Legal framework for electronic medical records in the Region of the Americas: definition of domains to legislate and situation analysis*

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ABSTRACT

Objective. To define a legal framework related to Electronic Medical Records (EMRs) and to determine the degree to which countries in the Region of the Americas are prepared in this regard.

Methods. The methodology consisted of two phases. In the first phase, a Delphi methodology was used to develop a questionnaire and define the framework and legal domains applicable to EMRs. In the second phase, the survey was conducted in each country. This included identifying national experts and the data collection process.

Results. Information was gathered from a total of 21 countries on their situation with respect to legislation and EMRs, including in the following domains: 1) specific legislation on EMRs, 2) protection of patient data and secondary use of data, 3) legislation on the actions of health professionals, 4) regulations on EMRs and the role of patients, and 5) health standards and EMR promotion programs.

Conclusions. There has been progress in the region with respect to new legislation covering the main areas related to EMRs (for example, protection of sensitive data and use of digital signatures). However, it is necessary to continue to address issues such as access to and updating information in EMRs. This study contributes information on the essential components of legislation on EMRs, as well as reporting on the situation in the Region of the Americas.

Keywords   Medical records; health records, personal; legislation as topic.

An Electronic Medical Record (EMR) is an electronic record of information on the health of a patient, which can help health professionals in decision-making and treatment (1). EMRs can have legal value and fulfill several objectives; one of the most significant objectives being to serve as a means of communication between the health professionals caring for a patient (medical staff, nurses, kinesiologists, etc.). Meanwhile, EMRs have significant legal value, especially in cases of medical malpractice, and they are useful for obtaining data for medical management and research (2).

Although EMRs are acknowledged as a highly useful tool in the field of health (3), barriers that hinder their adoption have also been described (4). A study carried out by the Pan American Health Organization (PAHO), in which 19 countries in the Americas were examined, some of the main barriers to the implementation of EMRs were found to be the lack of funding to develop and support these programs and the lack of evidence to support their efficacy (5). Although the financial barriers are clear, literature also discusses other barriers, which include technical, psychological, social and organizational barriers. The

lack of regulatory and legal frameworks is also mentioned as a main factor (6).

Despite the high level of interest mentioned above, and the potential benefits reported in literature on the use of EMRs, the rate of adoption worldwide is still low, especially in the Americas. For example, according to the World Health Organization eHealth country profiles, the rate of adoption of EMRs is less than 30% in most countries (7). In the 2015 report, 10 countries reported having a national EMR system in place (5). As the literature describes, one of the main needs in order to facilitate this progress is to have a legal framework that supports the computerization process (8).

The objective of this study is to analyze the degree of preparation in countries in the Region of the Americas in relation to a legal framework on EMRs. Therefore, this study aims to establish which legal aspects should be covered by local legislation on EMRs in order to support the implementation of these records at the different levels of the health sector and to determine the status of legislation on EMRs in the countries of the Region of the Americas.

MATERIALS AND METHODS

The methodology was divided into two phases. In the first phase, a questionnaire was developed that was used to carry out the survey on the situation in the countries during the second part.

During the first phase, a group of health informatics experts with experience in the design and implementation of EMRs and legislation was consulted. A total of nine experts participated: six from Argentina, two from the United States of America and one from Honduras. The selection of participants was purposive, at the discretion of the authors. The objective of this phase was to develop a useful tool for surveying the situation regarding EMR legislation in the region. We used documents from the European Region, and the needs in that region described in a previous report (8).

A qualitative Delphi method was used to draw up the theoretical framework and define the domains (9). This method was chosen because it enables a group of experts to reach a consensus. Initially, two participants individually developed a taxonomy of domains to be included in the framework and questionnaire. Each researcher then identified the key issues in relation to EMRs and their legislation that should be surveyed. Then, with the help of a facilitator, the experts reviewed each of the topics separately until they reached an agreement on the content of the questionnaire. Once the first draft of the questionnaire had been prepared, its content was validated by another information systems specialist with professional experience in Central American and Caribbean countries. This second version of the questionnaire was sent to a group of seven professionals working with health information systems in the Americas. The experts made suggestions, which were taken into account in a new version of the questionnaire, which was sent back for further validation. In the second review of the questionnaire, a general agreement was reached on its contents. The final questionnaire was translated into English in order to gather information in English-speaking countries. In the case of Brazil, the individuals contacted understood English and Spanish, therefore it was not necessary to translate it into Portuguese.

