

A Global Socio-economic-medico-legal Model for the Sustainability of Longitudinal Electronic Health Records

Part 1

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Summary

Objectives: This paper pursues the challenge of sustaining lifetime electronic health records (EHRs) based on a comprehensive socio-economic-medico-legal model. The notion of a lifetime EHR extends the emerging concept of a longitudinal and cross-institutional EHR and is invaluable information for increasing patient safety and quality of care.

Methods: The challenge is how to compile and sustain a coherent EHR across the lifetime of an individual. Several existing and hypothetical models are described, analyzed and compared in an attempt to suggest a preferred approach.

Results: The vision is that lifetime EHRs should be sustained by new players in the healthcare arena, who will function as independent health record banks (IHRBs). Multiple competing IHRBs would be established and regulated following preemptive legislation. They should be neither owned by healthcare providers nor by health insurer/payers or government agencies. The new legislation should also stipulate that the records located in these banks be considered the medico-legal copies of an individual's records, and that healthcare providers no longer serve as the legal record keepers.

Conclusions: The proposed model is not centered on any of the current players in the field; instead, it is focussed on the objective service of sustaining individual EHRs, much like financial banks maintain and manage financial assets. This revolutionary structure provides two main benefits: 1) Healthcare organizations will be able to cut the costs of long-term record keeping, and 2) healthcare providers will be able to provide better care based on the availability of a lifelong EHR of their new patients.

Keywords

Social change, ethics, politics, economics, information medical record linkage

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1. Introduction

Legal changes and technology advancements now enable health consumers to have their medical records^a transmitted electronically (e.g., to a web site [1] or to a personal device such as a smart card [2] or a memory key [3]); these advancements can potentially result in a lifetime EHR. A naive approach to sustaining a lifetime EHR is to have it held and maintained by the individual patient. Each of us is considered a health consumer, but does it also apply to the medical information? Some people may be reluctant to get hold of their medical records because they prefer “not to know too much” or even deny certain conditions, which may be defined as medical conditions after examination. In special cases (e.g., psychiatric), the information might even be harmful to the patient.

Healthcare providers are obligated to keep the medical records according to local regulations and typically prefer that medical records remain under their control [4]. Many providers even claim to be the owners of these records [5] and only release copies of the records in accordance with a patient's bill of rights. Providers dealing with an ever-growing number of lawsuits [6] might be concerned by additional increase based on the data recorded in patient-held EHRs. In addition, providers have considerations regarding the process of creating standardized medical records. This standardization is

necessary in order to realize the aggregation of medical records from different sources. The standardization process may be accompanied by strict guidelines, which would be detrimental to the more “artistic” parts of their work [7-10].

This paper reviews different approaches and models for the sustainability of patient's longitudinal clinical information and argues for the separation of responsibilities: providers will provide care and will stop functioning as the long-term record keepers [11]. The paper envisions the establishment of independent entities that facilitate a non-centric model of EHR sustainability. This model focuses on the interests of all parties, and supports the following: providing quality care to patients and better support of their privacy; reducing costs to providers and insurers; and providing accessibility to high quality data for government agencies, as well as for pharmaceutical and research organizations, upon patients' consent.

The use of electronic medical records (EMR^b) within healthcare enterprises is already a common and well-appreciated practice [12]. It facilitates the documentation process required for medico-legal reasons, administrative procedures, and bio-clinical research [13]. It also increases the availability of clinical data at the point of care [14]. This paper focuses on a lifetime EHR, which is different from an enterprise EMR in the sense that it aggregates recordings created by all healthcare enterprises from which the subject of the lifetime record has

^a The term “medical record” usually refers to any recording/documentation of medical care given to a patient.

^b Also known as computerized patient records (CPR) in American literature or electronic health care records (EHCR) in some European references.

received medical care throughout his/her life. This kind of entity does not exist yet. The advantages of a lifetime EHR could be seen when a patient moves from one healthcare provider to another for various legitimate reasons, such as work relocation or simple freedom of choice. Today, people are changing jobs, professions, and places of residence more rapidly than ever before. Taking into account the increasing mobility of people throughout the world, the availability of personal health data is becoming a high priority need for many people.

