Handbook for Electronic Health Records Implementation

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Note to technical reviewers

- This document is intended as a working draft for discussion, with an expectation of finalizing the document in a publishable form. Hence, this document is not complete.

- Reviewers are encouraged to provide constructive input and suggest structural and conceptual changes to achieve a near-final publishable document.

- The reviewers are expected to bring their practical/implementation perspectives while editing the document so that the final document would reflect the inclusion of country-contexts, thereby making the document more practical and usable in the field.

- The final document will undergo an editorial review to comply with WHO and PAHO recommended standards for publication of this document. As such, the reviewers are encouraged to focus on the technical content of the document and not the linguistic construction of the document.

- Finally, the current layout of the document is for easy reviews. The final laying out the document in print format especially with more graphic design to visualize some content will substantially reduce the number of pages of this document.

Acknowledgements

The World Health Organization (WHO) and the Pan American Health Organization (PAHO/WHO) are grateful to its collaborators in particular, the Hospital Italiano de Buenos Aires and the consultants whose dedication, technical know-how, and support have made possible the preliminary version of this document.

Coordination and technical review

The preliminary version of this publication was produced under the overall coordination of:

- Department of Information, Evidence and Research. Health Systems and Innovation Cluster. World Health Organization (WHO).
- Office of Knowledge Management, Bioethics & Research. Pan American Health Organization (PAHO/WHO)

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Abbreviations

AHIMA - American Health Information Management Association
CCD - Continuity of care document
CCR - Continuity of care record
CDA - Clinical Document Architecture
ICPC - International Classification of Primary Care
CIO - Chief information officer
CMIO - Chief medical information officer
CDR - Clinical data repository
CDSS - Clinical decision support system
CPOE - Computerized physician order entry
EHR - Electronic health record
EMR - Electronic medical record
EMRAM – EMR adoption model
HL7 – Health Level 7
ICD – International Classification of Diseases
IOM - Institute of Medicine
IT - Information technology
HI - Health Informatics
HIE - Health information exchange
HIMSS - Healthcare Information and Management Systems Society
HIPAA - Health information privacy and accountability act
HIS - Health information systems
HIT - Health information technology
HMN - Health metrics network
MPI – Master patient index
NHIN - National Healthcare Information Network
NIST - National Institute of Standards and Technology
PACS - Picture archiving and communication system
PHI - Public health informatics
PHR - Personal health record
RHIO - Regional health information organization
ROI - Return on investment
SNOMED CT - SNOMED Clinical Terms
WHO - World Health Organization

Purpose of the document

Implementation of Health Information Technology (Health IT or HIT) aims to guarantee that healthcare-related information is safely provided to the right person in the right place at the right time, in order to optimize healthcare quality, safety, accessibility, equity and efficiency.

This document provides a guide for policy and decision makers addressing the most relevant challenges of implementing electronic health records (EHR) at national or regional level.

This guideline primarily targets ministries of health and science, as in most member states these are responsible for healthcare and health-related information policies. But other decision makers at regional or organizational level, including those without technical knowledge, can benefit from using this guideline to improve clinical documentation and healthcare related processes. Depending on their local situation, policy and decision makers may operate at national, sub-national, regional, local or institutional levels.

Health information systems (HIS) are organized sets of elements that interact to process data and information, aiming for efficient information exchange to support operations management, planning, provision of medical care, and documentation of healthcare encounters. This handbook aims to guide EHR implementation based upon these principles. It can also be used as a policy tool for governmental action to increase EHR adoption.

How to use this document

This document is designed for simple and easy use, and need not be read in a linear fashion from beginning to end. It is designed to be used in ongoing efforts to develop health information systems in national and sub-national contexts, and in accordance with countries' strategic health development plans and public health policies, which often address the need for electronic health records.

The EHR implementation handbook is a milestone in our understanding of the challenges that arise in planning and executing an EHR implementation, and of the impact of such an implementation on healthcare processes and organizations. It is a comprehensive, practical guideline that can be adapted to suit varying circumstances and different visions and goals.

Health information systems (HIS) are organized sets of elements consisting of people, data, activities and material resources that interact to process data and information, aiming to distribute and exchange this information in the most efficient manner, in order to achieve organizational objectives. Health information systems provide communication between members of healthcare teams and support the information needs of an organization for operations management, planning, provision of medical care, and documentation of healthcare encounters. They do this through applications such as EHR.

Any application or software acting as EHR would be doomed if planning did not take into account (1) the general context in which it would play and (2) the information system that comprises it. While strategic planning of a national HIS is beyond the scope of this guide, it must be borne in mind that in order to ensure a successful EHR implementation, decision makers should lay the fundamental groundwork for a Health Information System (HIS) which supports EHR.

Figure 1 – Relationship between EHR and other components of a National HIS Strategy
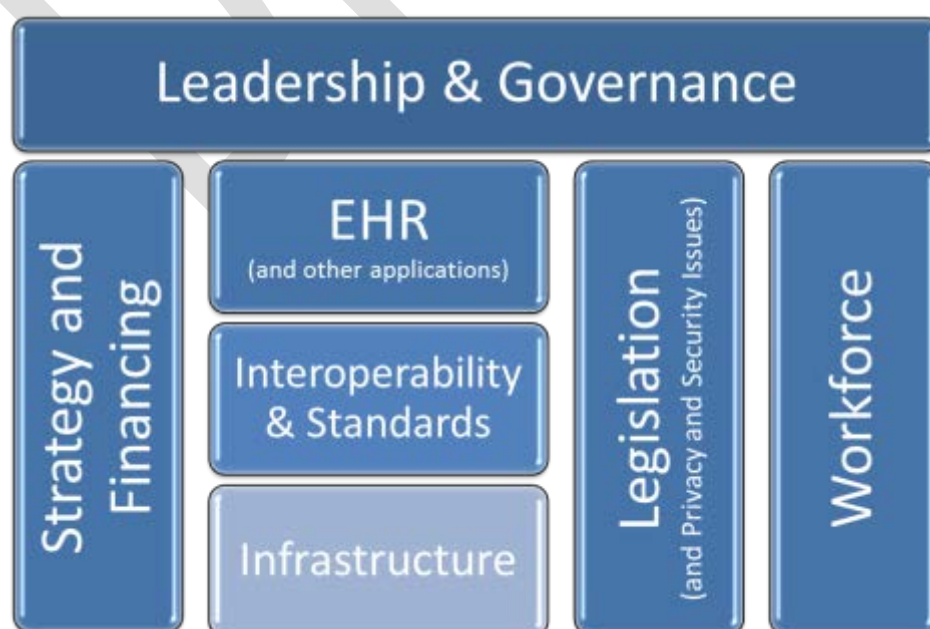
Figure 1 is a proposed scheme of national health information system components that shows the relationships between other HIS components and EHR (and other healthcare applications such as disease registries and personal health records). This document adapts many of these components to the central topic of EHR implementation. Each component will be addressed in a segment or chapter of this handbook (see Figure 2).

Figure 2 – EHR implementation components described in this guideline

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Infographic overview

This overview provides a graphic outline of the handbook.

Figure 3 – EHR handbook infographic overview

FINANCING

Consider different ways of financing	Establish a minimum expected requirement for ROI	Conduct cost - benefit analysis
Take into account the scope of the project and the time needed	Consider different types of incentives	Consider non-financial benefits of the project
Perform a cost analysis of each component	Account for temporary productivity losses	

WORKFORCE TRAINING AND CAPACITY BUILDING

Understand the unique needs of the local setting	Develop a local map of IT roles and skills needed	Search or develop an informatics educational program
Make a comprehensive assessment of the spectrum of roles involved in HIT	Identify all individuals who require formal training	Create a professional and educational accreditation board for HIT certification
Perform a good characterization of the local workforce	Contact local HI societies	Cooperate with other countries or institutions involved in HIT

CHANGE MANAGEMENT

Understand Organizational and Behavioral issues	Identify the stakeholder groups	Strategic Communication Plan
Create a climate for change	Engage Stakeholders	Establish realistic expectations
Engage and enable the organization	Implement and sustain the changes	Train, retrain and provide technical support

STANDARDS FOR INTEROPERABILITY

Understand the need for interoeperability	Consider implementation of a national MPI	Evaluate national use of a reference terminology
Create a national entity in charge of interoperability	Develop a national plan or roadmap for interoperability	Unique identifiers for healthcare providers, workers, facilities, and procedures
Identify standards for collection and exchange of health information	Stablish Infrastructure for Interoperability	Consider use of clinical document standards

CLINICAL DATA AND PUBLIC HEALTH INFORMATICS

Understand Clinical Context Challenges	Consider the requirements for useful data	Implement international standards for data
Data Format (Structured Vs. Free)	Strive for primary data capture	Integrate organizations that work on Public Health Informatics
Information Variability (Form and Source)	Data Source Issues	Create and enforce policies for Public Health Informatics

PRIVACY, ETHICAL AND LEGAL ISSUES

Balance between data availability & security	Strengthen information Security	Consider use of electronic/digital signature
Define a security strategy	Select an adequate strategy for user authentication	Use MPI as the cornerstone of access control measures
Training and awareness of involved people	Review local privacy and data security regulations	Define User Access Profiles

Electronic health records definition and key capabilities

Box 1: Improving quality of care

Countries should adopt EHRs in order to improve quality of care and access to care, and to optimize costs and use of resources. In this context, EHRs can act as a basis for indicators and design of individual actions. Countries should therefore implement EHRs with strong focus on equitable distribution of benefits.

An EHR is a health record residing in an electronic system.

This section covers the basic aspects of EHR, including definitions, key capabilities, and an eight-level system of increasing levels of implementation. EHR offer many benefits compared to paper records: accessibility, support for multiple views, improved communication between providers, communication with patients, data aggregation, access to knowledge bases, and integration with decision support tools.

But there are several barriers to their adoption and implementation, including issues of finance, technical concerns, time, psychology, social and legal issues, and obstacles to organizational and change processes.

Box 2: Health management and cost

Countries should adopt EHRs in order to improve health management processes and patient safety at an affordable cost. The adoption of EHR and the application of technology to a country's health priorities must ensure that the system's coverage extends to all citizens. E-Health/Health Informatics must be a public good that enables universal health access and universal health coverage. To achieve this, it is recommended that EHR implementation should be modular and/or incremental, and should begin with core components representing the HIMSS EMR Adoption Stages 0 and 1. This includes a patient administration system with demographics, structured diagnosis and procedures data, and admission/discharge/transfer (ADT) and ancillary systems for lab, pharmacy and radiology services. More high-level components, including clinical decision support (error checking and clinical protocols) and structured templates for physician documentation should be implemented at a later stage, when the EHR is more mature.

Figure 4 – EHR introduction chapter components

Definition

EHR are health records residing in an electronic system specifically designed for data collection, storage, and manipulation, and to provide safe access to complete data about patients. They are clinical decision support tools, offering important clinical information for the care of patients.

EHR must include:

1. A longitudinal collection of electronic health information for and about persons
2. Immediate electronic access to person- and population- level information by authorized, and only authorized, users
3. Provision of knowledge and decision support that enhances the quality, safety, and efficiency of patient care
4. Support of efficient processes for health care delivery.

Key capabilities of EHR

Key capabilities that an EHR must support are listed in Table 1.

Table 1: Key capabilities of an electronic health record system

Key capabilities	
	Storage and retrieval of health information and data
	Results management
	Order entry/management
	Decision support management
	Electronic communication and connectivity
	Patient support
	Administrative processes
	Reporting & population health

EHRs in surveillance

Countries should utilize EHRs in routine and syndromic disease surveillance to increase timely, complete and efficient reporting. Benefits may include use in large-scale data aggregation; improved completeness of reporting; improved public health response; and better traceability and contact tracing. The process should be tailored according to the country's specific needs, and requires resources including staffing.

EHR staging

The Healthcare Information and Management Systems Society (HIMSS) developed the EMR (electronic medical record) adoption model (EMRAM), to classify different systems according to functionality. The model has eight stages that grow in complexity, with each stage containing the cumulative capabilities of previous stages. Capabilities required for each stage are shown in Table 2.

Table 2: HIMSS EMR adoption model (EMRAM)

Stage 7	Medical record fully electronic and health information exchange (HIE) capable; data warehousing; data continuity
Stage 6	Physician documentation (structured templates), full clinical decision support system (CDSS) (variance & compliance), full picture archiving and communication system (PACS)
Stage 5	Closed loop medication administration
Stage 4	Computerized provider order entry (CPOE), CDSS (clinical protocols)

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Stage 3	Clinical documentation (flow sheets), CDSS (error checking), PACS available outside radiology
Stage 2	Clinical data repository (CDR), Controlled medical vocabulary, CDSS inference engine, may have document imaging
Stage 1	Ancillaries – laboratory, radiology, pharmacy
Stage 0	All three ancillaries not installed

EHR benefits and barriers

Paper records have several limitations, including but not limited to: accessibility problems, inadequate organization of information, incompleteness and fragmentation of information, redundancy, security problems, difficulties in reusing data, and legibility issues.

