# Regulatory and Institutional Framework to implement Digital Health

## Technical Recommendations

**NETWORK FOR THE DEVELOPMENT OF THE DIGITAL HEALTH IN LATIN AMERICA AND THE CARIBBEAN**

BID

RACSEL
RED AMERICANA DE COOPERACIÓN SOBRE SALUD ELECTRÓNICA

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# 1. Introduction

A patient's health record is one of the essential elements of the doctor-patient relationship and caregiving process, becoming a critical tool for decisions made by health professionals. It is used as a supplement to various sources of observation and diagnoses by the physician about the health condition of the user/patient. The patient/doctor interaction is guided by a systemic process, adjusted in practice by experience acquired by the doctor through knowledge from his/her own professional practice, in combination with the organization, academia, and geographic area, among other social conditioning factors.

During the last decade, information technology has permeated clinical and caregiving scenarios, allowing for digital registration of clinical information, with the electronic health record becoming a fundamental tool to support patient care processes.

The benefits of electronic record keeping aim to improve health care, providing greater efficiency, safety and quality to the patient. The digitization of health information brings new challenges to the need for integrating such information into health contexts. Information is supported by technologies that must be adjusted to users' needs to have a real value for various interested parties.

Awareness of these technological advances for health make it necessary to create a forum to share current experiences in **Electronic Health Record System (***EHR System*) design and implementation in the region, generating the first governmental recommendations to support *EHR System* development, and discuss the principles of regional integration. The **Latin American Cooperation Network on Electronic Health (***RACSEL*, in Spanish*)* has consolidated the *EHR* System experience of five countries in **Latin America, producing thoughtful reports and recommendations regarding various fundamental elements for** *EHR System* evolution in our countries.

*RACSEL* emerges as a South-South cooperation initiative to facilitate the development of digital health in the region, placing emphasis on *EHR Systems*. *RACSEL* has been developed with the support of the Inter-American Development Bank (IDB) as part of a *Regional Public Goods* for the progress of *EHR Systems* in **Latin America and the Caribbean. Member countries at the time of writing this report are Colombia, Costa Rica, Chile, Peru and Uruguay.**

*RACSEL's* activities promote collaboration, dialogue and exchange of knowledge and experience among member countries for the development of digital health. In addition to sharing experiences, the network retains international consultants for activities such as development, training and capacity building, to create a knowledge base among government agencies.

Principal matters addressed by *RACSEL* are products made available as a *Regional Public Good* and include a compilation of technical matters related to the institutional and regulatory framework for *EHR Systems,* architecture of *EHR* information systems, interoperability health standards, pharmaceutical terminologies, electronic prescription, and guidelines for measurement of information and communications technology (*ICT*) in health care. Learning courses are also available on a website platform to be freely used by various interested parties.

*RACSEL* has made an initial effort to document the *EHR system* fundamentals so that countries and regions that are progressing in *EHR system* developments have a reference for their initiatives. Based on its health model and context, each country can analyze, adjust, adapt and adopt, or not, proposed recommendations. We hope that the value of discussions included herein, which are based on the vision of a network of governments, provides inspiration so that digital health brings more equality, solidarity and quality to our citizens.

# 2. Conceptual Model

The users of *Health Systems* have evolved, just as the epidemiological profile and available clinical resources have changed in LAC. This requires that we think of a different institutional framework to adapt to these changes.

Patients are more empowered, have more access to information and are more demanding of health systems. New, integrated technologies allow for expanding the horizon of professionals and patients, even under conditions of budget constraint. Technology facilitates the tailoring of benefits and improves the efficiency of health services. But it must be managed to take advantage of each opportunity, using the strengths of each system. The appropriate implementation of new technologies requires a well thought out institutional and regulatory structure, one that must include specific approaches that are deemed relevant, such as infrastructure and interoperability. Above all, implementation must be planned in such a manner to obtain and maintain political and social support.

## 2.1. Scope

The deployment of an *EHR System* involves several processes and structural changes in the health organizations of each country. It is not only a technological transformation, but an alteration of the paradigm in medical care and health systems that involves a radical change in the way that people work.

Therefore, *EHR systems* deployment is a very complex process of change that in addition to the inherent technological aspects, involves human factors that must be properly managed for an appropriate implementation of the project.

In the case of an *EHR System*, there may be a trend to focus attention on the adoption of the international standards required for its deployment and on those features related to the technological infrastructures as are necessary for its implementation, especially at the beginning of the process. However, it must be emphasized that successful implementation requires considering the background of previous, similar experiences, the relationship of future users with technology and/or the fear of and reluctance to a technological change of this magnitude.