A basic assumption in this paper is that no single healthcare provider is likely to be capable of sustaining a lifetime EHR. The major reasons for this assumption are: 1) The provider's business continuity typically doesn't last a lifetime; and 2) high archiving costs and the lack of interest in a lifetime EHR result in the relatively short-term availability of the medical records. When accepting the above assumption, certain questions naturally arise. Who can compile, retrieve, and sustain health records over the entire lifetime of individuals and what are the main models of sustaining lifetime EHRs?

One possible model is based on better connectivity between healthcare providers and the creation of a "virtual health record"^c at the point of care [15]. This is done by collecting any available records from the various healthcare providers visited by the patient. The virtual record is created on-the-fly and is not persisted beyond the current encounter. Each provider continues to hold the records it created for its patients. This model can be seen as a provider-centric model.

Another possible model is centered on government initiatives such as the NPfIT of the UK NHS^d [16] or NICTIZ in the Netherlands^e [17]. In such initiatives, national repositories of EHR data (or just EHR meta-

data) are established and run by government agencies or public-private operations. The main advantage here is the ability of governments to use the centralization of the model as well as other incentives and encourage providers to send their data to the national (or regional [18, 19]) EHR repositories. Note that the regional-centric model is similar in principle to the government-centric model in the sense that the executive authority in a specific geo-political region or community centralizes its residents' EHRs by establishing regional repositories and/or registries.

Another focal point can be the health consumers themselves. Since the beginning of the dot.com wave, we have seen a flourish of Internet sites that offer consumers private EHR space. Consumers can maintain their data, typically by manually entering copies of the medical records they got from their healthcare providers [20]. Such records are also called patient-held records to emphasize the focus on ownership [21] and control given to healthcare consumers over the records that contain their personal health data. In contrast to the three models mentioned above, this paper suggests a non-centric model that attempts to objectively serve the interests of all parties – consumers, providers, and insurers, as well as government agencies, pharmaceutical companies, and research institutes. This model requires the establishment of new organizations called independent health records banks (IHRBs), who deal solely with keeping health records. These organizations will be independent of all existing players in the field and operate in accordance with new legislation. A health consumer will be able to open an account with any regulated IHRB, where all his/her medical records will be aggregated. Consequently, it is foreseen that a true lifelong health record will, at last, emerge from the raw medical records. This lifelong health record will provide clinicians with a summary of the patient's health condition based on innovative knowledge management processes [22]. This information is invaluable to the clinician, especially when taking into account the time constraints under which a typical encounter is conducted. Making this summary coherent and useful, yet linked to the attested raw data for proper evidence,

will be one of the major specializations of IHRBs. This summarization will be based on the new generation of health informatics standards as well as on innovative information technologies such as GRID, software agents, and web-based health ontologies.

The following subsections discuss the ethical, legal, and technological background relevant to the lifetime EHR sustainability models, which are described in more detail in the next section.

2. Ethical Background

Achieving a clean ethical separation between the medical record producers and keepers could prevent the conflicts of interests we see when providers do not document their actions properly^f or even modify them after the fact [23]. A principle of independence will assure maximum objectivity of the record keepers in serving all interested parties. A good example of an entity that combines different health services is an HMO (health maintenance organization)^g. These organizations provide patients with health insurance, care, and record keeping – all under one umbrella. HMOs need to take care of their patients, but at the same time they are obliged to minimize costs and protect their employees (i.e., physicians and other healthcare professionals). Thus, HMOs may have contradicting interests and might not always act in the best interest of the health consumers [24]. The benefits of the separation principle are best demonstrated in a democratic political system where there is clear separation between the legislative, executive, and judiciary authorities resulting in minimal conflicting interests at each authority.

Medicine is in the midst of a professional evolution, driven by a refocusing of medicine's regard for the patient's viewpoint [25, 26]. A few decades ago none of the important medical schools had courses on medical

^c Also referred to as a "logical record," or a "federated" record, as opposed to an "integrated" record, which is the result of actual data integration processes.

^d NPfIT is the new National Program for IT of the NHS (The National Health Service in the UK).

