## Process Design Table – Appendix H

| Step | Description | Key Attributes | Descriptions | Feedback on Step description | | Feedback on Attribute description | | Any other comments<br><br>Any questions? | Questions<br><br>(one question, or up to 3 if necessary) | Answers |
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| | | | | Does the step exist in current system?<br><br>(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?<br><br>(yes/no) | How does it relate to an existing step, or would it fit within a new step? | | | |
| 1.<br>**Is there a functioning TB Recording and reporting system in place?** | Assess whether the current TB recording system consistently applies WHO-recommended case definitions and recording standards across all facilities. Identify any gaps in functionality and ensure that both WHO and national TB guidelines are followed. | Case definitions | Ensure that the system records patient types such as bacteriologically confirmed, clinically diagnosed, pulmonary (PTB), extra pulmonary (EPTB), new, relapse, and other patients as per WHO standards. | Yes | This step relates to the existing step. There is a functioning TB recording system in place | Yes | Yes. The case definitions are defined in the National guidelines | Case definitions are well explained 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? | 520 TB reg sites in compliance with WHO standards.<br>Denominator=-all ART sites<br>Evaluated quarterly |
| | | 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 recording and recording standards follow the WHO standards as outlined in the guidelines | The guidelines follow WHO standards and are followed across facilities | | |
| | | 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 guidelines in place and the current version is 2024. They are reviewed every 5 years | All facilities follow the national guidelines | What percentage of TB cases in your facility are recorded in compliance with WHO and national TB guidelines, and how often are compliance reviews conducted (e.g., quarterly)? | Probably 100% |
| | | 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 | The guidelines recommend that all facilities must have staff that are trained. | Staff are trained and refresher trainings are done during the quarterly support visits | 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 50% trained. Staff turnover. Lack of refresher trainings |
| 2.<br>**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 step relates to the current system. There is a multi-stakeholder team comprised of government, partners like WHO, CDC Universities And NGO's that oversee TB work for Malawi | Yes | Users and beneficiaries are clearly defined in the guidelines that include TB Officers, Nurses, Clinicians, Manage and National TB Control Program M&E | Users and beneficiaries are clearly defined in the guidelines that include TB Officers, Nurses, Clinicians, Manage and National TB Control Program M&E | Are there key stakeholders or a steering committee that manages the system's design and implementation?<br><br>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, Facility representatives, Partners, CSOs, DHA, IT EXPERTS, District Managers<br><br>NTP (m&e). Reviewed every 5 years. |

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| | | TB care providers | Frontline health workers responsible for entering patient data, managing cases, and following up with patients | | | Yes | This relates to the current system which is guided by the guidelines | TB Care providers include Volunteers, Nurses and TB Officers as described 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 sets and control health policies for Malawi. | The ministry of health is mandates to set policy directives for health systems in Malawi. It oversees the activities of the National TB Control Program | | |
| | | IT experts | Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure | | | Yes | This relates to the current setup where we have IT experts sitting within the Ministry and also IT Experts that provide support from other partners | IT experts provide overall IT support | | |
| | | District managers. | Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts. | | | Yes | This relate to the current setup. District managers manage health sector activities for the district. | District Managers oversee all health facilities in a particular district | | |
| | | National TB Program | Ensures alignment of the system with the country's TB control strategy and WHO's recommendations | | | Yes | We have the National TP Control Program (NTP) that oversees the TB management for the country. | This is a department in the ministry of health responsible for TB management. | | |
| | | Laboratory networks | Feed lab test results into the system, ensuring timely diagnosis and data accuracy. | | | Yes | The attribute relates to the various laboratory networks across the country that offer various tests including TB | Laboratories vary according to the tests being offered. Tests are referred to different laboratories depending on type | | |
| | | Legal Experts | Ensure that the system complies with patient data privacy laws and data-sharing agreements. | | | No | This step does not relate to the current setup | We do not have legal experts | | |
| | | External agencies | Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives. | | | Yes | This step related to the current step where we have organisations like WHO, CDC, Universities, Churches and NGO's | WHO, CDC, Academia, NGO's, Churches. | | |
| 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 | This step relates to the current objectives of the TB Recording and reporting system that include improving TB surveillance, improving resource management and improving patient care. This is according to the National TB guidelines | Yes | This relates to the step in the national guidelines where the TB recording system helps improve surveillance | Data recorded in the TB recording system is used by the NTP to improve TB surveillance | What are the primary objectives of the TB recording and reporting system at your facility? | Improve surveillance and public health, Improving clinical care of individual patients, Improving Programme and resource management, |
| | | 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 step in the guidelines where TB data is used to improve resource management | Data recorded in the TB recording system is used by the NTP to improve 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 has been effective in improving TB surveillance, resource allocation & patient management. Increased number of presumptive TB cases, Improved TB case notification (Record high in 2023), improved TB treatment success rate |