## 2.2. Risks

Several uncertainties and risks typical of any technological project arise when an attempt is made to implement a *digital health* project. In many cases, these projects fail because they are not properly managed.

### 2.2.1. Typical characteristics of health care processes

In the health sector, there are specific conditioning factors due to the complexity and delicate nature of the information recorded, stored and shared, to protect the continuity of care.

The volume of data generated by caregiving activity is much larger than that generated in other aspects of human work.

### 2.2.2. Users' expectations

Expectations that are not commensurate with reality usually tend to prevail in this type of project. Requirement gathering s not always properly guided and communications are not still clear enough to balance

expectations of potential users and patients.

Normally, users show significant reluctance to change. Patients usually are skeptical with respect to the confidentiality and protection of their data. These conditions require appropriate change management and creating a suitable scenario for deployment.

### 2.2.3. Project management characteristics

Sometimes, objectives have not been sufficiently defined, the periods and terms are unrealistic, or the complexity of the project has been underestimated.

The lack of clear leadership to carry out a change management plan can influence the most important success factors and the capacity to involve management levels. Such a large and multilevel project requires aligning participation of the most diverse stakeholders.

## 2.3. Initial Approach

Leaders of organizations must create a climate favorable to change, making the people involved aware of the need for change and designing implementation and sustainability strategies that involve and engage every level of the organization. Employees must assimilate the new *digital health* project, as if it were their own, understanding that changes mean initial difficulties, though their final objective benefits the organization, the country and themselves. Creating the appropriate climate is critical to implementing change in organizations engaged in health care as many organizations have not developed a culture for implementing new technology projects.

The team leading the project must implement and sustain the changes, resolve problems, promote solutions, help modify individual behavior to achieve the proposed goals, training and recycling, and provide necessary technical support. The objective here is to assist the transition in the conduct of individual behavior.

Participation of stakeholders is another essential issue, that is, people or groups who can be positively or negatively affected by the development of a project. They not only include players directly involved in the organization, but it is also essential to consider the needs, expectations and demands of groups related to the organization, but not belonging to the health sector.

The correct identification of stakeholder expectations and demands, and their integration into the strategy of the organization is one of the most powerful tools to achieve success. The first step any organization wants to establish is a management model with the stakeholders for the development of this type of process that includes identification of those who may be included as stakeholders.

In the case of health organizations, stakeholders refer to high-level government, academic and management entities or committees, doctors and health professionals, workers and administrative employees, insurance companies, legal practitioners, associations of patients, caretakers, families and community groups.

## 2.4. General organization required for a digital health project

In general, there are two distinct levels

- A *country level*, which defines the global strategy, general policies, the interoperability model, the

regulation of support, accreditation centers, and benchmarks to measure standards.

- A *tactical level*, where each organization or group of organizations establishes its computerization project.

It is necessary to identify the government entities responsible for decision-making and strategic management at the beginning of the *country level* analysis. In principle, it is expected that the main agencies (mainly the *Ministry of Health* of each state), but also other high-level entities of the health sector such as autonomous institutions (for example, the *Caja Costarricense del Seguro Social* – Costa Rican Social Security Fund – in the case of **Costa Rica), exercise a leadership role to carry out deployment of an** *EHR* system. However, the scenarios are not uniform. Each state may have various regional entities with the power to exercise and manage their own health services and, consequently, capable of leading initiatives for the deployment of their own solutions. It can also happen that some of these powers correspond to other ministries or agencies. Therefore, it should be noted that the leadership strategy of the organizations that want to embark on the *EHR* system project path is a complex endevor and many factors and players can participate.

The following factors must be considered for the analysis of this process:

- *Localization of responsibility* to establish policies for each dimension (standards, interoperability, secondary use of information, data protection, citizen participation).

- *Infrastructure* centralized or federated policies must be consistent with the definitions for the acquisition of infrastructure.

- *Human Resources* – responsibility for development of human capital is at the highest level of the organization

- *Legal* – the people responsible for updating the legislation may not be the same as those who define *digital health* policies, but the various entities must coordinate to make the country project a legally consistent one.

- *Technological* – prioritization of standards, type of code (open or closed), inclusion of public property can influence the progress of a country project.

It is likely that some of these conditions are beyond the capacity to mobilize resources of the corresponding ministry or another entity with a similar hierarchy. However, there is no doubt of the leading role it must take, in addition to mobilizing *EHR system* initiatives and the necessary coordination to make them successful.

Lessons can be drawn from successful experiences of providing entities that have promoted the innovation and adoption of an *EHR* system and align them in the country strategy. Decision-making should not necessarily be imposed as a cascade process, neither should efforts made at other levels be set aside.