During the second phase of the research, the questionnaire created during the first phase was administered in order to determine the situation in the countries. The survey was carried out during the months of July, August and September 2015. In an attempt to obtain more responses, a second survey was carried out using the same questionnaire in August 2016.

Identification of national experts

During the initial phase, a list of the 49 PAHO member countries was created (10) and individuals with knowledge on the matter of EMR and legislation in each of the countries were identified. We started by contacting people with experience in EMR development known by the authors, who were also asked to recommend experts on the subject to increase the base of possible participants, with snowball sampling. Between one and three interviews were conducted per country. The experts were individuals selected on the grounds that they belonged to a national digital health project or based on their experience in matters related to legislation and health. In some cases, the country's experts answered the questionnaire themselves and were given contact information in case they had any queries when completing it.

Data collection process

In the cases in which one or more participants agreed to complete the questionnaire, we organized individual telephone interviews. In the event of contradictions between the responses from the same country, the experts were contacted again in order to reach a consensus on the final answer. Only responses from countries with more than one participant who agreed to answer the questionnaire and did so in full were taken into account.

RESULTS

The questionnaire was developed over five rounds of talks with the experts. The final number of domains identified was five and we generated a total of 57 questions distributed among the five domains (table 1).

TABLE 1. Domains identified as relevant to regulating electronic medical records

Domain	Features
1	EMR Act Types of information on the EMR Minimum data to be included on the EMR
2	Protection of personal data Exchange of information Security in the storage of patient data Secondary use of health information
3	Digital signatures of professionals Access restrictions Access in case of emergency
4	Patient consent for generating EMRs Patient identification Patient access to their EMR Patients and the right to edit their RME
5	Interoperability and standards National health coding

EMR; electronic medical record.

The domains identified as those in which it is important to have regulations on EMRs were: specific legislation on EMRs, protection of patient data and secondary use of information, legislation on the actions of health professionals, regulation of EMRs and the role of patients, and standards on eHealth and programs to promote EMRs.

We contacted representatives from 24 countries, with whom we scheduled telephone interviews. Out of these 24 representatives, we were able to conduct an interview and obtain a complete response from participants from 21 countries. The countries surveyed were: Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, United States of America, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Peru, Suriname, Trinidad and Tobago, Uruguay and Venezuela. We interviewed 32 participants because we received responses from more than one representative per country.

The responses of the countries are described by area of analysis.

Domain 1. Specific legislation on EMRs

In this study, we found that some countries have decided to legislate on electronic medical records with specific laws and regulations that define the type of information and the minimum data that they must contain.

According to the responses of the participants in this study, only 33% of countries in the Americas (seven countries out of those surveyed) had legislation on EMRs at the time of this survey. Figure 1 shows the percentages of the total of the responses represented by each of the countries for the areas surveyed on the existence of laws on EMRs.