EHR offer many benefits over paper records:

➢ **Accessibility:** EHR can be used by more than one person at a time, and can be accessed from multiple locations.

➢ **Support for multiple views:** EHR can offer different visualizations tailored to user-specific needs. Clinical information is complex, and the way it is presented to providers impacts the way they interpret it.

➢ **Improved communication between providers:** healthcare teams are composed of many members, and depend on adequate communication to coordinate actions. EHR facilitate the exchange of information between collaborating providers.

➢ **Communication with patients:** EHR can also improve communication with patients. A growing number of EHR are being linked with personal health records (PHRs) with this goal.

➢ **Data aggregation:** EHR can support the creation of groups and summaries from big volumes of data.

➢ **Access to knowledge bases:** EHR provide contextual access to knowledge bases when providers need it.

➢ **Integration with clinical decision support system (CDSS):** one of the main reasons for collecting clinical data in a controlled manner is to offer support for clinical decisions in the form of contextual information, alerts and reminders.

Despite the potential gains in quality, efficiency and safety that EHR can provide, several barriers exist to their adoption and implementation. These barriers are summarized in Table 3.

When forming strategic plans for the adoption and implementation of EHR,

decision makers should consider the risks that these barriers pose to the objectives of an organization, and ways to overcome them.

Table 3: Barriers to the acceptance of electronic medical records perceived by physicians

Financial	High start-up costs
	High ongoing costs
	Uncertainty about return on investment (ROI)
	Lack of financial resources
Technical	Lack of computer skills of physicians and/or staff
	Lack of technical training and support
	Complexity of the system
	Limitation of the system
	Lack of customizability
	Lack of reliability
	Interconnectivity/standardization
	Lack of computers/hardware
Time	Time to select, purchase and implement the system
	Time to learn the system
	Time to enter data
	More time per patient
	Time to convert the records
Psychological	Lack of belief in EHR
	Need for control
Social	Uncertainty about the vendor
	Lack of support from external parties
	Interference with doctor-patient relationship
	Lack of support from other colleagues
	Lack of support from management
Legal	Privacy or security concerns
Organizational	Organizational size
	Organizational type

Change process	Lack of support from organizational culture	21
	Lack of incentives	
	Lack of participation	
	Lack of leadership	

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Strategic plan (policy and governance)

A strategic plan for a large-scale EHR implementation requires high-level leadership (national or ministerial), to facilitate policy-making and ensure project governance. This can be broken down into the following aspects, which will be explained in this chapter and which are represented in Figure 5:

1. Review the national eHealth strategy context
2. Set up a coordinating team
3. Conduct a situation analysis
4. Set goals and objectives
5. Develop a work plan and monitoring system
6. Communicate and disseminate.

While all these points will be addressed, the main objective of this chapter is to focus on the first two.

Figure 5 – Recommendations for EHR strategic planning
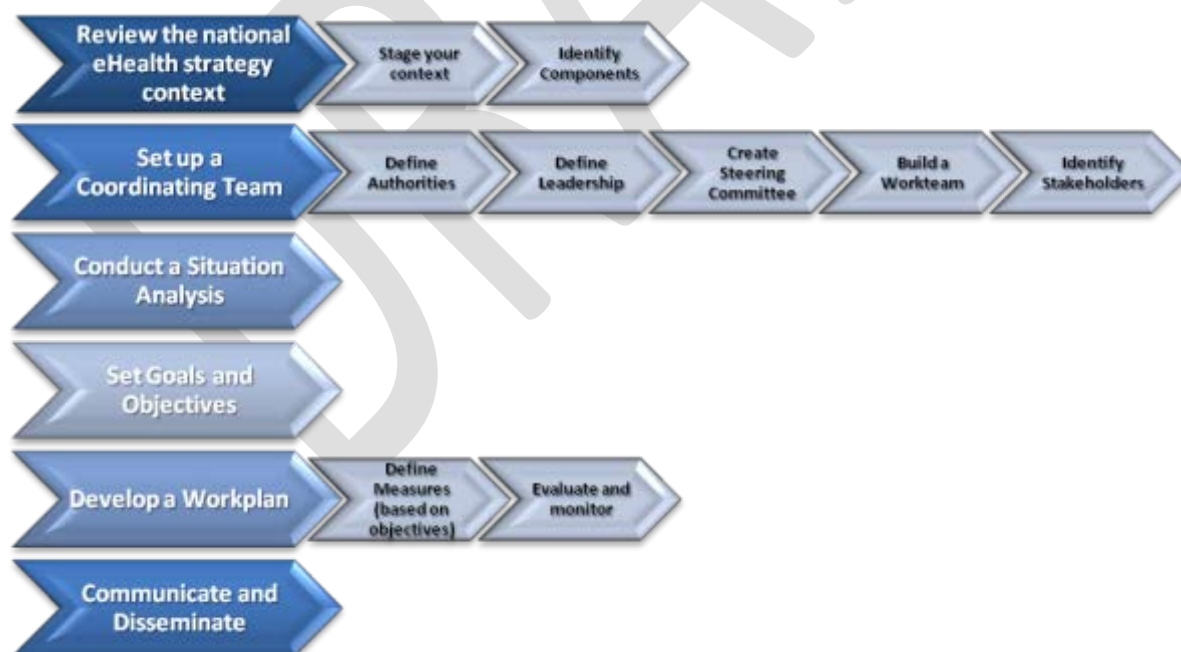
Box 3: Readiness assessment

Countries should begin with a full assessment of their readiness to adopt EHRs, including through looking at infrastructure, standards adoption, business and clinical processes, education and training, human resources capacity and public willingness. The assessment

process should be tailored to specific needs of the country, and will require resources, including staffing.

eHealth strategic context

Health Information Technology (HIT) is changing healthcare delivery and has largely infiltrated the core of health systems with different levels of efficiency. Several healthcare processes are information- and communication-based, and rely on various different technologies.
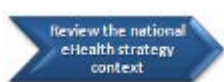
When the adoption of HIT is not articulated with a health systems strategic plan, development of partial or fragmented solutions results, and this is inadequate for the implementation of nationwide EHR. HIT should seek to reach all citizens with high-quality, equitable and safe care, and meet public health goals.

A national approach is therefore needed, based on strategic integrated action and collaboration between the health care and IT sectors, public and private. It should start from the current eHealth environment, considering available and potential resources, and be based on the national health plan and its goals.

The eHealth strategy context can be considered in terms of two dimensions:

➢ The IT environment, representing the IT market and actual penetration (computing and networking infrastructure)

➢ The enabling environment for eHealth, which is based on governance, policy, legislation, standards and human resources that support scaling up and sustaining eHealth (and EHR) adoption.

Based on these two dimensions, it is possible to describe the national context for eHealth in three possible stages (Table 4):

➢ Experimentation and early adoption

➢ Development and building up

➢ Scaling up and going mainstream.

Table 4: Stages for national eHealth development (WHO: National eHealth Strategy Toolkit)

Stage	Characteristics
Experimentation and early adoption	• Usually small, few and disconnected eHealth initiatives
	• Proof-of-concept pilots where IT is introduced in a limited context
	• Projects rarely sustainable, lacking infrastructure, skills and integration
	• Commercial IT market fragmented, with little local expertise

24	• Funding provided by aid agencies, donors and external actors
	• International obligations for public health reporting cannot be met.
Development and building up	• Larger eHealth projects with greater awareness of potential
	• Applications emerge but remain vertical, fragmented and not scalable
	• Commercial IT market, with international and local IT vendors
	• Aid agencies and donors are still funders; private sector investment in development and adoption of cost-effective technologies
	• Public-private partnerships increase in number
	• International obligations for public health reporting can sometimes be met through vertical systems
	• Examples: telemedicine networks, limited adoption of EMR, procurement and stock tracking systems, and mHealth trials.
Scale up and mainstream	• Investment and adoption scales up
	• Commercial IT market with larger vendors, both international and local
	• Health sector takes a leading role in planning and using eHealth
	• Health IT industry is active
	• International obligations for public health reporting can be met
	• HIS are increasingly linked, but still face problems due to legacy systems
	• Examples: hospital and care networks, home health monitoring, chronic disease management applications, personal health records.

A national or regional plan for EHR should take these stages into account.

There are several further points to review, independent of what stage the national eHealth context is in.

If a country is:

➢ In the first stage, strategic planning should focus on the enabling environment
➢ In the second stage, the priority should be on legal, policy and standards aspects
➢ In the third stage, focus should be on users, monitoring and evaluation.

Finally, the national eHealth context components are related to strategic aspects, which will also be considered in this framework. Most of these components are related to the enabling environment; only infrastructure is related to the IT environment.

Figure 6 – Stages and points to review
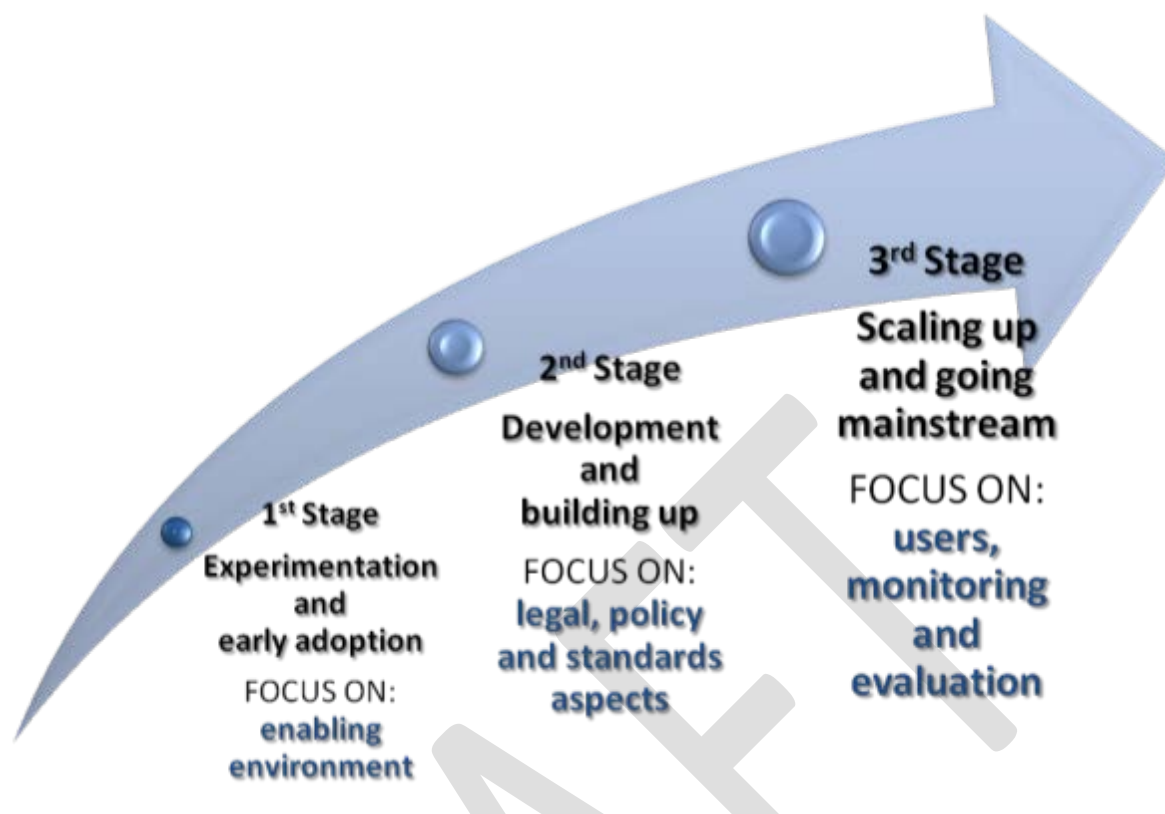
Box 4: Governance and policy

Governance is a prerequisite for a successful national EHR implementation. Countries should ensure that they have a multi-sectorial eHealth governance body to oversee their EHR implementation, backed by a combination of policies, legislation and regulation to ensure good practice, patient rights and privacy. This body will have a number of roles: it is important in aligning the national EHR strategy with the country's health policy objectives (and ensuring health system priorities that consider equity, ethics and human rights); ensuring that national EHR strategic objectives are assigned and managed within a framework for clearly understood and transparent decisions, rights and accountability; providing stability; and assisting in overcoming limitations that may exist in the organizational structure.

Set up a coordinating team

Defining high-level authority for the project is necessary in order to establish the policy framework and governance responsibilities, and identify to whom project leaders should report progress and changes in the objectives and/or scope.

A large-scale EHR initiative should be based on national health goals. Any nationwide EHR project is health-driven and IT based, and it should therefore be expected that the lead of the project reports to the ministry of health (and not the ministry of technology, science, infrastructure, or equivalent). Regardless of which ministry takes the lead, an EHR initiative

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should link these ministries. This is the first step: define high-level authorities, who will lead, and to whom will they answer.