Widely shared by the countries, regardless of their size, language or the typical characteristics of their health networks are features such as the creation of a single **Master Patient Index** *(MPI)*, the availability of a telecommunications network infrastructure, advocating the decision to use a terminological server and a platform for the integration of health applications, and improving training of professionals in health-specialized **Information and Communications Technologies** *(ICT)*; **or promoting legislative changes they are widely shared by countries, whatever their size, language or own peculiarities of their health networks.**

**Needs of providers and the ultimate needs of patients are fundamental factors to consider; factors**

**that may require involvement of organizations that consider understanding and including requirements from the design of the respective projects.**

**On the other hand, there is a level that directly corresponds to the deployment of** *EHR* systems at the provider level. A country *EHR system* project will include *country coordination* and regional coordination (that combine different levels of care) or coordination by the center, establishing links between the global project and individual deployments, regardless of the existence of regional or coordination work groups at another level (for example, interregional or with other entities at *country level).*

## 2.5. Recommendations

It is a partial truth that traditionally *Information Technologies* have been associated with infrastructure and equipment such as networks, servers or computers. Essentialy, these elements are required, but are clearly insufficient.

Regarding networks and communications, many **Latin American countries have initiatives in process for improving infrastructure, but the margin for improvement is still significant. In these projects, it is particularly relevant to extend coverage to rural areas, which generally means greater challenges for delivering health care, due to problems such as geographic dispersal of the population or a difficult mountainous terrain, compared to large cities and urban centers.**

**In this context, strategic plans to improve infrastructures of a country, allowing health institutions to have appropriate access to communication networks, must be aligned with** *EHR* system projects. This area of action is beyond the scope of competences of the **Ministry of Health. Therefore, it is necessary for coordinated action of efforts at the highest level. In other words, we can hardly talk about extending the** *EHR systems* if communications networks that must support it do not exist or are uncertain.

Another relevant premise is the size and complexity of projects for implementation of *EHR systems.* Without a doubt, these are long-lasting and unquestionably complex projects. It is proper for the governing entities to assume these factors, as the timeframe for deployment of *EHR* systems at the country level can be decades and give rise to significant economic investments. Therefore, it is crucial to reach an appropriate long-term political consensus, as these projects necessarily span several legislatures. Although technical decisions may adapt to changing or unexpected conditions, the political commitment must remain firm over time.

Aspects regarding *Interoperability* and *Use of Standards* as fundamental elements of *EHR systems* projects have been addressed before. Among other functions, the existence of organizations involved in their communication, the impulse to adopt standards and the definition of integration guidelines at the *country level*, is highly advisable. These functions must be performed by existing organizations with the capacity and funding to do so; or alternatively, through the creation of a **Technical Health Interoperability Office with a nationwide scope. Its responsibilities would include setting several short- and long-term objectives (connected through a** *scorecard,* for instance) that can follow up on the adoption of standards throughout the country and keep a register of projects and professionals who have received training on standards. Thus, in a given period of time, it is possible to determine the number of professionals who have trained in Health Level Seven (*HL7*) standards; or, to determine the number of projects in the country that use standards such as Digital Imaging and Communications in Medicine (*DICOM*) or adopt the Integrating the Healthcare Enterprise (*IHE*) guidelines. Looking ahead, this office creates the opportunity of collecting experiences, for example, in projects carried out in a region or health care providing center; software knowledge and/or developments that can be leveraged and used at centralized level and replicated and extended to other regions.

If there is a cross-functional team engaged in implementing *EHR system* at the country level, the *Technical Health Interoperability Office* can be integrated into that team, to handle interoperability requirements.

These recommendations must be adapted to typical case studies of the country, as the scenario of a state with regionally distributed *EHR* systems is entirely different from a scenario with a single *EHR* system. Although the paths may differ, the ultimate end is the same. Therefore, it is highly advisable to assign the ultimate empowerment and responsibility for interoperability to an organization.

Under different names and scopes of competence, there are currently diverse experiences in this area in several countries in **Latin America. The aforementioned functions can be performed by these existing entities or by newly created ones, if necessary. This decision must correspond to the authorities of the ministry, based on their own analysis, needs and previous experiences.**

**Below is a list of recommendations (non-exhaustive) for deployment of** *EHR* systems structured in four large areas, namely, *Institutional and Legal, Terminological, Standards* and *Architecture*[1].

Each of these areas would concisely answer a question:

- What changes must necessarily be made to the body of law and institutions so that they can properly support development of an *EHR system* at country level?
- How to promote *Interoperability* and adoption of *Standards*?
- What strategies must be advanced for the adoption of controlled vocabularies?
- What criteria must be considered when designing the systems that would support *EHR system*?