Some countries, such as Chile and Costa Rica, stressed that, although they do not have a specific law on EMRs, this issue is addressed by other general laws governing the exercise of the medical profession. It is for this reason that the percentage of positive responses is greater in Figure 1B. Furthermore, in some countries, such as Argentina, the same law provides a list of data to be included on the record, whatever its format; in other words, the content is specified regardless of whether health professionals use electronic or paper records. Some examples of content specified by law are: the date on which the record was created, identifying data of the patient and their nuclear family, details of the treating professional and their specialty. This situation is also reflected in other countries such as Uruguay, where it is specified that the medical record should include the evolution of the patient's health status from birth to death. As well as specifying the format of the medical record, other countries such as Chile and Costa Rica also specify the minimum content that the record must contain.
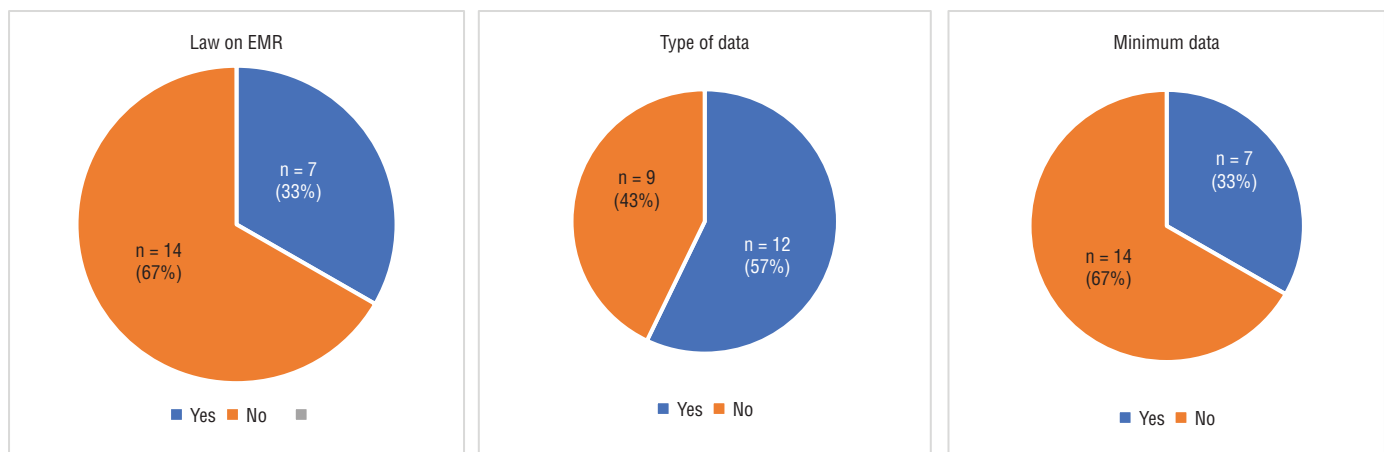
Domain 2. The protection of patient data and secondary use of data

One of the recurring concerns when planning and implementing an electronic medical record system is the protection of personal data, particularly health-related data, which is classified as sensitive data in most countries. This concern is perceived as a barrier to EMRs, both by health providers and by patients. Participants in this study confirmed that most countries have laws that protect sensitive patient data. Most countries have no legislation on other types of regulations such as the exchange of that information and the auditing processes of how this information should be safeguarded (figure 2A).

Figures 2A and 2B show the contrast between the high rate of countries that have laws on the protection of personal data and the low number of countries that have regulation on more technical aspects, such as who is responsible for storing this data and what mechanisms should be implemented to ensure that storage is secure.

One section to be developed within the protection of sensitive data is the secondary use of health information, which is generally regulated along with the protection of personal data. This secondary use of information can be applied to scientific research, epidemiology, management, public health, etc. Some

FIGURE 1. Percentages of the total responses of each of the countries for the areas investigated. A. Number of countries with specific EMR law, including its definition; B. Percentages of countries in which there is a law that defines the type of information that EMRs must contain; C. Countries in which there is a law that defines the minimum data set required in EMRs.
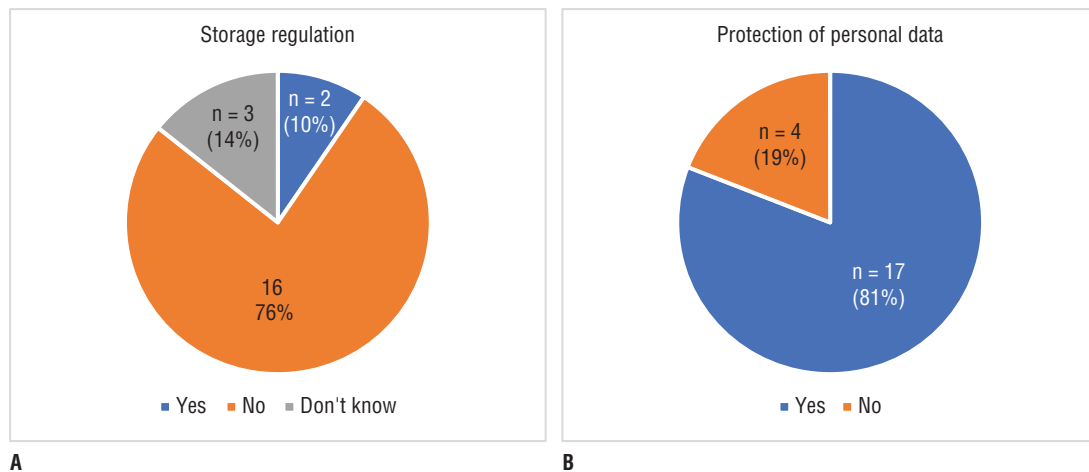