^e NICTIZ is the Dutch organization attempting to create a national healthcare infrastructure.

^f The known cases are rare indeed but in the current practice it is hard to verify the completeness and accuracy of medical documentation.

^g E.g., Kaiser Permanente in the USA.

ethics, but today, every respectable medical school offers such a course to its students. At the center of medical ethics stands the relationship between the physician and the patient. Four models of patient-physician relationship were suggested by Emanuel [27]: paternalistic, informative, interpretative, and deliberative. While most of the medical encounters in the past could be characterized as paternalistic, today many physicians have switched to the other extreme. They follow the informative model, in which they inform the patient about all the alternatives with no recommendation and let the patient decide alone. Between these two extreme approaches, the deliberative model suggests that the physician engages the patient in active discourse in order to incorporate the patient's perspective when determining the optimal course of action. The active discourse is essential because appropriate informed consent must be tailored to the individual patient, that is, to the patient's culture, personality, perspective, values, preferences, and above all, to the extent that the patient is willing to be informed. Enabling patients to access their medical records could support the deliberative model.

An important issue in medical ethics is how to inform patients with serious illnesses. If these patients have access to their records, this issue becomes more problematic. Any constellation of sustained medical records should respect the decisions of public ethical committees that restrict the information process in special cases.

Human rights movements and patient's rights associations advocate that each person should have control over the information collected about him or her, since it is considered personal information. However, as mentioned above, psychological issues might work in the opposite direction. People may be reluctant to get hold of their EHR because they may prefer "not to know too much" or because they may be emotionally affected or even hurt by the information recorded in their EHR [28]. Therefore, the right balance should be maintained regardless of who has control and what is the selected approach to longitudinal EHR sustainability.

Making the medical records available to the patient technically solves the sensitive issue of getting a second opinion. However, the request for a second opinion often involves the "first opinion" physician. Once the latter realizes that his opinion is not enough for the patient, he sometimes reacts in an irrational way, such as limiting the availability of data already known in this case. Thus, even though the formal data could be available in a new constellation, it is far more effective if the two physicians cooperate and exchange views. This could be facilitated by the availability of the patient's lifelong EHR.

In a seminar on bio-medical ethics [29] it was claimed that the principle of patient autonomy has been widely accepted in the West and that arrogance and patronization have decreased among parts of the physicians' community. The challenge is to find the balance between the physician's paternalism and the patient's autonomy that is appropriate for each individual patient.

Healthcare providers prefer that the EMRs they create remain under their control. For example, the American Hospital Association has a Patient's Bill of Rights [5] stating that patients only have the right to review the records pertaining to their care. Another reason for their objection might be that many therapists feel that their work is partially artistic, in the sense that no algorithm currently exists with regard to how to handle a specific case. They feel that "medicine is not a science" and that their work involves intuition, rules of thumb, and so forth [7-10]. Recording all their actions in a standardized EHR, which is based on one of the new medical informatics standards, will force them not only to record many details that are not recorded today, but also to follow the guidelines on which the standards are based. It is true that healthcare enterprises push their medical staff to document their actions as much as possible in order to improve the enterprise management process; however, the transfer of all records outside of the healthcare enterprise will put greater pressure on clinical documentation.

In summary, it seems that letting patients access their medical records and have control over them could contribute to better patient-physician relationships by supporting

a non-paternalistic relationship pattern. On the other hand, unrestricted access to the records is problematic and thus moving the medical records out of the hands of the providers into objective entities could take care of the exceptional cases (e.g., psychiatric patients) based on guidance from ethical committees, while allowing access to parts of the records by authorized parties.

3. Legal Background

The legislative processes in various countries involving different versions of a patient's bill of rights represent one of the major legal changes in this field. Some form of a patient's bill of rights is now established in most western countries to include a few basic principles: 1) the right to appropriate care; 2) the right of the patient to autonomy over his/her body; 3) the right to a second opinion; 4) the right to receive copies of the medical records; 5) the right to receive information before making decisions (informed consent), and 6) the right to change providers while the previous provider is committed to enable the continuity of care.

