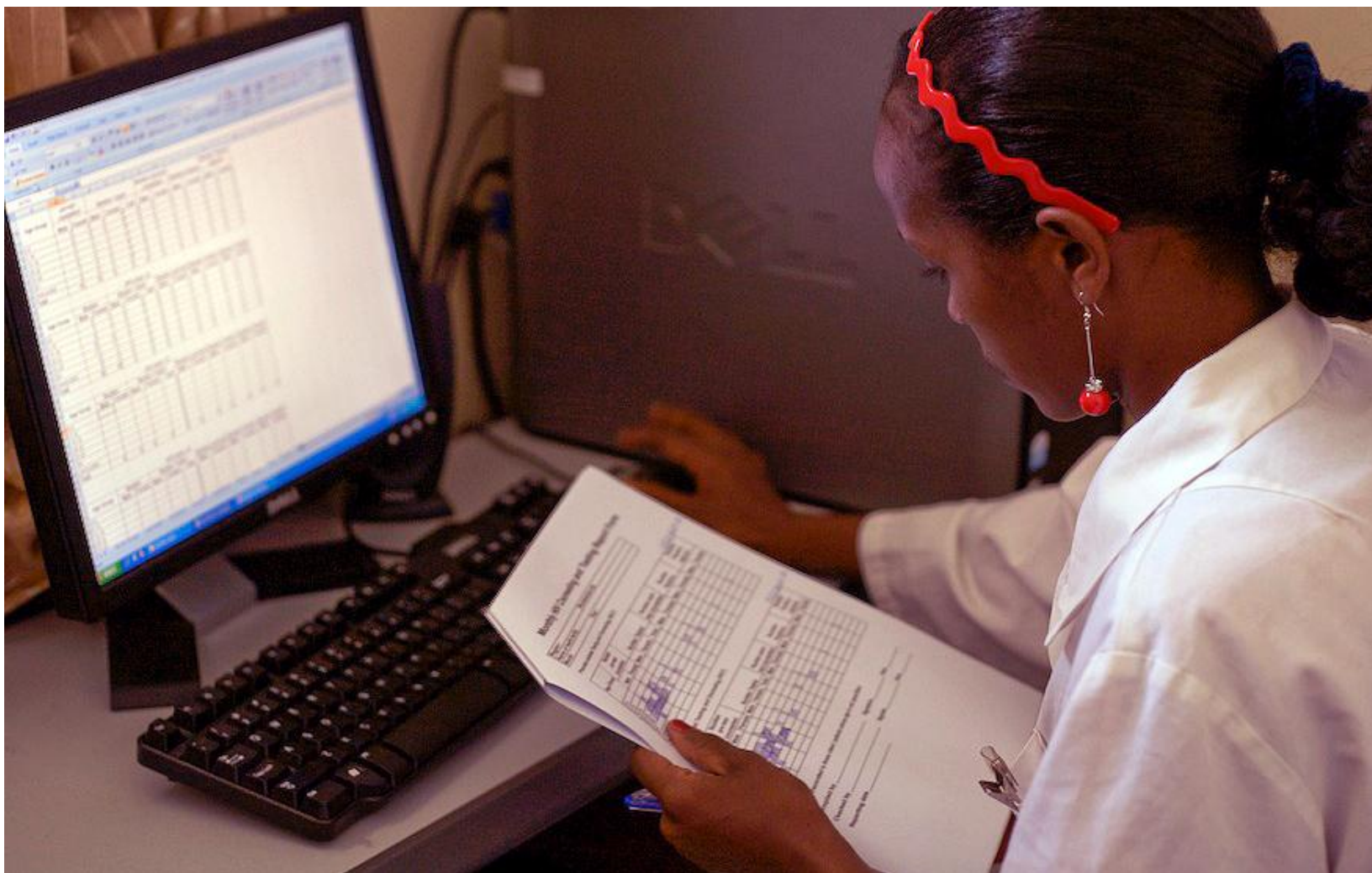




Ministry of Medical Services
Ministry of Public Health and Sanitation

Standards and Guidelines for Electronic Medical Record Systems in Kenya



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Foreword

The mandate of the Ministries of Health is the provision of quality health services, promotion of equity in access, financial risk protection and overall governance and stewardship of the health sector. To execute this mandate there is an absolute need for information to guide policy making, intervention options, programming and effective management of health facilities and health districts. Over the years harnessing of this information has been a challenge both in the public and private subsectors. This has partly been due to the weak health information infrastructure, a poor information culture that does not spur demand for information, multiple and parallel information systems, a thin and stretched human resource to support data collection, transformation, presentation and archiving among others.

It is with this background that the ministries through the Division of Health Information system (HIS) undertook to develop a health information policy and strategic plan (2009-2014) to guide the health information strengthening agenda in the country. In its Strategic Plan, the HIS has planned to improve data management and strengthen the use and application of information technology in data management. To effectively do this, there is need to develop standards that will ensure quality of software, compatibility of data sharing, ease of maintenance and common understanding among the workforce.

Data complexity, volumes of patients served and the desire to have efficient health information systems have defined the need for Electronic Medical Record (EMR) Systems in Kenya. EMR systems, when well developed and implemented, can improve the process of data collection resulting in better quality and more reliable health information. These systems can also greatly improve aggregation and reporting of data from facilities. EMR systems support provision of health care through the integrated clinical decision support functions and by ensuring that patient information is available across facilities for continuity of care.

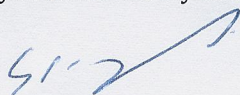
Coordination of development, deployment, implementation and maintenance of these systems is fundamental to their success in the health sector. This first edition of the Standards and Guidelines for EMR Systems in Kenya aims to provide guidance for the development of EMR systems for use in Kenya and set an environment for successful implementation and use of these systems. This document is a product of consistent work carried out by the Division of Health Information Systems in the Ministry, National Aids and STI Control Program, Kenya Bureau of Standards and I-TECH, working through

a technical working group consisting of other implementing partners and donor organizations.

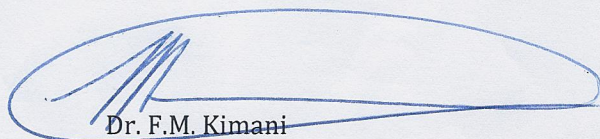
The document is laid out in an understandable format that clearly addresses issues from the minimum desired functionalities of an EMR system, implementation process, development, actual operations, and monitoring and evaluation of EMR systems. Even though the need to define EMR standards was driven by existence of varied forms of ART EMR systems, this document is designed to offer guidelines to the minimum standards for any generic electronic systems in a health care setting.

This document is the first attempt in Kenya to ensure that the process of scaling up the implementation and use of EMR systems is well coordinated. We would like to emphasize the adherence, by all EMR developers and implementers, to the specifications contained here-in to ensure a standardized approach to this initiative.

Finally, we would like to thank all those who have participated in the development of these standards and guidelines document and hope that this is the beginning of making Kenya an EMR ready country.



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Acknowledgements

This initial publication, *Standards and Guidelines for Electronic Medical Systems in Kenya*, has been developed from international standards, WHO guidelines, and best practices for electronic medical records (EMR) installations in Kenya and other similar settings. Coordination of the development of this document has been provided by the EMR Technical Working Group through the Ministry of Public Health and Sanitation and the Ministry of Medical Services.

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Technical Glossary and Acronyms

ADR	Adverse drug reaction
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
BMI	Body mass index
BSA	Body surface area
CCHIT	Certification Commission for Health Information Technology
CPG	Clinical Practice Guidelines
CRIS	Country reporting information system
DHIS	District Health Information System
DHMT	District Health Management Team
EMR	Electronic medical record / electronic health record
HIS	Division of Health Information Systems
HIV	Human immunodeficiency virus
HR	Human resources
HRIO	Health records information officer
ICT	Information and communication technology
IT	Information technology
LMP	Last menstrual period
MUAC	Mid upper arm circumference
OI	Opportunistic infection
OS	Operating system
OBS/ GYN	Obstetrics and gynecology
OPD	Outpatient department
PMTCT	Prevention of mother-to-child transmission of HIV
SOP	Standard operating procedure
TB	Tuberculosis
TCO	Total cost of ownership
UPS	Uninterruptible power Supply

TERM	DEFINITION
Functional Profile	“Selected set of functions that are applicable for a particular purpose, user, care setting, domain, etcetera.” ¹
EMR	A computerized legal medical record created by organizations delivering health care, such as a clinics and hospitals. Electronic medical records tend to be a part of health information system, allowing for the storage, retrieval and manipulation of records. ²
eHealth	E-Health architecture is the overall structure of the health information system,

¹ HL7 EHR System Functional Model DSTU July 2004

² http://www.providersedge.com/ehdocs/ehr_articles/Electronic_Patient_Records-EMRs_and_EHRs.pdf

Architecture	comprised of components such as electronic medical records systems, laboratory information systems, monitoring and evaluation systems, and other HIS components, the technologies upon which those components depend on, the data formats used to exchange information between the components, and the circumstances of that information exchange.
Enterprise Architecture	A rigorous description of the structure of an enterprise, its breakdown into subsystems, the relationships between the subsystems, the relationships with the external environment, the terminology in use, and the guiding principles for the design and evolution of an enterprise. ³
HL7	<p>“An ANSI accredited, not-for-profit standards-development organization, whose mission is to provide standards for the exchange, integration, sharing, and retrieval of electronic health information; support clinical practice; and support the management, delivery and evaluation of health services.”⁴</p> <p>The HL7 Standards referenced within this document are:</p> <ul style="list-style-type: none"> • Clinical Document Architecture (CDA) is an exchange model for clinical documents (such as discharge summaries and progress notes). Using CDA, documents are both machine-readable, so they are easily parsed and processed electronically, and human-readable, so they can be easily retrieved and used by the people who need them.⁵ • Indicator Exchange Format (IXF) and Statistical Data and Metadata eXchange for the Health Domain (SDMX-HD) are UNAIDS and WHO implementations of xml based data formatting standards to allow health systems to exchange indicators and metadata. • Quality Reporting Document Architecture (QRDA) is a standard for communicating health care quality measurement data. It conforms to the requirements of HL7 CDA 2.0.
Privacy, Confidentiality, and Security	<p>Privacy</p> <ul style="list-style-type: none"> • A legal concept referring to the protection that has been accorded to an individual to control both access to and use of personal information. Privacy protections vary from one jurisdiction to another and are defined by laws

³ Giachetti, R.E., Design of Enterprise Systems, Theory, Architecture, and Methods, CRC Press, Boca Raton, FL, 2010.

⁴ HL7 EHR System Functional Model DSTU July 2004

⁵ <http://www.hl7.org/implement/standards/index.cfm>

	<p>and regulations. Privacy protections provide the overall framework within which both confidentiality and security are implemented⁶.</p> <p>Confidentiality</p> <ul style="list-style-type: none"> Concerns the right of individuals to the protection of their personal data during storage, transfer, and use, in order to prevent unauthorized disclosure of that information to third parties. <p>Security</p> <ul style="list-style-type: none"> Security refers to the collective body of physical, electronic, and procedural processes designed to prevent breaches in information confidentiality. Security also concerns system availability, including the identification and management of predictable risks to data systems, such as power outages, staff shortages, natural disasters, and user error.
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Introduction, Background, and Rationale

The Division of Health Information Systems (HIS) has recognized the need to improve the use of ICT in health. Under Strategic Objective Five of the HIS Strategic Plan 2009-2014, the HIS aims to strengthen the “...use and application of information and communication technology, in data management”.⁷ Tethered to this objective is the need to have standardized and interoperable ICT applications, including EMRs.⁸ It is with this objective in mind that the Ministries of Health, through the HIS, embarked on a process of standardization of EMRs in Kenya.

Electronic Medical Record (EMR) systems are increasingly being adopted in Kenya to improve medical record management, health program management, and the quality of patient care. However, the development and implementation of these systems has not been properly coordinated, resulting in multiple EMR systems with varying objectives and functionality, which

⁶ CDC and UNAIDS, *Interim Guidelines on Protecting the Confidentiality and Security of HIV Information: Proceedings from a Workshop in Geneva*, May 2006

⁷ Ministry of Health, *Health Sector Strategic Plan for Health Information System, 2009-2014*, 2009

⁸ Ministry of Health, *Health Sector Health Information System Policy*, 2009

and without the ability to share patient information with other systems, programs, and the Government.

To date, three assessments have been conducted to describe the functionality of existing EMR systems implemented in Kenya.^{9,10} Commissioned by the National AIDS and STI Control Program (NASCOP) and HIS, these independent assessments identified various EMR systems and other software that are supporting the provision of health care in the country. The identified software can be grouped as follows:

- i. Patient Management Software(e.g., C-PAD, OpenMRS, IQ-CARE and EDPMS)
- ii. Hospital HMIS Software /ERP Systems
- iii. Data Collection and Reporting Software(e.g., C-PAD, OpenMRS, IQ-CARE, EPI-INFO)
- iv. Data Analysis Software (e.g., SPSS, S-PLUS)
- v. Administration/Management Software
- vi. External Systems(e.g., MSH tool for stock control and supplies chain management)

The assessments identified EMR or patient management software specifically designed to support chronic HIV care. These include: C-PAD , OpenMRS, IQ-CARE, and EDPMS.

The assessments revealed numerous problems with the software, including:

1. Variable levels of functionality and data security
2. Unpredictable vendor/technical support
3. Issues with long-term sustainability
4. Variable reporting functionality
5. Limited feedback of data in EMR systems for patient care and
6. Limited ability to exchange information between systems

⁹ National AIDS and STI Control Program, The EMR Systems Assessment, Harmonization Report. November 2009

¹⁰ EMR Systems Assessment, Harmonization Report. September 2009

One approach to addressing these issues may be to adopt a single EMR for all health care settings in Kenya (whether public or private, high or low volume, rural or urban). However, it is acknowledged that information needs differ across settings and even within the public health sector, according to facility size, technical capacity, the presence or absence of specific activities such as clinical trials which may impact workflow and health information, goals and requirements of donor agencies, development partners, and other factors. Given that needs, capacity, and funding differ across institutions, and that a number of EMR systems tailored to meet these different needs are already in use across Kenya, it is neither technically nor organizationally feasible to enforce a single national EMR approach. Such an approach would fail to meet the needs of the health care system country-wide.

At the same time, in order for EMR system to be part of well-defined national eHealth information architecture, the functions of an EMR system, and the information exchange between the EMR and other systems, must be well defined. A comprehensive definition of requirements can both ensure that EMR systems in use in Kenya address the problems identified by the assessments, as well as facilitate their role and contributions in the national eHealth architecture.

Vision for the EMR Initiative in Kenya

Kenya's Ministries of Health, through the Division of Health Information System (HIS), envision a health information enterprise that has, as one of its components, EMR systems that support the provision of holistic health care while improving on health records management and contributing to improved quality of patient care. Fundamental to this vision is the need to have systems that can:

- Maintain the validity, integrity and confidentiality of health information
- Ensure security through integrated system checks that prevent access and misuse of data
- Validate the accuracy of captured data.

The single most important feature of the EMR is the facilitation of information sharing between different users. This inter-operability and data exchange is vital for the success of the HIS enterprise architecture. In relation to clinical systems, a patient management system should be able to share relevant patient-level data with a pharmacy or laboratory information system and vice versa.

Additionally, patient management information systems should provide a degree of decision support that would help clinicians improve the quality of patient care.

Purpose of this document

This document provides guidance for EMR system developers and implementers, as well as health facilities in Kenya that are contemplating or currently using EMR systems to manage patient data.

These guidelines are based on various local and international reference documents, including:

- WHO and Kenyan HIV treatment guidelines
- The Kenya HIS strategic plan and policy
- International and Kenyan health informatics standards, including those from the International Organization for Standardization (ISO)
- Experience from MOH and partners using EMRs in Kenya
- Experience from groups using EMRs in other countries
- Published medical and public health literature

Audience

This document is intended for the following audiences:

- Developers of EMR systems for the Kenyan market
- Health facilities or health systems currently using EMR systems
- Health facilities or health systems considering procuring, adapting, or installing an EMR system, including public, private, mission, and NGO-supported facilities
- Health policy makers at all levels
- Donors providing resources to support the Kenyan health system

Structure of the Standards and Guidelines Document

This *Standards and Guidelines for Electronic Medical Record Systems in Kenya* document is divided into 3 sections that provide requirements and offer guidance to discrete target audiences throughout the process of EMR systems development, deployment and implementation. The content in each volume is tailored to the understanding and implementation roles of the identified target audiences.

Section 1: Building an Electronic Medical Record System – This section outlines the pre-requisite processes of EMR system development and identifies basic functional requirements for

EMR systems in Kenya, as well as the EMR software attributes needed to ensure quality patient data and secure systems. This section is mainly targeted at EMR developers.

Section 2: EMR System Interoperability – This section describes how EMR systems interact with other systems within the HIS eHealth architecture. The section provides profiles for interoperability and draws on cases studies to demonstrate potential applications.

Section 3: Implementing an EMR System – This section outlines the conditions that must be met in order to create an environment for successful EMR system implementation. The section primarily targets program managers in EMR implementing agencies and provides guidance throughout the implementation process.

Throughout the 3 sections, this document defines ***requirements*** to describe both the functions and the information interactions and exchanges of EMR systems and offers ***implementations guidance*** as to how those requirements can be met. Specific guidance draws on standards, best practices, and previous experience, as relevant.

Scope and Evolution

Both the EMR requirements and EMR recommendations should be viewed as evolving guidelines. In some cases, these guidelines may become more specific as to the necessity and feasibility of a particular set of practices demonstrated over time and across the country. In other cases, the guidelines may change due to rapidly evolving technologies and capabilities. In either case, the process to identify and agree upon the EMR requirements and recommendations presented in this document is more important than the guidelines contained in this initial version.

The Government of Kenya, with the support and technical assistance of the international community, should reevaluate, refine, and extend this guidance as the healthcare system, the maturity of information systems, and available technology within the country evolve over time.

Policies and International Standards

The implementation of electronic health systems in the entire health setting is a complex process. The widespread adoption of these systems across the health sector (clinical, pharmaceutical, laboratory) has highlighted the need to develop standards governing system functions and the promotion of information sharing between systems.

