Mozambique Monitoring & Evaluation Information System Requirements

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Final Report

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Overview

The primary goal of developing an electronic national monitoring and evaluation (M&E) information system is to efficiently collect health system data, and to provide in time quality information and analyses that enable health system leadership to: (1) efficiently and effectively monitor the conduct and impact of health programs, (2) allocate resources to and between these programs, (3) identify operational and structural issues requiring further management, and (4) address both programmatic and national priorities.

M&E and Surveillance Systems

The systems and software to support M&E activities are typically developed with different perspectives, purposes, and timelines than those for disease surveillance. However, based on the informatics methods used in these two application areas, M&E and surveillance systems share important design characteristics, including the desirability of building both to use a variety of data sources, including both directly entered data and computerized data from systems operated by healthcare and other institutions, such as electronic medical record systems (EMRs), laboratory systems (LIS), pharmacy systems, and others. These shared characteristics suggest that both systems can be developed using common methods, and operated in an integrated architecture, as is demonstrated by the integration of disease reporting into the current Modulo Basico system in Mozambique.

The technical goals of both M&E and surveillance systems are to develop and sustain ongoing, systematic collection, analysis, interpretation, and dissemination of health-related data for use in public health action[1]. In order to meet these goals, a M&E information system should be a component of a well thought out national health information architecture or, in the absence of such an existing architecture, be designed so that the M&E information system can become an extensible building block of a national approach. To do so, the system must address core functionality in several areas: data collection, standardization of information storage, transmission, data quality management, and data utilization.

An Example of a M&E Architecture

The following figure shows an example of a national monitoring and evaluation architecture, with lines representing the flow of information between systems at the facility, district, national, and international levels. The vertical sections represent different configurations of facility and district level systems to support patient care, which may feed into a common national level M&E information system. An architectural view encourages direct conversation about both the choices made for specific system configurations, and the business rules that drive information exchange between different levels and organizations.

1 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm

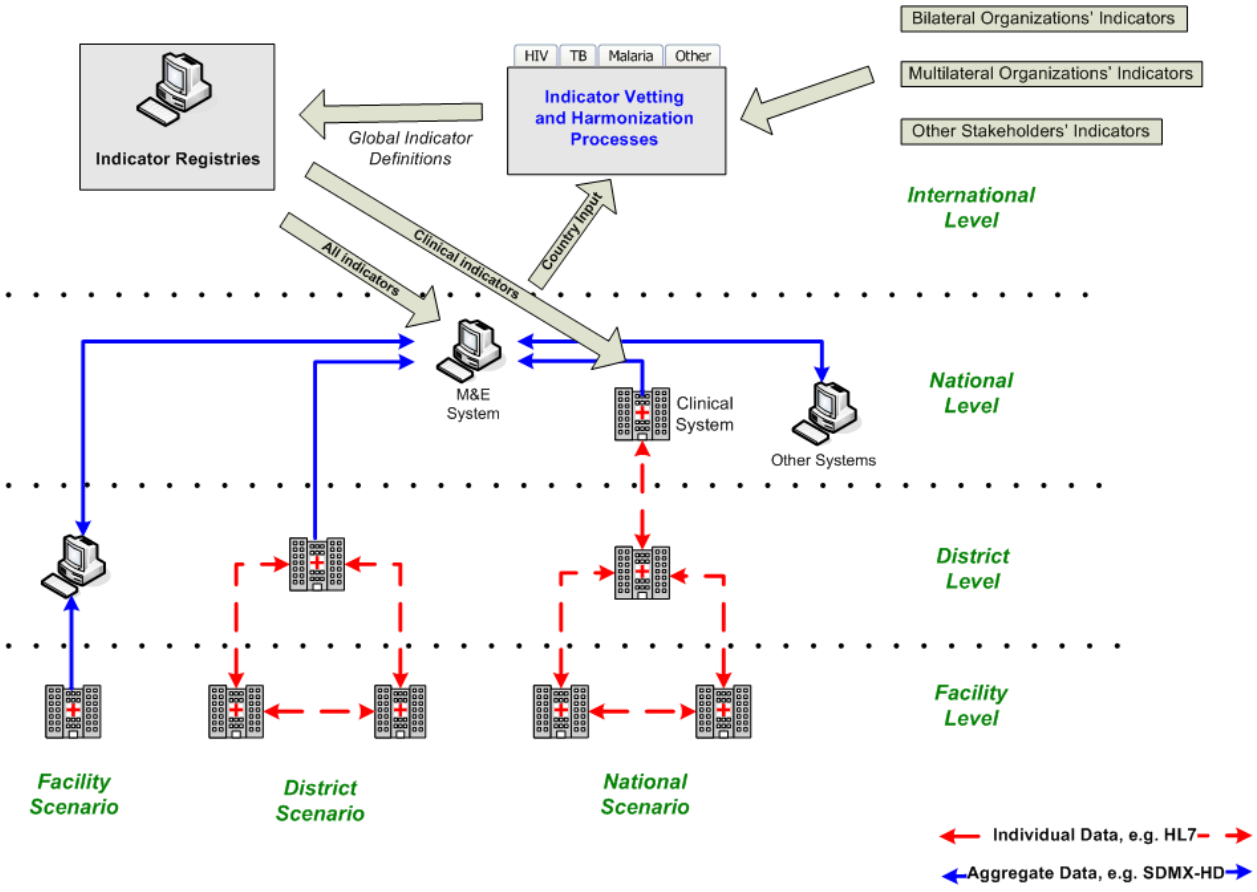

Figure - National M&E Architecture[2]

Scope and Contents

The scope of this requirements document is the development of a national M&E information system, incorporating the functions and practices of the presently deployed Modulo Basico system, but with additional features and capabilities to allow it to serve as the foundation for a more robust national HMIS. It is expected that this system will continue to focus primarily on the collection, aggregation, use, and reporting of aggregate data, with additional interoperability with clinical systems collecting individual level data an added functionality of the system.

Within this scope, the values underlying the document are sustainability and Ministry "ownership" of the system, which means that the Ministry has sufficient understanding of the system to direct its further development and implementation without the absolute need to external consultants or partners. These values of sustainability and "local ownership" impact the establishment of requirements around staffing, technical direction, and key principles in the process for development of the system. For a system to be sustainable, it must continue to receive funding support. For this to happen, the system must support crucial decision making processes at all necessary levels. With this in mind, there must be a balance between the existing M&E functions and potential future uses.

2 SDMX-HD Google Group: http://groups.google.com/group/sdmx_hd

Local ownership is more complex than sustainability. The term *cognitive mastery* can be used to describe what is needed for a country to have local ownership of informatics assets, such as an M&E information system and its data. Cognitive mastery denotes that in order to be able to depend on, operate, and further develop a system, the system must be thoroughly understood. To thoroughly understand the system, both the required technical skills and the information about the system must be accessible. Technical skills include both specific technical knowledge and experience within the country, along with the funding, organization, and political support for appropriate staff possessing those skills. Access to the information includes the usage of open standards and open source in order to provide known ways to access the data without the limitations of a proprietary commercialized system. In this case, it may be enough to simply use open standards for the data to be accessible. But it is also possible that standards alone are not sufficient because there is a need to access the inner workings of the system.

In order to meet the primary goal of the system, and ensure that the system is locally owned and sustainable, the following four types of requirements should be addressed:

- **human resources requirements (who uses the system)** describing the type of positions needed at each level. These requirements explain what types of users will interact with the system and what skills they will need.
- **functional requirements (how the system will be used)** describing its scope and capabilities from the users' perspective. These requirements specify what the system can be expected to do, and what it does not do.
- **technical requirements (how to build the system)**describing how the system will be designed and developed to meet the functional requirements. These requirements tell the programmer how to build the system.
- **process requirements (standards to follow while building the system)** explaining best practices in building and deploying systems. These requirements describe the best practices for the development and implementation processes, both for the conduct of the project, and for its direction and management.

This requirements document is not a complete strategic plan. Such a proposal would, in addition to a discussion of how to satisfy the requirements from each of the three categories described above, include strategies to address other aspects of the system development, deployment, and management including:

- Project Governance
- Project management and reporting
- Specific deliverables
- Cost estimates
- Timelines

NOTE: This document is expected to change as the requirements for the M&E information system evolve. Changes in the scope of the eHealth architecture and changes in technology will shape the requirements and the overall architecture of the system.

Requirements will also change based on dependencies between them. For example, if we could assume connectivity was available at the district level that would impact the system architecture requirements.

Methodology for Requirements Development

The gathering of requirements for the public health surveillance information system has involved several specific sets of activities, drawing heavily on an assessment of the currently implemented Modulo Basico system. This assessment was described more fully in "Phase I assessment" document.