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| | | 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 | This relates to a step where data collected in the TB recording system is used to manage patients thereby help improving patient care according to the guidelines | Data recorded in the TB recording system is used by the NTP to improve patient management | How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement? | Availability of TB recording and reporting tools.<br># of presumptive TB cases registered, TB cases notified, lab tests performed |
| 4.<br>**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 step relates to the step where users and beneficiaries are clearly defined in the TB guidelines | Yes | This step relates to the guidelines that define volunteers, TB Officers, Nurses, Clinicians and Lab officers as the ones entering data | These include TBO, Nurses, Clinicians, Lab and volunteers | 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?<br><br>Who will be entering data, using data, or receiving reports from the system?<br><br>How does the system support different types of users in their roles (e.g., data entry, case management, reporting)? | Nurses, clinicians, TB officers (HSAs), lab personnel, data clerks, TB volunteers.<br>**Daily (Routinely**)<br><br>Same as above<br><br>Data entry, case management, reporting. Different registers in different settings within the facility. Most registers in the TB office |
| | | Who will be using data directly while interacting with the system | Health workers and clinicians use real-time data for decision-making and managing patient care. | | | Yes | This relates to the current step where Nurses, Clinicians, TBO and Lab interact directly with the system and using the data | Lab, TBO, Nurses and Clinicians | | |
| | | 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 | According to the guidelines and the practice currently, District Managers, M&E staff and external stakeholders use the reports from the system | District Managers, M&E, External stake Holders | | |
| | | Who will be extracting data for analysis | Health analysts and IT experts responsible for extracting data to identify trends and produce reports for TB surveillance and program performance evaluation. | | | Yes | This relates to the current system where M&E consolidates the data and extract the data for analysis according to the guidelines | M&E extracts the data for analysis | | |
| 5.<br>**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 relates to the current step that is defined in the guidelines where all diagnosed TB patients are covered by the system | Yes | This relates to the current system where all diagnosed TB patients are covered by the system according to the guidelines | All diagnosed TB 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? | Surveillance records cover all patient types. DR-TB management and reporting done at district hospitals only |
| | | only MDR-TB patients | Initially, the system may focus on MDR-TB patients as a priority group before expanding to other patient categories. | | | No | This does not relate to the current system as all patient are covered | All patients are covered | Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system? | No |
| | | Expand coverage to all TB patients | The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease. | | | No | This does not relate to the current system as all patient are covered | This does not relate to the current system as all patient are covered | | |

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| | | Links to different systems | Specifies the integration of other health systems to track different TB patient sub-groups (e.g., HIV co-infected) | | | Yes | This relates to the current system where data collected is aggregated and used in the DHIS system thus linking and integrating the system | Data from the TB system is used in the DHIS 2 and HIV system to improve health services | Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage? | Yes |
| 6.<br>**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 | This step relates to the current step that is defines in the guidelines that recommend that the TB system should cover all locations. | Yes | The attribute relates to the current system which recommend that the system should be implemented in all locations according to the guidelines | TB services and system must be implemented across all locations and all service providers | 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? | Primary focus on TB registration sites irrespective of location. Fully evaluated |
| | | Geographic location | Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage. | | | Yes | This related to the recommendation that the TB system should be implemented in all geographical locations | System implemented in all geographical locations | Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)? | Yes |
| | | Type of facility | Consider the range of facility types (public, private, military, prison, etc.) to ensure that the system is adaptable to different settings. | | | Yes | The guidelines recommend that the system should be implemented in all types of facilities | System implemented in 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.<br>**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 relates to the current system where the guidelines recommends that the system be integrated with other electronic systems | Yes | This relates to the current practice. The systems integrated with include DHIS 2, Electronic Medical Records (EMR), Lab Information System and HIV system | Systems include DHIS 2, LIMS, HIV and EMR. | Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems? | Integrate with other system THAT include DHIS 2, LIMS, HIV and EMR. |
| | | 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 current system integrate its data with DHIS 2 and HIV systems so the step relates | The system integrated include 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)? | Effective, holistic management of patients.<br>Easy collection of data.<br>Easy & timely reporting |
| | | Data Compatibility | Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability. | | | Yes | The data is aggregated and formatted so that it is compatible with other platforms like DHIS 2 | Data is formatted accordingly to ensure compatibility | | |
| | | Security Requirements | Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches. | | | Yes | Currently the other systems like HIV system and DHIS 2 have access control and encryption mechanisms to ensure data protection | Ensure that encryption and access control is implemented to provide data protection | What challenges might arise during system integration (e.g., data compatibility, security, training)? | Limited technical capacity for integrated case management |
| 8.<br>**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 | Legal requirements | Certain legal obligations may require retaining paper-based records for a specific period before fully transitioning to a digital system. | Yes | This step relates to the current step where paper records are retained for some time before being archived. | Yes | The guidelines recommend retaining paper records for 7 years before archiving them | Retention policy recommends 7 years before archiving | What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system? | Patient demographics, Treatments plans, reports |
| | | 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 current system retains the records for 7 years for patient well-being and referencing | Paper records are retained for patient wellbeing | Do you believe that some data should remain paper-based for a certain period after the electronic system is implemented? Why or why not? | System sustainability? (Routinely available for use, Downtime).<br>Recommend the phased transition |