These questions do not have a single, isolated answer over time. To the contrary, they must be raised on a regular, cyclical basis, as the explosion of technological innovations, social and/or economic changes, alterations in health care network models or other factors that may exert certain influence, turn *EHR system* into an issue of ongoing debate, open to improvement and adaptable to change.

### 2.5.1. Legal Recommendations

While this issue is addressed in further detail in another section, worth highlighting is that any *digital health* project raises several ethical, legal and institutional concerns. The development of regulatory frameworks in the field of information security and data protection has followed different paths in different countries. Some have issued specific regulations for health information while others have general regulations that include matters related to health.

In any case, there are fundamental aspects shared by various regulations. Generally, laws on privacy and security must include:

- The duty to inform the citizen that he/she must authorize the acquisition, processing and transmission of data, çby being aware, prior to authorization, of the purpose for which data are collected. Every citizen must know if information concerning him/her is being processed and be able to request timely corrections or rectifications.
- The patient's consent
- The identification of patients
- Security measures in the authentication and validation of the professionals who participate in the process and which have been addressed in the section on safety.

1 Architecture is an abstract plane that includes the designs of processes for an information system based on design principles and within a methodological framework.

It is imperative to designate a supervisory authority responsible for compliance with data protection principles. The unstoppable boom in the use of cellular devices has accelerated the need to establish guidelines and protect the entire field of activity related to data protection.

### 2.5.2. Recommendations on Standards

The responsibility of the *Technical Health Interoperability Office* or an existing organization that takes on responsibility for promoting and communicating standards has been mentioned. Along these lines, the need to provide appropriate training to professionals on *Standards* may be added by encouraging active training and certification policies. Other initiatives may endorse events. For example, quickly spreading **Connectathons aimed at testing health solutions through the application of** *Interoperability* tests support an active exchange of experiences and knowledge.

### 2.5.3. Recommendations regarding the use of Terminology

Indispensable to progress to an interoperable *EHR* system are tools that manage controlled vocabularies, usually called *Terminological Servers*, allowing information systems to identify, compare and operate using the information stored in such servers.
This type of vocabulary is the normalized language designed and created to represent concepts of one or more domains (scopes of application such as diagnoses, procedures, medicines, etc.). Some of them include ICD-10[2], SNOMED CT[3], LOINC[4], NANDA[5], ...

The following table shows the generic recommendations regarding the provision of terminological services:

Table 1 Strategy for the Provision of Terminology Services

| |
|---|
| Start working on the adoption of an own terminological server following these general steps:<br>1. Evaluation of existing solutions<br>2. Decision to acquire or develop independently<br>3. Identification of necessary improvements/adaptations<br>4. Development of necessary improvements/adaptations<br>5. Adoption<br>6. Suitability test and testing<br>7. Deployment |

It must be taken into account that medical language is a difficult domain for the exchange of information due to specificity of terms; dependence on context; variability among regions (even with the same language); a large number of synonyms or use of acronyms and abbreviations.

### 2.5.4. Recommendations regarding the Architecture

One of the most important considerations for **Health Information Systems Architecture is** *centralization versus decentralization*. Is this a system or systems located in a central node where all the national pro-

2 International Classification of Diseases

3 Systematized Nomenclature of Medicine – Clinical Terms

4 Logical Observation Identifiers Names and Codes

5 Originally: North American Nursing Diagnosis Association

viders are connected? Or, are these separate systems located in the servers of providers that potentially establish exchanges of information with the central node?

In reality, the existence of pure scenarios – either totally centralized or totally decentralized – is unlikely, leaving instead hybrid types that favor one of the two poles. There are multiple factors in the set of decisions that affect these scenarios, such as budget restrictions, the condition of telecommunications networks, the status of development of distributed *EHR* systems, if any, capacity to mobilize nationwide sufficiently qualified resources and coordination with other entities competent for the provision of health care, to name a few.

Whatever scenario is selected, it has its own specificities, with an extensive group of possibilities facilitated by both the standards and the use thereof through the *IHE* profiles.[6]

It is advisable to use comparative reference tests such as the *EMR* adoption model *(EMRAM)*[7] *that hospitals use to follow up on their progress to a fully digital and paperless environment. This model classifies hospitals in accordance with their progress to complete the eight phases for the creation of an electronic patient record environment. One of the great contributions of this evaluation is that, in addition to identifying the level of each center, it provides an analysis of the gaps that hinder its progress in the adoption of ICT* and recommends a roadmap to reach the objectives.

