more details

		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	For the purpose of reporting, data is aggregated after it is collected from supervision	Unique data is aggregated for reporting and use 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 relates to the current system and follows the National Guidelines	Yes	This relates to the current system where patient details like Name, address, age, sex, occupation, location and status are collected	Name, address, age, sex, occupation, location and status are 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, status, Location, occupation, contacts, HIV status, TB signs. Quarterly updated Adopted from WHO and National Guidelines National ID, GIS,
		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	The step relates. Data is collected at patient level to enable tracking of individual patient	Data is collected at patient level to enable patient management and tracking		
		Work flow management	Data fields that track the workflow of health workers, ensuring that patients receive care at every step of the TB care continuum.			Yes	The current system has various forms and registers that show patient flow from registration to finishing treatment	At every step, there are registers that record patient interactions and show patient care workflow		
		system administration data items	Data related to the management of the system itself, such as user access logs and system performance metrics.			No	The step does not relate to the current manual system	The current system is manual		
		System monitoring and audit data items	Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies.			No	The attribute does not relate	The current system is paper-based		
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	This step relates to the current system where various forms and registers show the data flow from one point to the other following the National Guidelines	Yes	This attribute relates to the current system. Patients are registered at the TB Office or wards. TB samples are registered at the Lab. Tb treatment is recorded at the TB Office	There are registers and forms at the TB Office, Wards, OPD, Labs where data is entered	Who will be entering data into the TB recording and reporting system?	TBO, Nurses , Clinicians, Volunteers, Lab
		Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			Yes	This attribute relates to the current system. Different data entry tasks are done at different point according to the tasks like patient registration, sample registration and treatment	Various registers are at different data entry points in different office to manage workload	Are there any bottlenecks or challenges in the data entry process?	System downtimes, internet problems, insufficient gadgets, capacity.

		Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	The guidelines define how data flows. Data is collected at the local facilities and it is aggregated at district level and it is then aggregated at National level	Data is collected at the local facilities and it is aggregated at district level and it is then aggregated at National level	How does data flow from the point of data collection to reporting?	Community collect sample and send to TB OFFICE for registration. TBO, Wards and OPD, ART also collect samples and send to TBO. TBO will then send the sample to the lab for testing. Results send back to TBO who will then send results to where they come from. If positive case, TBO will contact patient for treatment enrollment.
		Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			No	The current system is paper based therefore data is not transmitted in real time	This is not applicable in the current system	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?	100% data is entered in real time. No delay Data reporting is done Quarterly
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 step relates to the data quality assurance that is done by the program	Yes	This attribute relates to the data fields recorded at the point of entry which must be entered	Ensure that all fields are entered in registers at the point of entry	What data quality assurance protocols (e.g., audits, validation checks) are currently in place, and how often are they reviewed to ensure data accuracy and completeness? What percentage of data quality issues are flagged during audits, and how often (e.g., monthly) are these challenges addressed and resolved?	Data audit done monthly by the districts to ensure completeness and accuracy 5 % due to data entry staff. Yes the challenges are resolved
		System generated alerts	Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries.			No	The attribute does no relate to any existing steps	Not related		
		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			No	The attribute does no relate to any existing steps	Not Related		
		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 attribute relates to the current Data Quality Audits (DQA) that happen monthly and quarterly supervisions	The step relates to the monthly DQA done by the districts and the quarterly supervisions		
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			No	No	No		