Globally, several organizations have developed standards around medical information exchange, medical terminologies and electronic health record systems functionalities. Additional standards have covered areas around security of health information systems. Among standards available for electronic health systems are ISO standards, HL7 standards, International Classification of Diseases (ICD-10), LOINC and SNOMED.

The Kenya Bureau of Standards¹¹ (KeBS) is the government body mandated with the development and adoption of standards in Kenya. KeBS sets standards that govern the industries in Kenya, whereas the enforcement and implementation of those standards is the responsibility of the relevant stakeholders such as the Ministries of Health. KeBS has embarked on a process of adoption and domestication of the ISO Health Informatics Standards developed by ISO TC 215¹². A Health Informatics Technical Committee comprised of various stakeholders meets under the auspices of KeBS to review and adopt standards relevant for the Kenya health setting.

The EMR standards proposed in these guidelines complement standards that have been developed and gazetted by the Kenya Bureau of Standards (KeBS). These standards seek to provide concise, hands on, implementable resources for groups implementing EMR systems.

The following international standards are either undergoing review or have undergone review for adoption by KeBS and will be referenced in the remainder of this document:

¹¹ www.kebs.org

¹² http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=54960

Reference	Category	Scope
ISO 22220	Health Informatics	Identification of subjects of health care
TR 20514	Health informatics	Electronic health record — Definition, scope and context
ISO 13606	Health informatics	<p>Health informatics — Electronic health record communication Parts 1,2,3 and 4</p> <p>- Part I of ISO 13606 specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data</p> <p>Part II of ISO 13606 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository</p>
ISO/TR 18307:2001	Health informatics	Interoperability and compatibility in messaging and communication standards — Key characteristics
ISO/TS 18308:2004	Health informatics	Requirements for an electronic health record architecture
ISO 27799	Health informatics	<p>Health informatics — Information security management in health using ISO/IEC 27002</p> <p>This International Standard specifies a set of detailed controls for managing health information security and provides health information security best practice guidelines. By implementing this International Standard, health care organizations and other custodians of health information will be able to ensure a minimum requisite level of security that is appropriate to their organization's circumstances and that will maintain the confidentiality, integrity and availability of personal health information</p>
ISO 17090:2008	Health informatics	Public key infrastructure Parts 1, 2 and 3

Revision and Updates

This document represents the first compilation of the proposed electronic health record standards for Kenya as recommended by the National EMR Technical Working Group. We welcome feedback on this document, as well as input that can be incorporated in future versions. Because technology and approaches to managing health information are constantly evolving, we plan to update this document when there are significant changes to approaches in technology or national policies, or on an annual or bi-annual basis. . This is a living document that represents the experiences and best practices of individuals from across the health informatics system in Kenya. Comments can be sent to the following contact persons on behalf of the national Technical Working Group. All feedback

will be reviewed by the technical working group approval given for any changes to this document before finalization.

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SECTION 1: ELECTRONIC MEDICAL RECORD SYSTEMS: DEVELOPMENT AND FUNCTIONS

Section Introduction

The section describes the requirements that shall be considered in the design and development of an EMR system. The section is targeted at EMR system developers and answers the following questions commonly asked by developers:

1. How should I build the EMR system?
2. What functions should I build into the EMR system?

The EMR System Development Process

Meeting EMR System Requirements

Requirements

1. EMR system development must be a participatory process involving all stakeholders
2. EMR systems must meet functional requirements as defined by the Kenya Ministries of Health

Implementation Guidance

1. EMR systems developers will ensure a participatory approach that allows users and stakeholders to contribute to the development process.¹³ The advantage of this approach is that existing EMR user knowledge and expertise can be incorporated into the system, ensuring it meets user needs and expectations.
2. Development of EMR systems shall keep in mind the expectations of the Ministry of Health and the standardized functions of the EMR systems as defined under the *Minimum EMR*

¹³ Strategies for building National-Scale longitudinal patient monitoring systems for HIV treatment and care in PEPFAR countries: Developing and Electronic Medical Record (EMR) system Implementation Plan.

Functional Requirements. All systems will be pre-tested to ensure they meet the Functional Requirements.

3. System development should, where possible, use locally available resources to reduce reliance on external sources. It is, however, recognized that some desired technical skills and capacity may not be available at the local level.

Documentation of EMR System Development

Requirements

1. The process of EMR system development must be well documented
2. Health Facilities wishing to implement EMR systems must ensure that the selected system is accompanied by the defined documentation.

The development of EMR systems should be appropriately documented to facilitate continuity among developers and the system users. The following types of documentation are required:

Implementation Guidance

1. *Technical documentation* is vital for technical development and maintenance teams. It should include the system design and development process. Technical documentation provides an overview of the system, diagrammatic illustrations of system data flow, description of the software design methodologies, system code base, description of the database design and the system's data dictionary. Technical documentation should also include maintenance and installation guides.
2. *User documentation* is needed by EMR end users and should be written in simple, user-friendly language. User documentation includes user reference guides and training manuals. This document provides a step-by-step guide on EMR system functionalities and instructions on how to use the system. It should cover how to run the system, how to enter data, how to modify data and how to save and print reports. It should include a list of error messages and advice on what to do if something goes wrong.

The above listed documentation requirements are essential for gathering more in-depth details on the technical and functional specifications of the EMR. This documentation can be used to clarify and prioritize system requirements and to inform system design.

Functional Requirements for EMR Systems

Introduction

Electronic medical records can be developed to address different goals and health settings, and consequently emerge with different functions and capabilities. However, it is desirable to maintain a core set of functions in each EMR system in order to support similar workflows and encourage best practices in clinical care. This chapter details the functional requirements for EMR systems, including required and recommended capabilities. The Use Cases section offers specific scenarios to demonstrate the applicability and use of these capabilities.

The functional requirements defined in this chapter can be categorized into 6 key functional areas that are critical to the definition of an EMR: (i) basic demographic and clinical health information; (ii) clinical decision support; (iii) order entry and prescribing; (iv) health information and reporting; (v) security and confidentiality, and; (vi) exchange of electronic information. These 6 functional groupings form the basis for the review and approval processes of the MOMS/MOPHS.

Standards Referenced

This section references the following standards:

1. ISO /TR 20514: Health Informatics – Electronic Health Record – Definition, scope and context
2. ISO/TS 22220: Health Informatics Identification of Subjects of health care
3. HL7 Electronic Health Record – System Functional Model, Release 1 February 2007
4. ISO/TS 18303: Health informatics — Requirements for an electronic health record architecture
5. CCHIT Certified 2009 EMR Certification Criteria

This section draws heavily on ISO 18303 specifications and the HL7 Reference Information Model (RIM); reference is also made to ISO TS 22220 in defining the identification of subjects of care (including the demographic details specifications). The section also reflects EMR requirements set

forth by the Certification Commission for Health Information Technology (CCHIT) which are used in the United States in determining eligibility for federal funding. The list consists of functionality, interoperability, and security requirements that ensure EMR systems exchange data effectively, maintain confidentiality and provide necessary functionality. The defined functionalities may be used to develop a similar certification process to encourage standardization of EMR systems.

Minimum EMR Functional Requirements

Requirements

EMR systems must address the following 6 key functional areas:

- i. Basic Demographic and Clinical Health Information
- ii. Clinical Decision Support
- iii. Order Entry and Prescribing
- iv. Health Information and Reporting
- v. Security and Confidentiality
- vi. Exchange of Electronic Information

Basic Demographic and Clinical Health Information

This refers to patient-related information and includes patient identification information and clinic attendance or encounter information.

EMR systems are required to:

- i. Collect and display essential demographic patient information such as: name, birth date, gender, etc.
- ii. Manage patients problem / diagnosis list: coded diagnosis, onset date, history, chronicity, date resolved
- iii. Collect and display patient medication
- iv. Collect and display patient allergies
- v. Collect and display test results
- vi. Accept encounter clinical data: vital signs, weight, height, calculate BMI
- vii. Accept clinical notes in structured format and in free text format

Clinical Decision Support

This refers to functions and processes that assist health workers in making clinical decisions to enhance patient care.

EMR Systems are required to:

- i. Highlight abnormal test results
- ii. Alert provider of abnormal (outside the normal range) vital signs
- iii. Alert provider if a known allergic drug is prescribed or if a known drug interaction is likely to occur
- iv. Provide reminders of recommended care due such as tests due and medication due

Order Entry and Prescribing

Order entry is the process by which a health care worker electronically enters instructions for the care and treatment of patients under his or her care.

EMR systems are required to:

- i. Allow providers to enter orders with required details
- ii. Accept prescription orders
- iii. Order and administer immunizations: capture dose, site given
- iv. Manage referral orders with details of referring provider and referred-to provider.

Health Information and Reporting

One advantage of EMR systems is to improve the reporting and use of health information. To support this function, EMR systems are required to:

- i. Generate reports from clinical data to support quality improvement
- ii. Generate aggregate reports for submission to health ministries and other consumers.

Supporting Security and Confidentiality

Health data security and confidentiality is fundamental to any EMR system to ensure that the privacy of patient data is maintained. EMR systems are required to:

- i. Have access control functions that limit access to health data to selected individuals, based on defined and document roles
- ii. Maintain detailed audit trails of all events within the EMR system
- iii. Follow defined standard practices on logins and passwords
- iv. Ensure data protection by meeting requirements regarding data backup, recovery and documentation of systems
- v. Incorporate technical security functions in line with requirements regarding encryption and data transmission.

Exchange of Electronic Information

EMR systems co-exist with other systems in the health care setting. These include other EMR systems, laboratory systems and pharmacy systems. In order to promote inter-operability between systems, EMR systems are required to:

- i. Receive patient information as a clinical document using a recognized standard
- ii. Generate patient summary information as a clinical document using a recognized standard
- iii. Generate aggregate clinical care information using a recognized standard

Implementation Guidance

The following table outlines the functional requirements for the EMR systems in greater detail to provide guidance on how to meet the 6 key functional areas described above. This table is intended for use by EMR system developers to ensure that systems meet minimum specifications for quality care provision and reporting. Health managers may also use this table to evaluate the EMR systems for compliance with these requirements.

This functional profile aims to ensure that quality data is collected and used for follow up, patient management and generation of required reports. The profile also aims at ensuring the integration of decision support in medical systems to guide and ensure timely patient care decisions.

Key to PRIORITY column

The table categorizes the EMR system functionalities as either **highly** prioritized or **lowly** prioritized.

H = Requirements. These items are prioritized for immediate implementation in EMR systems. All systems are required to have these features.

L = Recommendations. These items are desirable, though not critical, for current implementations. However, these items will likely *become* requirements as information system implementation evolves in Kenya

Specifications	Priority
1. General	
1.1. System supports a function where the contents of the paper record as defined by standardized MOH forms can be entered for inclusion in the EMR.	H
1.2. System supports a total paperless function using a point of care system.	L
1.3. System captures data that can be used for individual patient care as well as for program monitoring and evaluation.	H
1.4. System shall associate key identifier information (e.g., system ID, medical record number) with each patient record.	H
1.5. System allows for summarized information in different parts of the system to be sorted and filtered by date or date ranges and chronology.	H
2. Demographics/ Patient Identification	
2.1. System supports the generation and use of a unique identifier and allows for the storage and use of more than one identifier for each patient's record.	H
2.2. System captures and maintains demographic information. At minimum, the system should capture the following demographic information:	H
2.2.1. Patient names: surname, first name and other name.	H
2.2.2. Other vital information includes: sex, date of birth, place of birth, patient's physical address, patient's telephone contact and next of kin.	H
2.2.3. Additional information may include: Biometric identifiers	L
2.3. System displays multiple types of patient identifying information at each interaction with the patient record to facilitate accurate patient identification.	H

2.4. System shall provide the ability to maintain and make available historic information for demographic data including prior names, addresses and phone numbers.	H
2.5. System is capable of importing existing patient demographic data from an existing EMR system via a standardized MOH HL7 interface format.	H
3. Patient History	
3.1. System allows the capture or entry of past patient history as relates to medical, surgical, obstetrics/gynecology, pediatric and other care.	H
3.2. For each new patient, the system captures and stores risk factors. For example: TB status, tobacco use and history, alcohol use and history, drug use and history, chronic illnesses such as hypertension, diabetes.	H
3.3. For each new patient, the system captures and stores, at minimum, the following social history elements: marital status, occupation, socioeconomic status, and education.	H
3.4. System has the capability to import patient health history data from an existing system using a standardized MOH HL7 format.	H
3.5. System documents hospitalization and OPD data including: visit dates, admission and discharge dates, chief complaint, diagnosis, procedures performed and discharge summary.	H
3.6. System documents all existing allergies, intolerance and adverse reactions to drugs and interactions, including dietary and environmental triggers.	H
3.6.1. System records, at a minimum, the allergen (drug), type of reaction and date the reaction occurred.	H
3.6.2. System captures the reaction type and severity of the reaction	H
3.7. System captures history of received immunizations and is able to display a report on the patient's immunization status.	H
3.8. System collects and stores family history, including, but not limited to:	H
3.8.1. History of chronic diseases such as hypertension, diabetes and cancers, including date of diagnosis. If deceased: date and cause of death	H
4. Current Health Encounters	
4.1. System supports the capture / entry of all clinical events, encounters and/or episodes relevant to the care of a patient.	H
4.2. System includes forms for data capture as well as patient and treatment forms as defined by Ministry of Health data requirements.	H

4.3. System has the capability to receive clinical documentation and notes via a standard MOH HL7 interface.	H
4.4. System has the capability to capture vital signs data. At minimum, the system collects height, weight, pulse rate, respiratory rate, blood pressure, BMI (calculated), and MUAC for children.	H
4.5. System has the capability to capture and edit health data regarding the patient's current health status, including (as applicable): chief complaint, onset and duration of symptoms, physical examination findings, diagnosis, performed/planned laboratory procedure, medications prescribed, patient education, non-drug prescriptions such as exercise and diet plans, and follow-up plans, including dates of next visit.	H
4.6. System enables the documentation and tracking of referrals between care providers or healthcare organizations. The following information is captured for every referral: reason for referral, date, referring provider and referred-to provider	H
4.7. System applies security controls to clinical notes to ensure that data cannot be deleted or altered except within the current session and by an authorized user. The only exception to this is that if an entry clerk has made an error transcribing paper clinical notes into the system, a correction may be allowed subsequently by an authorized user. The correction including the original text will be visible to anyone subsequently viewing the notes.	H
4.8. System supports the capability to collect the minimum data elements defined by the associated clinical practice guidelines, e.g. minimum data elements for HIV care, TB care.	H
5. Problem Lists	
5.1. System creates, maintains and reports all active problems associated with the patient.	H
5.2. System provides a problem status (active, inactive) for each shown problem.	H
5.3. When capturing problem information, the system captures at minimum: diagnosis/problem date(s), and the severity of illness.	H
5.4. System provides the ability to maintain a coded list of problems/diagnoses.	H
6. Clinical Practice Guidelines (CPG)	
6.1. System includes and maintains evidence-based Clinical Guidelines (for diseases such as HIV, TB, and Malaria) published and maintained by credible sources such as the MOH, NASCOP, Malaria and TB program. The guidelines incorporate alerts and reminders.	H
6.2. System includes decision support prompts to support clinical guidelines and protocols.	H
6.3. System has the capability to allow revision of clinical practice guidelines.	H

6.4. System allows the provider or other authorized user to override any or all parts of the guideline. System is able to collect exceptions for NOT following the guidelines including reasons for overriding and details of provider.	H
7. Prevention	
7.1. System has the capability to display health prevention prompts on the summary display. The prompts must be dynamic and take into account sex, age, and chronic conditions.	L
7.2. System includes a patient tracking and reminder capability (for patient follow-up).	H
7.3. System includes the incorporation of immunization protocols:	H
7.3.1. For children as per Kenya Extended Programme for Immunization (KEPI) schedule.	H
7.3.2. Captures and shows immunization due dates.	H
8. Patient Education	
8.1. System has the capability to create, review, update, and delete patient education plans and materials as defined by disease programs such as NASCOP, The Division of Leprosy, TB and Lung Disease (DLTLD), and Malaria.	L
8.2. System has the capability to create, review, update, or delete patient education materials.	L
9. Results	
9.1. System has the capability to manage, and present current and historical test results to appropriate clinical personnel for review, with the ability to filter and compare results with previous tests.	H
9.2. System is capable of receiving test results from laboratory and radiology (imaging results).	H
9.3. Laboratory and radiology results are received via a standard MOH HL7 interface.	L
9.4. When displaying results, the system, at a minimum, displays the patient name, date and time of order, and date and time results were last updated.	H
9.5. System uses visual cues to highlight abnormal results.	H
9.6. System allows the provider to comment on received lab results, or allows data entry personnel to capture comments on results.	H
10. Medication and Immunization Management	
10.1. System creates prescriptions or other medication orders with detail adequate for correct filling and administration, and captures the identity of the prescriber. At minimum, system should capture: the name of the drug, the dose and frequency of administration.	H

10.2. System has the capability of creating and maintaining a current medication list for each patient.	H
10.3. System presents clinicians/users with list of medications that are to be administered to a patient and captures administration details including dose of medications and route of administration. The clinician is able to select prescribed drugs from pull down menus.	H
10.4. System identifies drug interaction warnings at the point of medication ordering.	H
10.5. System provides the capability to select the drug to be prescribed from pull down menus.	H
10.6. System maintains patient-specific adverse reaction lists and allows on reporting from such lists.	H
10.7. System provides the capability for electronic transfer of prescription information to a selected pharmacy for dispensing.	L
10.8. System provides the ability to recommend required immunizations and when they are due based on the Kenya Extended Programme for Immunization (KEPI) immunization schedule.	H
10.9. System is capable of preparing a report on a patient's immunization history.	H
11. Confidentiality and Security	
11.1. System supports secure logon into the EMR system.	H
11.2. System controls access to and within the system at multiple levels (e.g., per user, per user role, per area, per section of the chart) through consistent identification and user authentication mechanisms.	H
11.3. System verifies and enforces access control to all EHR/EMR components, information and functions for end users.	H
11.4. System secures all modes of EMR data exchange through the use of data encryption; destination and source authentication and other standard security measures used to ensure security and privacy considerations.	H
11.5. System incorporates an audit trail covering all access and system transactions, including look-ups of patient data.	H
11.6. System provides analysis of audit trails and unauthorized access attempts.	H
12. Clinical Decision Support& Alerts	
12.1. System includes alerts based on clinical guidelines and protocols at the point of information capture or entry. The alert details include, but are not limited to: text describing the alert, as well as data and time of the alert.	H
12.1.1.	
12.2. System allows the user to document rationale for following/not following an alert.	L