Background work

In this second phase of the work, I-TECH was asked to use the assessment performed in the first phase to develop detailed system and process requirements that would address gaps in the current system, areas for improvement, and to reflect the changes in technology and understanding of requirements for routine health information systems from the past several years. The first set of activities relating to the development of these detailed requirements began prior to the initial visit to Mozambique, and involved interviewing medical informaticists familiar with the currently implemented Modulo Basico system, as well as, experienced experts in the field of HIV treatment programs who were involved in patient-level monitoring/tracking systems.

Initial visit

In October of 2008, the initial assessment visit was made by the team, including Dr. Bill Lober (I-TECH/UW) and Christina White (I-TECH/UW). They were joined by Dr. Janise Richards (CDC Global AIDS Program). During this visit, stakeholders were interviewed to gain a better understanding of the structure of and programmatic relationships within the healthcare system in Mozambique, the M&E needs and practices within the country, the MOH initiatives around development of a national health information architecture, the current capacity for healthcare IT activities in Mozambique, and the goals of a computerized monitoring and evaluation system. To become familiar with the overall flow of information and to understand how users would interact with a surveillance system, users of the current Modulo Basico system were interviewed at all four of the hierarchical levels within the healthcare system – Health facility, District, Province, and Central (MOH). Additionally, NGO representatives and University affiliates working with Health Information Systems at individual and aggregate levels in Mozambique were met with to discuss their experiences and impressions of the current system, including criticisms and opportunities for improvement around meeting monitoring and evaluation needs.

In addition to understanding the functional requirements of the system, during the assessment visit the team met with the primary developer of the Modulo Basico system for a thorough introduction to the technical aspects of the software.

Follow-up assessment

While in Mozambique, the team obtained an electronic copy of the Modulo Basico software and documentation for an independent review by the Seattle-based ITECH development team. This also is provided some insight into the current technical requirements for the system and how well they have been addressed.

Also following the visit, for further knowledge surrounding data quality issues within the healthcare system in Mozambique, the team spoke with UCSF regarding an evaluation they had been undertaking in collaboration with Ministry of Health, the US Government, and clinical HIV partners assessing HIV care and treatment facility-level electronic medical record systems evaluation in Mozambique. Lastly, to evaluate local capacity in IT support in Mozambique, the team researched the health informatics program (M-OASIS[3]) at the University Eduardo Mondlane (UEM), exploring current plans and opportunities for graduates and students of that program.

During a second visit, I-TECH worked closer with the Ministry, specifically the Department of Planning and Cooperation's Department of Health Information Systems, who have taken on the responsibility of Modulo Basico, and the M-OASIS/UEM team, who by this time had been charged with providing some essential maintenance and enhancements to the software system.

I-TECH worked with the Ministry in several ways: indentifying current problems with Modulo Basico, classifying those problems based on their threat to system operations, and developing proposed solutions and timeline. A short-term action plan was defined to address all issues critical to the functioning of Modulo Basico and the key functional specifications for phase 2 implementation of Modulo Basico. I-TECH met with both ministry and key stakeholders to better understand the scope of the problems to be addressed with a national reporting architecture and to better understand the limitations of the current system. I-TECH also participated in a workshop where the ministry and other stakeholders discussed a list of core technical specifications and decided which would be appropriate for a phase 2 implementation. In addition, using the feedback from the workshop, I-TECH worked with the Ministry to define 32 core functional requirements for Modulo Basico 2, which were used as the basis for this document.

Lastly, I-TECH worked with M-OASIS to begin the technical requirements and to develop an action plan for short and medium term maintenance and development of Modulo Basico.

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3 M-OASIS is the Mozambican node of OASIS (Open Architecture and Standards in Information System), based out of the South African NGO Jembi, with the objectives of:

1) Providing services to public and private institutions (inc MOH and NGOs) to strengthen e-Health initiatives;
2) Supporting MOH to implement National HIS Strategic Plan;
3) Acting as the reference organization for e-Health architecture and standards in Mozambique;
4) Building capacity in HIS among UEM informatics students and MOH health workers for e-Health development and sustainability; and
5) Serving as a laboratory for innovative projects. It receives funding from IDRC (Canada), USG, and other partners.

In June/July 2010, a consensus workshop was held, convened by DIS, with the participation of key stakeholders including DIS, MOH Program Focal Points, individuals working with Modulo Basico at Provincial and District level, M-OASIS, and technical partners (including WHO and CDC.) The workshop was facilitated by I-TECH staff. Objectives of the workshop were:

1. Mozambique stakeholders understand the concept and importance of a national eHealth architecture. These stakeholders also understand the role of the monitoring and evaluation (M&E) system, and how it evolves to maintain relevance within the developing eHealth architecture.
2. The draft M&E system requirements are reviewed by stakeholders and modified as needed to ensure the use cases are relevant, assumptions are correct, and the human resources and equipment requirements are realistic.

During the workshop, a draft of the requirements document was presented and each section discussed in large or small group. Recommended modifications and corrections to the various aspects of the requirements document were noted and incorporated into the final document.

M&E Information System Requirements

These requirements are broken into the following four areas: Human Resources, Functional (Use Cases), Technical, and Process.

Human Resources Requirements

The staff required to operate and support the M&E information system are described below in terms of their roles and tasks, not in terms of specific job titles. These roles may be filled by staff that has other responsibilities at the facility, especially at the district levels. Roles may also be filled by more than one staff member at each level. Furthermore, some or all of these roles may already be in place in the current system and within MISAU. The term “actor” is used in order to be consistent with the use case methodology employed to describe the functional requirements, or “how the system is used”.

Health Unit

a. Health Unit Data Clerk- This actor requires basic computer skills (data entry or other computer skills), basic data aggregation skills (in the case that a health unit still utilizes a paper-based system), and training in use of the system for data entry. In some districts the supervisor may also act in the role of a data clerk.

b. Health Unit Data Reporting Officer (Focal Point/Responsável dos Dados) - This actor requires knowledge of aggregating data, completing monthly summary reports, and calculating indicators.

District

c. District Data Entry Clerk (from District Statistical Nucleo, NED) - This actor requires basic computer skills (data entry or other computer skills), basic data aggregation skills (in the case that a district still utilizes a paper-based system), and training in use of the system for data entry.

d. District Heads of Programs - This actor serves as the validator and certifier of data that is reported. Typically this is the medical director, or operations director responsible for the validity of the reported data.

e. District System Administrator – This actor will handle technical issues; such as network connectivity problems, operating system issues or system administrative tasks that arise. The System Administrator role may be best accomplished by an external organization or technical expert.

Province

f. Provincial Data Entry Clerk - This actor is similar to the District Data Entry Clerk. These positions will require basic computer skills, and training in use of the system for data entry.

g. Provincial Data Manager - The data manager is an actor with the skills of a data entry clerk, and training in basic epidemiology. They will be trained on the reporting and visualization components of the system, in order to produce reports and statistics at the provincial level.

h. Provincial Statistical Technician – The provincial statistical technician is an actor with more advanced skills and training in epidemiology and analysis than the Data Manager. The Technician will have the capacity to generate analyses (e.g. peer to peer comparisons and other benchmarks) as well as more advanced analyses, visualizations, and maps.

i. Provincial Heads of Programs- This actor serves as the validator and certifier of data that is reported. Typically this is the medical director, or operations director responsible for the validity of the reported data

National

j. National Data Analyst –This actor is similar to the Provincial Data Analyst role. There should be a minimum of two staff members assigned to this role.

k. National Informatics Officer - Actor(s) are responsible for maintenance of M&E information system at the National Level. This role could be performed by the data analyst.

l. National Heads of Programs - This actor serves as the validator and certifier of data that is reported. Typically this is the medical director, or operations director responsible for the validity of the reported data.

m. Program Coordinators -Staff who access indicator and performance measures for specific programs whose data are collected by the M&E information system, such as HIV, Immunization, Mortality or Integrated Disease Surveillance.

n. System Administrator – This actor will handle technical issues; such as network connectivity problems, operating system issues or system administrative tasks that arise. The System Administrator role may be best accomplished by an external organization or technical expert.

o. Software Developer – Staff who addresses software issues, such as software bugs, customizations, and new reports. The Software Developer role may be best accomplished by an external organization or technical expert.

Functional Requirements

The main purpose of the M&E information system will be to collect information such as counts (aggregated facility level data) and population data starting at the District level, aggregate at the Provincial level and make it available at the National level. Data will be transmitted between levels as needed.

In the near future, health services in major cities may be moving to the Municipality level. In this case, municipalities will function like the District level, receiving information from the Health Units. When this occurs, required functionality will need to be expanded to include new use cases that encompass the functionality that would occur at the Municipality level. This would most likely be a modification to the District level use cases.

The functional requirements addressing the areas of: data collection, data transmission, data quality management, reporting, and data utilization, can be expressed as a series of use cases, or scenarios that describe this in the district, provincial, and national levels. This section consists of a summary of the required functionality followed by the specific use cases.