The second task is the appointment of a steering committee to support the leadership and accompany the strategic decisions of the project leader. This committee must include ministerial authority to provide political support (secretaries and coordinators of related units) and it must be multisectoral, including leaders from other government structures and representatives of sectors including healthcare and IT, academic and commercial, and public and private, to ensure representation of all stakeholders.

The assembly of operative follow-up and functional teams is the next step, and is part of the leading structure. This step defines the team or teams responsible for monitoring the progress of the project and articulating the various committees and discussion groups.

These teams aim to facilitate and promote integration of joint work by all relevant stakeholders from all levels (national, regional and local).

Once these three main tasks of setting up a coordinating team are completed, other tasks should be taken into account:

- **Identifying stakeholders** is the first step in creating opportunities for discussion. A comprehensive survey of projects and system groups, leaders and other accountable parties should be performed, in many levels.
- **Integrating health information system groups** at national level, through a cross-management strategy for health information, and managing interactions between different offices.
- **Establishing a decentralized operational structure** (if geographic characteristics apply), reviewing existing structures, and identifying leaders and working groups currently carrying out related projects.

Figure 7 – Steps for setting up a coordinating team
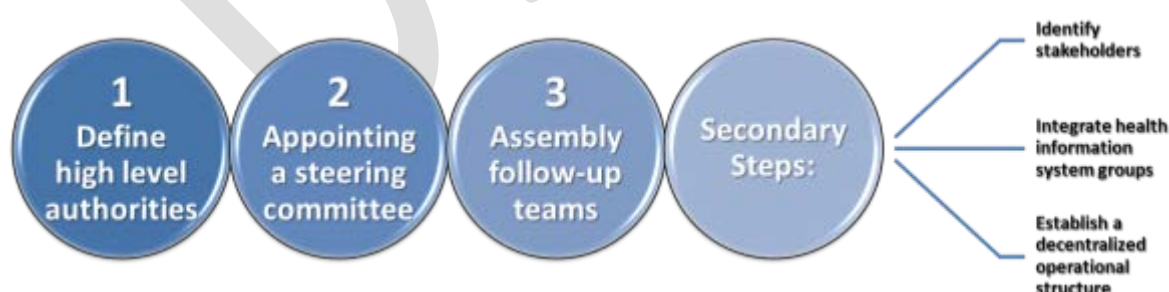
Conduct a situation analysis

Situation analyses are essential for the development of policies and for planning the actions reviewed in this handbook. Besides the eHealth context already reviewed and the existing structures described above, situation analysis must be undertaken for every component discussed in this document.

By providing a baseline assessment, a situation analysis helps the coordinating team to understand the needs, resources and conditions relevant to planning interventions.

Set goals and objectives

Using the information gathered in the situation analysis, the coordinating team, in collaboration with the steering committee, will define the goals and objectives necessary to clarify what the interventions aim to achieve. After that, it will be possible to measure and evaluate the extent to which the desired outcomes have been reached.

Goals can be defined as broad statements describing the overall desired improvements related to an EHR implementation. They can then be broken down into:

➢ Process and output objectives: describing what will be changed or implemented to achieve the outcome objectives

➢ Outcome objectives: defining what is to be achieved through the interventions.

It is desirable to set short-, medium- and long-term goals and quantify the barriers to achieving them; link health system goals with EHR project goals; and finally review the impacts of these goals on stakeholders. Annual milestones should be planned, giving the project public visibility that allows the coordinating team to continue moving towards long-term goals while showing incremental and tangible progress in the shorter term.

Develop a work plan and monitoring system

Once goals are defined, the project's leadership will propose a work plan to implement them. This can be known as an EHR Digital Agenda— a strategic plan for EHR at the national level. It must be agreed and planned in conjunction with other stakeholders and the steering committee (as established in the coordinating team section).

Monitoring and evaluation are vital in order to measure effectiveness, usefulness and level of acceptance (and any other measures proposed by the leading team) of an EHR implementation. It is important to consider monitoring and evaluation at the beginning of the planning process, and assign appropriate responsibility and funding. This process should take place at regular intervals and make use of the correct indicators.

Communicate and disseminate

This area will be addressed in depth in the fifth part of this document (change management and behavioral issues). Wide dissemination of information about the nationwide EHR project is necessary in order for it to reach its target audience and to promote adoption. Dissemination of the policy document to all relevant

stakeholders can be done through formal and informal channels. Key messages from the policy can also be disseminated through various channels.

Infrastructure

Box 5: National eHealth architecture & framework components

The eHealth Governance Body should mandate the adoption of national eHealth architecture. This is an essential requirement that provides a roadmap with all components for the development, implementation and maintenance of the national EHR. A long-term project requiring strong methods and best practices to guarantee its scalability and robustness, this architecture must perform a number of functions. These include: ensuring health information is consistent, accessible and used cost-effectively for improvement of health services; supporting patients, health professionals and managers with the adequate data for decision making; supporting evidence-based practice and health services planning, quality and safety; and providing an organised approach to ensuring that investments in EHR systems are aligned with the national healthcare priorities. This architecture requires skilled human resources, health informatics standards and interoperability and continuous and sustainable funding, backed by cooperation of all stakeholders including government, private organizations, vendors, health professionals, and patients.

Framework components

The national eHealth Architecture should include a framework with the following components: national registries (e.g. civil registration); clinical terminologies and classifications; interoperability; privacy, security and safety regime; EHR repositories; and census data. These will help provide a systematic approach to developing EHR. For example, registries assure universality by including all citizens; people will be more willing to share their data (and providers will be more willing to adopt EHRs) if there are clear privacy and security policies; data warehouse/EHR repository can provide a larger perspective for health policy making; and clinical terminology and classification can assure semantic and syntactic interoperability. The investments must be in packages following a proper sequence. Firstly, civil registration (including location) system and infrastructure, followed by operational cost of registering all citizens; secondly, facility registration including service capacity; and thirdly, an analysis of disparities in access to services according to location.

There are several challenges to creating a national infrastructure through which healthcare networks can connect effectively to one another and provide the benefits of health information technology. These include, but are not limited to, the development of physical components (hardware); the links between these components (networks); and the form in which they are used, as determined by software customization and its usability throughout the implementation and optimization

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process.

Decision makers will need to invest in national infrastructure with strong security protocols in order to promote trust and ensure that the network will handle information appropriately. They must address concerns of service availability and disaster recovery that might otherwise jeopardize the sustainability of an implementation project.

This does not necessarily mean having to construct a significant new national infrastructure from scratch. Rather governments, in close collaboration with stakeholders, must identify current infrastructure availability, determine existing gaps, and develop plans to address them.

Figure 8 – Challenges described in infrastructure component

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Figure 9 – Recommendations for infrastructure
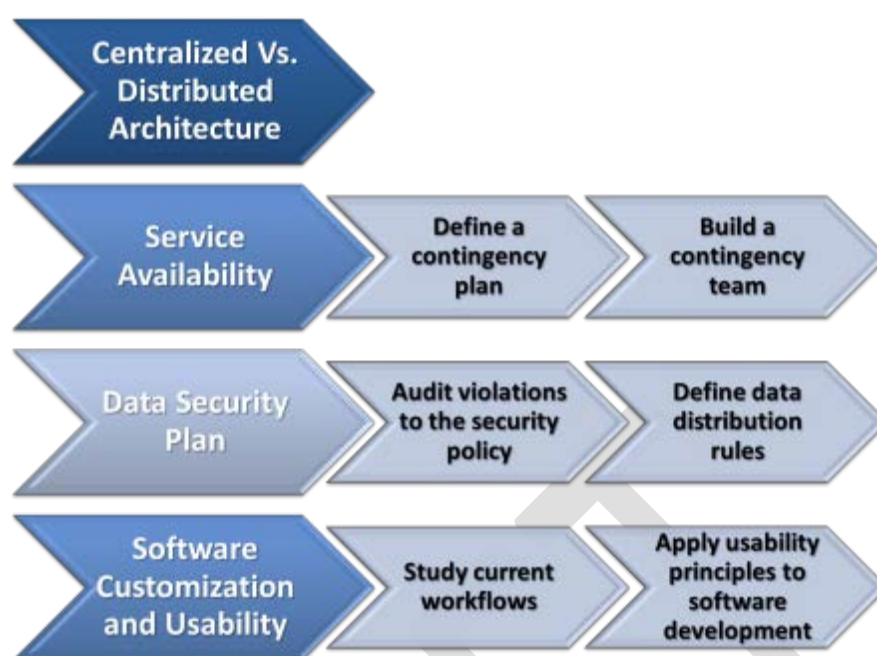
Centralized vs. distributed architecture

One of the key decisions when managing multiple remote sites is whether to centralize all resources or manage the infrastructure in a distributed fashion. Two methods might be utilized to facilitate the electronic transfer of information throughout a health information network. Each has intrinsic advantages and limitations:

➢ **The first method (M1) is based on centralized data storage**. In this model, health-related data is collected from local sources, but stored in **a central repository**. If an entity requests data, the transaction is routed through the central repository. Such architecture permits local entities to maintain autonomy while cooperating to provide data at national or regional level.

➢ **Method two (M2) is known as a 'federated' or 'distributed' model.** Each participating entity maintains separate control of the data it gathers, typically in special 'edge servers' at its own location, and shares patient-specific data on request from other entities.

Security risks are a major concern for M1, because all health related information is stored centrally. A single breach or 'hacking' incident on the central data repository could therefore potentially expose all records in the system. The risk inherent in the M2 approach is lower because information (other than patient identifiers) is not stored centrally; however, in this model the main sources of risk are variable because security depends on the privacy and security measures of each independent data source. The security policy should follow local privacy and security rules.

A fundamental challenge of all models is data matching. Network requirements in terms of data representation are extensive with M1; for M2, accurate matching of patient data is needed between the local system and the central repository or other systems. The absence of government-issued shared identifiers would be extremely hazardous; however other strategies or matching algorithms could be utilized. Data collection standards and messaging formats must be consistent, and this requires well-defined standards (see the 'standards for interoperability' section of this handbook).

Although we describe two very distinct models, it is worth noting that several hybrid models can exist, as variables in their implementations change.

Service availability

In the clinical arena, the availability of services provided by an EHR is a critical factor to consider when ensuring the continuum of care. Despite advances in robustness of infrastructure, which may include the duplication of critical components or functions of a system with the intention of increasing its reliability, it is necessary to establish a clear contingency plan in case of emergency, with support from all stakeholders.

A contingency plan must include management policies and procedures designed to maintain or restore business operations, including computer operations, possibly at an alternate location, in the event of emergency, system failure, or disaster.

Decision makers and project leaders should take every precaution to prevent and minimize the impact of a system failure. Whatever the cause might be, a single point of failure greatly increases risks for the availability and integrity of data, compromising quality of care, patient safety and information security.

A contingency plan must be defined that can be activated when all instances of 'redundancy' are exhausted.

➢ **First step, build a team**. Assembling a local contingency planning team is a vital first step. This team should include not only technicians and policy makers but also practicing clinicians, to ensure that the technical components align with and support the clinical processes and workflows impacted by their decisions.

➢ **Plan ahead and plan in detail**. However unlikely, every possibility must be accounted for when defining a contingency plan. Overlooking possible scenarios could make a health system vulnerable when crisis happens. Instances as extreme as natural catastrophes (floods, tornadoes, earthquakes) or man-made threats (accidental or intentional) must be considered thoroughly, as must such mundane concerns as simple scheduled hardware or software updates.

- ➢ **Communicate and educate.** Contingency plans are only valuable when users are knowledgeable of their existence and their content. Users must be well aware of the detailed guidelines and procedures set in place for a contingency.

- ➢ **Update your plans and learn from every episode**. Maintain contingency plans as living documents. Update them regularly to reflect changes in any influencing factors. Review previous incidents with key personnel involved, to identify lessons.

Figure 10 – Contingency plan main steps

Data security plan

Define a clear and sustainable security plan. All the safeguards (administrative, physical and technical) must be consigned in the organization's **security policy**. There is no 'one size fits all' solution available when defining a security policy for a system or organization, but as a standard it should contain the following statements**:**

- ➢ The **expectations** for safety and confidentiality. The security policy must define standards and guidelines on how many and what kind of security measures will be implemented.

- ➢ **Procedures** for the implementation and enforcement of guidelines. Establish the rules that govern the system and state clearly how they will be applied.

- ➢ The **audits** required to detect and record violations of these rules.

Security modelling and data distribution rules

As described in other segments of this document, each component of a clinical information system can be described in terms of the set of functions it possesses. These components can be manipulated by different actors with specific profiles according to their role and a set of rules that derive from that role. These **profiles must be defined** and described as data distribution rules. Each agent of the information system, whatever role it plays, must be characterized by a name, a unique identifier and some mechanism to ensure correct identification (password, biometrics, etc). To access each component must be a member of

the authorization profile of the component. This clearance is given by a security administrator and is valid for an established period of time.

Software customization and usability
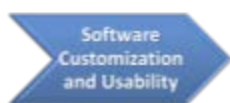
A major consensus in the literature is that general EHR designs are often poorly developed for clinical purposes, and that they need to be continuously customized to meet the needs of any given organization. It would be safe to say that lack of vision regarding the importance of usability—as it applies to human-computer interaction—could be responsible for the failure of any implementation in the field of healthcare informatics.