12.3. The Reminders/Alerts screen pops up whenever a patient record is accessed and active alerts are in place.	H
12.4. System identifies trends that may lead to significant problems and provides prompts for consideration. For example, identifies trends of worsening laboratory results.	H
12.5. System triggers alerts to providers when individual documented data indicates that critical interventions may be required, such as a change or stoppage of treatment, etc.	H
12.6. System automatically triggers an alert upon documentation of a diagnoses or event required to be reportable to outside agencies including the MOH, WHO and Centers for Disease Control and Prevention (CDC).	H
13. Reporting	
13.1. System allows for the electronic generation of MOH aggregate reports, including disease specific reports for programs such as TB, Malaria and NASCOP, for transmission to the next level (e.g., the District Health Information System).	H
13.2. System electronically transmits aggregate reports to the District Health Information System or any other defined 'next' level using MOH standardized transmission protocols.	L
13.3. System creates and maintains patient-specific summary views and reports that include, at minimum: problem list, medication list, treatment interruptions and restart dates, adverse drug reactions, care history, and missed appointments.	H
14. Chronic Disease Management	
14.1. System supports chronic disease management by:	H
14.1.1. Allowing patient tracking and follow-up	H
14.1.2. Integrating all patient information within the system	H
14.1.3. Providing a longitudinal view of patient medical history	H
14.1.4. Providing access to patient treatments and outcomes	H
14.2. System tracks / provides reminders and validates care process. For example, the system validates the follow-up of a diabetic patient and provides reminders to do blood sugar tests.	H
15. Consents, Authorizations, and Directives	
15.1. System has the capability for a patient to sign consent electronically or store a scanned manually signed consent form.	L
15.2. System has the capability to create, maintain, and verify patient treatment decisions in the form of consents and authorizations when required.	L

16. Children’s Health	
16.1. System displays the age of a child.	H
16.2. System displays growth charts showing plotted values of height, weight, head circumference, and BMI against age and sex data.	L
16.3. System allows for capture, storage and management of pediatric specific laboratory tests such as HIV-DNA PCR tests, CD4%.	H
16.4. System verifies appropriate drug dose for children when given the child’s weight in kgs or BSA in cubic meters.	H
17. Pregnancy Care	
17.1. System accepts coded input for historical items that are asked at each pregnancy visit such as loss of fluid, fetal movement, etc.	H
17.2. Where collected, the system makes obstetric past history available to the provider for future pregnancies.	L
17.3. System records fetal heart rate, fundal height, weight, urine analysis and blood pressure at each visit, along with antenatal profile results.	H
17.4. System provides for capturing dates to be used for notifications and alerts such as date to start ART prophylaxis, date to schedule for caesarean section, date to perform a check ultrasound, etc.	H
17.5. System displays the estimated date of delivery (EDD) given the patient’s last menstrual period (LMP).	H
17.6. System will calculate an EDD given an ultrasound date and the estimated gestational age (EGA) given by the ultrasound.	L
17.7. System creates a printable view of all visits, labs, due date, ultrasound, problem list and plans which can be given to a patient for purposes of communicating with providers on a Labor and Delivery floor.	H
18. Orders	
18.1. System supports the recording and tracking of clinical orders and requests such as prescriptions and other treatment orders, laboratory investigation requests, and referrals.	L
19. Audit/Logging	
19.1. System keeps an audit of all transactions.	H
19.2. System dates and time stamps all entries.	H

20. Validation	
20.1. System includes error checking of all user input data, including, but not limited to:	H
20.1.1. Check diagnosis against gender and age	H
20.2. Date checking for validity as well as to ensure a valid chronological order of events (diagnosis before treatment, scheduling after birth, etc.).	H
21. Communication	
21.1. System supports the export and import of data received using standard MOH HL7 protocols.	H
22. Input Mechanisms	
22.1. System uses pre-coded data and choice selection (such as from radio buttons, checkboxes, dropdowns, etc.) where applicable, to minimize data input efforts.	H
22.2. System has the ability to allow inclusion of free text.	H

Information Security Management for EMR systems

It is important to ensure continued security, confidentiality and privacy of health data through the processes of collection, storage, use, and dissemination.

- i. *Security* can be defined as a collection of approaches that address issues covering physical, electronic, and procedural aspects of protecting information collected as part of health care.
- ii. *Confidentiality* relates to the right of individuals to protection of their data during storage, transfer, and use, to prevent unauthorized disclosure of that information to third parties.
- iii. *Privacy* is both a legal and an ethical concept. The legal concept refers to the legal protection accorded to an individual to control both access to and use of personal information and provides the overall framework within which both confidentiality and security are implemented.¹⁴ All information that can be potentially linked to an individual should be considered confidential.

¹⁴ UNAIDS/PEPFAR. Interim Guidelines on Protecting the Confidentiality and Security of HIV information: Proceedings from a Workshop, 15-17 May 2006, Geneva, Switzerland. 15 May 2007

The recommendations in this section are derived from the ISO 27799¹⁵ and ISO/IEC 27002¹⁶ standards. Both offer guidance on how best to protect the confidentiality of personal health information. Reference is made to the UNAIDS interim guidelines.⁶ This document, Volume 1 of the *Standards and Guidelines for EMR Systems in Kenya*, is limited to defining how information security can be in-built into EMR systems.

Requirements

EMR systems must have in-built security controls including:

1. Access Control
2. Audit Trails and
3. Back up procedures

Implementation Guidance

Access Control

This is a system of controlling entry and use of the EMR system, in part or in its entirety. Depending on one's assigned roles and responsibilities, access can be limited to specific areas such as reports or the performance of specific functions, such as viewing, editing or deleting patient data.

- EMR systems must provide a means to authenticate user identity using a user name and password before enabling the user to perform any functions. The system should allow for the allocation of area-specific access rights. .
- Password length should be a minimum of six characters. Where feasible, 10-12 characters strengthen password security. The length of the password shall be enforced by the system.
- User account passwords should be changed every ninety days at minimum. The system shall automatically enforce the regular changing of passwords.

¹⁵ Health informatics — Information security management in health using ISO/IEC 27002

¹⁶ Information technology — Security techniques — Code of practice for information security management

- Users on special function accounts that perform privileged functions (system administrator, security administrator, etc.) should change their password at least every 30 days.
- The EMR system should have a timed lock-out/screen blanking mechanism, which automatically engages after no more than ten minutes of inactivity or when manually invoked.
- Confidential information residing on a fixed disk should exist in encrypted form to avoid compromise by unauthorized persons. EMR systems may have built-in encryption protocols.
- The system may enforce that the same password is not reused by a given account for a period of one year.
- The EMR system shall terminate a login session and disable a user account after a maximum of three consecutive invalid login attempts.

Audit Trails

An audit trail/audit log is a chronological sequence of audit records, each of which contains evidence directly pertaining to and resulting from the execution of a business process or system function.

The EMR systems must log audit trails as evidence of user transactions within the system. Audit trail records should be captured for all levels of access. These records, at a minimum, must include the following:

1. Date and time of the event
2. User ID or name
3. Type of event and the success or failure of that event

Defined significant security events must be logged and include:

1. Multiple failed logons;
2. Access at unusual times or from unusual locations
3. Sudden unexpected increases in volume
4. Significant computer system events (e.g., configuration updates, system crashes)

Audit logs will be reviewed frequently to allow detection of unauthorized events before a significant loss has occurred.

Backup

Backup is the procedure for making extra copies of data that can be called on in the event that the original is either lost or damaged.

Backup of EMR data should be automated within the system wherever possible to ensure consistency.

Data Validation

Requirements

EMR systems must have in-built data validation functions to ensure accurate and reliable data

Data quality functions for EMR systems are needed to ensure that the data collected and processed are accurate, reliable, and organized in a way that assures credibility for reporting and program evaluation. Various EMR users, ranging from the clinicians to managers, rely on accurate data for decision-making. Data validation can either be synchronous or asynchronous as described below:

1. *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, a data entry user receives on-screen error messages at the time that data is entered into the form.
2. *Asynchronous validation*: occurs after data has been loaded into the repository and involves running of algorithms against data stored in the database to determine anomalies within the data.

Implementation Guidance

There are 4 validation levels that need to be factored into the EMR system, especially during the design process to ensure that validation checks are properly integrated. These levels are:

1. ***First order validation*** verifies that data elements are entered in a valid format and value. It is important to ensure that all data elements, especially numerical and date fields have valid

formats and ranges. This may be achieved through automated procedures for range checking where the data element is validated against a range of allowable values for that element, and by finding missing data for required fields. First order validation detects obvious data entry errors, while leaving more complicated errors for data managers to resolve asynchronously. For example, the EMR system checks the entry for hemoglobin levels against the normal range to prevent erroneous outliers.

2. **Second order validation** is the historical comparison for the same data element so that an alert is prompted if an indicator increases or decreases abruptly. For example, an EMR system should flag an abrupt increase in weight from 50 to 70 kgs within a one-month period.
3. **Third order validation** assesses data elements for consistency within a specific form or set of indicators. For example, a red flag would be raised if the number of women receiving PMTCT services was larger than the number of pregnant women treated for a given time period.
4. **Fourth order validation** is the assessment of any 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.

Case Example: Building an EMR system for HIV chronic care

This case example describes an EMR system for the management of HIV in the context of the outlined functional profile. Similar case examples can be derived for systems used for the management of other diseases or for systems used in specific departments in the health setting such as EMR systems for cancer care, EMR systems for pediatric care, EMR systems for OPD use or EMR systems for in-patient use. The defined minimum functional requirements aim at informing the minimums for all these systems.

Functional requirements for HIV Specific EMR

Minimum Data Set

In 2004 the World Health Organization (WHO) released ART patient monitoring guidelines, which provided the minimum data set for longitudinal follow-up of patients receiving HIV care.¹⁷ The guidelines were revised in 2006. They summarize the minimum data set for HIV care into 4 categories:

- Demographic information
- HIV care and family status
- ART summary
- Patient encounter information

In recognition of the expanded nature of HIV care, WHO, in 2009, improved on the patient monitoring guidelines and released the 3 interlinked patient monitoring system¹⁸ that incorporates key data elements on:

- HIV care and Treatment
- Maternal Child Health and PMTCT and
- Tuberculosis care

¹⁷ Patient Monitoring Guidelines for HIV Care and ART 2004, and 2006

¹⁸ Three interlinked patient monitoring systems for HIV Care/ART, MCH/PMTCT and TB/HIV: Standardized minimum data set and illustrative tools

The 3 interlinked patient monitoring systems support integrated service provision, follow-up of mother-infant pair and monitoring of key TB-related and pediatric variables.

Both the ART Patient Monitoring guidelines and the 3 interlinked Patient Monitoring System forms booklet provide, in detail, the minimum data that each EMR system should collect for the provision of care in a HIV clinic. They also define the different data elements to be collected and offer guidance on when the data is collected; at enrollment, once during HIV care or repeated at every clinic encounter. EMR systems are required to collect data as defined by the guidelines.

These guidelines and booklet can be downloaded for reference from the WHO, NASCOP and MOH websites:

- www.who.int
- www.aidskenya.org
- <http://www.publichealth.go.ke>

The following is a summary of the essential list of data elements that every EMR must collect for HIV care. *(Adapted from the summary list in the Patient Monitoring Guidelines)*

Demographic Information
<ul style="list-style-type: none"> • Unique ID number, patient clinic ID number • Name, sex, date of birth, age at registration, marital status • Address, telephone, contact information
HIV Care and Family Status
<ul style="list-style-type: none"> a) Date and location confirmed HIV-positive, HIV subtype b) Entry point into HIV care c) Current health facility, district, district clinician/team d) Treatment supporter(s) name/address/contact information e) If family members/partners: name, HIV status, HIV care status, unique ID number, date of birth/age at registration f) Drug allergies
ART Summary
<ul style="list-style-type: none"> • ART history prior to entry • ART START date/treatment cohort:

- Date medically eligible to start ART
- Why medically eligible; baseline CD4, clinical stage
- Date medically eligible AND ready to start ART
- Date medically eligible, ready AND selected to start ART
- Functional status, clinical stage and weight at ART start
- First-line regimen
 - Original first-line regimen (list drugs)
 - If SUBSTITUTE within first-line regimen: dates, reasons, new regimens
- If SWITCH to or SUBSTITUTE within second-line regimen or higher: dates, reasons, new regimens
- ART interruptions: dates, reasons
 - STOP ART: dates, reasons
 - LOST (temporarily): dates
 - RESTART: dates
- Transfer In, Transfer Out: date, facility transferred from or to
- DROP: dates
- DEAD: date

Encounter Information

1. Encounter date, whether scheduled or not, next scheduled follow-up visit date
2. Months on current regimen
3. Current functional status, clinical stage, weight, height (for children)
4. TB status, TB treatment start/stop dates
5. Pregnancy status, estimated date of delivery (EDD), family planning method(s), prevention of mother-to-child transmission of HIV (PMTCT) referral/provision
6. Possible side-effects (including drug allergies), severity
7. New symptoms/diagnoses/OIs
8. Laboratory test dates and results
9. Prophylaxis: medication, dose dispensed, start/stop dates, reason for discontinuation
10. ART dispensed: regimen code, dose dispensed, (start/stop dates)
11. Adherence assessment (pill count, self-report, other) and reasons for both ART and prophylaxis non-adherence
12. Referral or link to other clinical or supportive care
13. Hospital days since last outpatient visit

Note: It is desirable that EMR systems collect more than the defined minimum data set for HIV care and be usable in the provision of holistic care to patients as a whole. This minimum data set does not restrict EMR developers from collecting more data.

Data Validation and Quality

To improve on data quality, the EMR systems are required to adhere to the set validation guidelines. The following overview provides general guidance to how data validation should be incorporated in the HIV care EMR systems.

First order validation

First order validation verifies that data elements are entered in a valid format and value and are within an acceptable range.

- EMR developers should ensure that data elements are not left blank when capturing patient-level data. Some data elements are mandatory to collect (as defined in the minimum data set definitions).
 - The system should generate an alert when an incorrect regimen combination has been prescribed.
 - The system should alert the provider or data entry personnel of a change of treatment regimen that occurs without an indicated reason.
- EMR systems should validate all date formats.
- Dates should be checked for range and limits. For example:
 - Date started on ART should not be before date found eligible for ART
 - Date enrolled in care cannot be before date of birth
- Dates should be displayed in the format dd/mm/yyyy as per Kenyan date formats.
- All laboratory results data should be validated against set ranges. For example:
 - Hemoglobin levels should be validated against the normal ranges for both male and female patients,
 - CD4 counts and CD% should be validated against the normal range.
- Vital signs shall be validated against normal human ranges, including:
 - Weight

- Height
- Blood pressure
- BMI

Where applicable, EMR systems should have listed data in lookups to reduce data entry time and limit errors. Lists should be defined and changed by the authorized users.

Intra-field validation should be implemented where there is a logical or causal relationship. For example:

1. The system should not allow for selection of pregnancy tests when the client is male.
2. The system should allow for collection of PMTCT data for a pregnant woman and keep these elements invisible for a non-pregnant woman.

Second order validation

Second order validation is the historical comparison for the same data element so that an alert is prompted if an indicator increases or decreases abruptly.

- All data should be validated for trends and change, for example:
 - Weight shall be validated for sudden increases and decreases.
 - Laboratory tests such as CD4 counts and CD% shall be validated for sudden change in trends.

Third order validation

Third order validation assesses data elements for consistency within a specific form or set of indicators. For example:

- Number of women receiving PMTCT services checked against the number of pregnant women treated for a given time period.
- Number of clients receiving cotrimoxazole therapy checked against the number of clients enrolled for care.
- The number of clients tested for HIV checked against the number counseled for HIV testing.

Fourth order validation

A data manager or epidemiologist, in the process of cleaning data, performs this validation. The data manager looks for outliers in the collected data. A data quality assessment plan should be in place in every EMR using facility.

Decision Support Functions

EMR systems should provide decision support to help improve the quality of patient care. Guidelines should be integrated in the EMR to facilitate this. Decision alert using prompts should be used to remind the HIV care team of some pending actions. Selected decision support functions to be included in HIV specific EMRs are:

- i. The system should indicate when a client is newly eligible for ART based on new laboratory results or advancing WHO clinical staging.
- ii. The system should have a prompt for due or delayed CD4 counts and other laboratory tests using the defined testing schedule, e.g., baseline, 6 months, 12 months as defined by WHO.
- iii. The system should alert for a due or delayed immunization.
- iv. The system should alert in cases of declining CD4 counts indicative of treatment failure.

Reports generated from the systems may also double as decision support tools as described below.

Order Entry and prescribing

EMR systems for use in HIV clinics are required to maintain electronic orders for laboratory tests and prescriptions issued as part of the patients' records.

Where drug regimens are well-defined, such as for ART, lookups should be used to list and select drugs prescribed to minimize data entry or capture errors.

Reporting Functions

The Ministries of Health define the reporting requirements for health systems in the country. HIV-EMR systems shall generate reports in line with MOH requirements, in pre-defined formats with pre-defined indicators. The required indicators may be changed by MOH in line with country and donor needs.

Current reports that should be generated out of the HIV-EMR systems include:

- Form 711 - Cross-sectional quarterly (or monthly) facility-based HIV care/ART report form
- ART cohort analysis report form

Additionally, the EMR systems should generate a variety of facility-based reports that can be used in facility decision-making. These may include, but are not limited to:

1. Graphical (trend) report on the number of clients enrolled in HIV care over several months.
2. Graphical (trend) report on number of clients started on ARVs over several months.
3. Listing of clients expected to attend the clinic on a particular day.
4. Listing of clients who have missed appointments or defaulted on treatment.
5. Listing of clients due for CD4 counts in a particular month.
6. Listing of clients due for other laboratory tests.
7. Listing of clients with declining CD4 counts

Supporting Security and Confidentiality

EMR systems used in HIV clinics are required to meet all security and confidentiality requirements as defined under the security section of the technical requirements in this document.