Summary of Required Functionality

The following summary groups required system functionality and references the use cases described in the following section.

1. Data Entry

The M&E information system will provide several electronic data entry forms for different levels and types of data. For example, the District and Province levels will both need forms to enter monthly and weekly surveillance data. Data entry forms and data reports will mirror paper forms as much as possible.

Use Cases

2.1 District Direct Entry of Monthly Program Data

2.2 District Direct Entry of Weekly Surveillance Data

3.2 Provincial Direct Entry of Monthly Program Data

3.3 Provincial Direct Entry of Weekly Surveillance Data

4.11 Backup Data Entry for District/Provincial Level

4.12 Maintain data elements and forms

2. *Data Import*

Indicator data will be imported from systems capable of export. This may happen at the district, provincial, or national level. For example, other district, provincial or national electronic systems such as SIS-H, SIS-ROH, SIS-MOR or TB may have the ability to export data in a standard format for the use of the M&E information system.

Receive-interchange data from other systems:

a. Hospital Health Information System (SIS-H)

b. Hospital Death Register Health Information System (SIS-ROH)

c. Others hospital systems

d. Others provincial electronic systems (TB, nutrition etc.)

e. Others patient based systems in the future (mainly HIV)

f. Other systems including Human Resources Information System; Supply Chain Management/Logistics Management Information Systems; Laboratory Information Systems

3. *Data Aggregation / Transmission*

Aggregation is combining Data transmission will either be done physically, through email, or automatically using a web service protocol based on resources and site capabilities. Explanations of the data protocols and specific technologies are described in the 'Technical Requirements' section.

a. Physical Transmission

Health Units currently do not have the capacity to transfer data through email or web protocols. As a result, the data will be submitted to the district level using paper forms, USB, CD or other physical media. Districts without Internet access will also submit physically submit data.

Use Cases

1.1 Health Unit Manual Transmission of Data

1.2 Health Unit Manual Transmission of disease surveillance data

2.4 District Transmission of Facility Aggregate Data to province

b. Email or Automated Transmission

The Provincial and National levels will all have access to the Internet. This will allow them to transmit data using email or web services protocol.

Use Cases

2.4 District Transmission of Facility Aggregate Data

3.5 Transmission of provincial data to National Level

4.3 National Transmission of Validated Data to a Consolidated Site for Wider Use

4. Validation and Quality Control

To ensure data quality, validation will occur at the District and Provincial levels. The specific validation and quality control processes are described in the "Technical Requirements" section.

Cutoff Dates for Data Entry

During the June 2010 discussion of functional requirements at the MISAU workshop in Maputo, following the discussion of direct entry of data there was a rich discussion of the merits and disadvantages of imposing a strict cutoff time. Several points were made that affect the validation and quality control use cases at the health unit, district, provincial, and national levels.

1) The system can accommodate a variety of mechanisms around imposing a cutoff date, or providing a reporting and visualization view of data as of the official cutoff date but still allowing subsequent entry and edits of data to improve accuracy.

2) Epidemiologists would like the data to be as accurate as possible, at any point in time when the data are retrieved.

3) Management and decision makers would like the data to be stable so the bases for their decisions are clear and repeatable.

4) If districts and provinces have the sense that they can enter data late, it may be that they will be less motivated to meet specific legislative guidelines on the entry of both monitoring and evaluation and surveillance data.

Use Cases

2.3 District Validation of Reported Data

3.4 Provincial Validation of Reported Data

4.8 Management of Data Entry Cutoff

5. Program-Specific Reporting

Data from the M&E information system will be made available to the other groups or organizations.

Use Cases

4.3 Visualization of and access to national data for wider use4.4 Restricted access and view of National Program data

6. *National Reporting /Visualization /Benchmarking*

a. Visualization

Data will need to be presented in a meaningful way using visualizations.

Use Cases:

3.6 Reporting and Visualization of provincial data

4.3 Visualization of Provincial data

b. Benchmarking

Each region will need the ability to compare data against different regions. For example, Districts can compare their data against Provincial data. At the Provincial and National levels, visualizations and reports will need to be generated and sent to the lower levels in the system.

During the June, 2010 discussion of functional requirements at the MISAU workshop in Maputo, a discussion occurred around comparison with normative or peer data.

The use cases as presented to the workshop participants incorporate the idea that districts and provinces would be able to compare their own indicator data with baseline, average, or target data supplied by the level to whom they reported. For instance, districts would be able to compare their indicators with some normalized district data supplied by the province. During the discussion, this idea was modified in several ways, as follows:

1) Comparison of indicators with those from other similar organizational units was felt to be valuable in understanding and improving local performance.

2) In addition to comparing indicators reported by a district or province, it will also be useful to compare indicators which reflect the use of the monitoring and evaluation system, such as indicators that reflect the timeliness or completeness of data entry from a district.

3) While the use cases were worded to allow comparison of either data from peer districts or provinces, or comparison with a normalized, representative, or “ideal” district or province, the conclusion of the workshop was that there would not be barriers in Mozambique to the direct sharing of one district's data with another district and that those comparisons would be most valuable

4) The notion of comparisons with a target for specific indicators was also raised during the workshop. While one mechanism for comparison with target values would be the construction of visualizations or reports that highlighted the differences between reported and target values, the workshop participants did not discuss the process by which a province, or the Ministry at the national level,

might set targets for indicators at the district level. This process may already exist in Mozambique, or it may need to be specified.

5) Feedback to health units is not defined in this set of use cases, however use cases should be developed that specify a flow of information which will help health units understand both the indicators which they submit and the contribution of those indicators to the district's overall statistics.

6) Allowing districts to compare their data with that of other districts will be a good first step in encouraging the good districts to effectively use the data, though further training and capacity development at the district level will be needed.

See changes, for instance, to the wording of use case 2.5.

Use Cases

2.5 Compare District Data to Provincial Data

3.7 Compare Provincial Data to National/Regional Data

3.8 Send Provincial Data to Districts

4.5 Send National/Regional Data to Provinces

c. Reports

The M&E information system will have reporting functionality at different levels of the system. Reports will be used to understand and analyze the data.

Use Cases

3.6 Reporting and Visualization of provincial data

4.2 Periodic Production of Reports for Strategic Planning

4.4 Restricted access and view of National level data

Use Cases

We have used use cases to describe the functional requirements, or capabilities, of the system as a series of tasks. The skills and experience, and any specific training required by the person who carries out those tasks are described in the 'Human Resources Requirements' section. In use case terminology, the tasks are referred to as actions, and the people are referred to as actors.

These use cases are a combination of the existing workflow for Modulo Basico, modified by our initial assessment of how these actions should be performed, and what actors should be available to perform them. We have also made some comments to indicate areas where further development of the system may further impact the system workflow.

1. Health Unit Level Use Cases

1.1 Manual Transmission of Indicator Data	
Description	The Health Unit needs to report certain indicators to their corresponding District by the 2nd of each month
Actors	• Health Unit Data Clerk
Actions	1. Each month, the data clerk compiles summary indicators based on the data collection tools defined by the Health Unit (i.e. log books, forms, agenda books). 2. The indicators are compiled on MOH paper forms. 3. A copy of the paper forms are kept locally and a copy are sent to the district office.
Comments	• At present, electronic data transmission from the Health Unit level does not occur • This use case may need to be expanded to include flexible, reliable electronic transmission from future local electronic systems over inconsistent and/or moderate bandwidth communications pathways such as IP over the digital cell network.

1.2 Manual Transmission of disease surveillance information	
Description	Every week, the Health Unit needs to report disease surveillance information to their corresponding District.
Actors	• Health Unit Data Reporting Officer
Actions	1. Each week, the data reporting officer compiles disease surveillance information from the log books. 2. The indicators and disease surveillance information are compiled on MOH paper forms. 3. A copy of the paper forms are kept locally and a copy are sent to the district office.
Comments	• At present, electronic data transmission from the Health Unit level does not occur • This use case may need to be expanded to include flexible, reliable electronic transmission from future local electronic systems over inconsistent and/or moderate bandwidth communications pathways such as IP over the digital cell network.

2. District Level Use Cases

2.1 Direct Entry of Monthly Data	
Description	Every month, the District needs to enter monthly indicator data for each site. This is part of consolidating data for reports.
Actors	• District Data Entry Clerk (from District Statistical Nucleo, NED)
Actions	1. District receives monthly indicator data from a site on a series of paper forms 2. Data entry clerk logs into the system so that data entry may be attributed to a specific individual entering the data 3. Data entry clerk navigates main menu to find an appropriate form 4. Data entry clerk enters data using appropriate form 5. As data are being entered, the system will perform first order and second-order validations, as described under the data quality in the technical requirements section. The system flags any questionable entries. 6. Flagged entries will be communicated back to the health unit for corrections with the permission of NED. Furthermore, a report of errors will go to district health officer, statistical group, or head of program (exact workflow to be determined, but does not impact system design) 7. Based on communication with the health unit, the data entry clerk resolves any questionable entries, or flags the form for review by the District head of program
Comments	• Double entry of data[4] of all or a subset of entered forms increases time required (and therefore expense) of data entry, but can significantly reduce typographic errors which are not so obvious as to trigger one of the validation rules. The trade-off between expense and accuracy should be considered by MISAU in making a policy decision.