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| | during the migration process. | 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 | Transitioning to electronic system while maintaining the paper based system and move gradually is recommended, most records will be in paper based system according to the retention policy | Phased transition is recommended. | How do you currently ensure that essential paper records are preserved? | Locked cabinets, secure storage rooms. Summary reports |
| **9.**<br>**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 relates to the current system. The basic unit of data recording is patient level or unique patient data according to the guidelines | Yes | The guidelines and the current practice is Unique patient data as a basic unit of data recording | Patient level or unique patient data | 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?<br><br>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?<br><br>What benefits do you foresee in using an alternative unit for recording data? | Patient data. Monthly/Quarterly<br><br>Patient data provides more detailed information that can be analyzed as required for programmatic use/action<br><br>Triangulation (data comparison), data security |
| | | Aggregated Data (sub-national or local patient identifiers) | Data can also be aggregated at the local level (district, facility) for broader analysis without losing patient-specific information. | | | Yes | Data is collected and aggregated for analysis. But the basic unit of recording is Unique patient data | Data is collected and aggregated for analysis and use in other systems like DHIS 2. | | |
| **10.**<br>**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 relates to the current step where the guidelines clearly define the data items collected when managing patients | Yes | This relates to the patient demographics, laboratory tests and results, patient history and treatment progress and history | Patient demographics, laboratory tests and results, patient history and treatment progress and history | 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?<br><br>How do these data items align with WHO guidelines or national TB reporting standards?<br><br>Are there additional data items that you believe should be included to improve patient care or program management? | Patient demographics, Laboratory information, TB treatment history, Site of Disease, Regimen, Treatment monitoring/outcome, Contact investigation (List of contacts and TB screening outcome), TB preventive therapy, Reports<br><br>Adopted from the latest WHO guidelines<br><br>No |
| | | Patient management data items | Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care. | | | Yes | According to the guidelines this include patient demographics, treatment progress and history, laboratory tests | Patient demographics, treatment progress and history, laboratory tests | | |

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| | | 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 | This relates to the different registers that manage every step a patient is taken. This include the TB registration register, lab register and treatment register. It also include TB registration form | Register at various stages that include TB registration register, Lab register, Treatment register | | |
| | | 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 TB system but it is highly recommended | This is highly recommended. The guidelines recommend a secure system therefore this attribute is highly recommended | | |
| | | System monitoring and audit data items | Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies. | | | No | The current paper based system does not relate. | The guidelines recommend a secure system therefore this is highly recommended | | |
| 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 relates to the current step where the guidelines clearly defines how the patient moves in the recording system | Yes | The starting points include TB office/ community/ OPD/ ward where patients are registered. Then Laboratory where samples are collected and tests done and registered. Then back to TB office where treatment is managed and recorded. | Include TBO, Community, Wards, OPD and Lab | Who will be entering data into the TB recording and reporting system? | TB officers, nurses, clinicians, lab personnel, data clerks, volunteers |
| | | Workload | Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work. | | | Yes | According to the guidelines, various stages in data entry are done by different departments therefore managing workload | Work is distributed between departments | Are there any bottlenecks or challenges in the data entry process? | Untrained staff |
| | | Data flow | Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting. | | | Yes | Data flow from TB office/ community/ OPD/ ward where patients are registered. Then Laboratory where samples are collected and tests done and registered. Then back to TB office where treatment is managed and recorded. | Include TBO, Community, Wards, OPD and Lab | How does data flow from the point of data collection to reporting? | Community to TBO/OPD/ART/Ward to Lab to TBO/OPD/ART/WARD(Results) to (TB confirmed?) to TB office (TB treatment to Contact Investigation to TPT) to Report writing (Quarterly) |
| | | Real-time data | Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases. | | | No | This is not currently being done but it is recommended | Highly recommended | 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?<br><br>What is the typical turnaround time from data collection to reporting? | 95% are entered in real time<br><br>Data collected routinely, Reporting to be done on 5th after quarter ends |