Law on EMR

n = 7 (33%)
n = 14 (67%)

■ Yes ■ No ■

A

Type of data

n = 9 (43%)
n = 12 (57%)

■ Yes ■ No

B

Minimum data

n = 7 (33%)
n = 14 (67%)

■ Yes ■ No

C

EMR, electronic medical record

FIGURE 2 Data protection and secondary use of data. A. Countries that have laws or regulations on the management of health data storage; B. Number of countries with laws on the protection of personal data.

A

B

countries, such as Brazil and Mexico, stated that they have legislation on this matter. This legislation is usually developed within laws on the protection of personal data and, in most cases, it is not permitted to use databases for purposes other than those for which they were created.

## Domain 3. Legislation on the actions of health professionals

The situation regarding legislation on health professionals was quite heterogeneous. A high percentage of countries answered in the affirmative about the presence of digital signature laws (figure 3), although the majority answered in the negative on other issues such as regulations on who can access EMRs.

Although there are several countries that have laws on EMRs and others that regulate the security and integrity of records, such as digital signature laws, very few nations have regulations on EMR access rights, i.e. regulations that specify which professionals can access which sections of the records or, for example, whether medical staff treating inpatients can access outpatient care records. One exception is Peru, where legislation enables professionals of certain specialties to access specific information and to access further information in emergency situations.

## Domain 4. Regulations on EMR and the role of patients

Patients play a broad role in relation to EMRs. On the one hand, there are recommendations on the need for patients to agree to the creation of EMRs, since they are not only a working tool for health professionals, but also an instrument for capturing sensitive data of the population of a country. Another matter addressed in this domain is related to the role of patients in the generation of content and the control they can exercise over the information held on their medical records. Personally identifiable information is also always a controversial matter due to its relationship with the confidential nature of health data.

FIGURE 3. Number of countries with electronic signature laws
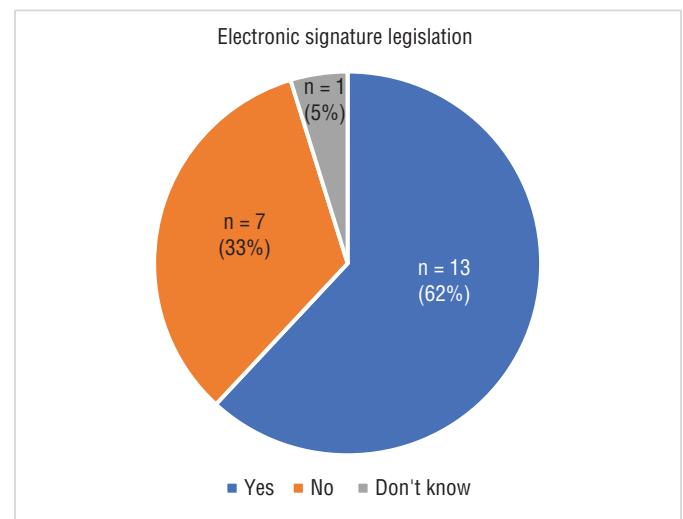
As with other examples of legislation and EMR, the presence of this type of regulation depends in part on the health system model and the health information system model. For example, a model in which all records are generated on a national level is not the same as a model in a country in which regulations stipulate that each health institution is able to generate EMRs for the patients it handles. In this sense, there are very few countries in the region in which this situation is regulated. One example is Peru, where EMR legislation establishes the need for the patient's consent to open their record. In Uruguay, these aspects are regulated by the same laws that regulate general informed consents in health. Although in most countries legislation identifies patients as the owners of their EMRs, very few have active policies in place that truly empower patients and put them in full control of their records. As shown by figures 4A and 4B, some countries have legislation on patient access to EMR, but very few have any type of legislation on editing or modifying it.