4 Double entry of data is a process used in many health information systems that involves entering each data element twice into the system in order to compare the two entries for consistency. The system can then flag the entries for inconsistencies and provide reports and alerts to make corrections and improve the quality of the data.

2.2 Direct Entry of Weekly Surveillance Data	
Description	Every week, the District needs to enter weekly disease surveillance data for each site. This is part of the national disease reporting system, which follows WHO integrated disease surveillance reporting guidelines.
Actors	• District Data Entry Clerk (from statistical group)
Work Flow	1. District receives weekly disease surveillance data from a site on a paper form 2. Data entry clerk logs into the system so that data entry may be attributed to a specific individual 3. Data entry clerk navigates main menu to find an appropriate form 4. Data entry clerk enters data using appropriate form 5. System applies validation logic as data are being entered and flags any questionable entries. Report of errors go to district health officer, statistical group, or head of program (exact workflow to be determined, but does not impact system design) 6. Data entry clerk resolves any questionable entries, or flags form for a review by District head of surveillance program.
Comments	• Double entry of data of all or a subset of entered forms increases time required (and therefore expense) of data entry, but can significantly reduce typographic errors which are not so obvious as to trigger one of the validation rules. The trade-off between expense and accuracy should be considered by MISAU in making a policy decision.

2.3 Validation of Reported Data	
Description	Initial validation of reported data takes place at the District level.
Actors	• District heads of programs
Work Flow	1. As the data entry clerk enters the data, the system will perform first order and second-order validations, as described under the data quality in the technical requirements section. The system flags any questionable entries. 2. If double entry of data is required than the data entry clerk will need to review the summarized data on the system against that which was entered from the paper forms. This will be done through a facility level report

	specifically designed to support data entry review. 3. The data entry clerk will correct questionable values as they are able to, based on contacting the Health Unit for additional information. 4. In the event the data entry clerk is not able to correct questionable volumes, the entered data will be electronically marked as having been accepted with errors, with an accompanying comment. . Furthermore, a report of errors will go to district health officer, statistical group, or head of program (exact workflow to be determined, but does not impact system design)

2.4 Transmission and Monitoring of Facility Level Aggregate Data	
Description	Facility level data are transmitted to the provincial office by the 5th of each month.
Actors	• District Data Entry Clerk • Provincial Data Entry Clerk
Work Flow	1. At the appropriate reporting interval (clarify this) the data entry clerk will arrange for transmission of data from the district level to the provincial level. The system will generate a standards-based file of indicators (see technical requirements under data standards).This file can be transmitted one of three ways. a. Physical transmission -- the file can be copied onto digital media such as a flash drive or writable CD/DVD, and that media may be sent to the provincial office. b. E-mail transmission - the file can be attached to an e-mail and e-mail to the provincial office. c. Automated transmission -- the file may be transmitted to the provincial office directly from the application using a Web services protocol (see technical requirements under data transmission protocols). 2. The data clerk will receive electronic confirmation that their transmission has been received by the provincial office, either manually through e-mail, or as an e-mail generated directly through the automated transmission system.

	3. The provincial data entry clerk will confirm the receipt of data and the data will be automatically computed and viewable in the provincial level format where it can then be validated. If data are not sent, provincial data clerk will contact district.
Comments	• Automated transmission is inherently secure, as it can easily be implemented using encryption. We need to assess the extent to which the Ministry values encryption for both physical and e-mail transmission. Both are technically feasible but require additional steps on the part of the data clerk and on the part of the provincial office receiving the data.

2.5 Reporting and Visualization of District Level to district peers	
Description	Review monthly and weekly data from districts and compare to similar data reported by peer districts
Actors	• District heads of programs
Work Flow	1. Receive data from districts from the provincial level in one of the following two ways: a. Electronically – the peer data are received electronically and reports and visualizations are displayed of local data versus the comparison data. b. Manually -alternatively, the data and the comparative reports and visualizations may be received as a PDF or on paper from the province. 2. The District heads of programs review and compare the local data versus the norm.
Comments	• Ideally, the District will have access to the comparison data to analyze it themselves. However, if it cannot be transmitted electronically, the comparison may need to be done at the Province level. See use case #3.7

2.6 Data Backup	
Description	The database will be backed up regularly so that any loss of data can be easily restored. The purpose of backing up a database is to ensure that data will not be lost if the original database is destroyed. The reason a database may be destroyed can range from a hard disk failure to the server being destroyed in a fire.
Actors	• District system administrator
Work Flow	1. On a regularly basis, the M&E information system data should be backed up using appropriate practices as identified in the technical requirements? section. 2. A copy of the data should be kept by the chief medical officer and the district health officer at the district level 3. If there is an issue with the original database, such as data loss or database corruption, the backed up data will be restored. The system will use the records of imported data to recreate data transmissions into the system, essentially recreating the history of changes to the database along with restoring the data.
Comments	• See also the section on backups in Technical Requirements for a more complete discussion of centralized, off-site backup.

3. Provincial Level Use Cases

3.1 Receipt and Confirmation of Electronically Reported Data	
Description	In cases where data is electronically transmitted, the data will be accepted and imported appropriately
Actors	• Provincial Data Manager
Work Flow	1. The data clerk will be prompted on login that there is data pending import from the district. 2. The data clerk will verify the district and date range, and then accept or reject the requested import 3. If accepted, the data will be imported and viewable in the system, and the provincial version of the form will be computed and filled in automatically 4. If data have errors, they will not be imported and notification should be sent to the district
Comments	• Data imported that overlaps data that has previously been reported for a specific health unit and reporting period will be updated with a record of the change stored appropriately • The system should store any data imported which is electronically received so that it can be retransmitted into the database to recreate the history of changes. In addition, a log file should be maintained by the system which records both the date-time and source of data imports, as well as the date-time of any manually entered data or data edits. See Technical Requirements section on Audit history

3.2 Direct Entry of Monthly Data	
Description	If electronic data transmission did not occur for a specific set of district data, then those data should be entered by a user into the system at the provincial level.
Actors	• Provincial Data manager • Provincial Statistical Technician
Work Flow	Note that the following process is identical to that described at the district level, with the exception of validation, and documentation of that validation, by an individual other than the data manager. In the event that electronic data transmission did not occur:

	1. Province receives monthly indicator data from a site on a paper form 2. Data manager logs into the system so that data entry may be attributed to a specific individual 3. Data manager navigates main menu to find an appropriate form 4. Data manager enters data using appropriate form 5. As data are being entered, the system will perform first order and second-order validations, as described under the data quality in the technical requirements section. The system flags any questionable entries. 6. Flagged entries will be communicated back to the district for corrections. Furthermore, a report of errors will go to statistical technician. 7. Based on communication with the district, the data manager resolves any questionable entries, or flags the form for review by the Province Statistical Technician. 8.
Comments	• At the provincial level, where more staff are available, and data entry should be validated by a second person, typically a supervisor or analyst • Double entry of data increases time required (and therefore expense) of data entry, but can significantly reduce typographic errors which are not so obvious as to trigger one of the validation rules. The trade-off between expense and accuracy, and the actual occurrence rate of errors, should be evaluated before policy is finalized.

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3.3 Direct Entry of Weekly Surveillance Data	
Description	If electronic data transmission did not occur for a specific set of district data, then those data should be entered by a user into the system at the provincial level.
Actors	• Provincial Data manager • Provincial Statistical Technician
Work Flow	Note that the following process is identical to that described at the district level, with the exception of validation, and documentation of that validation, by an individual other than the data manager. 1. In the event that electronic data transmission did not occur: Province receives weekly disease surveillance

	data from a site on a paper form 2. Data manager logs into the system so that data entry may be attributed to a specific individual 3. Data manager navigates main menu to find an appropriate form 4. Data manager enters data using appropriate form 5. As data are being entered, the system will perform first order and second-order validations, as described under the data quality in the technical requirements section. The system flags any questionable entries. 6. Flagged entries will be communicated back to the district for corrections. Furthermore, a report of errors will go to statistical technician. 7. Based on communication with the district, the data manager resolves any questionable entries, or flags the form for review by the Province Statistical Technician.
Comments	• At the provincial level, where more staff are available, and data entry should be validated by a second person, typically a supervisor or analyst • Double entry of data increases time required (and therefore expense) of data entry, but can significantly reduce typographic errors which are not so obvious as to trigger one of the validation rules. The trade-off between expense and accuracy, and the actual occurrence rate of errors, should be evaluated before policy is finalized.