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| 12.<br>**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 current monthly data quality audits that the program does in all health facilities. These are done by the districts in line with the national guidelines. | Yes | The current system has forms that guide the patient registration process and it clearly shows any elements that have been entered and not entered | The form guide on what information to enter | 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?<br><br>What percentage of data quality issues are flagged during audits, and how often (e.g., monthly) are these challenges addressed and resolved? | Validation checks, DQAs (Partial), Data compare (SUPERVISION Vs DHIS2), Double data entry (For high volume sites only<br><br>Less than 5 percent, Quarterly |
| | | System generated alerts | Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries. | | | No | The current paper based system does not generate any alerts | This feature must be considered in the electronic system | | |
| | | Error detection algorithms | Use automated algorithms to flag errors, anomalies, or missing data for review and correction. | | | No | The current paper based system does not do any error detection | This feature must be considered in the electronic system | | |
| | | Regular audits. | Conduct regular data quality audits to identify gaps and ensure data integrity. Use manual checks and automated validation to clean the data. | | | Yes | There are monthly data quality audits that are done by the districts in line with the national guidelines | DQA are done once every month | | |
| | | External data checks | Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards | | | Yes | The program conducts quarterly supervisions which among other things check the data at facility level and check the DQA in line with the national guidelines | Quarterly supervisions are done by NTP to ensure compliance with reporting standards | | |
| 13.<br>**How is feedback provided to the system?** | Design interactive user interfaces that provide real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies. | Engaging users | Ensure the system allows for feedback loops that engage data-entry users actively, making data entry an interactive process. | No | This step does not relate to any steps in the current set up | No | The current system is purely paper based therefore it does not engage users | This feature is recommended for the new electronic system | 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?<br><br>What challenges do users face in receiving and acting on feedback from the system? | The current system does not send real time notifications. But 100% System should send reject errors<br><br>Unrealistic parameters |
| | | Real-time feedback | Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy. | | | No | The current system does not provide any real time feedback as it is paper based | This feature is recommended for the new electronic system | | |

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| 14.<br>**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 reporting step in the paper based system. These reports are used by the program to achieve its objectives. They are also shared with various stakeholders for coordination and decision making | Yes | The current system data is collected and analyzed elsewhere where various data visualizations are done to help the program make decisions. | This is a highly recommended feature to be incorporated when developing 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?<br><br>What additional analyses do you believe are necessary for effective TB management but are currently not available?<br><br>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? | TB case detection effort, TB case notifications, TB/HIV integration, treatment outcomes,<br><br>Quarterly<br><br>GIS Mapping, dashboards<br><br>Delayed reporting to stakeholders<br>Delayed resource mobilization, Distribution, etc. |
| | | Reports | Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels. | | | Yes | The data from the current system is consolidated once every quarter and from that reports are done. | It is highly recommended that the new electronic system to be developed should have a reporting feature | | |
| | | Statistical Analysis | Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software. | | | Yes | This related to the step where data from the manual system is collected and statistical analysis is done with the M&E team. | Its highly recommended that the electronic system should be doing statistical analysis | | |
| **15.**<br>**What are the data entry screen or interface requirements?** | Consult with stakeholders to design user-friendly data entry screens and interfaces that are intuitive and familiar, ensuring they meet the needs of all users. | System language | Set up system language options based on users' preferences and comfort. Ensure that technical language is minimized for ease of use. | Yes | This step relates to how the current paper based tools are designed, the language and the layout | Yes | The current paper based system is designed in English and Chichewa a local language. This is in line with the national guidelines | It is recommended to follow the current set up | 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?<br><br>What specific tools (e.g., software, dashboards) are used to generate reports, and how are they shared with relevant stakeholders?<br><br>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? | Quarterly trainings, data review meetings, onsite mentorship during supervision, DQAs<br><br>Online summary reports, that can be exported into downloadable excel sheets. Dashboards.<br>Shared as electronic files through digital means<br><br>Barcoding/ unique IDs. Integrated disease conditions/programs |
| | | Screen layout. | Ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers. | | | Yes | The current tools, that include forms and registers are designed according to the user roles in line with the national guidelines | It will be good to ensure that the screen designs mimic the paper based system for easy transition | | |