13. **How is feedback provided to the system?**	Design interactive user interfaces that provide real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies.	Engaging users	Ensure the system allows for feedback loops that engage data-entry users actively, making data entry an interactive process.	No	This step does not relate to the current system. However, it is a desirable step.	No	The attribute does not relate to the current paper based system.	This is a desirable attribute for the electronic system to engage users and provide feedback	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?	Notifications for incomplete data is done monthly and not in real time, 100% of users receive the notifications. Feedback loops are reviewed monthly with the data audits and quarterly with supervision Difficult to track patients, adding more work.
		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			No	The attribute does not relate to the current system	Real time feedback is a desirable attribute for the electronic system		
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 where reports are done when data is collected and consolidated after supervisions.	No	The current paper based does not produce any data visualization	This is desirable for the electronic system	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, TB HIV, TB Outcome, community tb intervention, TB in Mining, Contact Tracing, IPT, Lab . Done Quarterly Dashboards, Graphs, GIS. No delays.
		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 current reports that are consolidated after quarterly reports.	Data collected is consolidated and aggregated to produce various reports		
		Statistical Analysis	Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software.			No	This is not relating to any attribute in the current system	This is desirable for 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 is not available in the current paper based system	No	This attribute does not relate to any in the current system	System language determination is a desirable step for the electronic system	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?	Training are not often done, mainly mentoring and reviews are done quarterly Excel, SMS, pdf, email SMS, Alerts, emails, dashboards. During implementation
		Screen layout.	Ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers.			No	This is not relating to the current system	This attribute is desirable for the electronic system		
		Use date or time formats	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.			No	This is not relating to the current system	This is desirable for the new system		
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 data confidentiality and security measures in the current system.	Yes	This attribute relates to the current step where TB records and registered are restricted to the health workers	Health workers are the only people authorised to access TB records	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?	All data, mainly personal identifiable data must be encrypted Theft, fire, flooding but these do not occur frequently. Data security protocols are audited monthly
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			No	This is not related to the current system	This is desirable in the electronic system		
		Data Anonymization	Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.			No	This is not related to the current system	This is desirable in the electronic system		
		Encryption	Encrypt data during transmission and storage to prevent unauthorized access and ensure data security.			No	This is not related to the current system	This is desirable in the electronic system		
		Physical Security	Ensure secure physical locations for servers and backups to protect against theft or damage.			Yes	This relates to the current step where records are stored in secure cabinets only accessible to health workers	It is desirable for the electronic system to have servers and backups in secure locations		

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 step relates to the current practice. The guidelines defines the roles hence the staffing required	Yes	This attribute related to the current system. The available roles include TBO, Nurse, Clinician, Lab and Monitoring and Evaluation	The available roles include TBO, Nurse, Clinician, Lab and Monitoring and Evaluation	Are all roles and responsibilities for TB system users (e.g., data entry, analysis, reporting) clearly defined and reviewed at least once per year to ensure clarity and accountability?	Yes, they are clearly defined. They are reviewed during guidelines reviews, that is every 5 years
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			Yes	The guidelines outlines the training plans ensuring staff contingency	Training ensures staff availability for contingency	What percentage of staff are trained for data entry and system maintenance, and how frequently (e.g., annually) is staffing capacity assessed to ensure adequate coverage? What challenges do you face regarding staff capacity or turnover?	100% for data entry. Staff capacity is accessed during the quarterly reviews and mentoring is also done. Yes, there is high staff turnover and this affects the program because we need to train more staff to manage TB patients.
		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	Trainings are done and also during quarterly supervisions there is mentoring on system use			
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 related to the ongoing mentorships that happen during quarterly supervision visits	No	The attribute does not relate to the current system	This is desirable for the electronic system	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?	Supervision visits and mentoring. Helpdesk support. 100% issues are resolved within 24 hours.
		Technical assistance	Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.			No	The attribute does not relate to the current system	This is desirable for the electronic system	Are there "how-to" guides or standard operating procedures (SOPs) available for users?	Yes. There are printed guidelines to support.
		Training	Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system.			Yes	This attribute relates to the ongoing mentorship done quarterly during supervision	Quarterly supervisions has mentorship component for the health workers		
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 available in the current system	No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	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?	Help desk, HMIS and IT technical support is available. The routine support in quarterly. Whenever there are network challenges which is 5 times a month