3.4 Validation of Reported Data	
Description	Validation of both data entered by a user and automatically transmitted data takes place at the provincial level.
Actors	• Provincial Statistics Technicians • Provincial Data Manager
Work Flow	1. For data entered by a user, as the data entry clerk enters the data, the system will perform first order and second-order validations, as described under the data quality in the technical requirements section. 2. The data entry clerk will correct questionable values as they are able to, based on contacting the Health Unit for additional information. 3. In the event the data entry clerk is not able to correct questionable volumes, the entered data will be

	electronically marked as having been accepted in error, with an accompanying comment. 4. For automated data and for data entered by a user, once the actions above have been completed, the data analyst will produce reports designed for third order validation (see technical requirements for data quality). 5. The data analyst will investigate any discrepancies and annotate any unresolved discrepancies directly in the system.
Comments	

3.5 Transmission of provincial Data	
Description	Facility level data are transmitted to the national office by the 10th of each month.
Actors	• Provincial Data Manager
Work Flow	Note that this process is essentially the same as that at the district level, with the exception that all transmission of data from the provincial to the national level should be electronic, with manual transmission used only as a backup. 1. At the appropriate reporting interval (clarify this) the data entry clerk will arrange for transmission of data from the provincial level to the national level. The system will generate a standards-based file of indicators (see technical requirements under data standards).This file can be transmitted one of two ways. a. E-mail transmission - the file can be attached to an e-mail and e-mail to the national office. b. Automated transmission -- the file may be transmitted to the national office directly from the application using a Web services protocol (see technical requirements under data transmission protocols). 2. The data analyst will receive electronic confirmation that their transmission is been received by the national? office. If the data are not sent, the National level data analyst will contact province.
Comments	• Automated transmission can be made inherently secure, as it can easily be implemented using encryption.

	• We need to assess the extent to which the Ministry values encryption for both physical and e-mail transmission. Both are technically feasible but require additional steps on the part of the data clerk and on the part of the provincial office receiving the data.

3.6 Reporting and Visualization of provincial data to provincial peers	
Description	The data will be made available for monitoring and decision-making at the provincial level. Review monthly and weekly data from province and compare to similar data reported by peer provinces
Actors	• Provincial Statistical Technician
Work Flow	1. Receive data from peer districts at the provincial level in one of the following two ways: a. Electronically – the peer data are received electronically and reports and visualizations are displayed of local data versus the comparison data. b. Manually -alternatively, the data and the comparative reports and visualizations may be received as a PDF or on paper from the province. 2. At a monthly, quarterly and yearly interval, technician will use both reporting and visualization functions of the system to create a provincial level report disaggregated by level (province, district, facility), indicators, program, period etc 3. At a weekly interval, the technician will use reporting and visualization functions to produce a disease report for the province with different desegregations. 4. At appropriate time the data analyst will produce the standard provincial report 5. The Provincial Statistical Technician reviews and compares the local data to the peer data.
Comments	• In order to support a cut-off date, the visualization of data at the provincial level should be available either considering all available data entered, or considering only those data entered prior to a cut-off date

	• The Province will have access to the comparison data to analyze it themselves. However, if it cannot be transmitted electronically, the comparison may need to be done at the National level

3.7 Compare Provincial Data to National Norms	
Description	Review monthly and weekly data from Provinces and compare it to the actual and targets from National level..
Actors	• Provincial Statistical Technician
Work Flow	1. Receive national data norms electronically. Visualization and maps are displayed of local data versus the norm data. 2. The Provincial Statistical Technicianreviews and compares the local data versus the norm.
Comments	• Provinces and National level should all have internet connection and the ability to send data electronically. In the case that internet connection is not available, reports of the comparison data should be able to be generated from the system and delivered to the province. See use case #2.5 for transmission explanations.

3.8 Send District Peer Data to Districts	
Description	Generate and send visualizations/maps to district level for comparison.
Actors	• Provincial Statistical Technician
Work Flow	1. Provincial Statistical Technician generate visualizations/maps of peer comparison data. 2. Send peer comparison data to Districts either electronically or manually. See use case #2.5 for transmission explanations.
Comments	

4. National Level Use Cases

4.1 Receipt and data quality checks of provincial Data	
Description	This use case combines the manual receipt of electronic data, the receipt and monitoring of automated data, and the initial validation of all received data.
Actors	• National Data analyst • National Heads of Programs
Work Flow	Note that this process is similar to the provincial level, with the exception that should almost entirely involve automated data transmission processes, with e-mail or usb transmission of electronic data, and manual entry, in the event automated transmission is not working. 1. For automated data, the national data analyst will receive e-mails indicating when data have arrived, or when data that are anticipated have not arrived after a certain period 2. The analyst will contact provinces for which data is missing and attempt to determine the reason for that data, annotating province specific notes in the system. 3. Using system reports and visualizations to display third order validations, the analyst will review the data and further attempt to resolve anomalies.
Comments	• In order to deal with the larger volume of data at the national level, a much more experienced data clerk, or data analyst, will be needed to receive and integrate the aggregate data.

4.2 Periodic Production of Reports for Strategic Planning	
Description	To find reports across all programs will be produced periodically for monitoring and strategic planning at the leadership level in the Ministry
Actors	• Data analyst
Work Flow	Though specific workflow will depend on the required interval and nature of the reports, in general these actions will describe periodic production of predefined reports, as well as ad hoc database analysis to support specific initiatives.
Comments	• We anticipate that a minimum of two analysts would be needed at the national level to operate the system, receive data, and provide routine and customized analysis

4.3 Visualization of and access to national data for wider use	
Description	The data will be made available for monitoring and decision-making at the national level
Actors	• Data analyst • Informatics Officer • Program Coordinators
Work Flow	1. Data is packaged in a standard way and transmitted electronically to a secured consolidated site for access by Program Coordinators and others. 2. On an ad hoc basis the analyst will produce reports and visualizations to help explore anomalies at the national and provincial level
Comments	• We need to explore whether the ministry would support the idea of national benchmark indicators being sent back to the provinces for local comparison.

4.4 Restricted access and view of National Program data	
Description	To securely access consolidated data from specified time periods
Actors	• Program Coordinators
Work Flow	1. Program Coordinators log in to a secured consolidated site to view data and visualizations pertinent to national programs.
Comments	• We anticipate that a minimum of two analysts would be needed at the national level to operate the system, receive data, and provide routine and customized analysis

4.5 Send National/Regional Data to Provinces	
Description	Generate and send visualizations/maps to Province level for comparison.
Actors	• Data Analyst
Work Flow	1. Data Analyst generates visualizations/maps of National data. See use case 4.3 2. Send norm data to Districts electronically. See use

	case #3.7.
Comments	

4.6 System Maintenance	
Description	The M&E information system will require IT support and maintenance.
Actors	• System Administrator
Work Flow	1. As IT issues arise, requests will be sent to System Administrator(s) who will troubleshoot and find solutions for the following technical areas: a. Computer issues b. Operating System issues c. Network connectivity d. Anti-virus management e. Application management 1. Apply software updates and patches 2. Administer user accounts by resetting passwords, adding and removing user accounts
Comments	• Some maintenance work may be done locally as needed by provinces. Depending on resources, a team of IT support could be developed at the Provincial level to provide support to Districts.

4.7 Software Development	
Description	The software modifications and additions will be needed to address bugs and provide new functionality.
Actors	• Software Developer

Work Flow	1. Software issues will be tracked and reported to Software Developers who will address the following types of requests: a. Add support for new or modified program b. Fix software bugs c. Add new visualization or report d. Customize software for different facilities e. User interface changes
Comments	

4.8 Management of Data Entry Cut off	
Description	To ensure data quality, changes to data will not be allowed from a certain cut-off date.
Actors	• Informatics Officer
Work Flow	1. Informatics Officer has the ability to modify the cutoff date or cut off criteria, such as data greater than one year old. 2. Requests to remove the cut off restriction will be reviewed by the Informatics Officer. If the request is deemed as valid, the Informatics Officer grants access to modify the data.
Comments	• Needs policy clarification

4.9 Data Backup

Description	The database will be backed up regularly so that any loss of data can be easily restored. The purpose of backing up a database is to ensure that data will not be lost if the original database is destroyed. The reason a database may be destroyed can range from a hard disk failure to the server being destroyed in a fire.
Actors	• National system administrator
Work Flow	1. On a regularly basis, the M&E information system data should be backed up using appropriate practices as identified in the technical department section 2. A copy of the data should be kept by the chief medical officer and the district health officer at the district level 3. If there is an issue with the original database, such as data loss or database corruption, the backed up data will be restored, and data transmissions "replayed" into the system, as a more reliable way of restoring data than trying to directly edit the database
Comments	• See also the section on backups in Technical Requirements for a more complete discussion of centralized, off-site backup.
4.10 Maintain National Health Unit List	
Description	Maintain national health unit facility directory with names and facility codes.
Actors	• Software Developer
Work Flow	1. The software developer is notified by the Provincial Data Manager that they have received notice of a new health unit or community based organization in the district 2. The developer assigns a new code to that unit, and notifies both the provincial data manager and the district health officer
Comments	• The workshop raised the issue that it is always a challenge to maintain a national registry when the information on new health facilities is best known

	locally. • It may be best to allow districts to create new facility codes, but then have them send identifying information to the national registry. This does not address the issue of creating inappropriate facility codes. • The issue of overlap between facility codes, and codes representing community based organizations was discussed – in certain programs the relevant unit of analysis may not be the facility, but rather an NGO program or region. • The workflow above represents the simplest approach to centrally assigned facility codes, and may need to be enhanced.