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| | | Use date or time formats | Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data. | | | No | The current system does not have any date or time formats | It is highly recommended to implement this | | |
| 16.<br>**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 system which prioritizes data confidentiality in line with the national guidelines | Yes | This relates to the current practice where only authorised users are allowed to view patient data | It is recommended that in the new system access control mechanisms are implemented to ensure data security and confidentiality | 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?<br><br>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? | 100 percent<br><br>Missing registers, worn out registers, too many registers. Done quarterly |
| | | User Authentication | Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts. | | | No | The current system does not have this feature | This must be implemented in the new system | | |
| | | Data Anonymization | Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws. | | | No | The current system does not have this feature | This must be implemented in the new system | | |
| | | Encryption | Encrypt data during transmission and storage to prevent unauthorized access and ensure data security. | | | No | The current system does not have this feature | This must be implemented in the new system | | |
| | | Physical Security | Ensure secure physical locations for servers and backups to protect against theft or damage. | | | Yes | In the current setup, servers are stored in secured server rooms | Ensure secure safe place for servers when implementing the electronic system | | |
| 17.<br>**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 setup where staffing is done according to the services provided by the facility | Yes | This relates to the current step where user roles depend on the staff responsibility | Implement user roles depending on the tasks required | 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 |
| | | Staff Turnover Contingency | Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel. | | | No | This does not relate | Need to plan and implement this | 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?<br><br>What challenges do you face regarding staff capacity or turnover? | 50%<br><br>Untrained staff manning TB services |

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| | | 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 related to the current practice where users are trained before they start working and regular mentorship is done quarterly during supervisions | This must continue as it is done currently | | |
| **18.**<br>**What user Support is needed?** | Establish clear response times and support mechanisms for user issues, including providing "how-to" guides or easy-to-follow standard operating procedures (SOPs), help desk or hotline services with defined response times, and a web-based discussion forum. Facilitate sharing of experiences and learning from users in other countries that have transitioned from paper-based to electronic recording and reporting. | Helpdesk services | Provide a dedicated helpdesk with clearly defined response times for addressing user issues and system troubleshooting | No | This step is not related to the current system | No | This is not related to the current system | This must be established in the electronic system | What kind of technical support is available to users when there are system issues or data-related challenges?<br><br>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? | Help desk services<br>Technical services/Maintenance |
| | | Technical assistance | Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly. | | | No | This is not related to the current system | This must be established in the electronic system | Are there "how-to" guides or standard operating procedures (SOPs) available for users? | yes |
| | | Training | Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system. | | | No | This is not related to the current system | This must be established in the electronic system | | |
| **19.**<br>**What technical support is needed?** | Plan for system administration, hardware maintenance, and bug fixes, while determining the technical support needed for the system's infrastructure and ongoing software maintenance. | System administration | Assign a dedicated team to manage day-to-day system operations, perform regular data backups, and handle system maintenance tasks (e.g., software updates, bug fixes) to ensure smooth system functionality. | No | This step is not related to the current system | No | This is not related to the current system | This must be established in 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?<br><br>How often do technical issues affect your ability to use the system effectively? | Same ones |
| | | Hardware Maintenance | Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment. | | | No | This is not related to the current system | This must be established in 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? | Power outages<br>System downtimes |
| | | Fixing software bugs | Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance. | | | No | This is not related to the current system | This must be established in the electronic system | | |