Regardless of whether the intention is to develop an application or acquire one, decision makers should consider the following concepts:

➢ Determine and apply a **level of customization**. There is no one-size-fits-all solution: consider the peculiarities of your own setting to avoid unintended consequences.

➢ **Consider user needs** as early as possible. Engage users in the design and implementation process. What you define early will save you time and resources.

➢ **Study current workflows**. Failure to understand user processes can lead to workarounds, user resistance and loss of efficiency.

➢ Capture **user feedback** at every stage of the implementation. Usable designs are only accomplished with constant feedback from users.

➢ **Monitor** post-deployment. Establish a monitoring process whereby users can report the results of their interactions with the system and suggest changes in a fluid way.

➢ Be knowledgeable and **apply usability principles**. The sustainability of a health IT intervention largely depends on designing usable clinical information systems. Usability principles include: simplicity, naturalness, preservation of context, consistency, minimizing cognitive load, efficient interactions, forgiveness and feedback, effective use of language and effective information presentation.

Figure 11 – User-centred design concepts to consider

Decision makers must educate themselves to understand the significance of these concepts and how to apply them, as they will shape the future of their project.

Financing

A sound financial plan is essential to ensure continuity and the fulfillment of any eHealth project's objectives. In this chapter, the most important financing concepts will be reviewed, with examples of regional or national experiences where applicable, ending with a series of strategic recommendations for a strong financial strategy.

Figure 12 – Recommendations for financing
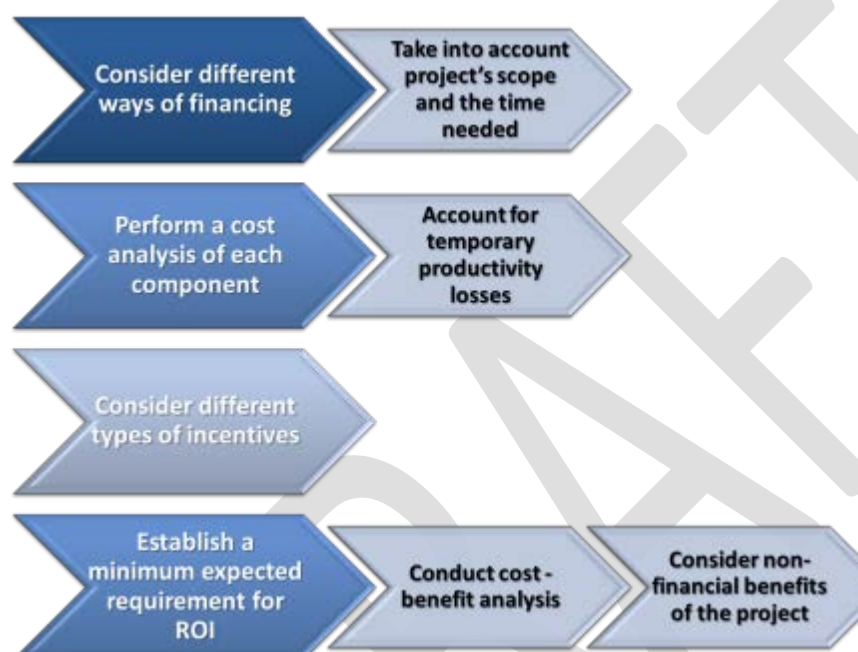
Means of financing
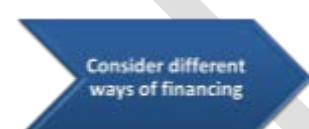
Depending on the local context and the strategic plan for eHealth, projects can be financed fully with public funds or in a mixed way, directly or indirectly:

➢ Public funds can stem from taxes designed specifically for that purpose, or from loans, usually granted by international organizations.

➢ In the case of mixed financing, the role of public institutions is to set a regulatory framework and to monitor its fulfilment; the role of private parties is to make the necessary investments, following market rules and legal requirements.

➢ Whether it is better to use direct or indirect funding depends on the primary target; eHealth may be developed and funded directly, or through another health-related project which encompasses eHealth initiatives (indirect).

The costs of IT projects

Perform a cost analysis of each component

A detailed cost analysis is important to ensure a project's medium- and long-term viability. Capital and operating/maintenance costs must be considered. The most important categories that must be taken into account are listed below, and laid out in Table 5:

➢ Costs related to the project team and **human resources**. These include salaries and benefits, and other expenses such as travel, food, and necessary materials.

➢ **Infrastructure** costs, including the acquisition of hardware and networking equipment, software development or acquisition, and web hosting expenses.

➢ **Maintenance** costs. These deserve a separate chapter: they are frequently higher than acquisition costs. The costs of software maintenance, equipment replacements or enhancements, and hardware maintenance must all be taken into account.

➢ **Training** costs and user support costs. These activities are essential for minimizing drops in productivity after workflow changes, and to minimize resistance to change, which can compromise the success of an implementation.

➢ Costs related to **productivity loss**. The literature describes a period after the implementation of an EHR when users experience a temporary drop in productivity, until they adapt to the new system and to changes in their workflow. These costs decrease gradually until productivity returns to baseline levels.

Table 5: Major EHR implementation cost categories

Hardware	Computer terminals, servers, network hardware, printers, scanners, and other related hardware.
Software	Designing and developing the EHR software and tailoring it to an organization.
Implementation	Workflow process redesign, initial training of IT personnel, and conversion of historical paper chart information into electronic data usable by the EHR.
Training	Staff support needed to train users on the new software system at the time following installation, and also during an intensive learning period that follows.
Support	Maintenance costs of hardware, updates to software, and ongoing long-term technical support for users.
Temporary reduction in staff productivity	One estimate of the expected productivity loss during an EHT implementation is 20% in the first month, 10% in the second month, and 5% in the third month, with productivity returning to baseline levels subsequently.

Incentive models

Health systems are complex adaptive systems integrated by multiple independent actors looking for their own benefit. The alignment of incentives of all interested parties is a critical requirement for the regional or national adoption of EHR. EHR implementations have high upfront and maintenance costs, which constitute an important barrier for their adoption, especially for physicians working in small or individual practices. Benefits obtained from the utilization of technology, such as fewer hospitalizations or better overall use of resources, are perceived by the employer that insures their own health benefit, by insurance companies, or by governments, but not by the physicians or practices that have to bear the costs. In the latter cases, incentive models have been shown to change adoption rates radically.

One example of realignment of incentives is the passage from a fee-for-service model to a capitated model whereby providers receive a per-patient per-month payment, and payment rates are tied to expected usage regardless of whether the patient visits more or less. In this model, physicians have an incentive to help patients avoid high-cost procedures and tests, in order to maximize their compensation.

Another model that attempts to realign incentives is the pay-for-performance model. This payment model rewards healthcare providers for meeting certain performance measures for quality and efficiency. It penalizes caregivers for poor outcomes, medical errors, or increased costs.

Return on investment

Comparing costs to benefits in healthcare IT projects can be disappointing, because costs are more evident, and benefits are more intangible.

Although there are no generally accepted standards, four strategies have been used to establish a minimum expected requirement for return on investment (ROI) on an IT project:

1. Set the ROI using the same values as when investing in capital expenditure
2. Use an ROI minimum that represents a higher standard than the value required for other investments
3. Set the ROI value at a break-even point. This is equivalent to a 0 percent ROI, and to a costs/benefits ratio of 1. This is the ROI objective for many public sector organizations. If the funds expended for projects can be captured, there is still value and benefit from the project through the intangible measures, which are not converted to monetary values
4. Let the client or project sponsor set the minimum acceptable ROI.

Another useful metric for evaluating EHR implementations is the break-even point. This is the time, usually measured in months, that it takes to recover expenses and start perceiving profits (usually about 12 months).

In low-income settings, the costs and benefits of implementing EHR are different than in high or medium-income countries or regions. Because the costs of capital and discount rates that low-income countries must endure are higher, positive ROI may be unattainable; however, financial benefits may outweigh costs even in low-income settings.

It must be noted that a cost-benefit analysis is only one part of a complete analysis of the effects of implementing an EHR. Not all benefits are measurable in financial terms, and EHR are a component of the strategic plan of an organization. As such, costs and benefits should be analyzed taking the whole picture into consideration.

Table 6: Costs and benefits of EHR implementation

	Apparent	**Hidden**	**Intangibles**
Costs	• Software: initial and maintenance • Hardware and network: initial and maintenance • Training of human resources • Vocabularies and terminology management • Implementation and training • Opportunity cost	• Users in training (productivity decrease) • Changes in medical-administrative processes • Institutional registration • Implementation of standards • 24 hour help desk • Operating costs of supplies (paper, toner). • Increased data capture human resources • Knowledge databases licensing	• Misconduct towards change • Political and economic concessions in implementations • Contingency costs
Benefits	• Computerized Physician Order Entry (CPOE) • Less misuse of resources (e.g. antibiotics) • Decrease in medical errors	• Increased efficiency of control and billing • Fewer human resources required for back-office and filing • Improvement and integration of redundant processes • Prevention of insurance system misuse • Possibility of 'disease management'	• Permanent access to EHR • Improved quality of care • Cost-analysis with case-mix adjusted by product • Governance over medical processes • Improved healthcare processes • Ability to monitor the implementation of preventive practices and disease management • Possibility of carrying out

			'mega-trials'.
			39

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Workforce training and capacity building

Box 6: Capacity building for EHR implementation & training

Capacity building is a key activity for EHR implementation, and is likely to be necessary in most before establishing a new system. Countries should therefore organize a national program on capacity building on health informatics standards and interoperability.

Training

An EHR system should not be deployed without a comprehensive training plan for medical personnel using the system; without a cadre of trained individuals, it is unlikely the benefits of EHRs can be fully realized. Countries should develop and train their health workforce to implement and operate EHRs in a safe, effective manner, to realize the full benefits of HER. Training must include the protection of patients' privacy, security and confidentiality. Properly executed training should result in fewer errors, better documentation, greater provider satisfaction with use, better communication when using EHRs, and the development of a workforce capable of extending, adapting and tailoring the EHR system as necessary.

Knowledge and skills in eHealth are widely acknowledged as crucial to the future of patient care, research in biomedicine, public health, and health policy design.

One key challenge to health IT implementation is the need for a skilled workforce that understands healthcare, information and communication technologies, and the human and organizational challenges involved.

Decision makers must therefore consider:

➢ It is important to identify and develop the skills, training, and competencies—consistent with local cultures, languages, and health systems—that will be needed to realize the full benefits of these technologies.

➢ The maturity of the domain and the demand on expertise require standardized training and certification of professionals.

Figure 13 – Recommendations for workforce training and capacity building
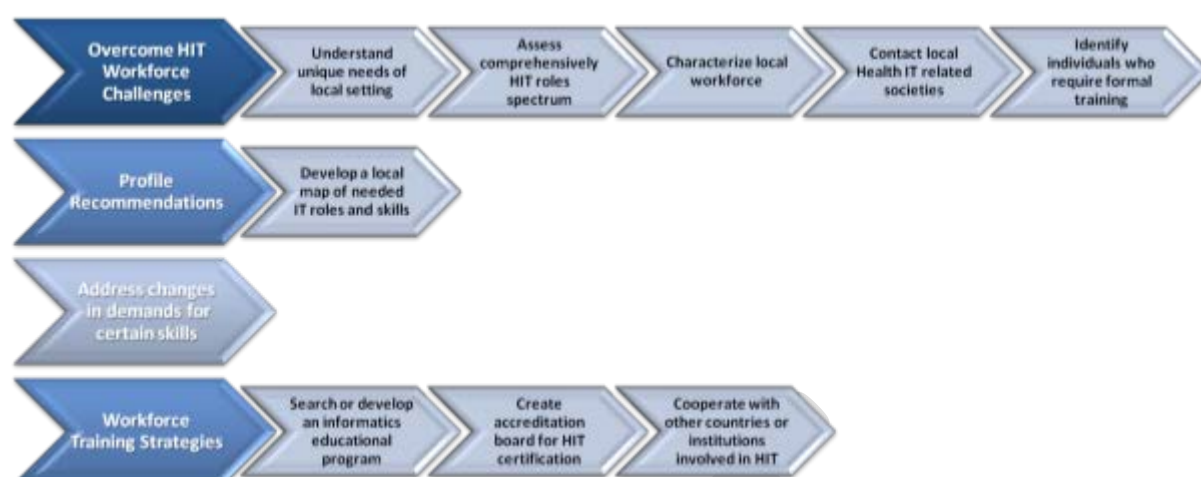
The development of health informatics as a formal and recognized profession would go a considerable way towards addressing the perceived lack of status of the profession, and might lead to improved working conditions and improvements in the culture. In addition, for public and private sector health informatics (HI) workforce provision, the assurance of individuals and of informatics services would improve informatics service delivery and patient safety, as well as the career prospects and morale of informatics staff.