4.11 Backup Data Entry for District/Provincial Level	
Description	In the event that only paper data are received from a district or province the national level will enter those data into the database. This is not expected to be the normal situation
Actors	• National Data Analyst
Work Flow	1. Use standard practices outlined in district level use case to enter and validate data directly into the system.
Comments	

4.12 Maintain data elements and forms	
Description	At the national level, the forms and the data elements on those forms need to be evaluated centrally to minimize duplication and ensure the best representation when new forms and program data are added to the monitoring and evaluation system.
Actors	• National Data Analyst • National Heads of Programs • Software developers

Work Flow	This workflow does not describe direct use of the system, but instead describes the development of enhancements. 1. A request to add new data to the monitoring and evaluation system comes from the national head of a program. 2. The national data analyst works with the software developers to identify the characteristics of the form and its data and ensure they are accurately representing in the system 3. The software developers make enhancements to the system and distribute the new release.
Comments	

4.13 Maintain master health unit list	
Description	At the national level, the health unit list needs to be maintained when new units are added or units are eliminated within the country.
Actors	• Data Entry Clerk
Work Flow	The level that this workflow needs to be determined. It would be logical for the maintenance to occur at the national level, however, this presents a problem when the district or provincial level need to do work that involves a change in the health unit list. This could result in the work being blocked until the national level completes the task. To avoid this, the system could allow the district or provincial data entry clerk privileges to modify the data, but then the system would need a way to reconcile the list between the district, provincial, and national levels. This will need to be resolved before this use case can be fully developed.
Comments	

Additional use cases may need to be added to this section, through discussion with the ministry, to describe how specific data sets will be made available to specific programs within the Ministry. In general, program staff will be able to access the system and look at reports and visualizations for their programs, as well as being able to download specific, predefined,

analysis sets in a simple to use format such as a comma separated value file or an Excel spreadsheet.

Technical Requirements

Technical requirements are difficult to define because technical direction often needs to follow other decisions that are made. An example of this can be seen in determining the system architecture or overall technical approach to the software. Utilizing an open source approach allows for obtaining freely distributed software that can be modified and improved upon by the acquiring party with full and open access to the collected raw data, but does not have the support of specific vendors for development, training, and maintenance. If MISAU decides to be closely involved in the software development of the M&E information system, using open source is a good choice because it offers an increased understanding and control of the system. As outlined earlier, this awareness and understanding of the system results in greater local ownership . On the other hand, if MISAU instead decides to issue tender for a commercialized product, that can result in an application that is less customized for the specific workflow within the program but that provides the security of being backed by a vendor that can be held accountable for such things as the reliability, development, support, and timeliness of the delivery of the system.

Just as the technical requirement around system architecture is supported by the decision around how closely involved MISAU will be to the software development, the determination of the overall technical approach can affect other technical requirements, such as the implementation of open standards around data management within the system. With an open source approach, MISAU would have the control of the decision of whether to require the implementation these standards into the system. By utilizing a vendor system, this decision becomes left to chance as to whether standards have already been included in the system (which is unlikely) or the willingness of the vendor to accommodate a request by MISAU to customize the system to include it in their particular implementation.

In order to define technical requirements in advance of these and other decisions that would normally determine feasible technical directions, assumptions must be made about what those decisions will be. For example, in detailing the technical requirements below around the system architecture, the assumption is that MISAU wants to be closely involved in software development and therefore, the requirements are based using an open source approach for the reasons outlined above.

Assumptions also need to be made around the availability of reliable communications. Having reliable communications allows for the requirement to centralize systems, which would be cheaper to implement and support, require less effort to exchange data (systems can be synchronized reliably, and can depend on each other in real time), and allow for systems to be maintained remotely. In addition, the approach to data replication for population uses, to backup and disaster recovery, and how data will transfer between sites is all dependent upon the support of reliable communications.

In developing the following technical requirements, assumptions had to be made in several areas that influence the requirements. As mentioned, one of those areas is the assumption that MISAU will be closely involved in directing the development.

Other assumptions were also made, including:

- There will be a strategic plan implemented for developing a national eHealth architecture. Therefore, the system should be architected as a building block of national data and workflow for this national architecture, rather than as a system that can only function within its initial purpose and boundaries. This assumption is made along with the assumption that there is a plan to exchange data with other systems (EMR, program systems, etc.) and that the usage of open standards is desired to implement this to be compatible with other systems in the national eHealth architecture that may currently exist or exist in the future.

- The best understanding of the data is at the site level, but that the best staffing for data quality monitoring and analysis is at the national level (which makes sense since more complex uses of the data are at the national level).

- Connectivity from the provinces is good but not perfect. In contrast, the connectivity from the districts is highly variable and should not be relied upon for applicable requirements (such as data backups, data exchange, etc.)

- Policy drives the operational rules that the system should support. In developing a system's functionality, it can either be developed to support these operational rules, enforce these operational rules, or get in the way of the operational rules. Although it might sound ideal to create a system that enforces those rules, the best practice would be to create the system to allow the functionality to follow those rules without creating such restrictions in that functionality that it does not allow for flexibility within or changes to the policy.

- MISAU would want to use standard practices around security of and auditing of health data, such as to ensure privacy and confidentiality of any patient information.

With these assumptions in mind, the following requirements detail technical considerations that need to be addressed during the software design and implementation stages of the project. These requirements are designed to build in system security, stability, and interoperability. Future work, as highlighted in the assumptions, has also been considered in an effort to anticipate system expansion and maintainability issues.

The technical requirements are categorized into groups and marked as core or secondary requirements. The core requirements are critical and mandatory for the system to function well. If the core requirements are not implemented, the system will not meet users' needs and the overall stability of the system will be comprised. Ideally, the secondary requirements will be implemented as well, but they are a lower priority than the core requirements.

System Architecture and Platform

The system will be implemented using a web-based architecture in order to build a robust, easily accessible system. An open source approach to development will be followed to encourage collaboration with partner organizations. To improve maintainability, technical documentation of the code will be developed and the code itself will be structured and commented using best practices.

System Architecture and Platform	
Core Requirements include:	• Open-source application ✓ File transfer of signed, encrypted data – in a media independent way • Web- based Architecture • System must included dynamic web elements and services where appropriate • Code will be structured and well documented • Will be able to function both on a network and as a standalone application

Database Architecture

Database management is the key to data quality and reporting capabilities. Database design best practices should be followed including reducing storage of duplicate data and maximizing query performance. Data quality issues also need to be considered. For example, each record should be uniquely identifiable and all required fields should be defined.

Database Architecture	
Core Requirements include:	• Each record should contain a key and a globally unique identifier • The records should be labeled with an internal and primary key that is not dependent solely on the data elements being stored • An audit history of database transactions should be efficiently maintained • Database will support overlaps of imported data without deletion or improper duplication of data • The database will be structured in such a way that there is a clear linkage between indicators of the same type • There will be a clearly defined access protocol and database security profile

Application

Good internationalization practices such as language independence, flexible data formats, and writing conventions will be used, with localization in Portuguese. The user interface will include all the necessary data entry forms as well as visualizations for reports. Aggregate data will also be viewable, but a cutoff date will be applied.

Application

Core Requirements include:	• Localized in Portuguese • Robust visualizations based on stakeholder and end user input • An interface to add/modify indicators and definitions • A web interface to view aggregate data up to a certain cutoff date • Include interfaces for entering data in all the forms that are attached to this document

Data Transmission and Interoperability

Interoperability is the ability for a system to securely communicate and exchange data in an accurate, reliable, and meaningful way with another information system so that the clinical or operational purpose and meaning of the data are preserved and unaltered[5].

Data Format Standards

With the exchange of information, data standards have been developed to ensure consistency of both structure and meaning of data between information systems.