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| **20.**<br>**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 the current system | No | This is not related to the current system | This must be established in 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?<br><br>What are the acceptable response times for system issues to be resolved? | Within two hours |
| | | Service level agreements | Define required uptime for the system to ensure constant access to health workers and prevent disruption of services. | | | No | This is not related to the current system | This must be established in the electronic system | 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 | This is not related to the current system | This must be established in the electronic system | | |
| **21.**<br>**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 is not related to the current system | No | This is not related to the current system | This must be established in 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? | Not enough |
| | | Hardware maintenance and replacement | Budget for regular hardware replacements to prevent system failures caused by outdated technology. | | | No | This is not related to the current system | This must be established in the electronic system | | |
| | | Software development, maintenance and licenses | Include ongoing costs for software updates, licenses, and feature enhancements | | | No | This is not related to the current system | This must be established in the electronic system | How sustainable is the system beyond the initial implementation phase? | Challenging |
| | | Staffing and Project management | Ensure funding for staff salaries and project managers to maintain system functionality. | | | No | This is not related to the current system | This must be established in the electronic system | | |
| **22.**<br>**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 relates to the current system where guidelines for data retention are stated | Yes | This attribute is available | Data is retained for 7 years | 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. Reviewed with guidelines |
| | | Secure access | Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive | | | No | This is not related | This needs to be established | How is secure access to archived data ensured? | Stored in lockable cabinets |
| | | Archiving Processes | Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data | | | No | This does not relate to the current system | This must be designed and implemented | How long do you believe electronic data should be retained to support patient care and public health initiatives? | 10 years because we want to see the trends |
| **23.**<br>**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, | User access methods | Determine how users will access the system based on internet availability, considering both online and offline functionality. | Yes | This step relates on how other systems are available to users | Yes | This relates to how users access the other systems | The system must be accessed through mobile application and web application like DHIS 2 and HIV system | How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity? | Mobile app and web application. |

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| | including servers, software, and hardware, to support this access. | 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 | This attribute relates to the current infrastructure used for the other existing systems | Network infrastructure is available in sites that have the DHIS 2 and the HIV systems | What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management? | all |
| **24.**<br>**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 devices that are current systems used at the facility | Yes | This relates to the current devices used by other systems like DHIS 2 and HIV system | Computers and Tablets are currently used by the existing systems | 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? | Computer, tablets, phones, |
| | | 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 | This relates to the current devices chosen for the current systems | Computers and tablets being used are user friendly and secure | Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system? | Coverage is limited |
| **25.**<br>**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 relates to the current step where we have other systems like EMR, DHIS 2 and HIV systems running databases | Yes | The current systems use SQL databases and the requirements for the TB system is almost the same it=n terms of functionality | This relates to the current SQL databases | What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security? | Adopting the current SQL databases will ensure scalability and security for the system |
| | | Compatibility | The database should integrate with other systems and support interoperability with external health data sources. | | | Yes | This relates to the current system. To ensure easy compatibility use the same databases being used | Adopt the SQL databases | How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)?<br><br>Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission? | By adopting the same databases will ensure easy integration with other systems<br><br>Yes. The electronic system will need to capture data in real time |
| **26.**<br>**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 | The step relates to recommendations by the TB guidelines regarding server and data hosting | Yes | This attribute relate to the guidelines that recommend data to be hosted within the country | Data must be hosted within country | Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users?<br><br>How will the server location affect system uptime, data access, and security, especially in rural or remote areas? | Must be hosted within the country centrally and local facility<br><br>Servers must be located at facilities and central location so that loss of connectivity should not affect work |
| | | 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 | Health data is owned by the government according to the laws and the guidelines | Data is owned by the 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 through the Ministry of health and NTP |

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| **27.**<br>**What communications networks are needed** | Plan for network infrastructure by considering LAN, internet, and mobile options, and identify suitable communication networks for effective data transmission. | Local area network, Internet and Mobile network | Implement reliable network infrastructure (LAN, mobile, internet) to ensure seamless data transmission from rural to urban healthcare facilities and support effective communication among healthcare providers. | Yes | The step does not relate to the current system but relates to the other systems used by the hospital | Yes | This step relates to the current infrastructure available for other systems like DHIS 2. | Local area network in place for other systems used at the facility | What communications networks are in place to support the TB system, and how often is network reliability evaluated, especially in rural areas?<br><br>How efficiently is TB data transmitted from rural to urban healthcare facilities, and what percentage of data is successfully transmitted without delay each month? | Government Wide Network, Mobile Wireless Network.<br><br>Data is transmitted efficiently 75% of the 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. | | | Yes | This relates to the reliability of the network used by other systems | Reliable network infrastructure 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? | The network is 90% reliable |
| 28.<br>**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 relates to the requirement in the guidelines that TB test sites must have power | Yes | The guidelines require TB cites to have power connection | Health facilities connected to power grid or have solar power | What backup power options are available at your facility to ensure continuous system operation? | Solar power and generator |
| | | Backup power | Install uninterruptible power supplies (UPS) and generators in health facilities to ensure that systems remain operational during power outages, safeguarding data integrity and availability | | | Yes | Some facilities have power backup | Some facilities have power backup but it is not a requirement in the guidelines | 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. |