Workforce research must go beyond a narrow focus on single groups (e.g. IT staff, HIS professionals, or clinicians) or applications (e.g. EHR or health information exchanges). Instead, it must focus on the larger picture of all involved in supporting the use of information to improve human health. Needs are likely to differ between countries, cultures, and political and economic factors, and so will solutions. Planning must include local stakeholders.

Challenges
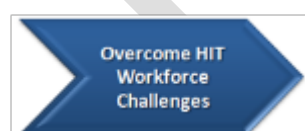
There is little data to characterize the Health IT workforce and, in particular, how it is best trained and deployed for optimal use of technology. Despite the acknowledged importance of a well-trained workforce there is a paucity of actual research to guide its development. Another problem is that in most hospitals and other healthcare settings, people think separately about IT professionals and clinicians, and do not know where pure IT ends and informatics begins.

To overcome these challenges is necessary to:

➢ **Understand the unique needs of local settings**, visiting representative locations where the applications or HIS are or will be in use

➢ **Make a comprehensive assessment** of the entire spectrum of those who develop, implement, evaluate, and play other roles in supporting the use of health IT.

➢ Perform a good **characterization of the local workforce**

➢ **Identify all the individuals** who need formal training in informatics (from vendors to Chief Information Officer/CIO and project leaders)

➢ **Search for an informatics educational programme**; the use of distance learning courses is growing

➢ **Contact local societies or anyone that can represent the country in question**. Many national medical informatics societies address educational issues for their members and students

➢ **Anticipate future needs** for information technology applications, the types of workers needed, and their desired qualifications.

Profiles

Recommendations for profiles—that is, the job roles and competencies for the workforce needed to lead Health IT projects—are as follows:

➢ There should be an average of 68 hospital staff per single IT staff member in health care organizations

➢ At least one physician and one nurse should be trained in medical informatics in each hospital

➢ Important skills desired go beyond technology and include: knowledge of clinical information, interpersonal skills, change management, relational databases, and project management.

➢ Public health informaticians should be trained to work on federal, state, and local public health organizations.

Figure 14 – Health IT workforce desired skills

Even if it is not possible to have a quantitative understanding of the medical informatics workforce, it is possible to define a framework of informatics practice and some desired skills (Table 7).

Table 7: Categories of informatics practices and desired skills.

Level of practice	Type of work	Example job title	Skills desired
Academic	Research or teach in an academic centre	Scientist or Professor	Research methodology, Educational competencies, clinical information knowledge
Applied	Work mostly in an operational informatics setting	CIO or CMIO Project Manager Trainer and Support Developer	Clinical information knowledge, interpersonal and communication skills, change and project management, understanding of healthcare environment relational databases and data processing and analysis
Liaison	Spends part of working time as local expert and interfaces with IT professionals	Clinical IT Liaison	Clinical information knowledge, assessing training needs, interpersonal skills and change management

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Skills shortage

Implementation of EHR will cause changes in demand for certain skill sets. Effective workforce planning and efficient action are required to address this. Shortcomings can be expected in system and business analysis, project and programme management, clinical coding and information analysis. Workforce planning should include:

➢ Understanding individual job responsibilities, levels of education, and perceived shortcomings of current education practices

➢ Standardizing learning objectives and competencies, curricula, and job roles across regions

➢ Developing a map of IT roles, skills needed and learning activities

➢ Improving education for workers and building workforce capacity.

Strategies

The strategies for developing a national or regional workforce involve:

➢ Improving the level of informatics knowledge, skills, and attitudes in both formal and informal training for healthcare workers

➢ Developing an educational and training programme for clinical informaticians

➢ Partnering with local universities and other institutions for emerging educational programmes to implement systems in a fashion compatible with local customs, culture, and health care needs

➢ Create a national or regional educational programmes accreditation body for professional HIT certification

➢ Share resources and expertise with other countries. Cooperative exchanges should be sought only between developed and developing economies, but also between developing countries.

Figure 15 – Strategies for workforce developing

Change management

Software projects have challenging factors. EHR inherit software issues, and implementation at national level or in large organizations brings new issues. Most of these factors are related to human aspects rather than technology. Change management is the process designed to deal with these human aspects.

A three-phased approach for managing change includes the following steps:

1. Creating a climate for change
2. Engaging and enabling the organization
3. Implementing and sustaining the changes.

Stakeholder engagement is another crucial issue, and involves working with individuals or groups of people with an interest or concern in the implementation of the EHR. Finally, strategic communications will help governments and decision makers to manage and respond to the challenges of the transition from current to future states.

Figure 16 – Recommendations for organizational and behavioural issues
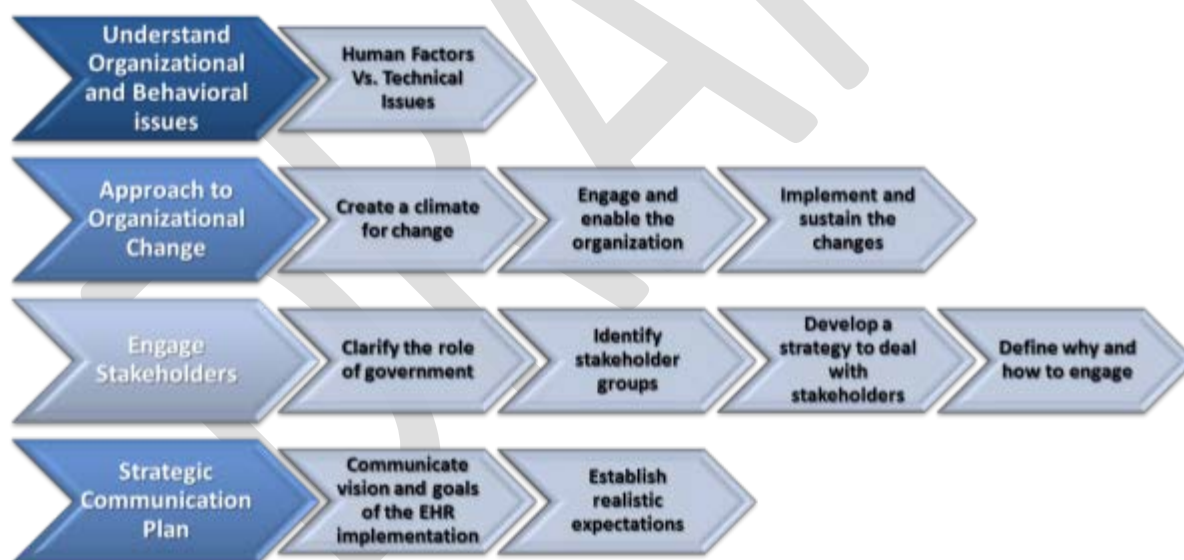
Organizational and behavioural issues

Less than 20% of software projects are completed on time and on budget. Challenging factors to overcome include, but are not limited to:

➢ Lack of user involvement
➢ Incomplete or changing requirements and specifications
➢ Unrealistic expectations

- ➢ Unclear objectives
- ➢ Unrealistic time frames.

EHR can have the same problems at the time of implementation, which can be a challenging and complex process. Factors affecting EHR implementations at large organizations include:

- ➢ Ineffective communication and training
- ➢ Culture and organizational issues
- ➢ Leadership issues
- ➢ Uncontrolled changes in project scope (scope creep)
- ➢ Underestimation of the complexity of the project
- ➢ Technology issues.

Correspondingly, at a national level there are similar elements. Assessment of long running national EHR programmes can determine important problems, including:

- ➢ Underestimation of complexity
- ➢ Deadlines and cost overruns
- ➢ Loss of credibility
- ➢ Non-adherence to project schedules and plans
- ➢ Scepticism about data protection and confidentiality
- ➢ Lack of data protection regulations at the time of assignment.

From the beginning of the project of implementing EHR systems, technical problems and standards tend to receive more attention. These are not, however, a critical factor, because ultimately the use of an EHR system is determined by human factors such as backgrounds, experiences with technology, fear, level of resistance, and degree of alignment of various stakeholder groups.

Change is not doing old things in a new way; it is the transition from the old way of doing things to a new way. The change process is described as an act of moving from one situation to another, ensuring that the people involved know why to leave the current position or state, why to move to the future state, the changes necessary to effect the move, the technologies and new skills required, and how to implement them. Change management is a process designed to deal with the human factors involved in such a project.

Approaches to organizational change

Leaders must ***create a climate for change,*** building the context and the vision for the future state, creating the necessity for change, and assembling and connecting the team needed to drive the transformation.

Leaders and involved people must ***engage and enable the organization,*** designing implementation strategies that will engage all levels of the organization in the change

process. In this phase, the team guides the transformation, creating a ripple effect and encouraging others to move forward. Communicating the future state, empowering more people, and planning for and creating short-term wins are crucial actions.

Finally, the guiding team **must implement and sustain the changes,** solving problems, promoting solutions, helping change individual behaviour to achieve organizational goals, training and retraining, and providing technical support. The objective is to support the transition in individual behavioural changes to align with the future state, rewarding and celebrating successes as often as possible.

Figure 17 – Proposed steps for change management

A number of factors must be taken into account when implementing change in large-scale national EHR programmes (see table 8).

Table 8: Specific actions plans needed to effect change management in EHR implementations at national level

Kotter's eight-step plan		Actions needed
Creating a climate for change **(led by leaders)**	Create a vision of a future state	Communicate the future state, priorities, and goals of the EHR implementation
	Establish the necessity of change from the current state	Translate current needs into a project plan
	Build a guiding team	Identify champions, and select staff supportive of the change who can keep the implementation process moving forward
Engaging and enabling the organization **(led by leaders and the guiding team)**	Engage stakeholders	Ensure staff have ownership of the process. Engage practice staff in all aspects of the process, including the evaluation of usability, system selection and the implementation process

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	Communicate the future state	Conduct demonstrations, videos, role-playing, simulated question / answer (Q/A) communication, and staff visits to practices that have had successful implementations. Conduct training; include ample time for training and implementation with staff
	Plan for and create short-term wins	Establish realistic expectations, developing a realistic time-line
Implementing and sustaining the changes (Led by the guiding team)	Solve problems	Update system based on feedback
	Train and retrain, provide technical support	Provide ongoing training and support for staff on updates and workflow efficiency
	Celebrate the successes	Reward staff

Stakeholder engagement

> ## Box 7: Stakeholder engagement
>
> To promote trust in EHRs, countries should engage all stakeholders throughout the process of designing, developing and operating the system. This will encourage buy-in, participation and ultimately success of EHR initiatives and build trust and credibility. It can also help to capture EHR requirements more fully and encourage compliance with privacy and security policies. Stakeholder engagement and promotion of trust are key in ensuring successful change management for design, development and operation of EHR's; stakeholder values and preferences cannot be anticipated by design and development teams and if they are not determined through stakeholder engagement, they may cause the EHR project to fail.

Engage Stakeholders

Stakeholder engagement describes the level of commitment that stakeholders have to the project and its goals. Implementing a national EHR involves working with and engaging a variety of stakeholders.

In order to develop and implement a national EHR system, it is important (see Table 9) to:

➢ Clarify the role of government
➢ Identify the stakeholder groups that need to be engaged
➢ Develop a strategy to deal with them
➢ Define why and how to engage those stakeholders.

The objective of engagement is to construct a network among the stakeholders, and to train and educate them for the future state, all the way through the process of vision development and the construction of the guiding team. Governments are responsible, directly or indirectly, for the development of the vision and for stakeholder engagement.

Table 9: Implications for the strategy and planning of the EHR development and implementation

Type of market	Government role	Stakeholder role	Content of the planning
Fully regulated market	Central authority or governance over the development of the national plan	There is limited consultation	Driven by the government
Guided market	Central coordination Responsible for leading and managing the development	Stakeholders work with government to develop the strategic context, vision and supporting recommendations	Driven by both the government and important multi-sector stakeholders
Free market	Responsible for facilitating the process with an advisory role	Stakeholders develop the national vision	Driven by stakeholders

The guiding team acts as a pivot between leaders and other stakeholders. The guiding team should develop the stakeholder consultation plan, describing how stakeholders will be engaged, taking into account the impact of the future new state.

Stakeholders can be defined as the individuals or groups of people with an interest or concern in the implementation of the EHR. In a national EHR development and implementation there are health and non-health stakeholders. These can be categorized, depending on their role on the project (Figure 18), as broader stakeholders and the general public; engaged stakeholders; decision makers; and key influencers.

➢ Government committees are part of the decision-makers group, responsible for vision and strategic direction

➢ Academics and senior executives in health, funding and investment organizations are part of the group of key influencers, advising key decision-makers

➢ Healthcare executives (private, public, vendors, industry), health practitioners and professionals, allied health professions, managers and administrators, attorneys, IT and administration staff, insurers, and patients' associations are engaged stakeholders, because they will be impacted directly by the implementation

➢ Individuals, caregivers, families, and community groups make up the broader stakeholders and general public group, interested in the potential impacts that EHR might have on them.

The different interests, expectations, values, levels of influence, and potential contributions of each stakeholder group should be identified, with the intention of engaging, planning and delivering benefits for every group.