Managers have not given enough importance to other elements fundamental to building the strong bases of a *country architecture*, for example, identification of patients and management and identification of objects *(**OID – Object Identifier**)*. The nationwide, unequivocal identification of patients avoids duplication of records and errors, enabling exchange of information between entities. To standardize this requirement, it is advisable to build a **nationwide master patient index** *(MPI)*, which permits querying through the network when an exchange of clinical information between providers begins.

An *OID* consists of a tree structure of codes and descriptions, in which branches represent the domains of values and leaves represent the different values that can be part of that domain. The use of *OIDs* facilitates the *semantic interoperability* between organizations. An example of its use in clinical information could be in the communications among various agents through electronic messaging. These messages usually contain coded clinical information. Not accurately knowing which catalog, classification or terminology is represented by those codes is a problem. *OIDs* enable one to unequivocally identify the source of information to which those codes belong. Each *OID* is created by an assignment authority. In turn, each authority can delegate the assignment of new *OIDs* under its root to other assignment authorities that are under its control.

For unequivocal identification of patients and management of *OIDs*, it is necessary to make a thorough analysis, conceive an appropriate country strategy and advance a plan that meets both needs.

6 Each IHE Integration Profile describes a clinical need for the integration of systems and the solution to carry it out.

7 Electronic Medical Record Adoption Model

# 3. Regulatory Framework

This section describes the most relevant regulations around which the nationwide ***EHR system*** is structured.

The enabling regulatory framework is fundamental to create indispensable foundations that make possible establishment of a health record system that takes into consideration the rights and legal guarantees necessary for all participants in the process.

Without a doubt, there are multiple involved subjects that play various roles with regard to *EHR* systems, whose activity must be regulated to achieve the pursued aim.

To prepare a regulatory reference framework for *EHR system*, it is suggested to consider the following areas:

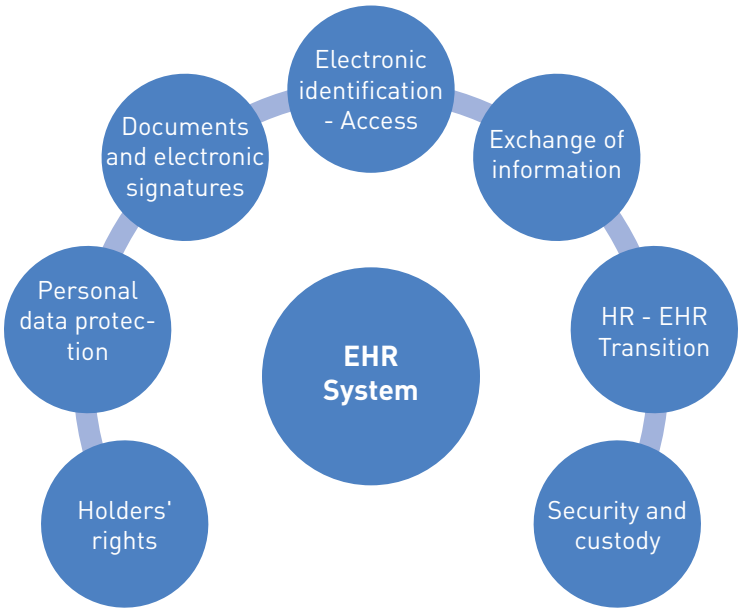


Figure 1. Regulatory reference framework for *EHR Systems*

The starting point of *EHR system* regulation must be the patient or the holder of the record and the rights to which he/she is entitled, among which it is essential to have regulations protecting his/her personal information and ensuring its appropriate processing and utilization.

Most important is that the regulation establishes parity between the legal value and effects of documents in print, and holographic signatures, with the electronic documents and signatures, confirming their functional equivalence for the purpose of ensuring their admissibility and probative value.

We must keep in mind that the health record is an electronic document. The system containing clinical information must ensure its security. Achieving this objective requires a correct electronic identification of system users and management of system access through assignment of various roles or permits, in accordance with the function to be performed.

The safe exchange of information between corresponding authorizations is fundamental to *EHR* systems.

Finally, it is necessary to set guidelines that enable health institutions or services to make the transition between the electronic world and print, for instance, by instituting guidelines for the preservation of patient health record files.

The following sections will analyze the basic regulatory elements for the implementation of the EHR system

## 3.1. Establishment of rights in favor of *EHR* holders

Based on the understanding that the *patient* or health care user is the core of any *EHR* system, it is mandatory to have a regulatory framework that governs his/her rights and duties, specifically regarding the *Health Record*:

The obligation of maintaining a complete health record that includes all essential information on a person's health.

To adhere to that which each regulation states with respect to ownership of and access to the health record.