The patient's bill of rights has not been well accepted by many physicians who feel that this bill reflects a lack of confidence in the medical community, despite the fact that most of them are devoted to their patients and work hard under difficult circumstances (e.g., disasters with large number of injuries). In a recent panel of physicians and legal experts that took place in Israel [4], one of the physicians emotionally argued that "we feel like we have been slapped by our patients although we have done all we can for them". Many physicians believe that their code of ethics is enough to realize the patient's rights and don't see the need for a patient's bill of rights in the first place.

The Israeli patients' bill of rights addresses the confidentiality of protocols of committees that investigate patient's complaints and death events. A history of court rulings shows that in most cases brought to court, confidentiality is removed and the committee protocols are revealed and handed to the patient or patient's relatives. Consequently, many physicians have

stopped cooperating with such committees because they are concerned that they might hurt themselves should the case reach the courts. Thus, in the eyes of many physicians, not only has the patients' bill of rights not contributed anything useful, but it also decreased the quality of the self-monitoring processes that physicians used to have when the committees' protocols remained confidential.

In preparing the patient's bill of rights in Israel with regard to the right to appropriate care, the physicians association wanted the definition of appropriate care to be based solely on the physician's professional discretion. The physicians association objected to the final version, which explicitly relates appropriateness to the quality of the medical care as well as to the human relations involved in the care. In its interpretation of the bill [30], the physicians association reported to its members that it strongly objected and that perhaps this item would remain solely declarative. Such arguments indicate that many physicians have a hard time relinquishing their paternalistic position, in which the only thing that matters is their professional considerations.

To prove medical malpractice in court, arguments must be based on documentation found in the medical records as well as on expert opinions. While expert opinions are available (though hard to get), the documentation issue is very problematic since not everything is documented and pressures that develop during surgery, for example, do not leave enough time for surgeons to document all details in the patient's record, especially when they are scheduled to perform another operation right away.

In summary, the patients' bill of rights laid the ground for more patient-oriented healthcare, but it has not been truly accepted by the providers and it lacks the details that would indicate what exactly should be documented and consequently what should be the content of the patient medical records. In each of the models for lifetime EHR sustainability, there is a need for further legislation in this respect.

4. Technological Background

Interoperability is the key technological issue to enabling any of the EHR sustainability models. While functional interoperability is ubiquitous nowadays with the enhanced networking capabilities of information systems, the big challenge lies in achieving semantic interoperability^h. The latter is highly dependent on agreed-upon health informatics standards. In the recent years there is an on-going effort to create standards for communication between medical applications, modalities, testing facilities and any entity that is engaged with medical data. In the medical imaging domain, the DICOM standard [31] is now ubiquitous and all medical modalities produce DICOM-compliant images. This led to the development of archives (PACS) that can store and process images from different modalities and render them in a variety of ways to enhance the quality of medical care. The European standardization body CEN has been developing standards for electronic health records [32] for more than a decade and is a pioneer in the field of EHR informational models. HL7 (Health Level Seven) is developing a messaging standard [33] for transactions that take place within a medical enterprise, between different enterprises, and between the medical enterprise and other players, such as insurers or public health agencies. The IHE (Integrating the Healthcare Enterprise) effort aims to provide a framework for both DICOM and HL7 by specifying integration profiles for common use cases in healthcare.

Medical records could contain codes taken from different medical taxonomies such as ICD, LOINC, SNOMEDⁱ and others, resulting in a lack of semantic con-

sistency at the very basic level of data. The National Library of Medicine in the USA has developed the UMLS [34, 35] – a meta-thesaurus of medical taxonomies. Thus, it is now possible to translate many of the medical codes from one taxonomy to another. Eventually, these developments will either lead to the acceptance of a single taxonomy with optional extensions or to fully exchangeable taxonomies.

Another important standard now under development is the HL7 CDA (Clinical Document Architecture) standard [36], which is aimed at offering a standard way to represent a clinical document for the purpose of exchange. Inherent in the HL7 CDA standard are mechanisms for dealing with the authentication and versioning of documents. A new release of the CDA standard^j attempts to bridge and intertwine unstructured data (e.g., physicians' narratives) and structured data such as lab results, diagnoses, and medications. It is important to recognize the role of unstructured data in medicine, which manifests the 'artistic' part of this practice [37].