Standard formats require agreement both on format (syntax) and meaning (semantics). Format is the order and structure of specific data fields, while meaning is expressed through the choice of coding schemes, rules, and other constraints on content.

There are no well established standards for aggregate data or indicator transmission; however there are two that are emerging. Quality Reporting Document Architecture (QRDA) is being developed on the HL7 Clinical Document Architecture (CDA) model, as well as, the WHO implementation into the health domain of SDMX-HD which is adapted from an existing ISO standard called Standardized Data and Metadata exchange (SDMX) which is implemented in banking and other commercial sectors. WHO is further constraining that standard to meet specific requirements of reporting in the health sector.

Data Transmission Protocols

There are a number of common standard data transmission protocols that provide reliable, secure transmission, such as HTTPS POST web services, SOAP web services, and SFTP. It is not difficult to support one or more of these standards

Data Transmission and Interoperability	
Core Requirements include:	• When connectivity is available, a mechanism to transmit data over a secured connection, with: ✓ File transfer of signed, encrypted data – in a media independent way • Secondary process for transmission of data for when connectivity is unavailable that could include paper reports and data entry into the system • Documentation of an Integration Profile for interoperability with facility based aggregate reporting systems • Automated, scheduled indicator data transmission • Defined process for paper reporting of indicators that integrates appropriately with the electronic system

5 Interoperability Standards for Health Information Systems, Bailey C, Boucher P, Spohr M, Whitaker P, July 2008

Data Quality

Data quality functions need to be established within the application to ensure that the data collected and processed are accurate, reliable, and organized in such a way that allows for users to trust the data for reporting and program evaluation.

Data validation checks can be built into a system to be synchronous or asynchronous. Synchronous validation occurs prior to the loading of data into the repository and verifies that all data elements are reported using a valid format and value. For example, the data entry user is provided with on-screen error messages at the time that data is entered into the form. Asynchronous validation occurs after data has been loaded into the repository and involves algorithms run against the data stored in the database to determine anomalies within the data, which can then be reported through a notification system to data managers. Within these two categories of validation there are four different levels:

1. 1st order validation verifies that data elements are input in a valid format and value. This includes range checking where the data element is validated against a range of allowable values for that element, and finding missing data for required fields. 1st order validation catches obvious data entry errors, while leaving more complicated errors for data managers to resolve asynchronously. This approach avoids putting data entry personnel in the position of needing to interpret the meaning of what is written on forms in order to save records.

2. 2nd order validation is historical comparison for the same data element, such as if an indicator increases or decreases abruptly.

3. 3rd order validation is assessing the data element for consistency within a specific form or set of indicators. An example being the number of pregnant women treated was larger than the number of women diagnosed as pregnant for a given time period.

4. 4th order validation is the assessment of the statistical outliers, which may or may not be accurate. This function is traditionally performed by an epidemiologist or statistician, in the course of cleaning a data set for analysis, however it is properly considered to be a form of validation.

The degrees of validation described above included in the data quality use cases, in the functional requirements section of this document. Fourth order validation is typically only done in the preparation of an analysis data set, but could be incorporated as part of routine data quality processes.

Data Quality	
Core Requirements include:	• A mechanism for a user to flag individual questionable data elements within forms for review • Basic synchronous first order validations, as defined by indicator definitions • Asynchronous validations: ✓ Basic reports which characterize and visualize gaps in data completeness or timeliness, as well as the integrity of data ✓ Clearly defined and documented district and provincial level procedures for data quality

Secondary Requirements	• Tools to support third and fourth order validations

System Installation and Upgrades

There should be a clearly defined process for system implementation and maintenance. The upgrade process should be seamless and as easy as possible, catering to an audience with intermediate computer literacy. The installation and upgrade process should consist of an initial piloting phase and with wider distribution and implementation following successful piloting.

System Installation and Upgrades	
Core Requirements include:	• Upgrades should have minimal impact on system availability • Application should be clearly and appropriately versioned for the tracking of releases • The release schedule should be ad-hoc, based on deliverables priority and direction of ministry staff • The upgrade process should be automated and easy to use, preferably as an executable file with a wizard interface • Clearly documented processes for selecting, testing, and validating new releases

Security, Backup, Confidentiality

Security is a collection of technical approaches that address issues covering physical, electronic, and procedural aspects of protecting information collected as part of using the system. *Confidentiality* relates to the right of individuals to protection of their data during storage, transfer, and use, in order to prevent unauthorized disclosure of that information to parties other than those authorized.[6]

System Installation and Upgrades	
Core Requirements include:	• The authentication layer will be clearly separable from the application layer • Support of role based authentication with: ✓ Administrative interface to add/modify users and roles ✓ Capacity to assign a user to more than one role • Clearly defined protocols for backups, including: ✓ Frequent automated backups on a local hard drive ✓ Less frequent external backups ✓ Periodic routine external offsite backups in the event that the host goes down • All staff involved should sign an appropriate non-disclosure agreement to secure the inappropriate use and/or sharing of data •

6 Strategies for Building National-scale Longitudinal Patient Monitoring Systems for HIV Treatment and Care in PEPFAR Countries: Developing an Electronic Medical Record (EMR) System Implementation Plan, CDC

System Auditing / Logging

Audit trails provide useful information about actions taken by users. For example, data modifications, application access, and report generation can all be tracked. This audit trail can inform investigations into data quality issues and provide status.

System Auditing/Logging	
Core Requirements include:	• A detailed audit trail should be recorded that tracks the following: ✓ Access to the application ✓ Database views and changes ✓ Report generation ✓ Data import and export • The audit history should contain the following ✓ Action ✓ Process content (if any) ✓ User ✓ Date and time

Reporting, Visualization, & Geographic Information Systems

A strong reporting capability is critical to the system's success. Users need the ability to extract data in a meaningful way, including graphical representations and visualizations. Reports will also need to be tailored for different types of users at different levels.

Reporting	
Core Requirements include:	• Flexible report generating architecture that supports: ✓ Automated report generation ✓ Automated transmission of reports ✓ Graphical representations and visualizations ✓ Intermediate interpretation of raw data ✓ Geographical distribution of indicators • National level reports in the areas of: ✓ Strategic Planning ✓ Data Quality • Provincial and District level reports in the areas of: ✓ Data Quality ✓ Program Management
Secondary Requirements	• National level reports in the area of: ✓ Financial Analysis (fiscal projections)

System Documentation

The system should be appropriately documented. Documentation types can be categorized as follows:

- Requirements: Statements that identify attributes, capabilities, characteristics, or qualities of a system.
- Architecture/Design: Overview of software, includes relations to an environment and construction principles to be used in design of software components
- Technical: Documentation of code, algorithms, interfaces, and APIs.
- End User: Manuals for the end user, system administrators and support staff

Documentation should accompany the software when it is deployed.

System Documentation	
Core Requirements include:	• Physical view of the system • Data flow between levels, interface diagrams • Software Design Description • Database Design Description • Maintenance and Installation Guide • End User Guide

Process Requirements

Process requirements are key principles by which we make decisions for development and implementation. Unlike technical requirements, these requirements do not rely on assumptions made but rather operate as best practices to be used in any development project.

Participatory Design

Best Practice: The system should be developed using participatory design, in which users are involved during the design phase to ensure that the system supports their work practices and patterns.

Participatory design is an approach to system design that stresses the importance of user and stakeholder contributions. The technical team maintains open communication with users and stakeholders to receive input and feedback about potential solutions. Interviews, meetings, prototypes and other collaborative efforts are used to bridge the gap between the technical team and the users. An advantage to this approach is that user domain knowledge and expertise can be captured and incorporated into the system. Strong participation from stakeholders also helps ensure that the design meets users' needs.

Usability

Best Practice: Usability testing should be done to ensure that the system meets the functional requirements expressed through the use cases.

Usability refers to the ease in which a user can interact with a system to accomplish tasks. Systems with high usability help users perform tasks efficiently, accurately, and easily. To test usability, users are asked to perform tasks under observation or users provide information about

their experience performing the tasks. Information gathered from the usability testing informs design decisions to improve the user's experience. Scenario descriptions, or use cases similar to the ones define in the Functional Requirements section, can be developed to formally define the tasks to be tested.

Development

Best Practice: Reduce reliance on development assistance from external resources.

To move towards the transfer of full responsibility for the system to the MISAU, existing local capacity and the development of local technical capacity should be considered while developing the system. Training staff in the areas of software development, IT implementations and on-going technical support will reduce the need for technical assistance. Also, the programming languages and development tools used to support and enhance the system will require specific technical skills that may not be available locally. This should be considered during the planning phase so that a critical reliance on vendors does not develop.

Best Practice: The software should be platform independent.