To ensure access to and consultation of the record by holders, as well as obtaining copy, even though it is in an electronic format.

Access by those who have the representation or guardianship of minors or those who are legally incapable and other provisions that may set forth restrictions or limitations regarding access to the record or to certain parts of it must be considered.

The regulation must include processes to inform the patient of both caregiving actions and health condition; and to obtain his/her consent when required; for example, for surgery or a specific procedure, considering that some processes may continue to be analog or in print.

## 3.2. Personal data protection - Confidentiality

Either in print or electronic form, the *Health Record* contains data on people's health, indicating that rights and appropriate guarantees regarding protection of this information have been, or need to be, expressly or tacitly enshrined.

The principal international **Human Rights** protection instruments, such as the International Covenant on Civil and Political Rights; the Pact of San José, Costa Rica; and the United Nations Universal Declaration of Human Rights include protection of private life and intimacy.

The ***American Convention on Human Rights*** specifically sets forth in Article 11 Protection of the Honor and Dignity of People, stating that:

"Everyone has the right to have his honor respected and his dignity recognized.

No one may be the object of arbitrary or abusive interference with his private life, his family, his home, or his correspondence, or of unlawful attacks on his honor or reputation.

Everyone has the right to the protection of the law against such interference or attacks."

Personal data protection involves enshrinement of a human right in favor of data owners that requires empowerment with respect to control of data use and secures freedom to supervise the use of personal information. Hence, personal data protection preserves the identity, dignity and freedom, known as the right of an individual *to be left on his/her own* and *self-determination in respect to personal information*.[8]

8 This is a right recognized in the scope of privacy with a long background, recognized by the authors, Warren & Brandeis: http://groups.csail.mit.edu/mac/classes/6.805/articles/privacy/Privacy_brand_warr2.html (Annex 3).

Some countries dedicate a special regulation to a set of data containing the most intimate aspects of the individual, regulating personal health data as *sensitive data* requiring consent of the holder for their processing.

These countries have a system of exceptions, to obtain consent in public health and hygiene, epidemiological cases, or in case of emergency.

For this reason, protection of health information involves setting forth rules regarding its communication or transfer to third parties, including what is considered international data transfer.

Consequently, regulations governing *EHR* systems shall enact, at a minimum, respect for the consent of the holder; implementation of provisions that guarantee secure data communication and a secure and appropriate exchange, in accordance with the purpose for said exchange.

## 3.3. Exchange of Information

The nationwide operation of a *Health Record System* requires exchange of clinical information among various health system operators of each country that mandates legal or regulatory authorizations.

For this purpose, the scope or objective of data exchange; the establishment of guarantees regarding traceability of the process; and determination of features of the standards to be used must be kept in mind so that the systems can understand and make use of the exchanged data.

## 3.4. Documents and Electronic Signatures

Another relevant characteristic of regulatory needs refers to preserving the equivalence of a record on electronic media, with its printed *Health Record*, including recognition of its probative value.

Establishing equivalence of one record with another ensures their validity as legal medical document with the prospect of using it in judicial proceedings, among others. Equivalence expresses the need for legal recognition of admissibility, validity and legal effectiveness of electronic documents.

Considering that **EHR systems** will be composed of electronic documents, they must bear electronic signatures, to grant them authorship and prevent the possibility of rejection or non-acceptance as valid documentation. Thus, it is necessary to have regulations that recognize the validity and regulate the legal effects of electronic signatures, in accordance with the concepts set forth in each country that, in turn, set forth the specific policies regarding the use of electronic signatures in *EHR systems*.

A regulatory framework of this type signifies that, since it supports health information, electronic versions of health records must have the same validity as the health record in print.

## 3.5. Management of Electronic Information: Security and Custody

Electronic management of information evidences a contribution to improving effectiveness and efficiency of health services provided to the users, from the viewpoint of improvement in services, costs and optimization of processes, and from the perspective of the appropriate protection of information, using secure and reliable systems, ensuring its availability, completeness and confidentiality.

Information security is not only a matter of technology, but it is expressed in other aspects such as organization and administration.

Security in the health environment is a fundamental requirement due to the nature of the data processed in this environment. Privacy and confidentiality regarding processing of health information must be the common denominator in any *Health System*.

Regulations need to set forth necessary methods to ensure secure handling and exchange of this information, in compliance with the principles of *availability, completeness and confidentiality* of information.