The major sources of clinical data are healthcare providers' information systems. For example, in a typical hospital there are two major types of information systems: 1) HIS (hospital information system), which manages mainly administrative data on patients, departments, billing, and so forth; and 2) CIS (clinical information system), which manages the clinical data associated with a patient, i.e., the medical record. It is common to see several kinds of CISs in a single hospital (e.g., specialized CISs in the cardiology and oncology departments address the different needs of these clinical domains). Each department defines different needs and perceives differently the notion of an electronic medical record [38]. Furthermore, several CIS applications allow the department to change the record structure dynamically whenever physicians in the department choose to do so [39]. This results in a greater diversity of clinical record formats and in proprietary data forms that are hard to interpret.

^h From the IEEE Standard Computer Dictionary: Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. Exchanging information is functional interoperability and using the exchanged information based on the semantics of the sender is semantic interoperability.

ⁱ ICD – International Classification of Diseases; LOINC – Logical Observation Identifiers Names and Codes; SNOMED – Systematized Nomenclature of Medicine.

^j HL7 CDA Release Two has been recently approved as an ANSI standard.

Issues with legal implications, such as authentication, digital signature, and versioning of documents, are treated differently by each CIS. For example, there are CIS systems that allow the medical staff to change the content of the record or even delete details, without leaving a traceable history of changes/versions.

Only a few of the CIS applications conform to standards such as HL7, and even these applications might have a 'site-specific' implementation of the standard^k. However, the number of standard-compliant CIS applications in the USA is expected to increase, following a newly created HL7 standard for the EHR Functional Model [40]. This standard defines the functions that an EHR system^l is expected to fulfill. Although this is still a functional model, an agreed-upon informational model will finally lead to true semantic interoperability [41]. Defining the requirements for an EHR system is essential to identify an appropriate information model.

The next parts of this paper will provide details for the various models of EHR sustainability, starting with the provider-centric model, through the consumer-centric model and the emerging models of national repositories and regional registries, and finally describing the proposed IHRB (independent health records banks) model in more detail.

5. Conclusions

All centric models presented in this paper will naturally emphasize the interest of their central stakeholder, whether they are the providers, the consumers, or the authorities (governments/regions). It is argued that only a non-centric, independent and regulated approach can ensure the objectivity of the lifetime EHR service, which is so crucial to many parties and specifically to patients and providers. The paper describes the non-centric model of Independent Health Re-

ords Banks (IHRBs) as a feasible alternative to the centric models and suggests guidelines for the new legislation needed in order for IHRBs to be established and operate successfully. It also describes the business considerations that could bring about a business transformation in the field of healthcare, focusing on the shift of archiving costs from healthcare providers to IHRBs and the benefit of lifelong EHR to patient safety, the quality of care and the ethics of record keeping.

The new approach proposed in this paper is not only about further technological development – rather it presents a comprehensive socio-economic-medico-legal model based on technological advancements. The adoption of this model will create a paradigm shift in the way health information is being handled and will let each player focus on its main role and speciality. All stakeholders in healthcare are longing for a change. Will it come from further development of today's paradigm that is based on better connectivity between healthcare providers? A major change is needed where health care providers will cease functioning as record keepers and custodians of long-term archives of incomplete medical records. New players, IHRBs, will emerge in the healthcare arena, and will be established as business entities regulated by new legislation. IHRBs will compete for better services but will comply with the new regulations. The essence of these regulations is to ensure that IHRBs will act objectively and serve all parties. Indeed, at first sight it might look as though this approach is yet another Internet site that offers health consumers an opportunity to aggregate their medical records in one place. However, it is not about that concept. It is not about ownership, since medical records are perceived as objects that need custody rather than ownership. None of the current players can really ensure the sustainability of medical records throughout the lifetime of an individual. The new players that will solely focus on that mission might be able to cope with that challenging goal and thus this vision deserves the chance to be publicly discussed and explored.

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^k Also known as z-segments in HL7V2.x messages.

^l The term EHR System encompasses the scope of both HIS and CIS applications along with the infrastructure needed for those applications to operate properly.

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