Access to the systems should be controlled with a username and password. User access levels should be implemented to control access to the various parts of the EMR system based on the roles and responsibilities of the users.

SECTION 2: EMR SYSTEM AND INFORMATION EXCHANGE - INTEROPERABILITY

Section Introduction

Within the health setting, EMR Systems coexist with several other systems such as Laboratory Information systems, Pharmacy Information systems, the District Health Information System and Demographic Surveillance systems. Exchange of information between systems is important for several reasons, including increased efficiency through decreased entry of duplicate data, decreased errors in medical information through the same mechanism, and increased availability of health information promoting better clinical decision making and improved continuity of patient care.

The following definitions apply to this section;

- **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.
- **Actors** can be people or information systems
- A **task** is a structured set of steps
- **Use cases** describe the specific reasons for a task that requires the transfer of information, and the steps required to complete that task. Use cases are descriptions of tasks by actors.
- **Transactions** are the specific information interactions that support each step. Transactions are implemented by specifying one or more standards and describing how they are to be used.

This section defines standards to be used in the exchange of clinical information in Kenya. Implementation of these clinical data standards will ensure that data in an EMR system are available and meaningful in another system, whether that system is a lab system, the national HMIS, a district health information system, or another EMR at a different health care facility.

This section is targeted at EMR system developers and program managers. It is designed to enable developers to integrate data exchange functions into their systems, and to outline EMR systems and their implementation in relation to other health information systems.

Data Transmission via HL7 and SDMX Messaging

1. EMR systems are required to have the capability to transmit and receive a defined minimum set of patient data via standardized HL7 messaging.
2. EMR systems are required to have the capability to transmit aggregate data to the DHIS via standardized SDMX messaging.

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.

Standard formats require agreement both on format (syntax) and meaning (semantics). For transmission of patient-level data, the most widely implemented messaging standard in use in the public health sector is recommended. The following international protocols are highly recommended:

Health Level 7 (HL7): HL7 is a flexible standard by which various health care systems can communicate with each other; it is typically used for transmission of patient level data.

There are no well-established standards for aggregate data or indicator transmission; however there are two that are emerging:

- i. Quality Reporting Document Architecture (QRDA)¹⁹ is being developed on the HL7 Clinical Document Architecture model.
- ii. Statistical Data and Metadata Exchange (SDMX-HD)²⁰ is a data exchange format. SDMX-HD has been developed by WHO, based on the ISO SDMX reporting standard, to facilitate exchange of indicator definitions and data in aggregate data systems.

¹⁹ http://wiki.hl7.org/index.php?title=Quality_Reporting_Document_Architecture

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.

Interoperability Profiles and Use Cases

Introduction

Interoperability profiles (also referred to as integration profiles), are defined as descriptions of standards-based interactions between information systems implemented to support provision and delivery of health care services.

The purpose of an interoperability profile is to describe, in clear and specific detail, how messaging standards are implemented to support complete and accurate exchange of health data and information across systems that are used to support provision of health care services.

The interoperability profiles described in this section have borrowed heavily from the technical framework of the Integrating the Healthcare Enterprise initiative (IHE)²¹. This is an implementation framework that makes recommendations based on various available options of implementing the following standards: ASTM, DICOM, HL7, IETF, ISO, OASIS and W3C. The interoperability profiles contained herein are therefore based on standards and transactions identified as part of the IHE interoperability profiles.

Of the numerous interoperability profiles, this section will focus and describe in detail the exchange of information between EMR system and Pharmacy Information System (EMRs-PIS), and EMR system and Laboratory Information System (EMR-LIS) profiles.

Several other profiles can be described such as EMR-Demographic Surveillance System (EMR-DSS), EMR-District Health Information System (EMR-DHIS), EMR to EMR, EMR to a supply chain management system, among others. At the most basic level, they can be divided into those profiles

²⁰ <http://www.sdmx-hd.org/>

²¹ www.ihe.net

that involve the exchange of patient-level data and those that involve the exchange of population-level data, such as aggregate or summarized data.

Purpose, functionality and focus vary per system. However, in the health system, these systems need to communicate with each other. The PIS collects and processes detailed medication, prescription and dispensing data, with only the minimum demographic data to positively identify the patient. However, pharmacists often require certain clinical data, such as allergies, diagnoses, and prior medications, to safely dispense. Supply chain management systems may draw and feed data into the PIS. The interoperability profile described here shall be guided by the clinical utility of health data and therefore, shall not include such support systems for now.

The goal of this section is to develop further constraints on the EMRs-PIS and EMRs-LIS IHE profiles in order to simplify these systems for use in settings where implementation and support resources may be limited. Policy and planning may be used to impose a standard set up operating rules to develop these constraints.

The profiles described below are specific enough to enable clear guidance in implementation of messaging standards relevant for the specific transactions, yet generic enough to enable reuse of the model in other interoperability settings involving EMRs and other identified systems.

Profiles

The two profiles described below will incorporate the following profiles already defined and described by the IHE as;

Patient Identifier Cross-referencing (PIX): This is a profile that provides description of cross-referencing patient identifiers in a situation where multiple patient identifiers from multiple domains are available. This enables consumer systems to correctly match a single patient even when the patient is known by different identifiers.

Patient Demographic Query (PDQ): This profile enables multiple distributed application systems to query for demographic information from a server hosting patient information directly into the application system.

EMR System Interaction to Pharmacy Information System

Actors in this profile are:

- i. EMR systems
- ii. Patient Identifier Cross-reference Consumer actor for patient identification which allows multiple systems using different patient identifier domains to determine patient identification from a different patient identifier domain using a cross-referencing manager.
- iii. PIS

In the interaction between EMR system and PIS, priority activities are correct patient identification, medication prescription and dispensing. The EMR system, which is the primary actor, serves to identify patients, place prescription orders and receive dispensing information. The EMR system requires the cooperation of the Patient Identifier Cross-reference consumer actor to provide support.

Therefore, the three use cases that can be implemented in this EMR-PIS profile are:

- i. Dispensing only – the pharmacist receives a paper prescription and creates a filler prescription in the PIS for dispensing.
- ii. Prescription and dispensing - Prescription placed by a clinician. The prescription is electronically transmitted to the pharmacy.
- iii. Prescription, dispensing and PIS identification of patients - Order placed by a clinician, electronic transmission of prescriptions, the PIS has the ability to query the EMR system for patient demographics, with EMR acting as a Master Patient Index (MPI), or directly from a MPI separate from the EMR system.

The information interaction between PIS and EMR can be summarized as follows;

- i. Patient Identification - Based on the Patient Identifier Cross-referencing (PIX) and /Patient Demographic Query (PDQ) profiles
- ii. Prescription transmission
- iii. Dispensing information transmission

In an ideal environment, the interactions listed above would be implemented in the order listed, with patient identification first, followed by transmission of prescription information, and finally the transmission of dispensing information. However, in a resource-constrained setting, greater clinical value is accrued by implementing the above interactions in reverse order, starting with transmission of dispensing information, followed by transmission of prescription information and patient identification. Description of the identified profiles therefore follows this order.

Use Case Title	Place prescription orders	
Summary	Clinician wishes to place prescription orders for a patient	
Primary Actor	EMR system	
Secondary Actors	PIS	
Business Rules	There are dosage/drug interactions rules that may need to be referenced.	
Pre-condition(s)		
Sequence of Events		
Action/Stimulus	System Response	
Clinician looks up patient record	Either, the EMR System: returns search results of correct patient or returns duplicate records, in which case the clinician selects the right patient or Fails to find a matching record and requests that the clinician create a new record. The clinician can elect to write a paper prescription. Note: If the EMR has already selected a patient, a prescription may be written for that patient.	
Clinician places prescription order	The EMR system checks against drug interaction safety databases, patient history and any other relevant information required for prescription purposes. Note: drug-drug interaction and patient-dose interaction are features that not all EMRs (or pharmacy systems) will implement.	
The EMRs confirms that the prescription order is complete, accurate and valid and conforms to protocol and drug interaction safety checks.	The clinician confirms prescription order and sends it to the pharmacy for dispensing.	

Use Case Title	Dispense medications
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Summary	Pharmacist wishes to dispense medication
Primary Actor	PIS
Secondary Actors	EMRs
Business Rules	There are dosage/drug interactions rules.
Pre-condition(s)	Correct Patient Identification
Sequence of Events	
Action/Stimulus	System Response
Pharmacist searches for/looks up prescription orders.	Either, the PIS: Returns search results of correct patient or Returns duplicate records, in which case pharmacist selects correct patient or Returns no matching record, in which case pharmacist enters demographics to create a new patient record.
Pharmacist dispenses according to prescription order.	The PIS checks against drug interaction safety database and patient history
The PIS confirms that the dispensing is valid.	The pharmacist dispenses the medication and the PIS transmit dispensing information back to the EMR system.

EMR System Interaction to Laboratory Information System

Fundamentally, three types of information interactions exist between LIS and EMR in any environment. While these interactions are not interdependent and may stand alone, with full-computerized integration, all three will be implemented. These interactions are:

- i. Patient Identification - Based on the Patient Identifier Cross-referencing (PIX) and Patient Demographic Query (PDQ) profiles.
- ii. Order transmission - Based on the Laboratory Testing Workflow (LTW) IHE profile
- iii. Results transmission - Based on the Laboratory Testing Workflow (LTW) IHE profile

Ideally, a complete workflow would start with Step 1, Patient Identification, and proceed through to Step 3, Results transmission. However, in resource-constrained settings the greatest value appears to lie in Step 3, Results transmission. While Step 2, Orders, and Step 1, Patient identification, remain important, in some cases these steps will likely remain paper processes. Therefore, these profiles are described below in reverse order.

Use Case Title	Results only
Summary	Laboratory expert wishes to run specific diagnostic tests and transmit results to a clinician.
Primary Actor	LIS
Secondary Actors	EMRs
Business Rules	
Pre-condition(s)	Correct Patient Identification
Sequence of Events	
Action/Stimulus	System Response
LIS receives diagnostic test results manually through direct data entry or electronically from analyzer.	LIS: May store results in pre-existing records, or Create new patient record(s) and store results there.
The LIS transmits test results to EMRs/Clinician.	The EMRs/Clinician acknowledges receipt of updated records.

Post Condition(s)	Test result transmitted into correct patient record and correct patient visit within that record.
Outstanding issues	Identity resolution in situations where there is intermittent EMR-LIS connection.

Use Case Title	Order and Results	
Summary	Clinician wishes to place lab test orders and receive results from the lab	
Primary Actor	EMR	
Secondary Actors	LIS	
Business Rules		
Pre-condition(s)	Correct Patient Identification	
Sequence of Events		
Action/Stimulus	System Response	
EMR transmits orders to LIS	LIS receives orders and: Matches orders with existing patient records; Fails to locate corresponding patient records and requests that the user create a new record; Returns duplicate patient records for orders received.	
The LIS receives diagnostic results manually through direct data entry or electronically from analyzer	The LIS: Cross-references patient identities of rest results received with patient records identities on LIS/EMR/MPI; Stores diagnostic results in existing patient records; Fails to locate existing patient records for test results received.	
The LIS transmits diagnostic results to EMRs,	EMRs acknowledge receipt of test result as correctly identified.	

Post Condition(s)	Test result transmitted only after validation. Test results correspond correctly with orders.
Outstanding Issue(s)	Correct patient visit record missing in EMR when test results are transmitted back. EMRs changes/updates demographics before

	<p>results are returned.</p> <p>EMRs changes/updates demographics after results are returned.</p> <p>EMRs cancels order after it is sent to LIS.</p> <p>EMR updates result.</p>
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In resource-constrained settings, the outstanding issues discussed in the use case above can be addressed in the following ways;

1. Correct patient record missing in EMR when test results are transmitted back. - Results will not match and a manual reconciliation will be required, otherwise the test result will be discarded.
2. EMR system demographics change/update before result is returned - Result will not match when sent back to system. This will need manual reconciliation.
3. EMR system demographics change/update after result is returned - EMR system will not notify LIS, therefore retrieval of results through LIS for a specific patient may be incomplete. In the case of an LIS -only installation, this will never happen. In the case of an EMR-LIS installation, the EMR is considered the official record for individual patient care.
4. EMR system cancels order placed through - This will be transmitted via a transaction message. The lab may choose to ignore this message, in which case the result will be discarded when transmitted back to the EMR
5. EMR system updates result - Updated transaction messages with updated results will be processed by the EMR.

Use Case Title	Order, Results and LIS identification of Patients
Summary	Clinician wishes to place specific lab test orders to LIS, LIS needs to correctly identify patients and transmit results back
Primary Actor	EMR
Secondary Actors	LIS

Business Rules	
Pre-condition(s)	Correct Patient Identification
Sequence of Events	
Action/Stimulus	System Response
EMR places lab test orders to LIS	LIS receives orders and: Matches them with existing patient records; Fails to locate corresponding patient records and requests that the user create a new record; Returns duplicate patient records for orders received.
LIS attempts to correctly identify patient records for orders placed by cross-referencing EMR/LIS/MPI.	The LIS: Identifies a correct match; Identifies multiple matches; Fails to locate a match and requests that the user create a new record.
The LIS transmits diagnostic results to EMRs.	EMRs acknowledge receipt of test results as correctly identified.

Post Condition(s)	
Outstanding Issue(s)	Similar issues as described in the above use case

SECTION 3: IMPLEMENTING EMR SYSTEMS

Section Introduction

The implementation of electronic medical records systems is a complex process requiring consistent oversight. Successful system implementation must take into account the way the process is managed from planning to roll out, and through ongoing operation. This section offers best practice guidelines on the implementation, operation and maintenance of electronic medical record (EMR) systems.

The section targets program managers who are implementing and managing EMR systems.

Implementation Planning

Requirements

1. A comprehensive implementation and management plan covering all phases of EMR implementation shall be developed in conjunction with all relevant stakeholders.
2. EMR implementers shall identify a team at the facility-level, representing all EMR stakeholders, to guide the implementation process.
3. A phased approach to EMR rollout will be adopted to minimize service interruptions.
4. The implementation team should plan for a post-implementation review within two weeks of EMR rollout.

Implementation Guidance

EMR system implementation is a complex and costly affair that should be well planned and managed. An implementation plan (Annex A) should be developed to guide the process. This plan will serve to guide the process from preparation through post-implementation and should contain the following information:

- *Preparatory phase:* Address budgetary and specification issues surrounding hardware and software purchases, governance structures for implementation, and identification of staff, their roles and training needs in line with defined competencies as listed in Chapter 5 Human Resource Requirements.

- *Implementation phase:* Specify processes for installation of hardware and software, usability testing, user acceptance testing, and competency testing.
- *Transition:* Specify how EMR users will transition from using the existing manual or paper-based health records systems to the new electronic system and address data migration issues such as entry of backlog data.
- *Post-implementation review:* following the implementation of an EMR system, stakeholders should conduct a joint review to identify areas of success and concern, and to document lessons learned for the improvement of future implementations.²² In the plan it is important to specify the timeline and persons responsible for conducting the review.

Pre- Implementation Requirements

Infrastructure Requirements

Hardware Requirements

EMR system developers must provide guidance on the minimum hardware requirements for the optimal operation of their systems.

Infrastructure requirements are likely to vary from one EMR installation to another. For example, a multi-level installation with fully functional pharmacy and laboratory information systems may require a server, whereas a single EMR installation on a stand-alone computer may not. Different EMR systems will also have variable computer specifications (hard-disk space, computer memory, etc.) to support their functions. System developers should be consulted to determine the required hardware specifications for a given EMR system.

Power supply requirements

²² Victor Balaban, Lela Baughman, Christopher Bishop, Meklit Hailemeskal, Xen Santas, Steven Yoon. *Developing an Electronic Medical Record (EMR) System Implementation Plan: Guidelines and Template*.

Requirements

1. Servers and workstations must be powered by an Uninterruptable Power Supply (UPS) sufficient to power the system for long enough to ensure safe shutdown, and to prevent corruption of databases.
2. Testing and maintenance of power backup units must be done to ensure their reliability.

Implementation Guidance

Successful use of EMR systems requires a reliable power supply. A variety of electric power sources may be available for different facilities, including the national power grid, solar power, generator power or wind power. It is important to note that each power option has specific operational and maintenance costs associated with its use.

Many UPS units developed for home or small office use are sufficient, assuming they are of capacity to meet the equipment's power requirements. A 1500 VA UPS can provide about 20 minutes of backup time for a single computer in case of power interruption²³.

Computers and other electronic equipment directly connected to battery-driven circuits do not require backup UPS units. Similarly, laptops with built-in batteries do not require UPS units

Surge protection and voltage stabilization should be provided to protect all computer equipment within EMR installations against power surge damage. Many UPS units also double as surge protectors.

All batteries, whether those in laptops or in UPS units, should be tested with sufficient frequency to detect any loss in capacity below the threshold for useful operation. Regular documentation of power testing should be maintained (see Annex B for a sample Equipment Maintenance Log). Every

²³ Victor Balaban, Lela Baughman, Christopher Bishop, Meklit Hailemeskal, Xen Santas, Steven Yoon. *Developing an Electronic Medical Record (EMR) System Implementation Plan: Guidelines and Template*.

facility or clinic manager needs to implement a maintenance schedule for power systems such as generators and UPSs.

Facility EMR Readiness Assessment

Requirement

Every health facility intending to use an EMR system will first be assessed to determine its level of readiness for implementation.

Implementation Guidance

Assessment of facilities prior to implementation enables program managers to evaluate the readiness of a site, and if necessary, to take action to ensure that all requirements are met for successful EMR system implementation. The assessment will include the availability of:

- Trained personnel;
- Desired infrastructure;
- Adequate security, support and maintenance protocols, and systems, and;
- Accessible management support.

An EMR readiness assessment questionnaire has been provided for use. (See Annex C for a sample EMR readiness checklist).