FIGURE 4. The role of patients in the electronic medical record. A. Percentage of countries with legislation on patient access to EMRs; B. Number of countries with legislation that mentions the possibility of patients interacting with EMRs, adding or modifying information.
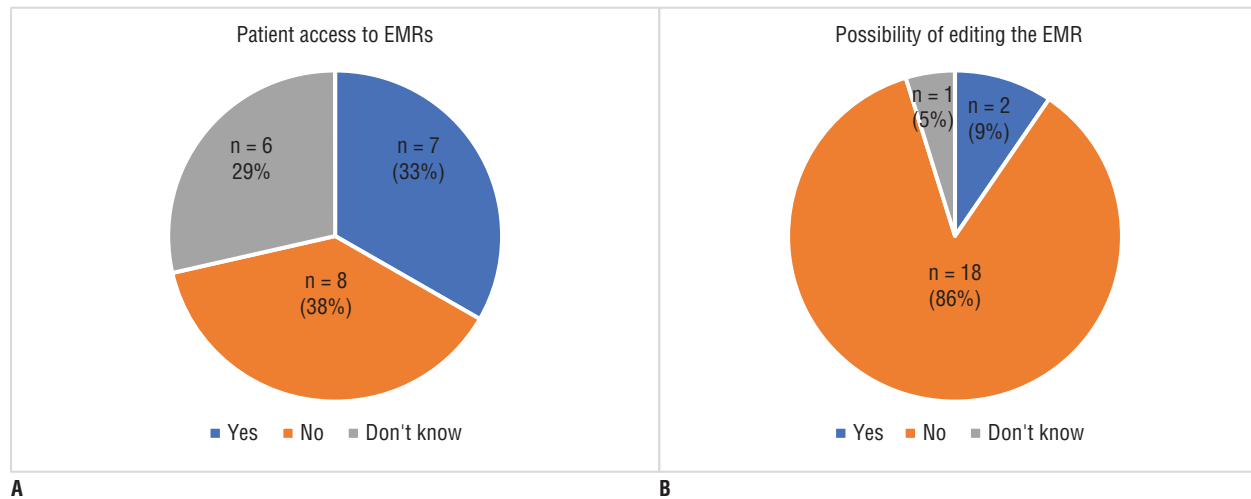
EMR; electronic medical record.

Domain 5. Health standards and EMR promotion programs

In this last domain, although several standards have been published by international organizations, the rate of adoption of standards on EMRs is still low in the Region. Most countries responded in the negative to having regulations on standards and interoperability on a national level. Meanwhile, some of the countries that completed the questionnaire stated that They have national agencies that centralize the management of health standards in the country. Some of the standards listed in the countries' responses include, for example, the case of Uruguay where the Salud.uy program promotes the use of IHE, HL7, CDA, DICOM and LOINC profiles, among others, although they are not currently regulated (11-13). This well-known use of health standards, within and outside of regulations, means that they are established as standards by consensus because they are useful to health institutions. Prior use of the corresponding standards can serve as a basis for the regulations that countries then establish, based on lessons learned from success stories. Programs created to drive the rate of adoption of EMRs, such as the HITECH program in the US, have also proven successful; however, very few countries have implemented such programs (14).

DISCUSSION

This study discusses the status of EMR-related legislation in the Americas. We were able to determine that a limited number of countries in the region have laws on the domains that should be legislated in relation to electronic records. In some countries, the protection of personal data and digital signatures are covered by legislation. It was also found that there is a need for improvement in aspects such as monitoring the users who are authorized to access the records. The countries also need to further develop regulations on the processes by which patients can update information related to their health on the EMRs.

We observed inequalities in the field of technology and health care among the countries surveyed. For example, there are countries that have laws on all of the central aspects of EMRs and programs to encourage their adoption, such as in the USA; but, at the same time, that there are countries where no legislation on any aspect in relation to this matter has yet been started. This finding is important since it makes it possible to identify the countries that need to work on their legislation and those which can be taken as examples and consulted.

Topics that are shared with other areas of society, and the use of technology such as digital signatures, are more advanced in most of the countries in this study. At the same time, legislation on certain issues, such as the role of patients and EMRs, must be handled with sensitivity given that, while health technology can facilitate the empowerment of citizens, it can also cause alarm among health professionals.