Software that is platform independent can run on any hardware platform (for example: PC, Mac) or software platform (for example: Linux, UNIX, Windows). This increases access to the system because users or facilities with a variety of platforms can all use the software. Installation effort is also reduced because of platform independence and the MISAU will have flexibility in terms of technical skills needed to support the system.

Best Practice: Standards should be used for both internal representation of data and for data transmission.

Best Practice: An incremental development approach should be followed.

An incremental development approach is a process of continually delivering new functionality at relatively short intervals rather than delivering all functionality at the end of development. This approach provides flexibility, allowing for phased deliverables and room for unforeseen but necessary changes needed as the problem spaces is better understood and requirements are subsequently refined.

Best Practice: Software should be open source, and other partners should be permitted access to the system and should be involved in the development and maintenance.

The source code of open source software can be used, modified, and distributed at no cost versus proprietary software which limits access and use based on intellectual property restrictions. An open source development environment supports collaboration between organizations with common goals.

Total Cost of Ownership

Best Practice: Minimize Total Cost of Ownership (TCO) while meeting minimum functional and operational standards.

Total cost of ownership is a financial estimate of both the monetary impact and human resource impact of acquiring, deploying, and retiring an information technology system over the life cycle of the product. It is comprised of a number of factors that can be grouped within three main categories – acquisition (one time) costs, operational (ongoing) expenses, and long term expenses. Overall, the goal is to select technology that minimizes TCO while meeting minimum functional and operational standards. These components of TCO should be considered whether in developing a custom product within MISAU or when comparing commercialized products. It is common for vendors to disclose initial procurement and setup costs without detailing operational and ongoing expenses to expect. In deciding between developing and purchasing a system, it is important to do a thorough analysis of available systems with the idea of all three of the cost components in order to fully understand which decision will make the most financial sense. When evaluating TCO, the following factors are to be considered:

1. Acquisition costs
    a. Software licensing
    b. Hardware (server, client workstations)
    c. Infrastructure (networking hardware and software)
    d. Technical support for installation and configuration costs

2. Operational expenses
    a. Hardware support
    b. Staff training
    c. Staff time required for data entry, quality assurance, and reporting
    d. Ongoing technical support required (excluding hardware support, listed above)
3. Ongoing costs
    a. Cost of modifying system (including making changes or adding functionality)
    b. Cost of all commodities (paper, ink, etc)
    c. Long term expenses
    d. Upgrades and scalability (broad community of developers or a strong vendor backing is preferred)
    e. Decommission and replacement

Configuration

Best Practice: Software data elements should be configurable by designated 'administrator' staff at the central level, including basic indicators.

To the extent possible, management of configurable aspects of the system should be done by ministry staff or support staff directly engaged by the Ministry. This will reduce reliability on vendors and encourage the development of local capacity within the MISAU and local educational institutions.

Testing

Best Practice: Several types of testing should be performed to ensure the system meets user needs and remains operational when changes are made. Ideally, system tests, integration tests, and acceptance tests are all thoroughly defined and performed but resource limitations may reduce testing capabilities.

The purpose of acceptance testing is to determine if user's needs are met. The tests are developed based on user requirements. This testing focuses on the user's needs and ensures that the system will provide the necessary functionality. Acceptance testing is a high priority. Ideally, the users and stakeholders perform the tests, but if resources are limited developers often do the testing themselves.

Integration testing is used to determine if interfaces between software modules work properly. Any testing of communication with external systems also falls under integration testing. These tests help developers make sure that functionality doesn't break when code changes are made. Usually these tests are created and performed by developers.

System tests are used to find defects within the system. This type of testing is continually performed throughout the development and maintenance phases in order to find bugs, uncover performance issues, and test corner cases.

Deployment

Best Practice: To the extent possible, distribution of new releases should be automated

Deployment consists of the preparation, transfer and installation of the new release or update. This process should be as simple as possible so that staff can apply the changes. Automatic updates would be the ideal way of updating the system. However, the ability to automatically distribute new releases will depend on the data transmission and update mechanisms available.

Maintenance and support

Best Practice: Help desk support should be provided by email or phone

The purpose of help desk support is to provide technical assistance and centralize issue tracking. Help desk staff will answer questions and provide troubleshooting guidance to users either by email or phone. They will also initiate onsite technical support as needed and escalate large scale problems to those with authority to take action.

Best Practice: Software bugs should be tracked.

Throughout development and maintenance, software bugs should be reported and tracked using an established work flow process. Open source tools are available to help manage the reporting and tracking of bugs.

Curriculum development and training

Best Practice: Develop thorough user training to ensure that the system is used efficiently, that the data are accurate, complete, and timely, and that users have the ability to extract the appropriate data as needed.

Training material will consist of end user training for several types of users and maintenance and support training. Users can be classified into groups based on their use of the system. For

example, data entry and usage of data generated by the system will require different skill sets. The actors described in the above Functional Use cases will provide a starting point for grouping users.

In addition to end user training, material for teaching maintenance and support will be needed. Staff members who install and configure the system and those who provide technical assistance to system users will need this type of training.

Next Steps

The workshop provided insight into the detailed operational specifications for the system. That has enabled the first of the three next steps recommended at the workshop:

e.1) With the input that we received from the participatory design sessions around the functional requirements use cases, we were able to revise several areas of the document to align with the current operations of MOH, matching the local capacity within MOH, and to broaden the scope of functionality to include new workflow necessary for a successful M&E information system in Mozambique that can serve as a founding component for a national eHealth architecture.

The two remaining next steps directly related to these requirements are:

e.2) The finalized requirements can either be given to a system developer assigned by the Ministry, or as the basis for issuing tender to procure or develop the system. In either case, this document will serve as the foundation to develop an initial detailed design of the system. This design should not only include the requirements outlined in this document, but also the detailed specifications of each system component and data element, and will become the "blueprints" or design document for the programmers.

e.3) Once the development of the system has begun, the process should be monitored and evaluated at all phases in order to ensure that the requirements outlined in this document are well understood, that any ambiguities are resolved, and that they are being completely addressed.

Appendix A: Indicators

An Indicators document similar to that produced for the ITS form should be completed for each form and program.

Indicator Name	Definition	Category	Source
1. Percentage of Health Units (HU) with functioning STI program.	Number of Health Units (HU) with functioning STI program / Total number of HU	Product	STI data collection forms

2. Percentage of STI cases registered in the HU (as compared to the national estimated goal).	Number of STI cases registered in the HU by sex and age group / Estimated number of STI cases per year as listed in the NSP STI/HIV/AIDS	Product	STI data collection forms
3. Percentage of partners or sexual contacts (of an STI patient) notified and attended to at the HU.	Number of partners or sexual contacts (of an STI patient) notified and attended to at the HU by sex / Total number of observed STI cases at the HU	Product	STI data collection forms
4. Percentage of STI patients diagnosed, counseled, and treated correctly according to the national protocols.	Number of STI patients (attending HU) diagnosed, counseled, and treated correctly according to the national protocols / Total number of STI patients attended to at the HU	Quality	Special MISAU survey evaluation to assess the quality of services.
5. Distribution percentages STI cases by diagnosis, sex, and age group.	Number of STI cases according to diagnosis, sex, and age group / Total number of STI cases at the HU.	Product	STI data collection forms
6. Percentage of pregnant women in their first pre-natal consult tested for syphilis.	Number of pregnant women in their first pre-natal consult tested for syphilis / Total number of pregnant women in their first pre-natal consult.	Product	STI data collection forms
7. Percentage of pregnant women in their first pre-natal consult testing positive for syphilis.	Number of pregnant women in their first pre-natal consult testing positive for syphilis / Total number of pregnant women in their first pre-natal consult who were tested.	Product	STI data collection forms
8. Percentage of pregnant women in their first pre-natal consult testing positive for syphilis and treated accordingly.	Number of pregnant women in their first pre-natal consult testing positive for syphilis and treated accordingly / Total number of pregnant women in their first pre-natal consult testing positive for syphilis.	Product	STI data collection forms
9. Percentage of health technicians capable of STI diagnosis, treatment, and counseling.	Number of health personnel (technicians, nurses, doctors) capable of STI diagnosis, treatment, and counseling / Total number of planned STI health technicians.	Process	Annual STI Component Survey Report (Including D.Formação, D.Enformagem, SMI, SAJE)

10. Percentage of HU with functioning STI programs using the correct protocols, manuals, and data collection forms.	Number of HU with the correct protocols, manuals, and data collection forms for the management of the STI component / Number of HU with a functioning STI programs.	Product	Special MISAU survey evaluation to assess the quality of services.
11. Percentage of HU per month with interruption in stock of the essential medicines for the treatment of STI	Number of HU per month with an interruption in stock of the essential medicines for the treatment of STI / Number of HU evaluated.	Product	Special MISAU survey evaluation to assess the quality of the logistic services.