Figure 18 – Stakeholder groups

Communication and dissemination plan

There is a relationship between the national implementation of an EHR and strategic communications, which can be defined in context as communications supporting national objectives. Such communication involves a systematic series of sustained and coherent activities, conducted across strategic, operational and tactical levels, which enables understanding of target audiences and identifies effective conduits to promote and sustain particular types of behaviour.

Strategic communications help governments manage and respond to the challenges of the transitions from current to future states. The objective is to promote the necessary changes in the current state; strategic communication should help develop an oriented campaign based on knowledge of the audience and involving a two-way process that includes feedback from interested audiences (Table 10).

Table 10: Seven steps to create a strategic communication plan

Steps	Actions
Preparing to plan	• Set clear goals for the planning process • Determine roles and responsibilities • Form a communications action team to facilitate the

---

	planning process
Situation analysis	• Analyse internal and external factors affecting the organization/project
Target audiences	• Focus communication efforts and resources on engaged stakeholders, or those easily prepared to become involved
Communication objectives	• Define what is expected of each target audience
Message development	• Prepare mission-driven messages that are audience-focused and action oriented
Vehicles and dissemination strategies	• Coordinate dissemination strategies utilizing all five forms of communication: face-to-face, print, audio, video, and electronic communications
Measurement and evaluation	• Evaluate success measures for the communications plan.

Box 8: Patient access rights

Patients need to be motivated and engaged in their own health care as a foundation for good outcomes. Citizens should have the right to access their own health data—but all related policies must include procedures for the management of high-risk disclosures. That patients control their own health data is fundamental to patient autonomy; paternalism, however well intentioned, may have adverse consequences for both patient health and for healthcare practices. Disclosure practices need to be sensitive to the level of health literacy in a population and cultural variability and context, but in general, it may be better to err on the side of excess disclosure than to withhold important information from patients. Patient access can result in increased patient satisfaction and convenience, improved patient safety through correction of errors and clarification of misunderstandings, and increased patient engagement.

Standards for interoperability

## Box 9: Ownership—adopting health informatics standards

Countries should enable an inclusive, open and participatory process to adopt, adapt and/or localize international health informatics standards for the EHR implementation. Ownership is higher when stakeholders participate in the decision-making process: those subject to standards will more readily use them if they were part of the selection process as opposed

> to simply being told what standards they must use. With this in mind, the participatory rural approach (PRA) engages communities and helps them understand and contribute to the process; it is recommended that this be considered where applicable.

To achieve adequate continuity of patient care, a continuous flow of health information is required between systems, healthcare organizations, regions and even countries. In general, this information is highly fragmented and distributed across multiple sources which tend to act as silos, preventing timely and ubiquitous access to information to support the care process, clinical management, administrative processes and data aggregation. No country is immune to this reality, which affects both developed and developing countries. To achieve information exchange between silos, it is necessary to ensure the interoperability of information systems through the use of standards.

Figure 19 – Recommendations for standards
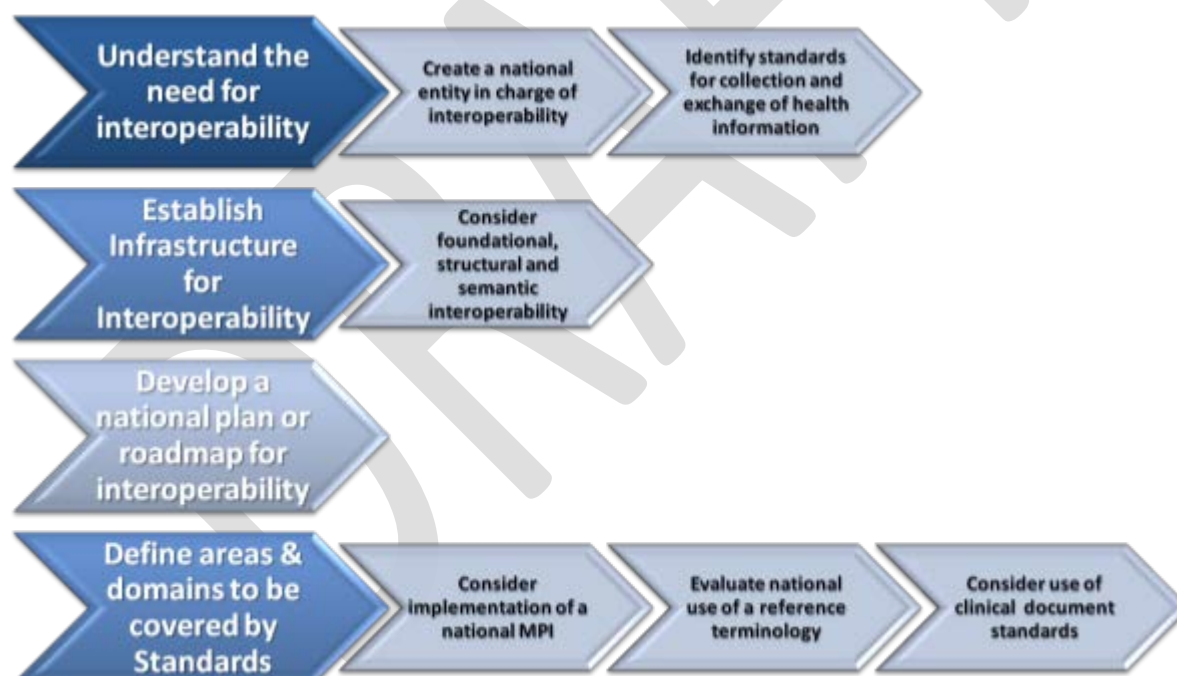
Healthcare records are increasingly digitized. Interoperability of EHR is crucial in order to allow information to be shared by and comprehensible to clinicians and healthcare organizations. As patients move around the healthcare ecosystem, their EHR must be available, discoverable, and understandable. Furthermore, to support automated clinical decision support and other machine-based processing, data must also be structured and standardized. Nations should have policies and regulations to facilitate these principles. Desirable objectives for eHealth standardization for data exchange and interoperability include (Figure 20):

➤ Development and implementation of national eHealth policies for standardization and interoperability; this should be a national effort and must include stakeholders

➤ Policies and standards that are patient-centered, emphasizing service quality, equity, patient outcomes, patient safety and population outcomes

➤ A participative approach to policy-making that encompasses public and private partnerships where necessary

➤ Health data and health IT standards set to ensure interoperability at data, device and system levels, in a framework containing a fixed core set of maintained standards allowing for a degree of innovation outside that core set

➤ Use of existing international standards where possible, and adaptation of specific standards to suit national contexts (taking necessary care to ensure interoperability and backward compatibility, as applicable)

➤ Provision of unique identifiers for patients, health care workers and health care facilities, with verification and authentication procedures.

Figure 20 – Desirable objectives for eHealth standardization for data exchange and interoperability

Development and implementation of national eHealth policies for standardization and interoperability should be a national effort and must include stakeholders.

Be patient-centered, emphasizing service quality, equity, patient outcomes, patient safety and population outcomes.

Start by a participative approach to policy-making, and encompassing public and private partnerships.

Set health data and health IT standards to ensure interoperability at data-, device and system-levels, in a framework containing a fixed core set of maintained standards allowing for a degree of innovation outside that core set.

Use existing international standards where possible and adapt specific standards to suit national contexts (taking necessary care to ensure interoperability and backward compatibility, as applicable).

Provide unique identifiers for patients, health care workers and health care facilities, with verification and authentication procedures.

Why interoperability is needed in health care

Understand the need for interoperability

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged; meaning that all individuals, their families and their health care providers should have appropriate access to electronic health information that facilitates informed decision-making, supports coordinated health management, allows individuals and caregivers to be active partners and participants in their health and care, and improves the overall health of the population.

At governance level it is important to create an entity or leadership group that works towards achieving interoperability. This group must identify the e-Health standards and interoperability components required to enable the consistent and accurate collection and exchange of health information across geographical and health sector boundaries.

Without interoperability, health information cannot be collected consistently, will be open to misinterpretation, and will be difficult or impossible to share due to incompatibilities in data structures and terminologies.

The importance of standards at a national level

Interoperability at national level should focus on the secure electronic exchange of health information. This goal is essential to enabling all individuals, their families, and their health care providers to have appropriate access to health information that facilitates informed decision-making, supports coordinated health management, allows patients to be active partners in their health and care, and improves the overall health of the population.

An infrastructure should be established to support the necessary exchanges of data among and between unrelated and independent parties. The general model for data interchange and healthcare interoperability is based on regional health data interchange areas, sometimes referred to as Regional Health Information Organizations (RHIOs), in which a person's data or pointers to that data are brought together and work as an individual's essential EHR.

As described in the infrastructure chapter, two models currently exist:

➢ The centralized model in which data is collected from the various sites of care and aggregated as the EHR

➢ A federated model in which data is retained at each site of care and is aggregated and exchanged as needed, but in which pointers to the different sites are kept in a central database.

There are three levels of health information technology interoperability: foundational, structural, and semantic (Table 11).

Table 11: Levels of interoperability

Foundational	Allows data exchange from one system to be received by another and does not require the receiving information technology system to be able to interpret the data.
Structural	An intermediate level that defines the structure or format of data exchange. Defines the syntax of data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.
Semantic	The highest level: the ability of two or more systems or elements to exchange information and to use the information that has been exchanged. Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data, including vocabulary, so that the receiving

> information technology systems can interpret the data.

Semantic interoperability starts with atomic data elements, which are the basic components fundamental to the expression of concepts to be documented and communicated as part of the healthcare and related processes. In present systems, data elements are poorly and ambiguously defined and vary in data type, name and other characteristics. Simple questions such as 'Have you smoked or do you smoke?' may be interpreted many ways; for example, what exactly constitutes 'unstable angina'? Yet clinical research and patient care are based on these ambiguities. The names of these data elements are the most confusing of all: there are over 200 identified 'controlled' terminologies in use, as well as many local and synonym variants.

National strategic plan for interoperability

It is important to develop a national strategic plan or roadmap that describes a set of overarching goals aligned with national health. In general this plan will aim to improve healthcare quality, lower healthcare costs and improve the health of the population.

An interoperable HIT ecosystem makes the right data available to the right people, at the right time, between disparate products and organizations in a way that can be relied upon, and meaningfully used, by recipients. And this should be the vision of a national strategic plan for health IT and interoperability. Individuals, care providers, communities and researchers should have an array of interoperable HIT products and services that support continuous learning and improved health.

Table 12: Recommended focus areas when developing a national strategic plan

Build upon the existing health IT infrastructure
One size does not fit all
Empower individuals
Leverage the market
Simplify
Maintain modularity
Consider the current environment and support multiple levels of advancement
Focus on value
Protect privacy and security in all aspects of interoperability

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> Scalability and universal access

Areas or domains to be covered by standards

Some of the important areas or domains on which standards should focus include patient identification, disease classifications and clinical terminologies, and standards for documents and Health Information Exchange (HIE).

Patient identification

Patient identification is a key issue in any EHR project; even at the organizational level it is very important to have the necessary processes established for correctly identification of the population under coverage. When patient identification is considered at a national level, this issue is even more important.

One strategy is the development of a Master Patient Index (MPI). The MPI is a database that maintains a unique index (or identifier) for every patient registered at a health care organization. The MPI is used by each registration application (or process) within a hospital to ensure a patient is logically represented only once, and with the same set of demographic/registration data in all systems at an organizational level. The MPI can be used as an enterprise tool to assure that vital clinical and demographic information can be cross-referenced between different facilities in a health care system. A MPI correlates and cross-references patient identifiers and performs a matching function with high accuracy in an unattended mode. A MPI is considered an important resource in a healthcare facility because it is the link that tracks patient, person, or member activity within an organization (or enterprise) and across patient care settings.

Disease classification and clinical terminologies

Clinical vocabularies, terminologies or coding systems are structured lists of terms that are designed together with their definitions to describe unambiguously the care and treatment of patients. Terms cover diseases, diagnoses, findings, operations, treatments, drugs, administrative items, etc., and can be used to support recording and reporting a patient's care with different levels of detail.

A classification system can be defined as a systematic arrangement into classes or groups based on perceived common characteristics; a means of giving order to a group of disconnected facts. Different groups or classes may have similar characteristics or may even be synonymous. Classifications capture snapshot views of population health using such parameters as death, disease, functioning, disability, health and health interventions, all of which inform management and decision-making processes in the healthcare system. Over time, they also provide insight on trends that informs the planning and decision-making processes undertaken by health authorities. The multiplicity of potential perspectives on health mandates a variety of classifications, and their necessary evolution poses challenges

for consistency. More recently, the increasing variety of different applications in health information systems and the general availability of different information and telecommunication technologies have highlighted the need for increased interoperability.

The baseline information that is aggregated for public health purposes is increasingly derived from health records that contain information related to patient care, as well as information crucial for management, health financing and general health system administration. Accuracy and consistency of health records is crucial in order to ensure quality of care and sound management of health systems resources. This calls for precise and consistent use of clinical terminologies and recognition of the importance of semantic interoperability.