Human Resource Requirements

Requirements

Facilities and implementers of EMR systems shall ensure that staff are well-trained and possess the competencies relating to their areas of responsibility.

Effectively managing human resources is an essential component of the successful operation of any health information system. Health information management tasks and responsibilities are becoming increasingly complex and technical in nature, requiring health workers to increase their

informatics skills in order to effectively perform these duties. Ensuring the availability of these well-trained and motivated health workers to the team is critical to a successful implementation and ongoing usage of a health information system.

The introduction of Electronic Medical Record systems has expanded the range of health workers and competencies required to effectively run a comprehensive health care facility. However, widespread adoption of EMR systems in resource-limited settings has been impeded by multiple factors, including varied availability of staff with the technical and informatics skills to perform the now expanded set of health information management responsibilities.

Training programs have traditionally focused on the use of paper record systems with little emphasis given to electronic systems. However, Forster et al. (2008) noted a positive association between the quality of data collected and training for data clerks and between the quality of data and the number of hours spent on an electronic database by data clerks.²⁴

It is important to note that over-emphasis on the availability of a specific and scarce cadre of staff (e.g. Health Records Information Officers (HRIOs) and data clerks) to determine EMR readiness only prolongs the delay in the adoption of EMR. It is better to realize that different implementation models will have different human resource requirements. The HR requirements for an EMR installation will be determined by:

- **The size of implementation** - A multi-computer networked implementation model in a provincial hospital with a patient load of 2000 patients will have different HR requirements than a stand-alone implementation in a health center with a patient load of 200 patients.
- **The functionality implemented in the EMR system** - e.g. clinical data entry, patient registration, patient billing, laboratory/pharmacy practice or data exchange, reporting, etc.
- **How those functions are to be performed (workflow) and by whom** - For example, will data-entry clerks enter clinical data following the patient visit or do clinicians do this during or following the visit; are any data scanned into the system or are all data elements entered manually?

²⁴ Forster, M., Bailey, C., Brinkhof, M. W., Graber, C., Boule, A., Spohr, M., Balestre, E., May, M., Keiser, O., Jahn, A., & Egger, M. (2008) *Electronic medical record systems, data quality and loss to follow-up: survey of antiretroviral therapy programmes in resource-limited settings*. Bulletin of the World Health Organization 86, .

- **The infrastructure requirements** – hardware, networking, and Internet connectivity are some examples of infrastructure requirements that need to be considered
- **The vendor agreement** – some vendor systems will come with a support agreement.

EMR implementations may adopt either a data clerk centered approach (*retrospective data entry*) or a clinician centered approach (*point of care systems*). Both approaches will have different HR requirements in terms of numbers of staff and their skill levels.

It is best practice to quantify HR requirements for EMR installations based on competencies and well-defined roles and responsibilities. It is also noted that within resource-constrained settings, one staff may assume multiple roles relating to an EMR installation.

3 general categories of staff have been identified for successful implementation and operation of EMR systems:

1. *Facility based users* who are responsible for collecting, entering, and reporting health data using the EMR system;
2. *Higher level managers* who use information collected and stored in the EMR system for service delivery and resource management decisions, and
3. *IT / system developers and administrators* who develop and maintain hardware and EMR software as well as provide general user support.

Required Competencies for a Functional EMR System

Defining the minimum recommended competencies for these three staff groups (facility-based users, higher-level managers and IT/system developers and administrators) to use and support an EMR system is critical to the success of an implementation. However, few training programs in developing countries comprehensively identify or address health informatics competencies for any of these cadres.²⁵ Experience from various developed countries indicates that some health information system and EMR system competencies apply across all three cadres, while other

²⁵ Hersh, W, Margolis A, Quirós F, and Otero P. ***Building A Health Informatics Workforce In Developing Countries***. *Health Affairs*, Supplement 2010; 29(2): 274-277.

competencies will be of greater use to a particular cadre than another.²⁶ For instance, facility-based users do not need to be competent in software development to use an EMR system correctly, and yet this is an essential competency for IT/system developers and administrators. However, facility-based users are better able to contribute to the development of new versions of software when they possess a basic awareness of specific deficiencies in the functioning of an EMR system software application. Similarly, higher-level managers must have a strong working knowledge of how to aggregate and use the information gathered and managed in the EMR system for evidence-based decision-making.

For each cadre, general competencies specific to their roles and responsibilities are discussed below. A comprehensive matrix of all required health information system and EMR system competencies according to skill level for each cadre is provided and should be used for guidance.

Facility-Based Users

Facility based users are those who are responsible for collecting, entering, and reporting health data using the health information system.

The following roles shall be assigned to users within the EMR-using facility. In some cases, due to limited resources and based on available competencies within the user base, a user may be assigned more than one role and may have overlapping responsibilities with other users.

1. Registration/clerical staff –staff with which the clients have first contact at the facility in order to retrieve their medical records. It may be a receptionist or a nurse or a support staff.
2. Data entry personnel –staff that will be entering data into the records system. This usually includes data officers, data clerks, or clinicians (nurses, COs, MOs). The exact staff assignment will be partly determined by the workflow within the facility and whether a retrospective data entry EMR or a point of care system is being implemented.
3. Data managers – HRIOs, data officers, or a clinician coordinating the clinic.

²⁶ O'Carroll PW and the Public Health Informatics Competency Working Group. *Informatics Competencies for Public Health Professionals*. Seattle, WA: Northwest Center for Public Health Practice, 2002.

The responsibilities of each role may include interaction with the EMR, but that level of interaction will be based on the functionality that is to be implemented within the EMR. Therefore, the list of responsibilities may include workflow that does not directly interact with the EMR. The key responsibilities of the facility-based users are:

1. Registration of new patients and scheduling of visits.
2. Using the visits scheduling to identify the patients expected on a particular day and to identify missed appointments.
3. Retrieval of the records of patients attending the clinic.
4. Entry of individual patient data into the EMR system. This includes demographic and clinical data.
5. Coordination of workflow in the clinics.
6. Oversight of the data capture and entry to ensure quality.
7. Generation of facility reports for transmission through the HIS reporting system.

Core competencies for facility based users

Although roles and responsibilities will vary, health workers with a basic understanding of how a health information system works and their role within this system are likely to experience greater motivation to perform their EMR responsibilities.

Where EMR systems are being used, facility-based users must possess additional knowledge and skills specific to information technology and the specific EMR package used at the site. In addition to basic computer literacy, facility based users should also understand how software relies upon administration, support, and maintenance and how to access support as needed. Different levels of support and administration ultimately enable facility-based users to successfully enter and manage the health data they collect and report on. The facility-based user plays an important role as they are typically the first ones to encounter errors that may affect the overall quality of the data collected, the completeness or timeliness of reporting, or the security of the EMR system.

High Level Managers

Another category of staff needed to be identified within the facility is the high level managers. Higher-level managers are those who use information collected and stored in the EMR system for service delivery and resource management decisions. A variety of high-level managers will be

responsible for utilizing the information generated from the HIS and the EMR system for decision-making. These include:

1. Regional Administrators – Provincial and District Medical and Public Health Officers
2. Facility Administrators – Medical Superintendents and Medical Officers in Charge
3. Clinic In-charges

The managers are a vital component of any EMR installation and their support must be assured in the planning stages. The managers will not be involved in the actual operations of the EMR systems but will need to know, from a general outlook, the role of the system within the health setting, the functions performed by the EMR, and how the EMR functions impact patient care within the facility.

The facility managers ought to be involved in the identification and assigning of specific roles and responsibilities to facility based users and IT support staff. Involvement of the health managers ensures ownership of and accountability for the health systems along with the data and information generated.

Core competencies for high-level managers

The primary competencies for high-level managers relate to the use of information for decision-making. Since their ability to make well informed decisions relies on the quality, accuracy, and timeliness of the data available to them, high level managers must be able to recognize quality data, understand the implications of data on their decision making process, correctly diagnose poor quality data and address the underlying causes. For instance, high level managers who are familiar with how data is collected, entered, and managed within the EMR and HIS system are in a stronger position to identify the source of poor data and to take the appropriate action to remedy the situation that resulted in poor data being made available.

As with facility based users, high-level managers will benefit from a basic understanding of how an EMR system functions. Since high level managers inform what data needs to be collected and stored in the EMR system, having a general understanding of the EMR software support and maintenance system similar to that of facility based users is recommended. This requires strong computer literacy skills as well as general familiarity with the basic functions of the EMR system.

IT System Developers and Administrators

The IT staff will develop and maintain the EMR software, the hardware, and provide general user support. The availability of this cadre of staff can be limited within Kenya, specifically within the public health sector. In the absence of IT staff, a facility must be linked to the most accessible IT support services available. It may also be possible to assign some basic IT roles to the most IT-experienced staff within the facility.

In evaluating the capacity of a facility to operate an EMR system, IT support must be identified and their role clearly defined. All staff in the facility must be informed of where to get support if needed.

Roles of the IT support shall include:

1. Providing technical and general end user support for the EMR for the facility.
2. Assisting with the purchase and configuration of all hardware for the implementation.
3. Depending on external support contracts in place, maintaining equipment or coordination of the equipment maintenance.
4. Configuration of hardware, operating systems, and software.
5. Applying operating system updates or patches to keep the operating system current with the latest release.
6. Applying software updates or patches to keep the software current with the latest release.
7. Troubleshooting computer errors.
8. Setting up the antivirus and anti-spyware solutions and policies.
9. Setting up access control and general user policies for all users of the systems.
10. Conducting security audits for the EMR systems
11. Conducting supervisory visits, particularly in the time immediately after rollout, when equipment misuse is most likely and users are developing habits around system use and upkeep

Core competencies for IT/System support and administrators

All EMR systems rely heavily on the ability of IT/System support and administrators to maintain hardware and software as well as resolve any advanced software problems. This requires a cadre of personnel who are well versed in installing, configuring, maintaining, and troubleshooting advanced software applications and operating systems. Because of the specialized nature of their

expertise, this cadre is also likely to be a reference for basic hardware or software problems and as a result, staff in this cadre are likely to have some level of interaction with both facility based users and higher-level managers reporting problems or seeking assistance. For this reason, this cadre should also possess a general awareness of work the other two cadres engage in and their roles within the health system and the EMR system, such as how the EMR and health information system work and what decisions are being made using the software's output.

Matrix of Competency Levels by Cadre

The range in the required competencies for EMR system implementations differs across the three cadres, from levels of awareness to basic and advanced programming knowledge. The table below illustrates the mandatory levels of knowledge and competencies for each cadre necessary for the continuous performance of the EMR system within the facility. A site with an EMR system should ensure that those responsible for implementing the EMR system in their facility meet the following competency levels. Sites with high-level managers and IT/System administrators must also ensure that each staff member meets the appropriate competency level for their roles.

NOTE: As a pre-requisite, all EMR users must be competent in the use of the paper-based data collection system.

Competency		Mandatory Recommended Skill Level By Personnel				
		Facility Based Users			High Level Managers	IT/System Admin
		Clerical	Data Entry	Data Managers		
General Health Information Systems (HIS) Knowledge	Describe the purpose of an HIS	Basic	Basic	Advanced	Advanced	Aware
	Explain the basic components of an HIS and how they function together	Aware	Basic	Advanced	Advanced	Aware
	Describe the roles and responsibilities of health workers throughout the HIS	Basic	Basic	Advanced	Advanced	Aware
	Outline the flow of data in an HIS	Aware	Basic	Advanced	Advanced	Aware
Information Use	Distinguish between data needed for service delivery and data needed for programmatic decision making and resource management	Aware	Aware	Advanced	Advanced	Aware
	Describe the main decisions and health outcomes informed by health data from an HIS	Aware	Aware	Basic	Advanced	Aware
	Determine appropriate uses and limitations of different types of data	n/a	Aware	Advanced	Advanced	Aware
	Extract and interpret data from different types of reports	n/a	Aware	Advanced	Advanced	Aware

	Identifies and applies basic research methods	n/a	Aware	Basic	Advanced	Aware
	Analyzes and uses data from a variety of sources to make key decisions regarding patient care, programmatic and policy directions, and use of human, financial, and other resources.	n/a	Aware	Basic	Advanced	Aware
	Presents data to effectively communicate information and advocate for decisions to lay and professional audiences	n/a	Aware	Basic	Advanced	Aware
Data Quality and Confidentiality	Explain the importance of data quality and confidentiality	Basic	Basic		Advanced	Aware
	Identify key threats to data quality and actions that can be taken to improve data quality	Basic	Basic	Advanced	Advanced	Aware
	Identify gaps in data	Aware	Aware	Advanced	Advanced	Aware
	Evaluate the strength and validity of data	n/a	Aware	Advanced	Advanced	Aware
General EMR System knowledge	Describe the purpose of an EMR	Basic	Basic	Advanced	Advanced	Aware
	Explain the role of the EMR in a functioning HIS	Basic	Basic	Advanced	Advanced	Aware
	Describe the roles and responsibilities of health workers using the HIS and EMR as well as IT/system administration and support providers	Basic	Basic	Advanced	Advanced	Aware
	Understand basic medical terminologies as they relate to the EMR and to the specific disease area.	Basic	Basic	Advanced	Advanced	Aware
EMR System Navigation	List various sources of data	Aware	Basic	Advanced	Advanced	Aware
	Explain how data from different data sources is collected	Aware	Basic	Advanced	Advanced	Aware
	Describe the forms and reports used in an EMR and how they correspond to a facility's workflow as well as the flow of information in an HIS.	Basic	Basic	Advanced	Advanced	Aware
	Navigate an EMR system and use a variety of techniques to enter data into fields (i.e.: using drop down menus, calendars, typing)	Basic	Basic	Advanced	Basic to Advanced	Advanced
	Understand the purpose of required data	Basic	Basic	Advanced	Basic to Advanced	Advanced

	fields					
	Recognize, analyze, and correct data entry errors and gaps	Basic	Advanced	Advanced	Advanced	Advanced
	Aggregate electronic data, generate and electronically submit appropriate reports in response to routine and ad hoc requests	Aware	Basic	Advanced	Advanced	Basic
EMR System Maintenance and Improvement	Access and use new versions of software	Aware	Basic	Advanced	Basic	Advanced
	Take basic action in response to simple software messages and errors	Basic	Basic	Advanced	Basic to Advanced	Advanced
	Refer complex software errors to the appropriate personnel	Basic	Basic	Advanced	Basic	Advanced
	Provide feedback on and suggestions for improvement to software to system administrators	Basic	Basic	Advanced	Basic	Advanced
	Identify and perform basic hardware and software support and administrative tasks	n/a	Aware	Basic	Aware	Advanced
	Find, analyze and resolve common end user problems or errors	n/a	Aware	Aware	Aware	Advanced
	Manage system user accounts and passwords	n/a	n/a	Aware	n/a	Advanced
	Maintain system security	n/a	n/a	Aware	n/a	Advanced
	Install, configure and maintain secure hardware and server systems	n/a	n/a	n/a	n/a	Advanced
	Install a virtual machine on hardware and run operating systems and applications on a virtual machine	n/a	n/a	n/a	n/a	Advanced
	Securely install, configure, update, navigate and edit an operating system	n/a	n/a	n/a	n/a	Advanced
	Securely install, configure, upgrade and maintain relevant software applications on a server system.	n/a	n/a	n/a	n/a	Advanced
	Proactively monitor and manage relevant software applications within an OS environment	n/a	n/a	n/a	n/a	Advanced
	Orient and support an on-site IT system administrator of hardware and relevant EMR software applications.	n/a	n/a	n/a	Aware	Advanced
Computer Literacy	Correctly identify and navigate components of a computer and its desktop	Basic	Basic	Advanced	Advanced	Advanced

	Demonstrate use of mouse functions	Basic	Basic	Advanced	Advanced	Advanced
	Troubleshoot basic computer problems	Basic	Basic	Advanced	Advanced	Advanced
	Open, edit, save, and exit a program	Basic	Basic	Advanced	Advanced	Advanced
	Explain the difference between a document and a program	Basic	Basic	Advanced	Advanced	Advanced
	Demonstrate an understanding of a computer's desktop, filing systems and drives	Basic	Basic	Advanced	Advanced	Advanced
	Navigate the Internet	Basic	Basic	Advanced	Advanced	Advanced
	Access specific web pages	Basic	Basic	Advanced	Advanced	Advanced
	Create a username and password and successfully log in to a web page	Basic	Basic	Advanced	Advanced	Advanced

Estimating Human Resource Numbers

Numerous proposals have been made on how to determine the number of staff needed to successfully implement and operate an EMR system. However, most suggestions have been program dependent and are difficult to generalize across the entire health sector.

The following table, generated from one such recommendation, offers a general guideline that can be used to estimate the number of data clerks needed to ensure quality data collection using an EMR system.²⁷

No. of Patients on ART in the clinic	Derived clinic load, patients/day (assuming 20 clinic days per month)	Data clerk hrs/wk needed	No. of full time data clerks required assuming 40 working hrs/wk
100	5	10	0.25
400	20	40	1
800	40	80	2

²⁷ Forster, M., Bailey, C., Brinkhof, M. W., Graber, C., Boule, A., Spohr, M., Balestre, E., May, M., Keiser, O., Jahn, A., & Egger, M. (2008) *Electronic medical record systems, data quality and loss to follow-up: survey of antiretroviral therapy programmes in resource-limited settings*. Bulletin of the World Health Organization 86, .

1000	50	100	2.5
2000	100	200	5

Managing and Supporting EMR System Operations

Enhancing System Security

In addition to security features integrated in software system design as discussed earlier, additional security measures need to be implemented at health facility level to ensure security, confidentiality and privacy of health data and information.

The following are additional recommendations derived from the ISO 27799²⁸ and ISO/IEC 27002²⁹ standards and the UNAIDS interim guidelines⁶ that will further enhance security. These recommendations should be applied during the entire life of the EMR system.

Requirements

1. Facility management must take a leading role in defining a policy to clarify their direction of, and support for, information security.
2. Health care facilities should have a written information security policy document approved by management and communicated to all relevant personnel.
3. Health facilities shall manage the security of information assets used in the handling of patient related data and information.
4. A secure physical environment shall be provided for computer equipment.
5. Health facilities shall screen personnel to ensure security.