As for custody, it is necessary to have a regulatory and legal standard that includes general requirements and standards that subsequently are regulated by protocols from the technical viewpoint. These protocols have to demonstrate the period of custody of *EHR* in accordance with the type of document or evidence; storage criteria at information and technical levels; safeguard of authenticity and inalterability of the documents; criteria for destruction of this type of information; criteria related to modifications, cancellations and authorizations of users, among others; criteria related to custody and maintenance or security of servers that store these digitized records; and rules related to generation of backup copies. This is required to ensure that information is stored in the securest possible way and ensure that information has not been altered or modified, except for the indicated assumptions.

## 3.6. Use of Electronic Identification Means and Management of Access

Considering that many players may participate in *EHR systems*, it is necessary to establish methods for their electronic identification, assigning roles to professionals and patients and managing access.

To protect EHR systems, pertinent legal or procedural regulations within institutions are obliged to determine forms and procedures of administration and custody of the electronic identification means used.

Those procedures shall recognize the existence of various roles and levels of access to information in a record, in accordance with the purpose of the action.

A formula must be established for the regional network that covers identification and authentication methods, while protecting compatibility with other types of national and international systems and, at a minimum, with countries that are part of the network.

The legal system to be built on a national basis will be required to include minimum and optimal technical requirements that enable various countries to identify the user, validate and authenticate him/her, whether the user is a professional who provides care to the patient or is the patient.

Regulations to authenticate identities must go beyond pure description. They must be accompanied by protocols or technical criteria issued by information or system security professionals who have experience in identification attributes that help determine how to properly authenticate a user in the system and specifically in the common network.

## 3.7. Regulation of EHR System

If a national *EHR system* strategy is developed, the details leading to its implementation and operation must be regulated, as it is paramount to determine the obligations and roles of health professionals, providers, institutions and/or services with respect to implementation.

Notwithstanding the adopted system, it is important to clearly define obligations regarding the custody criteria of the *EHR system*.

Said regulations stating technical qualities or adoption of technological standards required for operation of the system may be defined by the competent bodies.

Defining the essential information that every **EHR** must contain is of great importance.

## 3.8. Regulation of the Transition between Paper and Electronic Format

The adoption of a health record in electronic format requires establishing necessary guidelines for management and preservation of records or files in paper format, either at a general level or as established by each health provider, institution or service.

These provisions shall comply with regulations of each country with respect to civil and criminal statutes of limitations.

## 3.9. Interoperability and Standards

Regulations rising from the *Reference Model* must make provision for communication among different types of centers and systems, articulating, at a minimum, guidelines for creation of methods that enable systems and centers to have the necessary interoperability.

Authorization for interaction between dissimilar and different organizations and systems with agreed and common objectives and for obtaining mutual benefits needs to be determined at a legal level; specifically, to use the *EHR system* for cases so required, from country to country, gaining access to information about the patient who needs care.

Exchanging data between respective ICT systems requires legal authorization.

In addition to *Interoperability Governance*, it is essential to permit recognition of interoperability at three well-differentiated dimensions, at a minimum: technical, semantic and organizational, with such recognition established in regulations that authorize *EHR system* at the regional level.

## 3.10. Minimum Basic Data Set (MBDS)

A **Minimum Basic Data Set** *(MBDS)* of each patient who has received care enables processing the type of information shared.

As a reference, the Catalan model follows the same guidelines as the Spanish model that works with *MBDS* of each patient who has received care at each hospital in the country and, especially, at public hospitals.

MBDS contains valuable information to know the health reality of a population, as it includes:

- The usual demographics (age, sex, area of residence);
- Diagnosis that gave rise to a patient's admission (main diagnosis);
- Risk factors, complications evidenced by the patient during the admission (secondary diagnoses);
- Some relevant diagnostic techniques and therapeutic interventions, particularly surgeries used to treat the patient (the procedures); and
- Patient admission and discharge date, and the circumstance of his/her admission (urgent, scheduled) and the circumstance of the patient's discharge (discharged to his/her domicile, demise, transfer to another hospital, etc.).

There may be a classification that identifies the *MBDS,* for example, *MBDS-AH* that includes information and activity about hospitalization of acute patients; *MBDS-PC* for information on primary care; *MBDS-UR* for urgent care information; *MBDS-SSA* for the socio-sanitary area; *MBDS-IPMC* for in-patient mental health care and *MBDS-OPMC* for out-patient mental health care.

There is no ideal formula for *MBDS* parameters to be included, as it depends on the strategy and complexity found at the time of compiling certain information. Nevertheless, without a doubt, having an *MBDS* or a similar concept is critical for the development of an optimal *EHR system*

## 3.11. Other Elements to Be Considered by the Regulatory Reference Model

Given the magnitude of a project of this level and in accordance with the specific realities of each country, the aforementioned elements may not be the only ones that require a regulatory analysis, as it will be necessary to address other items for the complete development of *EHR system.*

Some, but not all of the elements to consider are:

1. Regulatory and institutional requirements related to implementation of an *Electronic Prescription*;

2. Particularities with respect to *Medical Leaves* (work leave);

3. Regulatory and institutional development concerning *Public Health Programs* (Epidemiological Surveillance);

4. Regulations that properly empower centralized or decentralized *Information Systems* with respect to the *EHR system*.