Possible synergies between classifications and clinical terminologies have been identified as crucial for future work, particularly considering the growing automation of information processing.

Reference terminology

A reference terminology is an ontology of concepts and the relationships linking them. In this context 'ontology' refers to a collection of terms similar to a dictionary or glossary, organized by meaning rather than alphabetically. A reference terminology can allow the concepts it contains to be defined in a formal way that can be processed by computer systems. For example, hierarchical relationships can be defined using the 'is a' link to identify which concepts are included within broader concepts. Along with other relationships, a network of meaning is created that is useful for computer representation and processing, and which allows a computer to answer basic questions such as: 'Is angina pectoris a type of heart disease?'

By creating computable definitions, a reference terminology supports reproducible transmission of patient data between information systems. It supports consistent and understandable coding of clinical concepts, and so is a central feature for the function of computerized patient records.

Document standards

There are several available standards for document sharing. These can foster interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning, thereby enabling improvements in patient care.

Clinical data and public health informatics

The data-information-knowledge continuum that is stored in the HIS poses many challenges related to the data cycle, from capture to output and analysis and consequent decision-making. Issues related to clinical content, which must be addressed, include:

➤ Data formats (structured vs. free text)

➤ Information variability, including the form in which information is stored and the information source.

Primary data capture must be an objective, because it takes place with the source in front of the documenter. At this point, there are many models of documentation; these can be classified by use and function. As seen in other segments of this handbook, decision makers must also address issues of health information representation, with data stored at different levels of detail according to the intended use of that information.

This leads to a conclusion: information analysis is not a simple task. The next segment in this chapter refers to public health informatics (PHI). This is a discipline based on data analysis: the application of health informatics to populations.

Figure 21 – Recommendations for clinical data content and public health informatics
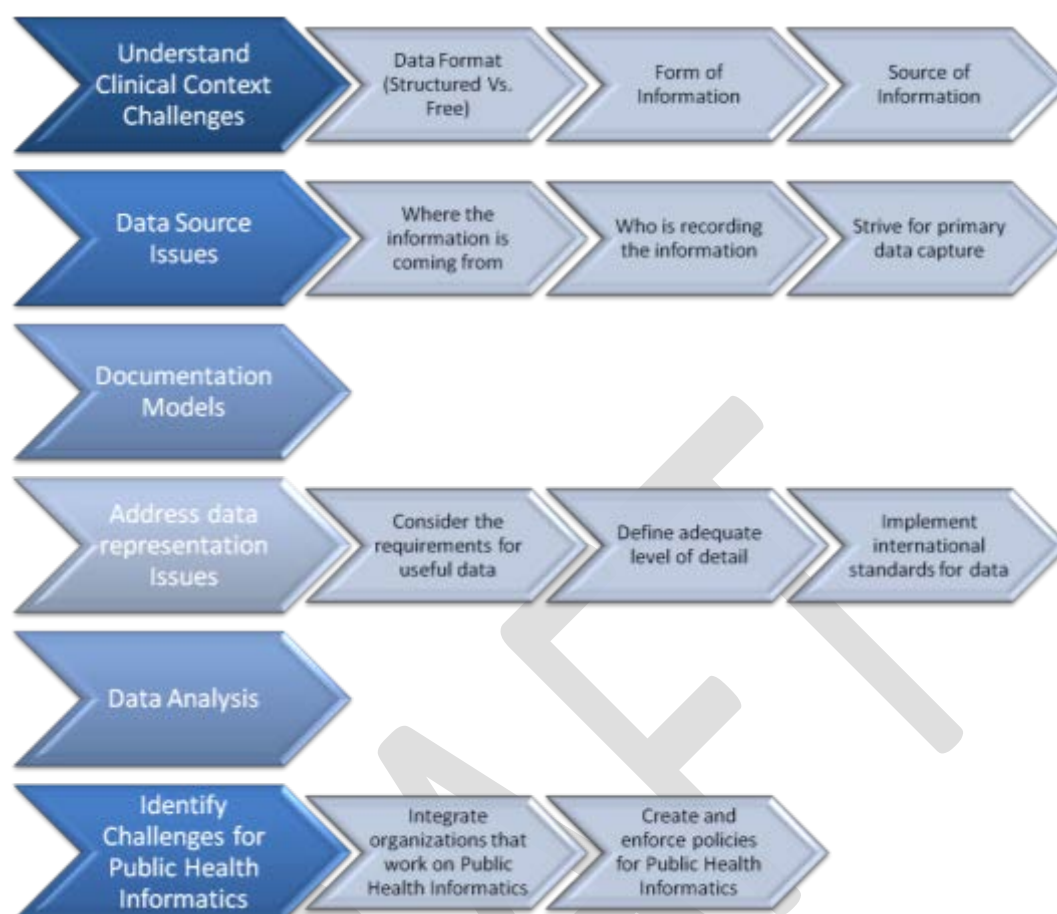
Clinical content

This dimension includes everything on the data-information-knowledge continuum that is stored in the system (i.e. structured and unstructured, types and sources). The first big challenge in reference to clinical content is to understand in which format data is stored, considering that health information can be recorded in different forms.

The first major division is between structured and unstructured data (free text). When it comes to the process of obtaining, recording and storing information, it is important to acknowledge the advantages and disadvantages of structured and unstructured information. Basically, structured data is easy to represent with a code and reusable by the system; and unstructured data is more easy to use.

Table 13: Structured vs. unstructured data: benefits and drawbacks

	Structured	Unstructured
Pros	Easy for IT solutions Easy to represent in international standards/easy to code	Easy for people Represents reality more accurately

Cons	Difficult to train people in its use	Difficult to process
	Reduced possibility of representing real data	Almost impossible to code

The next challenge is information variability. Here, there are two issues: the form in which information is stored (text, number, images); and the source(s) of that information (patient, provider, medical device). This means that even without reference to the source, healthcare information can be presented in many forms.

Table 14: Most common types of data

Type	Description
Text	The most common type of data in a health information system. Represents the basic source of data. Composes all narrative information. It is present in most clinical documents.
Numbers	Can be presented in integers or decimals. Lab results, vital signs and many other aspects of information about patients are expressed by numbers. This type of information must be often contextualized (units of measure).
Sound	Sounds may also be registered in healthcare information stored in the patient's EHR and accessed by physicians. Many patients' exams and clinicians' reports could be recorded as sound (auscultation, surgery reports, etc.).
Images	Images are also common sources of information. These may come from formal image systems as in a PACS, but may also be resources such pictures and drawings, which can be taken into account as healthcare image information.
Time stamp (date & hour)	The time stamp is an important source of data because it allows organization of information about a patient. Its format must be taken into account to avoid problems in data organization and retrieval.

Data source

Information contained in a health information system may arise from the scientific literature, and provides all the evidence according to which clinical practice is exercised. The other major source of information is the patient; in the case of the patient, information may come from clinical applications (studies, sensors, etc.) and may be generated by healthcare providers, or also—and increasingly—by the patients themselves.

At this point it is interesting to note the importance of the concept of 'primary data'. This refers to the data that is generated when a healthcare provider is in contact with the patient and the input of this data is made in real time by the same provider who is performing this task. 'Secondary data' is that which is recorded in the system by persons different from those who performed the activity that generated the information. Primary data allows the source (in this case the patient) to be in front of the documenter; and therefore primary data originates from a more accurate source of information. Collection of primary data also

allows the provider to interact with the system, which can offer CDSS and other resources to help both the documentation process and the healthcare tasks.

Patients also generate huge amounts of data from personal devices, and this trend must be taken in account. EHR must be prepared to support this kind of data, organize its storage, and provide an easy way to visualise and aggregate the data.

Administrative data is also an important category, and must be incorporated and integrated into the system.

Documentation models
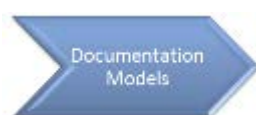
There are many models of documentation. These can be classified by their use and functions. Even though there are no standards or international classifications for documentation models, documentation reports are usually classified in three broad types (Table 15).

Table 15: Documentation models

Model	Description
Electronic health records (EHR)	EHR may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information. EHR also should offer support for search information and incorporate decision support systems.
Personal health records (PHR)	PHRs are health records in which health data and information maintenance is shared by patients and providers. The intention of a PHR is to provide a complete and accurate summary of an individual's medical history which is accessible online. The health data on a PHR might include patient-reported outcome data, lab results, data from devices such as wireless electronic weighing scales, and data that is collected passively from a smartphone. PHRs can exist integrated to an EHR or HIS, or can exist individually.
Disease registries	Disease registries focus on specific pathologies. Several developments follow this model, which used to be useful for research and follow up, but comprehensive EHR models now provide a more integrated vision of a patient's health.

Representation

Representing health information in HIS is not easy. Medical language is a difficult domain in this sense, because of the specification of terms, the dependence on context, the variability between regions (even with the same language), the large amount of synonyms, the lack of strong definitions, and the use of acronyms and abbreviations.

As stated in the previous chapter, terminology standards can represent a solution, but their implementation is hard, and not all terminologies or classifications can represent every

domain. Some terminologies can address this issue, but classifications may still be necessary because of regulatory issues. Interface terminologies are a plausible solution.

When the representation system is resolved, the other big issue is the level of detail at which data is stored. This depends on the use to be given to that information. If the goal is to implement a CDSS, the most granular detail possible must be incorporated; the same if the information is used for research. But if the project goal is only to use the information for governmental reports, less detail could be sufficient. Decision makers must know that the level of detail that is not preserved at the time the information is input into the system, is lost. This is known as granularity. Terminology services can help in this situation, because they provide the chance to capture data with a high level of detail and then recover it with the required level of granularity.

Analysis
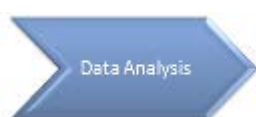
Information analysis is not a simple task. Data analysis for epidemiological purposes runs the risk of errors such as duplication of cases, gaps, sub-records and false positives; these must be taken into account. Terminology standards could help in this sense, but the quality of data input into the system must be controlled and supervised.

There are also new problems in the field. HIS must be prepared for the analysis of large amounts of information: acquisition, storage, processing, retrieval and display of large amounts of data are major issues to be resolved, and solutions are required in order to make all this data useful and available for physicians and for patients.

Public health informatics (PHI)

Public health informatics can be defined as the application of health informatics to populations. PHI has much in common with other informatics specialty areas, but it focuses on applications of IT that promote the health of populations, rather than of individuals; works mainly on disease prevention, epidemiology, and environmental health; and prioritizes the development of IT tools that allow the detection and follow up of outbreaks and special disease situations in populations.

The scope of PHI includes the evaluation and analysis of the 'life-cycle' of health information and requires the integration of several disciplines with relevance to public health, including, among others, epidemiology, microbiology and statistics.

Challenges and innovation, applied to healthcare informatics, also affect public health. A few recent examples of innovation include mobile technology, increasingly used by clinicians but also by patients, and with several purposes. Telehealth is also a big source of data and innovation. PHI must be prepared for personalized medicine, and ready to apply the benefits of the knowledge gained from specialized testing such as genetic screening. Personal health

records must also be part of the focus for PHI; data will come from these solutions in the near future, more so than from providers.

Data in PHI

PHI exists only if data exist. Not all data is created equal: quality can be poor and data can be inappropriately applied. Public health must increasingly discriminate between data that will and will not provide useful information. In this sense, data should fulfil some key requirements (Table 16).

Table 16: Requirements for useful data

Timeliness	Data must be updated frequently and accessed rapidly.
Accuracy	A key feature of high quality. Data definition, collection, management, and analysis must be under permanent audit.
Sufficiency	Data must be collected with sufficient granularity and provided in a useable format so that it can answer the health problem at hand and facilitate later merging with other data sources.
Relevance	A difficult point: data can be both abundant and lacking at the same time. Relevance must be defined in the context of needs and uses. Data should be evaluated based on applicability to the question.
Cost-effectiveness	How much data should be collected to be cost effective? This is also a difficult question, which could be answered in the same way as the question of relevance.

Sources of information for PHI

One of the big challenges of PHI has to do with data sources. PHI must obtain data from multiple disparate sources such as hospitals (public and private), social services, governmental agencies, police departments, surveys, etc. Its development in these different sources is also different, and standardization is not always possible. Data referring to particular individuals must be accurately combined from these various sources, aggregated, and made available (and understandable) for use.

The same data could also be presented in different formats, depending on the team that needs the information. Privacy and confidentiality of data must always be granted and preserved.

One issue that must be addressed is the use of international standards for representing information. The use of such standards can alleviate problems related to different sources of information.

Representation of data is not the only problem, however: other data must be taken into account in order to contextualize the information. Such data fields include time and date; number of cases; population group most affected (by age, sex, location); setting (school, workplace, restaurant, wedding, etc.); suspected or confirmed agent; most common clinical presentation; suspected or confirmed source and mode of spread; methods used to investigate agent; source and mode of spread; control measures recommended; control

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measures implemented; lessons learned for prevention of future outbreaks and improved investigation; and recommended response in future events. Systems must then be prepared to store, represent, analyse and visualize these kinds of data.