With respect to the use of standards and interoperability, in Resolution WHA66.24 of 2013 (15), the World Health Organization (WHO) urges its member countries to consider preparing a plan for the implementation of national and regional standards that include the different actors involved (authorities, academia, health providers, etc.). Different topics influence the choice of the best standards to be adopted, including the cost, the current level of adoption in the country and other nations, and the level of maturity of the standard and its implementation.

This work has several limitations, including that it was mainly answered by professionals working in the area of health and health information systems, with fewer responses from experts on legal matters. Another limitation is that some countries, such as the United States, have specific laws that depend on each state and very little is regulated on a federal level, therefore the answer to some questions was "Don't know" in some of these countries (16).

Having a knowledge of the situation in other countries across the Region can help provide less-developed nations with information on how to legislate on key aspects or to examine aspects

that have not yet been regulated, which is what makes the findings of this study useful throughout the Region.

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Contribution of the authors. DNO conceived the original study. DNO and DB planned the collection, analysis and interpretation of the data. DB wrote the first version of the manuscript. All authors reviewed and approved the final version.

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Marco legal para registros médicos electrónicos en la Región de las Américas: definición de dominios a legislar y análisis de situación

RESUMEN

Objetivos. Definir un marco legal relacionado con los Registros Médicos Electrónicos (RME) y conocer el grado de preparación que tienen los países de la Región de las Américas al respecto.

Métodos. La metodología contó con dos fases. En la primera, se utilizó una metodología Delphi para el desarrollo del cuestionario y la definición del marco y dominios legales sobre RME. En la segunda, se realizó el relevamiento por país, que incluyó la identificación de referentes nacionales y el proceso de recolección de datos.

Resultados. Se relevó información de un total de 21 países sobre su situación con respecto a los aspectos legales y RME incluidos los siguientes dominios: 1) legislación específica sobre RME, 2) protección de datos de pacientes y uso secundario de la información, 3) legislación relacionada al accionar de los profesionales de la salud, 4) regulación sobre RME y el rol de los pacientes y 5) estándares en salud y programas de promoción de los RME.

Conclusiones. Existen avances en la Región con respecto a la publicación de leyes que cubren los principales dominios de los RME (por ejemplo, la protección de datos sensibles o el uso de la firma digital). Sin embargo, temas como el acceso y la actualización de la información en los registros deben seguir siendo fortalecidos. Este estudio contribuye a informar sobre cuáles son los componentes mínimos que deben ser legislados en materia de RME, así como a ofrecer un estado de situación sobre el tema en la Región de las Américas.

Palabras clave   Registros médicos; registros de salud personal; legislación como asunto.

Enquadramento legal para os registros eletrônicos em saúde na Região das Américas: definição de domínios para regulamentação e análise da situação

RESUMO

Objetivos. Definir um enquadramento legal para os registros eletrônicos em saúde (RES) e identificar o grau de preparação dos países da Região das Américas neste sentido.

Métodos. A metodologia do estudo foi dividida em duas fases. Na primeira fase, foi usado o método Delphi para elaborar o questionário e definir o enquadramento e os domínios legais para RES. Na segunda fase, foi realizada a pesquisa por país, com a identificação de dados referentes nacionais e processo de coleta de dados.

Resultados. Ao todo, foram obtidos dados de 21 países sobre os aspectos legais e RES distribuídos nos seguintes domínios: 1) legislação específica para RES, 2) proteção dos dados dos pacientes e uso secundário da informação, 3) legislação relacionada à atuação dos profissionais da saúde, 4) regulamentação dos RES e papel dos pacientes e 5) padrões em saúde e programas de promoção dos RES.

Conclusões. Houve progresso na Região quanto à promulgação de leis que abrangem os principais domínios dos RES (p. ex., proteção de dados sensíveis ou o uso de assinatura digital). Porém, alguns aspectos precisam ser reforçados, como o acesso e a atualização das informações nos registros. Este estudo contribuiao descrever os aspectos básicos da regulamentação e informar a situação dos RES na Região das Américas.

Palavras-chave   Registros médicos; registros de saúde pessoal; legislação como assunto.