5. Details related to the terminology to be used (Diagnoses, Drugs, interventions...);

6. The establishment of a *Baseline Diagnosis* of a patient's initial condition and monitoring of progress in implementation of diverse treatments. For example, **Uruguay** has made two measurements.

7. Investment-related needs – the nationwide implementation of an *EHR* system requires investment studies to provide the resources or methods that make provision for the infrastructure.

## 3.12. Transfer of National-level EHR data between countries of the region

- **Minimum data set**

One of the most important issues for the transfer of *EHR* data between countries of the region is to identify the minimum clinical information to be exchanged, given that the objective of the project is international accessibility of information by countries that form the RACSEL Network.

Since minimum clinical information shall be enough and comprehensive for delivering health care service to the user, it is necessary to establish a methodology or process whereby the essential information required by various countries to provide medical service to citizens of each country can be ascertained.

It is necessary to legally regulate required essential information and, if applicable, the formula to determine how to obtain this minimum information. For example, (i) through a commission of experts or work group; (ii) by extracting information deemed essential by the different regulatory systems of each country

in the region; or (iii) by analogy or based on the experience of other territories where this process has been carried out. In the last case (iii), we cite examples such as the *Shared Health Record* in **Catalonia** or the *National System of Digital Health Records* in Spain, where what is deemed essential information for *EHR* system can be obtained.

This type of information shall be comprehensive, including everything necessary to provide health care services, as well as the specifics and characteristics of essential information of each citizen or patient.

Essential information shall integrate essential tests, operations, diseases or any other relevant information on the patient, so that he/she can be treated or cared for in another country in the *Network*.

The minimum data set is mainly the result of care consensus and instrumentation through application of international standards. It should start from an equivalent model or concept that helps at a national level to understand a patient's essential health information, and to determine what countries making up the network deem essential and, consequently, would be used to provide health care service in that territory when circumstances so require.

- **International data transfer**

Discussed in the annexes hereto, this type of model, such as the Spanish or Catalonian one, shows solutions that can be applied to the RACSEL project, to safeguard security in the transfer of data.

In the case of RACSEL, regulations of each country declare specifics regarding data transfers, demanding in most that a country sending health data to another must be assured that the destination country has the same security measures or equivalent data protection regulations of the originating one. Otherwise, information should not be sent, in violation of the user's right to intimacy, as data holder.

It is necessary to pass laws on the international transfer of health information, whose purpose is: (i) to share essential information of a patient from one country to another; (ii) for a necessary cause; (iii) based on compatibility of systems; and (iv) having a secure communication system for that purpose.

- **Security measures to be considered:**

From the information and technological viewpoint, the referenced models propose solutions to account for security factors necessary for development of *EHR systems* by countries and the network itself. Reliability of information transferred to the programs has not been analyzed, as this is the responsibility of the user and the provider or professional, as applicable, who collects that information.

Solutions to ensure technical security in the reference models have been implemented.

- **User identification and authentication**

It is necessary to establish a formula that grants including identification and authentication methods and establishes compatibility with other national and international systems; at a minimum with countries in the Network.

The legal system to be built on a national basis will have to include the minimum and optimal technical requirements that enable various countries to identify the user, validate and authenticate him/her, if he/she is a professional user who provides care to the patient or is the patient.

Consequently, regulations that develop this capability go beyond pure description and must be accompanied by protocols or technical criteria issued by information or system security professionals who have experience in identification/authentication. Such professionals can help determine how to properly identify and validate a user in the systems, and particularly, in the common network.

- **Reference in implementation phases and entities or people involved in the development and implementation of EHR systems:**

It is highly relevant to consider the provisions included in **Annex II**[9] **to this report regarding the Spanish model, as it clearly breaks down the level of involvement of different parties and the implementation process to date.**

**The recommendation is to establish a calendar with various phases, as in the Spanish case, that provides for planning and strengthening progress of the project, starting from the institutional and regulatory level.**

For specific examples of Institutionaland Regulatory Frameworks for EHR Systems and digital health in Costa Rica, Colombia, Chile, Peru, and Uruguay see section 4 of *the original Spanish Version of this document (only available in Spanish).*

9 See Annex II of the original Spanish Version of this document (only available in Spanish)


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