Implementation guidance

²⁸ Health informatics — Information security management in health using ISO/IEC 27002

²⁹ Information technology — Security techniques — Code of practice for information security management

Health facility management plays a key role and is ultimately responsible in ensuring the security and confidentiality of its patient data. The management must therefore lead the process of defining the rules and policies that will ensure information security.

An information security document outlines what the management intends to do to protect health information. Annex D provides a sample information security policy document.

Asset Management

All health institutions using EMR systems should maintain an inventory of information assets to be in a position to report on what information assets they hold, and to manage their security appropriately. Assets may include IT hardware, software, data, system documentation, storage media and supporting assets such as UPS's. The inventory record should include an identified owner who is accountable for the asset and the location of the assets. (See annex E for a sample asset inventory record)

Specifically in regards to the computer systems, responsibility for each system within the clinic network should be assigned to a custodian. This person is responsible for the security of the computer system and any data residing on it.

Removable and external electronic storage media (e.g. diskettes, CD ROMS, DVD, external hard drives, etc.) should be clearly labeled and secured in a locked desk or filing cabinet at the end of the workday and when not in use in accordance with the guidelines set forth in SOPs.

When disposing of any information classified as confidential the media should be either reformatted or physically destroyed to ensure it is unrecoverable.

Computers used for handling and storing health information should be dedicated to that function and not used for other purposes such as personal document processing, audio and video file downloads, Internet browsing, or other unrelated functions .

Physical and Environmental Security

Computers should be located in a physically secured environment (building, floor, or room) with access restricted to authorized personnel only in order to prevent unauthorized usage and to

prevent theft. Laptop or other portable workstations should be physically locked in a desk or cabinet when unattended or securely tethered to a fixed point.

A list of authorized personnel should be documented and reviewed at a minimum annually to ensure that access is still appropriate. Unauthorized personnel (e.g. visitors, maintenance support personnel) should be escorted. Detailed tracking records or logs should be kept of all persons entering a secured environment.

Human Resource Management & Security

Management should screen all personnel handling health information to verify, at minimum, their identity, address and contact information.

Staff with access to patient records should be offered continuous education and training on their roles and responsibilities towards health information security.

At termination or in the event of a security breach, access rights to health information systems should be removed in a timely manner to safeguard individual patient health data.

Backup of Patient Data

Facilities shall maintain a backup plan that documents backup procedures and routines.

Backup of information is fundamental to the reliability and recoverability of each system. A documented backup plan must exist which defines the backup routines. A backup plan aims at ensuring that information in backups is complete and sufficiently current. At a minimum, it should include the following details about the backup cycles:

- i. type of data and system that is being backed up: i.e. - network file shares, designated folders on individual hard drives – both desktop and notebook etc;
- ii. media used by the backup system: e.g. - tape, CD/DVD, network drive, USB drive;
- iii. frequency of on-site and off-site backups;
- iv. type of backup: full or incremental;
- v. person responsible for backups; and
- vi. Data restoration procedures.

A locally stored backup log should be maintained with the following information as minimum:

- i. name of media used;
- ii. Type of backup (e.g. full backup/incremental, differential, etc.);
- iii. date the backup was performed;
- iv. verification status (completed/failed);
- v. who performed the backup (automated or by specific staff); and
- vi. Location where the backup media is stored, date it was placed there, and who placed it there.

(NB: See Annex F for a sample Backup Log)

Backup procedures should allow for daily backups, as well as, include the possibility for performing day-to-day restorations or full data recovery.

The backup process should be automated wherever possible in order to ensure consistency.

Off-site backup media should be given the same level of physical and environmental protection that is required for the primary site as defined in this document. This includes security during the transportation of media and documentation between the facility and the off-site location.

A documented procedure should be in place that outlines the off-site backup process. At a minimum this should include a list of who is authorized to send data off-site, to where, and who is authorized to recall data.

Computer Virus and Spyware Control

1. All computer systems must have virus detection software installed and updated regularly.
2. Antivirus software should be configured to scan all removable media when inserted into the system for viruses.

Computer viruses are a significant threat to the integrity and confidentiality of data on computer systems. A facility operating an EMR system should have a written procedure on how to update the antivirus definition files, either automatically through the internet or periodically using remotely downloaded files. A full virus scan should be performed routinely and each time virus definition files are updated.

All software and data should be scanned before it is loaded onto any facility computer system. All software from public or private sources, including but not limited to the internet, electronic bulletin boards, etc., should be ensured virus and spyware free before use.

Upon the discovery of a suspected virus that cannot be removed or controlled with the installed anti-virus software, the computer system user should:

- i. Cease all operations;
- ii. Notify the responsible computer system support personnel;
- iii. Document conditions and status of the environment; and
- iv. Report the occurrence to the appropriate support.

EMR System Support

EMR systems will need regular maintenance and support for the hardware and software. The quality of the system support will ultimately determine the success or failure of an EMR system. Depending on availability of resources and local expertise, support capacity can either be assigned to staff within the facility using the EMR, shared resources between facilities, or outsourced.

Requirements

1. Every facility or institution using an EMR system will identify its source of support, which may be sourced either internally or externally through a service level agreement.
2. The source of support and how to access it shall be known to the management and to all users within the facility.

Implementation Guidance

- The most basic support structure is online help, context help and online tutorials that provide guidance to the user at the click of a button. Alternatively, users should be provided with printed support documentation mimicking system help. These provide users with a quick reference on how to use the system.

- User related issues could also be addressed by identifying key users of the EMR system (also known as ‘EMR Champions’). EMR champions possess a more advanced level of competencies and have a deeper understanding of the EMR system. Champions are able to support normal users of the system when difficulties with the system are encountered. These key users ideally should be staff within the facility running the EMR system, but could also be available via phone or email.
- Where external support is used, it will be necessary to develop and adhere to a service level agreement (SLA) that defines the level of maintenance and support to be provided. Such agreements are developed between EMR system developers or vendors and the health facilities. These agreements should be written documentation that is agreed to and signed before system installation. A service level agreement may also be signed with a third party support company capable of offering support for the installed system.
- Service level agreements define the nature of support to be provided and the expectations by the health facility of the support provider. These expectations can include defined levels of support during regular business hours and defined levels of support during non-business hours. An SLA usually includes the services that the technical staff can provide availability of technical staff, expected response time for initial request of support, general levels of response given the impact and complexity of the support request, and a process for making support requests. Annex G shows a sample Service Level Agreement.

Change Management Process

Requirements

1. There shall be a defined process for managing requests for changes and implementation of those changes to the EMR system. This process should be controlled by the health facility management or a group to which the responsibility has been designated.
2. Major changes to EMR systems should be accepted by all stakeholders.

Implementation Guidance

Enhancement and Change Requests

It is important to have a pre-defined process for making requests for changes to the EMR system. Any request for changes to the EMR should then go through this change management process.

A change management process would include the procedure for:

1. requesting the change, to whom the request is to be made;
2. how requests will be reviewed;
3. criteria for requests to be approved or denied;
4. how the approved requests are prioritized for implementation based on criteria such as importance, impact, and complexity of the request; and
5. How the request is processed for implementation.

Most change management processes involve the organization of a group that is responsible for receiving and processing the request. This group can be health facility management, or another designated group of stakeholders, such as a technical working group (TWG). Once prioritized, an agreement needs to be in place between the facility or group and the EMR development team for processing that request, including acknowledgment of request, estimation of development timeframe, deployment of request, and system documentation updates.

In addition to the development team making the change, training teams also need to be made aware of the change in order to determine the impact and plan for the training strategy for the modification to the system (including notifications to users, retraining users, etc).

Acceptance for System Modifications

It is imperative that there is a process for acceptance of any system modifications prior to deployment of those modifications. Bug fixes and minor changes may be considered an “express change” and may be decided by the change management group to not require review by anyone other than the development team. The types of changes that qualify as an express change should be explicitly decided on by the change management group before the EMR system is implemented in the facility. Larger feature enhancements that require a change in workflow and user training may require larger stakeholder acceptance before proceeding with deployment.

Upgrade Scheduling

The EMR system needs to be available during the hours needed for required operations. Therefore, a pre-defined process for handling deployments to the system should be well defined in order to keep disruptions to business operations at a minimum. This can include a regular maintenance schedule for minor updates (monthly, quarterly, or other) and a schedule of allowable upgrade times for more urgent requests.

Managing System Downtimes

Downtime refers to the period when the system is unavailable to provide or perform its primary function.

Requirements

There shall be a manual data capture and recording system to allow for continued operation during downtimes.

Implementation Guidance

Facilities using an EMR should have a ready manual or paper-based backup system for use during electronic system downtimes. This is particularly important for facilities using point of care systems and electronic registration systems. The transition from electronic to manual or paper-based health records management should be as seamless as possible to avoid interruption in the delivery of clinical services.

To facilitate smooth operation during downtimes:

1. All system users should have regular training on downtime procedures.
2. The facility should identify key staff to coordinate this process.
3. Planned downtime, such as system upgrades, should be communicated to staff in advance.
4. Notifications should be immediately sent to EMR users as soon as unplanned downtime is discovered.
5. Printed encounter forms and other documents should always be available in the facility for use during downtimes.

Supervision of EMR System Implementations

Requirements

Supervision shall be integrated across all phases of EMR implementation and use, and included in the implementation and management plan.

Regular supervision is necessary to provide continued support for EMR system implementations. Supervision visits can also double as forums for improving the skills and knowledge of the system users through integrated onsite mentorship. Supervision should be well planned with identified time lines and clear objectives.

Implementation Guidance

1. *Pre-implementation supervision* should occur to conduct an EMR readiness assessment and subsequently to review the implementation of recommendations from this review (where applicable).
2. *Immediate post-implementation supervision* will review and address issues arising immediately after implementation to ensure that users are able to use the EMR systems and the systems are generating the intended outputs.
3. Once the EMR systems have been installed and are in stable use, supervision visits should be scheduled at an agreed timeline with the facilities. The schedule is likely to vary depending on the duration since the EMR system was introduced and the skill level of the personnel.

Monitoring and Evaluation of EMR Systems

Monitoring and evaluation (M&E) plans are a core component to any EMR implementation plan.

Monitoring is an ongoing, continuous process of collecting data at multiple points during the implementation process to ascertain whether set implementation milestones are met or not whereas **evaluation** measures how well the EMR implementation objectives have been met³⁰.

Evaluation aims at determining how well the main goals of an EMR system have been met by answering the following questions:

- a) Does the EMR improve patient care?
- b) Does the EMR improve record keeping?
- c) Does the EMR improve reporting?

M&E is a continuous process and should be conducted through the entire life of the EMR and set intervals. M&E assessments seek to ascertain that implementations and operations are on track and that standards are adhered to. M&E activities for EMR systems aim at generating lessons learned and best practices that inform further EMR roll out efforts.

Different types of monitoring and evaluation strategies and methodologies may be employed for M&E.

1. All EMR implementations shall have a monitoring and evaluation plan to guide implementation and evaluate successes and failures.
2. The implementation team should identify and document key process milestones that will be used to monitor the EMR installations.
3. Additionally, the team should define key questions and outcome indicators for periodic evaluation of the EMR systems based on the overall objectives and expectations.

Annex H provides a draft Monitoring and Evaluation Plan whereas Annex I offers guidance on how to evaluate the use of an EMR system within the functional areas of an HIV clinic.

³⁰ Strategies for building National-Scale longitudinal patient monitoring systems for HIV treatment and care in PEPFAR countries: Developing and Electronic Medical Record (EMR) system Implementation Plan.

Sample EMR System Implementation Models

Different implementation models can be adopted for EMR systems' implementation. Human resource, infrastructural and operational requirements will vary depending on the models selected. The following are examples of models that may be used for implementation. These examples are not conclusive, and therefore, a facility or implementer may choose to use a different novel model. These examples give an indication of minimum requirements for the implementation of each model. Additional resources may be allocated depending on availability and complexity of implementation.

Case Scenario 1: Retrospective stand-alone EMR system	
A facility with a volume of 100 clients per day wishes to implement an EMR to improve their data collection. The facility manager would like to have a single computer running the EMR and used for retrospective data entry by the data clerk.	
Type of Implementation	Standalone data entry point EMR
Workflow Processes	Clinicians enter data manually into patient encounter forms. The data clerk collects all forms and transcribes the data into the computer. Reports are generated from the computer.
Hardware Requirements	<ol style="list-style-type: none">1. A single computer complete with CPU, monitor, mouse and keyboard2. Printer3. UPS
Other Infrastructural requirements	<ol style="list-style-type: none">1. Reliable power supply
Human Resource Requirements (recommended personnel required and roles).	<ol style="list-style-type: none">1. Data Entry Clerk <p>The data clerk should additionally possess the competencies to do data quality checks, data cleaning, and minimum data analysis for decision-making.</p>
Operational requirements	<ol style="list-style-type: none">1. Secured physical environment of IT infrastructure2. Daily-automated backups. Data clerk to verify the success and integrity of backups daily.3. SLA agreement for support or support available on call.

Case Scenario 2: Retrospective dual point EMR access
A facility wishes to implement an EMR model having the receptionist registering and retrieving client files for the clinicians and the data entered retrospectively from paper records into a computer by the data entry clerk. The receptionist needs to have a computer with access to the patients' demographic details in the EMR. When a patient visits the clinic, they give the receptionist their patient card showing their names and patient ID. The receptionist keys in the patient ID into the EMR system. The system retrieves the patient's demographics and displays them for confirmation. The system also generates alerts for laboratory tests that are due and care plans that are due based on the integrated decision support features. The receptionist writes

down these alerts on a notification sheet for the clinicians' attention.	
Type of Implementation	Dual networked computer system installation
Workflow Processes	Receptionist registers new clients into the EMR and retrieves records of existing clients. Clinicians enter data manually into patient encounter forms. The data clerk collects all forms and transcribes the data into the computer. Reports are generated from the computer.
Hardware requirements	<ol style="list-style-type: none"> 1. 2 Computers complete with CPUs, monitors, mouse and keyboards 2. 2 Printers 3. 2 UPS 4. Network Interface Cards (NIC) on each computer.
Other Infrastructural requirements	<ol style="list-style-type: none"> 1. Reliable power supply. 2. Network infrastructure to connect the reception computer to the data clerks computer. This can be a simple peer-to-peer connection with one of the computers acting as a host for the EMR.
Human Resource requirements (recommended personnel required and roles).	<ol style="list-style-type: none"> 1. Receptionist 2. Data entry clerk <p>The data clerk should additionally possess the competencies to do data quality checks, data cleaning, and minimum data analysis for decision-making.</p>
Operational requirements	<ol style="list-style-type: none"> 1. Secured physical environment of IT infrastructure 2. Data backup daily using an automated backup procedure. 3. SLA agreement for support or support available for call.

Case Scenario 3: Retrospective multi-point EMR access	
<p>An EMR installation in a high volume facility with a patient load of 3000 patients per month is expected to have multiple service points, namely:</p> <ul style="list-style-type: none"> • 1 Patient scheduling and registration point • 3 data entry computers • 1 pharmacy dispensing point with a pharmacy dispensing tool • 1 laboratory data entry point with a pharmacy information system <p>The facility management would like to have patient information available at every service point. Data entry will be retrospective.</p>	
Workflow processes	<p>A receptionist registers all new patients into the EMR and retrieves details of already existing patients. Additionally, the receptionist prints, on a daily basis, a listing of all clients expected to attend the clinic on a particular day. She checks off on this list every time a patient comes in for their clinic.</p> <p>Clinicians collect patient information on predefined forms. 3 full time data clerks working in a separate room collect the forms for data entry into the EMR.</p> <p>Laboratory tests are requested on pre-defined forms, a copy of</p>

	<p>which is left in the patient file and a copy taken to the laboratory. Laboratory personnel enter the test request details and results. In the event that the tests are done in a different laboratory, then the clinician will insert the test results into the patient file for capture by the data entry clerks.</p> <p>Prescriptions for medication and dispensing information are captured by the pharmacy personnel.</p>
Hardware requirements	<ol style="list-style-type: none"> 1. Computers for every service point (reception, data entry, pharmacy, laboratory), complete with monitor, mouse and keyboard. 2. A computer server to host the EMR and store patient information. 3. 4 Printers (for reception, data entry room, pharmacy, laboratory) 4. UPS's for every computer
Other infrastructure	A functional network to allow for sharing of patient information amongst the all service points.
Human Resource Requirements (recommended personnel required and roles).	<ol style="list-style-type: none"> 1. Receptionist 2. Three (3) Data entry clerks to enter clinical encounters 3. Data entry personnel for pharmacy and laboratory 4. Data Manager
Operational requirements	<ol style="list-style-type: none"> 1. Secured environment of IT infrastructure 2. Daily backup on high volume tapes automated to run at the end of each day on the server. 3. SLA agreement for support or support available for call within 24hrs to prevent backlog of work.

Case Scenario 4: Point of Care System

A facility wishes to implement a point of care EMR system. All care points (reception, nurse triage desks, clinician desks, laboratory and pharmacy) will have a computer with the EMR systems for data collection as care is provided.

Workflow Processes	<p>The receptionist registers all new clients by capturing their demographic and initial care details.</p> <p>The clinicians (nurses, clinical officers and doctors) enter encounter information directly into the computer. Laboratory test orders and prescriptions are entered directly into the computer.</p> <p>At the pharmacy, the prescription is electronically retrieved and medication is dispensed. In the event that a drug is not available, a hard copy version of the prescription is printed out.</p> <p>At the laboratory, the test order is retrieved and laboratory tests done. A hard copy of the order can be printed out when necessary. Results of lab tests are posted directly into the computer for retrieval by clinicians.</p>
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Hardware requirements	<ol style="list-style-type: none"> 1. Computers for every service point complete with monitor, mouse and keyboard. 2. A computer server to store patient information. 3. Networked printer able to serve multiple service points 4. Standalone printers for the reception, pharmacy, and laboratory. 5. UPS's for every computer.
Other infrastructure	<ol style="list-style-type: none"> 1. Reliable power supply. 2. A functional network to allow for sharing of patient information between the service points.
Human Resource Requirements (recommended personnel required and roles).	<ol style="list-style-type: none"> 1. Receptionist to register and schedule clients 2. Clinicians trained on data entry into EMR 3. Data Manager to do DQA 4. Resident IT administrator to solve arising problems to reduce downtime
Operational requirements	<ol style="list-style-type: none"> 1. Secured environment of IT infrastructure 2. A mirror backup server to ensure continuity of operations in case of server failure or, alternatively, daily backup on high volume tapes automated to run at the end of each day on the server. 3. Resident IT support 4. Fail over procedures to paper based system.