		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	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?	Network challenges, power challenges are the major issues. They affect data entry on electronic platforms like DHIS2. But TB data is on paper based systems so it is not affected
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system		
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 available in the current system	No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	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?	Main issues are to do with network connectivity. To minimize we need to have data hosted at facility level. Within 24 hours
		Service level agreements	Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	Are service level agreements in place to ensure consistent system availability?	No
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system		
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 steps in the current setup	No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	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. We rely on government and partners
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system		
		Software development, maintenance and licenses	Include ongoing costs for software updates, licenses, and feature enhancements			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system	How sustainable is the system beyond the initial implementation phase?	It can be sustainable if it does not require additional costs.
		Staffing and Project management	Ensure funding for staff salaries and project managers to maintain system functionality.			No	This attribute is not related to any in the current paper based system	This is desirable for the electronic system		
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 is related to the current system where the guidelines clearly state how data is retained and archived	Yes	The attribute relate to the current retention policy which is 7 years in line with the guidelines	Follow 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 according to the guidelines. These are reviewed every 5 years..
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			No	This does not relate to any in the current system	This is desirable	How is secure access to archived data ensured?	Normally access is for TB staff

		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			Yes	The guidelines clearly guide the archiving process which happens after 7 years	Data is archived after 7 years	How long do you believe electronic data should be retained to support patient care and public health initiatives?	7 years. This will allow complete history of patients to be accessible within 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 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 is not available for the current system	No	This step is currently available	This is desirable for the electronic system. Users must access the system on computers or tablets	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity?	Both online and offline. This will allow access to system even with network challenges
		Connectivity infrastructure	Ensure that necessary network infrastructure (e.g., LAN, internet, mobile networks) is in place to facilitate reliable access to the system across various healthcare settings**.**			Yes	These is connectivity infrastructure at the facility for DHIS 2 and HIV System	Connectivity infrastructure is available	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Tablets, Phones, Computers, Servers,
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 relates to the equipment currently used at the facility for other systems	Yes	There are computers and tables available for DHIS 2, EMR and HIV system	Computers, Tablets available must be used for the electronic system	What devices (e.g., tablets, computers) are currently used for TB data management, and are there plans to upgrade or replace outdated devices within the next fiscal year?	Tablets, Phones, Computers, Servers
		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.			Yes	There is already other systems being used at the facility and users are already using them	Gadgets are user friendly and being used for other systems	Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	We have some old computers. We don't have enough gadgets
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	This step does not relate to any steps in the current system	No	The current system is manual paper based so this does not relate	This is desirable for the electronic system. To ensure compatibility use the one already used for DHIS 2 or HIV system	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	Must be SQL like the other systems to allow integration
		Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			No	The current system is manual paper based so this does not relate	This is desirable. The current systems use SQL database	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?	There must be integration points where data can be pushed to other systems. Real time support is desirable since TB operations are real time
26. **Where will the servers be located?**	Assess server locations to ensure legal compliance and data accessibility, and decide on server placement based on legal requirements and data ownership considerations.	Data hosting legal requirements	Ensure that server locations comply with national data-hosting laws and provide easy access to data for authorized users.	Yes	This step relates to the current setup where we have DHIS 2 and HIV system hosted by the ministry and other server at the facility	Yes	The guidelines clearly state that data must be hosted by the ministry within the country	This is desirable.	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?	At facilities because when there are network challenges the system is still operational If servers are remote, any network failure may affect system access

		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	Data is owned by government	Data is owned by government	Who is responsible for the ownership and management of data stored on TB system servers, and how often is this ownership reviewed to ensure compliance with legal standards?	Malawi Government led by the NTP. This is reviewed with the Guidelines 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	This does not relate to the current system	No.	This does not relate to the current step.	This is desirable	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?	Mobile Networks, Government wide area network. Quarterly supervisions Reviews the network quality Data is very efficiently transmitted to urban sites through mobile networks without delay.
		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	This is desirable	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	May be 4 times a month.
28. **What are the electrical power Needs?**	Plan for power availability and backup systems to ensure continuous operation, ensuring reliable power sources for both urban and rural areas, including backup options.	Power availability	Ensure that health facilities have reliable power sources for system operations, including alternative backup options in case of outages.	Yes	This step related to the current step where TB sites are required to have electricity	Yes	This relates to the current system. It is a requirement for TB sites to have electric connections because of the testing equipment	Facilities are connected to power or have solar power	What backup power options are available at your facility to ensure continuous system operation?	Solar backup
		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 sites have power backup	Most facilities 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?	No. But we have solar backup that support the main electrical grid