PHI must also incorporate information on toxicology and environmental public health, public health laboratories, vital sign statistics systems, and immunization information systems. In this regard geographic information systems play an important role, providing powerful tools that can enable public health practitioners to analyse and visualize data and make informed decisions in a timely and relevant manner.

Decision support and expert systems in PHI

Considering the exponential growth in the amount of available data, challenges related to different sources of data, and the complexity of analysing and visualizing big amounts of data, decision tools will be needed in this field. At the same time that benefits of HIS are proven, tools for supporting the discipline must be developed in order to optimize resources and improve the quality of public health information.

In the context of these challenges, governments must define an agenda for PHI that explores and organizes these challenges and needs in order to grow in the right direction, and optimize the use of resources. This agenda must contemplate:

- ➢ **Organizations (governmental and non-governmental)**: these must be integrated to create and enforce policies to protect, monitor, and improve population health
- ➢ **Information and communications technologies (ICT)**: hardware, software, and devices that capture, store, manage, exchange, and create data and information used by public health organizations and their workforces.
- ➢ **People**: patients, but also all the healthcare providers that must participate in the development of this agenda.

Privacy, security and confidentiality

Box 10: Privacy and security

Privacy is a human right. Citizens' control of their health data should be supported by national EHR privacy and security policy. This must include procedures for redress for those who may be harmed by breaches. This can provide protection from social or economic discrimination and build trust in the health care system. Care must be taken, however, to ensure that critical health data remains accessible at the point of care, and systems must be in place to manage privacy protection in the context of communicable diseases and/or environmental hazards. Patients' control of their own data requires appropriate software and auditing infrastructure to track who has viewed a record and to whom it has been transmitted to. Infrastructure for monitoring for privacy breaches often requires creation of dedicated teams.
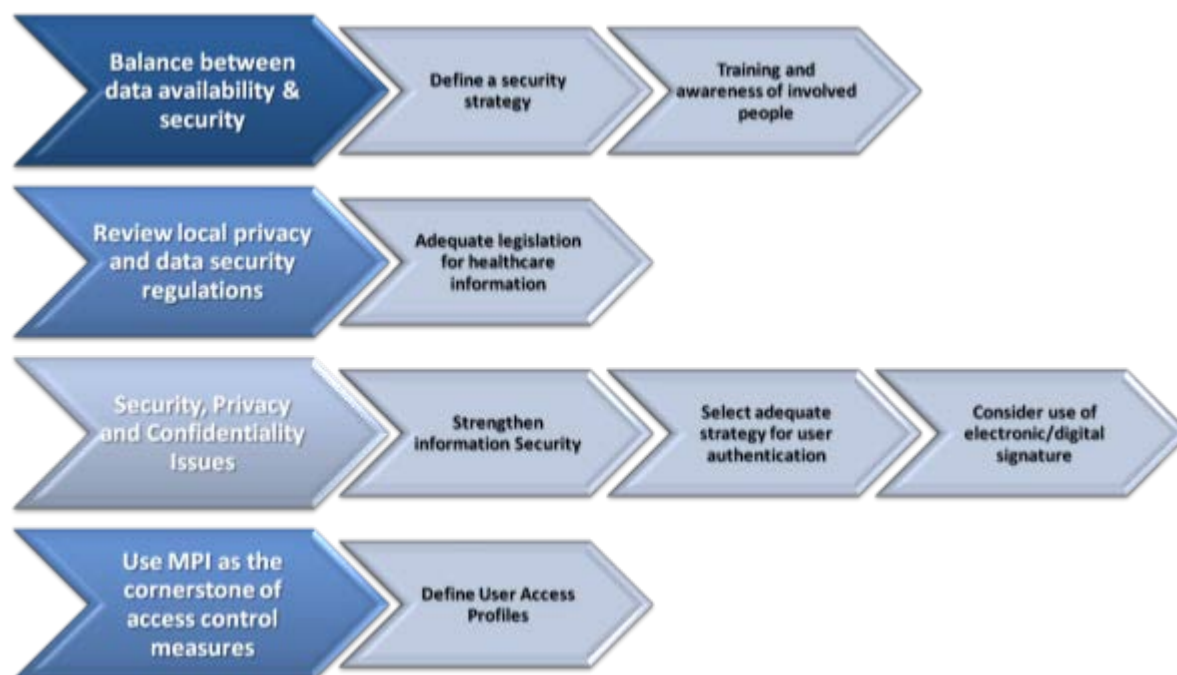

Despite their promise, the widespread adoption and use of EHR is threatened by many currently unanswered legal, ethical, and financial questions.

The development of regulatory frameworks in the field of information security and data protection has followed different courses in different countries, although most share some fundamental aspects:

➢ Establishment of the respect for privacy as an inalienable right of citizens

➢ Existence of specific regulations for the protection of personal data

➢ Classification of information of a personal nature in different levels according to the sensitivity of the data. Personal data relating to health aspects requires in all cases the highest levels of protection

➢ Designation of a supervisory authority which, in accordance with its domestic legal system, is responsible for overseeing compliance with the principles of data protection

➢ The duty of information to the citizen, who must consent to data capture, treatment and transmission, with prior knowledge of the purpose for which data is collected

➢ The principle of access, meaning that every citizen must know whether information concerning him is being processed, and be able to request corrections or cancellations.

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Figure 22 – Recommendations for privacy, security and confidentiality

Leadership must find a balance between the best security and privacy possible and the smooth functioning of organizations.

Box 11: Privacy policy framework

Countries should establish a comprehensive, countrywide privacy, security and confidentiality legal and policy framework for EHRs, explicitly incorporating the human right to privacy and confidentiality. The framework should include administrative and technical policies, procedures, guidelines and standards to ensure availability, integrity, confidentiality and physical security of health information, balancing the advantages of high availability for clinical care, public health planning and operations and research with protection of individual rights. Such a comprehensive framework should promote uniformity in EHR implementation and help to ensure consistency and completeness, thereby reducing the risk of unintended consequence. While all frameworks should be adapted to local needs, contexts, priorities and values, a clearly specified framework is strongly preferable to an implicit one. While generic frameworks may have advantages, it is important that each setting adopts a bespoke approach that addresses local contexts and issues.

Information security

There are working methods, good practice guides of a technical nature, and voluntary compliance principles that are reflected in international standards. On this basis, information security is often defined as the sum of three basic concepts, as described in Table 17.

Table 17: Basic concepts of information security

AVAILABILITY	INTEGRITY	CONFIDENTIALITY
Information must be available at any time and place, as necessary, regardless of the time and place in which it was generated.	Recorded information should be truthful and complete, and so it must be protected.	Access to information must be restricted depending on the person trying to access it and the relevance of such access.

Availability – confidentiality dilemma

There is no solution that satisfies both needs equally. Any measure to facilitate data availability penalizes its confidentiality, and vice versa. Therefore, a solution of information security should ensure a reasonable balance between the two extremes, as well as being flexible enough to adapt to the particular circumstances of each situation while maintaining that balance.

In the healthcare sector both requirements clearly converge, as the professionals who care for a patient need access to data recorded in the medical record to provide the best care possible. At the same time, this information is confidential and its consultation and modification requires the consent of the patient. This is reflected in the legal rights of citizens, including the right to protection of health and privacy, and health institutions are required to take the measures necessary to guarantee that protection.

There are technological means by which to implement any reasonable solution that is designed from the organizational point of view; this is where the basis for a plan of information security should be established. This basis should consider:

➢ Defining a security strategy
➢ The compromise between availability and data confidentiality
➢ Using IT tools for the implementation of designed measures
➢ Training and awareness of the people involved (both professionals and patients).

Figure 23 – Bases for information security plan

Legislation for the privacy and security of health information

The privacy and security of information are part of the legislative agendas of many countries. Legal regulations arise in the form of laws, acts and Constitutional articles, and impose responsibilities on institutions that store personal information and grant rights to individuals.

In some countries there are specific regulations for health information, and in other countries there are general regulations in which healthcare related issues are included. Healthcare data on individuals are considered some of the most 'sensitive,' because of the potentially great impact if a privacy violation occurs.

As a general rule, legislation on EHR privacy and security should consider ensuring that:

➢ Individuals can access their records and request changes
➢ Individuals are informed of the uses to which their information will be put
➢ Protected information is not shared or used for other purposes without consent
➢ Managers document their privacy standards and train their personnel accordingly
➢ There is confidentiality, integrity and availability of protected information
➢ There is protection against reasonably predictable threats and hazards
➢ Compliance of employees or sub-contractors is guaranteed.

Security, privacy and confidentiality

Table 18 lays out the relevant definitions of security, privacy and confidentiality.

Table 18: Definitions of concepts

Privacy	Right to keep information to oneself
Confidentiality	Right that information communicated to someone (in confidence) is not transmitted to third parties
Security	Means used to ensure confidentiality and prevent privacy violations and loss of information

Healthcare information ownership

Despite large amounts of evidence, there are still several issues related to medical records that allow some discussion, or at least which call for reflection: who owns medical information?

Classically, the owner was considered to be the institution or the doctor who recorded the information. Currently, however, there is an international trend towards considering the owners of the information to be the patients—and, therefore, to concede that they should have free access to it and be able to restrict its use according to their needs. But healthcare information must establish some privacy limits, meaning that privacy can be broken on the grounds of:

➢ Public health
➢ The right to investigate

➢ Evidence of crimes contained in the medical record.

Technologies to secure information

To strengthen information security, different technological strategies are implemented**.** These include:

➢ Alerts when displaying sensitive information and detailed logging of all user contact with information, called 'trail auditing', which ensures that users use sensitive information correctly and carefully

➢ Rules for managing software and allocation and access control

➢ Vulnerability analyses of systems

➢ The information used to ensure the strategy is the use of classic pair 'and password'. This tool may include different levels of complexity as will be discussed below.

Validation of identity through 'user and password'

Authentication is the act of establishing or confirming that one thing (or person) is authentic—i.e., is being asserted is true. Authentication of a person means verifying that person's identity. **Authorization** is the process of verifying that a known person is authorized to perform a task or operation. Therefore, authentication precedes authorization.

An important area of information security is authentication of users and passwords to access systems. Human factor authentication is classified as:

➢ Something the user has (card, security token, phone)

➢ Something the user knows (user name, password, passphrase, PIN)

➢ Something that is characteristic of the user (finger print, retinal reading, voice recognition).

Uni-factor identification is the most commonly used form of identification on the Internet and in health. Here, a user logs into the system by entering a username and password (user only factor: something the user knows). Uni-factor identification is based on the concept of 'something you know'. However this form of identification is the most vulnerable, as anyone who knows usernames and passwords can access systems. Besides, managing passwords in the healthcare environment is often a problem.

To further increase the security of a system it is necessary to add a physical device password (something the user has) or something that is characteristic of the user (such as a fingerprint) to the uni-factor authentication system. Such combined strategies are known as *multi-factor authentication* strategies and are currently under extensive development in many systems requiring high security (banks, shops, etc.). The use of biometric devices may also be useful, but in large-scale organizations the implementation costs can be very high. Some other device could be used, such as a smart card or USB 'key'.

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Multi-factor identification is a strong reinforcement to authentication. It is based on the use of two or more factors for authentication. The most widely used forms of multi-factor authentication are:

➢ Card + PIN: the example of the ATM (two factors: something the user possesses plus something the user knows).

➢ Password + fingerprint: (two factors: something the user knows plus something that is characteristic of the user).

As part of any strategy to increase security, consideration must be given to barriers that protect privacy.

Barriers to protect privacy

Barriers are implemented to ensure proper use of information. An example of such barriers is the requirement for authentication in order to interact with the system, as when users are identified by **username and password** for access. Some centres require **explicit authorization of individual physicians to access each medical record**. **Digital signatures** are a way of tracing actions on the system and, in some cases, even have legal validity.

Encryption is one of the most used technologies in information security. Implementing encryption alone is insufficient as a security measure, but its use is highly recommended when data is transmitted over public networks such as the internet.

User management and access control

This is a strategy, a technology, an obstacle and a recommendation. If a Master Patient Index (MPI) is the sole repository of the people who are going to act on a HIS, the provider exists in it; the difference between the provider and the patient, at system level, will lie in the inclusion of an intermediate structure that defines what role each will play within the HIS. This intermediate structure will also link data from other tables, containing information on individuals such as profession, medical specialty, and attending service (department, service, section, etc.). We can then define this structure as the link person-area-function, from which a person MPI happens to meet a certain role in a healthcare organization, and performs certain functions in a specific area according to their profession.

With this logic is possible to define access profiles for similar users/professions. From these definitions, the MPI can be the cornerstone of access control applications: according to their function, a person within the institution will require a certain level of access to a particular application. In this way access control is closely linked with potential functions in an institution and not with particular users. There will always be exceptions, of course, but these will be infrequent if the entire structure is properly represented.

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