Case Scenario 5: Centralized hosted EMR

A partner supporting a region develops an EMR to support decentralized data capture and entry from several facilities with a centralized hosted EMR database. All facilities are connected via a Virtual Private Network (VPN) or via the internet.

Workflow Processes	Data is collected on predefined forms. All data forms are collected and transcribed by data entry personnel into the EMR via a web interface. Each facility is able to generate its own facility-specific reports.
Hardware requirements	<ol style="list-style-type: none"> 1. Computer for the data entry personnel, complete with monitor, mouse and keyboard 4. Printer 2. UPS
Other infrastructure	<ol style="list-style-type: none"> 1. Reliable power supply 2. Internet connectivity
Human resource requirements	<ol style="list-style-type: none"> 1. Data entry clerk at the facility level (number will vary with work load) 2. IT support at the database site. One IT personnel maintaining the centralized database is sufficient to ensure operations across all linked facilities.
Operational requirements	<ol style="list-style-type: none"> 1. Secured physical environment of IT infrastructure 2. Daily backup (such as on high volume tapes) automated to run at the centralized server. 3. Resident IT support to minimize database downtimes.

SECTION 4: GOVERNANCE AND POLICY

System Costs, Ownership and Sustainability

Requirements

1. Health Managers (such as the DHMT) should be involved in EMR system implementations to promote ownership.
2. EMR systems should be developed in a manner as to minimize the Total Cost of Ownership (TCO) while meeting minimum functional and operational standards.
3. EMR system implementation should adopt an open source software where possible, to reduce on the costs of licensing and encourage the EMR community to contribute towards system development.
4. EMR system implementers should consider the resource constrained setting and minimize the resource requirements such as additional commodities that cannot be sustained by public health facilities.

Total cost of ownership (TCO) 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) expenses, operational (ongoing) expenses, and long term expenses. The overall goal is to select technology that minimizes TCO while meeting minimum functional and operational standards.

When evaluating the total cost of ownership (TCO), the following factors are to be considered:

1. Acquisition Expenses
 - a. Software licensing
 - b. Hardware (server, client workstations)
 - c. Infrastructure (networking hardware and software)
 - d. Technical support for installation and configuration costs
2. Operational (Ongoing) 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. Long Term Expenses:
- a. Cost of modifying system (including making changes or adding functionality)
 - b. Cost of all commodities (paper, ink, etc)
 - c. Upgrades and scalability (broad community of developers or a strong vendor backing is preferred)
 - d. Decommission and replacement

Health Data Ownership

Requirement

Health records shall only be transferred with appropriately documented request and approval as defined by the Government of Kenya. This applies to off-location backups.

The HIS policy³¹ states “while the records (the documents or disks) are unequivocally the property of the practitioner or institution, the data is not. Data is not capable of being owned, and many different people have an interest in it, including and especially the person to whom it relates.

To ensure that movement of health data is well documented, the HIS Policy will be enforced to ensure that:

1. All the health and health related data and information shall belong to the Government of Kenya (GoK).
2. GoK shall grant right to access health and health related data and information through the defined protocols.
3. Personal data as inpatient records are in reality the property of the facility and are held in trust on behalf of the patients. All patients shall have access to information contained in

³¹ *Health Information Policy*, Ministries of Health, Government of Kenya.

their health records upon request or whenever it is considered to be of benefit to the patient.

4. Health workers who have privileged access to patient's records shall be accountable to maintain the highest level of confidentiality and ensure that shared confidentiality is only practiced in the interest of the patient.
5. Notwithstanding the provision of item 3.6.6(d) and 3.6.7(b) on matters of litigation, health workers can divulge information obtained in confidence on the instruction of legal authority and in line with the existing laws.
6. The MOH shall ensure that data and information required for defined global surveillance systems is collected in compatible formats and submitted to relevant authorities in time / on schedule.

Regulatory Environment for EMR Systems

Regulation of development and deployment of Electronic Medical Record Systems in Kenya is the mandate of the Kenya Ministries of Health through the Division of Health Information systems (HIS). The HIS may appoint a disease program (e.g., NASCOP, DLTLD or Malaria programs) to regulate the implementation of EMR systems that are specific to that disease condition.

EMR developers and implementers as well as health facilities intending to implement electronic medical systems shall seek the guidance of the HIS or the relevant disease programs in ascertaining the suitability of the system they intend to use. The HIS shall review, for approval, all the EMR systems to ascertain that they meet the defined functional requirements.

The HIS shall enforce that all EMR implementations are in adherence to the standards and guidelines set forth in this document..

SECTION 5: ANNEXES

A. Sample EMR Implementation Plan

EMR Implementation should be a well-managed, all-inclusive process. The following is a broad sample implementation plan that can be modified and made more detailed for an implementation.

The plan addresses what activities need to be carried out, who are responsible for what, resources required, indicators of success and timelines of each phase. Timelines indicated are arbitrary for demonstration purposes.

Activity	Person responsible	Resources (facility/ HIS/partner support)	Output Indicators	Timelines	1	2	3	4	5	6	7	8	9	10	11	12
PRE-IMPLEMENTATION PHASE																
1. Stakeholder involvement a. Create an EMR implementation committee representative of all stakeholders, management and users	Facility management/ Implementing agency		- EMR Committee setup	1 day												
2. Assess existing system for: a. Policies & Procedures b. Scope c. Reporting requirements d. HR needs	Project lead		- Assessment report													
3. Needs determination and budgeting. a. Considering type of implementation desired, list out and budget for all needs (software, hardware, trainings etc)	IT manager		- Implementation activity report - Statement of Work - Budgetary Estimate proposal	1 Month												
4. Site Infrastructure readiness			Completed site readiness checklist	1 day												
a. Power supply infrastructure setup to ensure that it can support the hardware to be set up.			Power rating checklist	1 day												
b. Purchase/ Setting up of network, as per the requirements of the facility.			Network setup and functioning	1 day												

c.	Computer room security determination – Assessment of the security needs definition of the minimum computer room infrastructure. (Like self locking door to the server room, policy on who has the key to the server room, fire preparedness – fire extinguisher, door guard to the server room etc).	Computer room/ server setup	3 days – 2 weeks
d.	Purchase/ Setting up of hardware depending on the turnover of patients	Purchased Hardware	1 day to 6 months
e.	Setting up of software to support the EMR, and EMR – These include the desired operating system (Windows, Mac OS or Linux Based etc) and then the office automation products such as Microsoft Office	Purchased and configured support software	½ day per computer
5. Human Resource Readiness			
Define Roles of facility staff and EMR vendor		- Roles chart	Cross cutting
The various people performing various roles are listed and assigned different responsibilities in the EMR implementation process		- Responsibilities chart	
a.	Determination of required skills profile	Skills determination checklist completed	3 days
b.	Employment/ training of staff with appropriate skills	Staff employed or trained	-
c.	Sensitization of staff on workflow changes expected with EMR introduction – through trainings, site visits and demonstrations.	Sensitization workshops, trainings, site visits, demonstrations conducted	2 days
6. Change management Plan			
a.	Assess and make organizational changes brought about by	Changes documented	2 – 10 days

deployment of the EMR (i.e. change from paper to computer based information access.)		and disseminated	
b.	Assess and implement workflow changes brought about by use of EMR (e.g., removal of the role of manual retrieval of patient file for every visit – due to online reference)	Clinic workflow documented and disseminated	1 – 5 days
EMR IMPLEMENTATION PHASE			
1.	EMR installation – software installation, configuration and commissioning	Installed EMR	1 day
2.	On the job EMR use Training	Number of staff trained on EMR use	5 days
3.	Data Migration to new EMR system	Data migration complete and certified	Between 1 day to many, depending on amount of data
POST-EMR IMPLEMENTATION PHASE			
1.	Assisted system use/ mentorship	- Number of mentorship sessions conducted	Continuous
2.	System Support	- Support Reports	-Continuous
3.	Monitoring and evaluation of EMR system	- M&E Reports	Continuous at a defined frequency
4.	Post-implementation supervision	- Supervision reports	Continuous

B. Equipment Maintenance Log

Name of Site/Organization: _____

Date checked	Type of Equipment (PC, Laptop, UPS, Printer)	Serial Number	Check Status (Ok, Faulty)	Notes	Checked By (Name and Signature)

C. EMR Readiness Assessment Checklist

EMR Readiness Assessment Form

Basic Facility Information

Facility Name: _____ Date: _____

Name of Assessor: _____

Name of Facility representative: _____

Checklist

Management Support

Facility Management has been involved in EMR planning ☐ YES ☐ NO

Familiarity with existing systems

Assessor should randomly sample 20 patient files, the current disease register and the latest monthly report and evaluate for completeness and accuracy of data filled.

Site has well filled MOH data capture forms? ☐ YES ☐ NO

Site has well filled MOH disease registers? ☐ YES ☐ NO

Site has accurate MOH reports and summaries? ☐ YES ☐ NO

Definition:

Accuracy- a report is classified as accurate when the outputs produced by the report fulfill the user's needs and contains no errors

Well filled- a form/register is classified as "well filled" when the information contained is correct and error free.

Infrastructure

Electrical Power

Does the facility have electrical power capacity? ☐ YES ☐ NO

Number of full days without power in last month: _____

Number of hours without power in the last week: _____

The Primary source of power: ☐ Power Grid ☐ Solar ☐ Generator

The backup source of power: ☐ UPS ☐ Solar ☐ Generator

Are there voltage stabilizers or UPS for all equipment? ☐ YES ☐ NO

Physical Location and Security

Is a room identified to house the computer and other IT equipment? ☐ YES ☐ NO

What physical security has been implemented for the computer?

☐ Lockable Cabinets

☐ Grills on doors

☐ Bars on Windows

☐ Lockable Doors

☐ Security Guard

Data Communication and Data Collection

Method of voice communication available at site

☐ Landline

☐ Cell Phone

☐ Radio

☐ None

Number of days in the last month the available voice communication was non-functional: _____

Longest duration of time (in days) in the last month the voice communication was non-functional: _____

Method of Data Communication available at site

☐ Landline Modem

☐ Cell Phone Modem

☐ DSL Line

☐ Dedicated Line

☐ Satellite Link

☐ None

Number of days in the last month the available data communication was non-functional: _____

Longest duration of time (in days) in the last month the data communication was non-functional: _____

Is there a computer network at site? ☐ YES ☐ NO

How many of each of the following items, in good working condition, is at site:

Desktop Computer _____

Laptop Computer _____

Printer _____

Is there a computer at each point of service? ☐ YES ☐ NO

Operational

System Support

From where will the facility derive support for the EMR system:

- ☐ Facility Based Support available
- ☐ Remote support from _____ (indicate source)
- ☐ Service Level Agreement with Vendor

What is the estimated response time for the available support? _____ hrs

Data Backup and Security

Procedures for data backup are documented? ☐ YES ☐ NO

Antivirus

Antivirus system available for all computers? ☐ YES ☐ NO

Source of updates for antivirus systems:

- ☐ Direct Internet Connection
- ☐ Downloaded updates availed every _____ days
- ☐ None

Staff and Training

How many of the following staff are present at site and **will** use the system:

- | | |
|--|--|
| <input type="checkbox"/> Medical Doctors | <input type="checkbox"/> Health Records Information Officers |
| <input type="checkbox"/> Nurses | <input type="checkbox"/> Data Clerks |
| <input type="checkbox"/> Clinical Officers | <input type="checkbox"/> Data Officers |
| <input type="checkbox"/> Pharmacists | <input type="checkbox"/> Laboratory Staff |

How many staff have been trained on the following competency areas as defined in the EMR standards:

High Level Managers	_____	IT Administrators	_____
Data Managers	_____	Data Entry Personnel	_____

Summary

Please mark as appropriate:

- ☐ Site has access to power at least 75% of the day
- ☐ Site has computer equipment at minimum a desktop computer, a printer and a UPS
- ☐ Site staff has trained staff to use the system and to handle the workload based on defined competencies
- ☐ Physical Security of equipment is ensured
- ☐ Site has access to support personnel and this support is available within 24hrs of a reported problem
- ☐ Site has access to data communication facilities to transmit and receive data at least 75% of the times
- ☐ Site has access to voice communication facilities to contact support personnel at least 75% of the times

D. Security Policy Template

Document History

Revision History

Revision Number	Revision Date	Summary of Changes	Author

Approvals

This document requires following approvals:

Name	Title

Distribution

This document has been distributed to:

Name	Title

General IT Security Policies

“The purpose of this policy is to provide staff with guidance on the use of the IT resources, including, but not limited to the internet, email, and networks.

To encourage the appropriate use of IT resources, please adhere to the following policies:

Step	Action
------	--------

1.	Managers shall provide all staff with a written copy of these policy documents. All employees shall sign a statement indicating they have read this manual.
2.	Each employee's signed statement shall be kept on file for [X] years and while the employee is employed or provides services with Facility.
3.	IT resources includes, but is not limited to, all current and future Internet services, intranets, file transfer protocol (FTP), email, and other services.
4.	Facility shall undertake reasonable measures to secure Internet communications and the data transmitted by these systems and services.
5.	Facility shall install software and/or hardware to monitor and record all IT usage, including email and website visits. Facility retains the right to record or inspect any and all files stored on its systems.
6.	Facility IT resources shall be used solely for business purposes.
7.	Disciplinary action, including termination of employment, may result from prohibited activity obtained through monitoring and/or inspection of emails, files, or electronic storage devices. Illegal activities may be referred to the appropriate authorities for prosecution.

Prohibited Internet Usage Policy

Facility resources shall not be used for any activity other than business activities unless specifically requested by your Line Manager/supervisor.

1.	Employees shall not transfer Facility data, software or other licensed software out of the Facility's control without permission.
1.2	Employees shall not disclose confidential or sensitive information, client data, or information covered by existing privacy or confidentiality laws, regulations, rules, policies, procedures, or contract terms.
1.3	Employees shall respect copyrights, software, licensing rules, property rights, privacy for the duration of their employment.
1.4	Employees shall not download executable software, including freeware and shareware, unless it is required to complete their job responsibilities and dutifully authorized.
1.5	Employees shall not use IT resources to download or distribute pirated software or data, such as music or video files.
1.6	Employees shall not use IT resources to propagate malicious code.
1.7	Employees shall not use IT resources to disable or overload computer systems or networks,
1.8	Employees shall not use unauthorized access to the Internet from any device that is attached to any part of the Facility's network.

1.9	Employees shall not access, store, display, distribute, edit, or record offending and/or material like sexually explicit or extremist material using IT resources. Spam email shall not constitute a violation, provided it is promptly deleted and neither stored nor forwarded to others.
1.10	Employees shall not access or attempt to IT resources for which they do not have authorization, passwords, file permissions or legitimate access.
1.11	Employees shall not use IT resources to compromise the security of the Facility or other organizations.
1.12	Employees shall not use IT resources for illegal activity, gambling, or violate the laws of Kenya.

Computer Usage Policy

This policy is applicable to all Facility employees and refers to all IT resources. This policy applies to all computer facilities owned, leased, operated, or contracted by Facility including EMR software, Microsoft Office software, personal computers, workstations, and peripherals.

Step	Action
1.	Violation
1.1	Employees shall not violate any software license agreement; including copying or redistributing copyrighted software, data, or reports without authorization.
1.2	Employees shall not copy software except as stipulated by the owner of the copyright. Employees shall not copy software into, from, or by any system, except by license.
2	Interference
2.1	Employees shall not destroy, alter, dismantle, or prevent access to computer-based information and/or information resources. Employees shall not modify or remove computer equipment, software, or peripherals without proper authorization.
2.1	Employees shall not encroach on others' use of the IT resources, including, but not limited to, sending excessive emails; printing excess number of documents, files, or data; modify operating systems; damaging or vandalizing facilities, equipment, software, or computer files.
2.2.1	Employees shall not use programs which interfere with other computer users or which modify normally protected system or user accounts. Employees shall not use networks for personal use.
2.2.1	Facility reserves the right to limit, restrict, or extend computing privileges and access to its information resources.
3	Unauthorized access
3.1	Employees shall not seek to gain unauthorized access to information resources or enables unauthorized access; access computers, computer software, computer data, or networks without authorization; intentionally allow others to do so, regardless of whether the computer, software, data

	is owned by the Facility.
3.2	Employees shall report defects discovered in systems to the IT manager so steps can be taken to resolve the problem.
3.3	Employees shall be subject to civil and criminal liability if they disclose passwords or make IT systems available to others without permission.
4	Invasion of Privacy
4.1	Employees shall be subject to civil and criminal liability if they invade the privacy of individuals or entities without authorization.
4.2	Employees shall not use electronic communication facilities to send fraudulent, harassing, obscene, threatening, or other unlawful messages are prohibited.
4.3	Employees shall not provide information on, obtain copies of, or modify data, programs, or passwords belonging to other users.
4.5	Employees shall not attempt to gain unauthorized access to systems or private information. System Administrators may access staff files at any time for maintenance purposes and report suspected unlawful or improper activities.

Email Policy

Email is intended to be used primarily for business purposes. Any personal use must be of an incidental nature, and not interfere with business activities, involve solicitation, commercial activities, and potentially embarrass Facility.

1. Employees shall use email to send documents to other staff connected to Facility email system.
2. Employees shall use email for official business only.

E. Information Asset Inventory

Name of Site/Organization: _____

Name of Individual Completing Inventory: _____

Name of Individual Validating Inventory: _____

Date of Inventory: _____

Inventory to include IT hardware, software, data, system documentation, storage media and supporting assets such as UPSs

Description of Item	Serial Number	Location	Nominated Owner	Notes/Other

F. Backup Log Template

This log should be completed for every back up procedure depending on the frequency of back-ups (daily, weekly etc.)

Name of Facility/Organization: _____

Description of computer logged here: _____

Month: _____ Year: _____

Date of Backup (dd/mm/yyyy)	Media used (tape, CD, DVD)	Type of backup (full or incremental)	Status (Complete or unsuccessful)	Storage location (on- site or off-site)	Logged by (Name)

G. Sample Service Level Agreement

The following provides a sample upon which a service level agreement can be developed. Note that service level agreements are legal documents, detailed and spanning several pages. This sample is derived from a more detailed SLA and highlights key components of an SLA.

General Overview

THIS AGREEMENT is made this (date) **BETWEEN*******
(FACILITY) (Incorporated in the Republic of Kenya under Laws of Kenya and registered as a by Guarantee) of Post Office Box Number -, Nairobi in the said Republic (hereinafter called “**the Health Facility**” or “**facility**” which expression shall where the context so admits include its successors and assigns) of the first part and **VENDOR** a Limited Liability Company incorporated in Kenya under the Companies Act, Cap 486 and whose registered office is in Nairobi and of Post Office Box Number, Nairobi aforesaid (hereinafter called “**Service Provider**” which expression shall where the context so admits include its successors and assigns) of the other part.

WHEREAS:

- 1.1 The **Service Provider** has supplied, installed and commissioned EMR system at the Purchaser’s premises.
- 1.2 The **Service Provider** has provided support over a **-day warranty period from go-live date of the system.

1. SCOPE OF THE SUPPORT AND MAINTENANCE SERVICES

- 1.1 General advice and guidance on the use of the system
- 1.2 Support log
- 1.3 System upgrades
- 1.4 Technical support
- 1.5 Data conversion programs
- 1.6 An on-going training program
- 1.7 On-site training courses
- 1.8 Training advice
- 1.9 System ‘Health Check’

2. THE SERVICE PROVIDER’S UNDERTAKINGS

The Service Provider undertakes to the health facility that: -

2.1 The Service Provider will provide the following services to facility: -

- a) Its telephony enquiry and diagnostic service relating to the use of EMR, but that access to this service shall be available to facility only through its personnel who are recognized by The Service Provider as properly trained.
- b) Software updates incorporating such changes and modifications as may be required by reason of changes in legislation and fiscal requirements.
- c) Software updates incorporating relevant modifications and improvements to EMR considered by The Service Provider at its absolute discretion to be of general application to users of EMR

2.2 The Service Provider will provide at the request of facility the following further services;

- a) Such technical assistance and support as may reasonably be required by facility to enable it obtain maximum beneficial use of EMR
- b) Such adjustment as may reasonably be required to accommodate any changes in facility's-specific customization requirement for EMR
- c) Training for all the staff of the facility intended to operate EMR

3. FACILITY'S UNDERTAKINGS

Facility hereby undertakes to The Service Provider that: -

EHR will not be operated except by properly trained personnel

It will not modify EHR or incorporate or permit the incorporation of EHR into any other computer software program or system. At the request of facility, The Service Provider will avail the interface for integration purposes to the requisite systems.

It will permit The Service Provider to have access to the Operating Address at any reasonable time during normal business hours for the purpose of inspecting EHR.

It will implement any update of EHR supplied to it by The Service Provider in accordance with directions given to it by The Service Provide.

It will make payments promptly without demand, deduction or set-off on the renewal date

4. ROLES AND RESPONSIBILITIES

Customer Responsibilities

The Customer agrees to:

- Follow appropriate procedures when reporting issues to the Vendor service desk
-

- Determine appropriate incident priority (Critical, High, Medium, Low, and Minimal)
- Request and schedule special services (for example, after-hours support) well in advance.
- Be willing and available to provide critical information within 15 minutes of receiving a request for information from Vendor developers seeking to resolve an issue.
- Participate in the User Acceptance Testing and Review in order for the service desk to close an incident.
- Ensure data integrity especially with input data
- Provide feedback on service quality
- Escalate any unresolved issues as per escalation procedure above
- Proper operation of the equipment and application procedures

Vendor Responsibilities

Vendor agrees to:

- Maintain a Help Desk facility staffed with qualified personnel who will take problem reports, answer technical questions and attempt to resolve problems over the telephone.
- Provide names of technical support personnel, at least (3), any who will be in charge of support of facility EMR system and inform the facility of any management changes.
- Meet SLA resolution times associated with the priority assigned to incidents as defined in the annexure.
- Schedule maintenance (downtime) during the maintenance hour's window unless circumstances warrant performing maintenance at another time.
- Communicate in writing (e-mail) with facility ICT regarding issues involving change management
- Notify customer of any service interruption (planned or unplanned) and any updates or upgrades.
- Keep track of all Customer requests/incidents reported.

5. REPORTS

Both the assigned facility systems administrator and the vendor helpdesk administrative representative shall compile a monthly report showing helpdesk activity between the facility IT Operations department and the vendor helpdesk including but not limited to:

1. Number of calls escalated
2. Average call resolution time based on severity
3. Number and status of calls escalated but still open.

6. ANNUAL MAINTENANCE FEES

Subject to and in consideration of the payment by facility to The Service Provider of the annual maintenance fee and subject also to the observance and performance by facility of the obligations on its part hereinafter contained The Service Provider is hereby obligated to provide maintenance and support services as herein stated

The Annual maintenance fee payable shall be the sum specified at Part III of the schedule hereto and shall remain constant during the contract period and can only be subject to a review at the contract renewal.

Annexure **Reported faults prioritization**

<i>Priority 1</i>	<i>Critical faults affecting facility operations and requiring an immediate response</i>
<i>Priority 2</i>	<i>Faults requiring an urgent, though not necessarily an immediate response. Facility operations not affected.</i>
<i>Priority 3</i>	<i>Other faults</i>

Fault Response time

<i>Priority</i>	<i>Response</i>	<i>Resolution (Temporary solution)</i>	<i>Target for Correction of fault</i>
<i>1</i>	<i>Immediate</i>	<i>6 hours</i>	<i>2 working days</i>
<i>2</i>	<i>Within 1-3 working days</i>	<i>12 hours</i>	<i>3 working days</i>
<i>3</i>	<i>Within 15 working days</i>	<i>Not applicable</i>	<i>By agreement</i>

H. Sample EMR Monitoring and Evaluation sheet^{32,33}

Measure	Questions	Indicators
EMR use, acceptability and reliability	Is the EMR available during clinic hours? Is staff trained to use the EMR? Do staffs use the EMR system? Do the staffs feel that the EMR is useful to them?	No. of unscheduled power outages per week No. of times per week that computers malfunction % of staff trained and using the EMR % of patient records entered into the EMR % of staff who feel that the system is useful.
Improvement of patient care	Do providers use the EMR decision support features to guide patient management?	No. of staff who use EMR to support clinical decisions No. of staff who use clinic reports to guide patient management
Improvement of record keeping	Does the EMR system improve record keeping?	% of patient records entered correctly when compared with paper records
Improvement of reporting	Does the EMR improve timeliness of aggregate reports? Do the health managers use the EMR reports?	% of managers who use the EMR reports for decision making.

General Section (Observation)

Is the EMR System still in use? YES ☐ NO ☐

Is equipment in good working order? YES ☐ NO ☐

If NO, list out the equipment that is not working

Equipment	Fault Description	Fault Reported? Yes/No

³² G. Rutherford, S. Yoon, A. Johnson, G. Kennedy, U. Khan, L. Packel, N. Smith, H. Spindler. **Guidance document for Evaluating Electronic Patient Monitoring Systems for HIV Treatment and Care**, June 2008

³³ Victor Balaban, Lela Baughman, Christopher Bishop, Meklit Hailemeskal, Xen Santas, Steven Yoon. **Developing an Electronic Medical Record (EMR) System Implementation Plan: Guidelines and Template**.

Observe the use of the system. Is the EMR used for patient registration?

☐ YES ☐ NO

How many visits did you observe in which the EMR was used for patient registration? ____ out of ____

How long did it take to register a patient?

Patient 1	_____ minute(s)
Patient 2	_____ minute(s)
Patient 3	_____ minute(s)
Average registration time	_____ minute(s)

Observe data entry into the EMR. Does the EMR have a system of detecting data entry errors?

YES ☐ NO ☐

Sample 10 patient files and compare the records with the EMR records. How many patient records are correctly entered compared with the paper records?

_____ out of _____

User Survey

What is your role in the EMR system use? _____

How often do you use the EMR system?

☐ Never ☐ Always ☐ Sometimes (How many times? ____)

Have you received training for your role described above? YES ☐ NO ☐

How often do you receive mentorship for the EMR use?

☐ Never ☐ Monthly ☐ Quarterly ☐ Semi-Annually

How many times per week in the last month have you had problems accessing the EMR?

☐ None ☐ 1-3 times ☐ 4-8 times ☐ More than 9 times

In the last month, have you used the EMR to determine when to put a patient on ART?

☐ Never ☐ Always ☐ Sometimes (How many times? ____)

In the last month, have you printed out a report (of missed appointments, of late CD4 counts etc) to aid in clinic management?

☐ Never ☐ Always ☐ Sometimes (How many times? ____)

Please select the most appropriate answer:

The EMR system is easy to use:

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

The EMR system makes my work easier

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

The EMR system reminds me to do things I forget

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

The EMR system makes my work slower

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

Clinic Manager Survey

How many times per week in the last month have you had problems accessing the EMR?

☐ None ☐ 1-3 times ☐ 4-8 times ☐ More than 9 times

How many times per week in the last month have the EMR computers or network malfunctioned?

☐ None ☐ 1-3 times ☐ 4-8 times ☐ More than 9 times

How many unscheduled power outages have you had per week in the last month?

☐ None ☐ 1-3 times ☐ 4-8 times ☐ More than 9 times

Please select the most appropriate answer:

Generating reports from the EMR is easy

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

I use the generated reports for decision-making

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

I receive the monthly aggregate reports from the clinic within / after:

- ☐ Within the 1st week of the month
- ☐ In the 2nd week of the month
- ☐ After the 2nd week of the month

I. Evaluating the use of an EMR system within the functional areas of ART clinics

(Adapted from Guidance Document for Evaluating Electronic Patient Monitoring Systems for HIV Treatment and Care)

Functional areas	Attributes	Components to be evaluated	Measurements methods	Indicators
Registration	Usefulness	Did staff use systems when registering patients?	Data validation Observation	% of visits that used EMR for registration (<i>numerator=number of visits using EMR; denominator=total number of visits</i>)
	Simplicity	Did staff collect all information from patient as needed?	Data validation	% of complete registration records <i>num=#of complete registration records; denom=total number of reg records</i>)
	Flexibility	Are the data collection tools modifiable?	EMR system	Data collection tools are modifiable
	Data Quality	Is patient information entered correctly	Data Validation	% of fields entered correctly when compared to the paper system (<i>num=# of fields entered correctly in each record; denom-total # of fields in each record</i>) % of patient records without errors (<i>num=# of records without errors; denom=total # of records</i>) % of missing fields when compared to the paper system (<i>num = # of missing fields in each record; denom = total # of fields in each record</i>)
	Acceptability	Do staff members feel the EMR system is useful to them?	Staff survey	% of staff who feel the system makes their job easier to do (<i>num = # of staff who state 'system makes their job easier'; denom = total # of staff surveyed</i>) % of staff who use the system for every patient (<i>num = # of staff who say they use the system for every patient; denom = total # of staff who use the system</i>) % of staff who feel the system is adaptable to all of their needs (<i>num = # of staff who state system is adaptable; denom = total # of staff surveyed</i>)
	Timeliness	How long is the wait in line? How does it take for a clerk	Time-flow analysis	Average time of registration process

Functional areas	Attributes	Components to be evaluated	Measurements methods	Indicators
		to register a patient?		
Patient Visit	Usefulness	<p>Did the providers use the EMR as decision support for patient's health?</p> <p>Did the EMR help providers know when to start patient on ART?</p> <p>Did the EMR identify adherence issues (e.g., fill counts etc)?</p> <p>Did patients get referred to services as needed?</p>	<p>Staff survey</p> <p>Observation</p>	<p>% of providers who use the EMR (<i>num = # of providers who use EMR; denom = total # of providers surveyed</i>)</p> <p>% providers use the EMR for deciding when to initiate ART (<i>num = # of providers who use EMR for ART decision making; denom = total # of providers surveyed</i>)</p> <p>% of providers who feel EMR assisted with adherence (<i>num = # of providers who state EMR assisted with adherence; denom = total # of providers surveyed</i>)</p>
	Simplicity	<p>Do clinicians this the EMR is easy to use?</p> <p>Do clinicians think the EMR improves patient care?</p>	Staff Survey	<p>% of clinicians who think EMR is easy to use (<i>num = # of clinicians who state EMR is easy to use; denom = total # of clinicians surveyed</i>)</p> <p>% of clinicians who think EMR improves patient care (<i>num = # of clinicians who state EMR improves patient care; denom = total # of clinicians surveyed</i>)</p>
	Flexibility	Are the data collection tools modifiable?	EMR	Data collection tools are modifiable
	Data Quality	Is patient information entered correctly?	Data validation	<p>Percent of fields entered correctly when compared to the paper system (<i>num=# of fields entered correctly; denom-total # of fields</i>)</p> <p>% of visit records without errors (<i>num=# of vist records without errors; denom=total # of visit records</i>)</p> <p>Percent of missing fields when compared to the paper system (<i>num = # of missing fields; denom = total # of fields</i>)</p>
	Acceptability	Do providers feel the EMR system is useful to them?	Staff survey	% of providers who feel the system makes their job easier to do (<i>num = # of providers who state 'system makes their job easier'; denom = total # of providers</i>)

Functional areas	Attributes	Components to be evaluated	Measurements methods	Indicators
				<p>surveyed)</p> <p>% of providers who use the system for every patient (<i>num</i> = # of providers who say they use the system for every patient; <i>denom</i> = total # of providers who use the system)</p> <p>% of providers who feel the system is adaptable to all of their needs (<i>num</i> = # of providers who state system is adaptable; <i>denom</i> = total # of providers surveyed)</p>
	Timeliness	How long was the patient visit?	Time-flow analysis	Average time of patient visit
	Stability / Availability	Is there a back-up paper system in place?	Staff Survey	% of patients who have a back-up paper record (<i>num</i> = # of patients with back-up record; <i>denom</i> = total # of patients)
Data Entry	Usefulness	Did the EMR identify problems with data entered?	Staff survey Observation of system	<p>Does the EMR have a system to detect data-entry errors?</p> <p>% of staff who feel that the in-built data edit checks are adequate (<i>num</i> = # of staff who state that edit checks are adequate; <i>denom</i> = total # of staff surveyed)</p>
	Simplicity	Do data clerks think that entering data is easy? What problems occur when entering data?	Staff Survey	% of data clerks who think that entering data is easy (<i>num</i> = # of data clerks who state data entry is easy; <i>denom</i> = total # of data clerks surveyed)
	Flexibility	Can the system be modified while entering data? How well does the system handle data errors (e.g., does it freeze up)? Can the user override incorrect system assigned values?	EMR	System is modifiable
	Data Quality	Are data entered correctly? Is there a system for control checks on data? Is the system accurate in	Data validation Staff Survey	% of fields entered correctly when compared to the paper system (<i>num</i> =# of fields entered correctly; <i>denom</i> -total # of fields)

Functional areas	Attributes	Components to be evaluated	Measurements methods	Indicators
		reporting calculated indicators (age, BMI etc)		% of missing fields when compared to the paper system (<i>num = # of missing fields; denom = total # of fields</i>) Presence of a quality control system
	Acceptability	Does data entry staff feel the EMR system is useful to them?	Staff survey Data validation	% of patient records that are entered into the EMR (<i>num = # of records entered into EMR; denom = total # of records</i>) % of data entry staff who feel the system is adaptable to all of their needs (<i>num = # of providers who state system is adaptable; denom = total # of providers surveyed</i>)
	Timeliness	How long does it take to enter patient data?	Time-flow analysis Staff survey	Length of time following visit for data to be entered. Average time for data entry per patient file. % of data entry staff who feel they have adequate time to enter data into the EMR (<i>num = # of staff who state they have adequate time; denom = total # of staff surveyed</i>)
	Stability / Availability	How many unscheduled power outages occur per week? How many times per week do the computers malfunction?	Staff Survey	Number of unscheduled power outages per week. Number of times per week that computers malfunction. % of staff who rely primarily on the EMR (<i>num = # of staff who state they rely primarily of the EMR; denom = total # of staff surveyed</i>)
Reports	Usefulness	Are reports used by MOH officials for policy decisions? Are reports used by clinic staff for program decisions?	MOH Survey Staff Survey	Does MOH staff use the EMR to make policy decisions? Does clinic staff use the EMR to make program decisions? Type of reports generated. How many national / recommended reports are generated?
	Simplicity	Does clinic staff find the	Staff survey	% of clinic staff who find the reports

Functional areas	Attributes	Components to be evaluated	Measurements methods	Indicators
		reports useful and easy to understand? Does clinic staff find the reports easy to generate?		useful and easy to understand (<i>num = # of staff who state reports are useful and easy to understand; denom = total # of clinic staff surveyed</i>) % of clinic staff who find reports easy to generate (<i>num = # of staff who state that reports are easy to generate; total # of clinic staff surveyed</i>)
	Flexibility	Can the information in reports and the format of reports be altered?	EMR	Information and report format are modifiable
	Data Quality	Are data in reports correct?	Data validation	Presence of a quality control system
	Acceptability	Do staff feel the EMR report generating system is useful to them	Staff Survey	% of staff who feel the reports make their job easier to do (<i>num = # of staff who state the reports make their job easier; denom = total # of staff surveyed</i>) % of staff who use the reports (<i>num = # of staff who state they use the reports; denom = total # of staff surveyed</i>)
	Timeliness	How long does it take to generate a quarterly report? Are the reports received on time?	Time flow analysis Staff survey Submission validation	Time it takes to generate a quarterly report % of reports received on time (<i>num = # of reports received on time; denom = total # of reports received</i>) Average delay in reporting
	Stability / Availability	Is there a back-up paper report?	Staff survey	Number of paper reports printed and filed at the clinic