

Who's Afraid of Lifetime Electronic Medical Records?

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Abstract

While technology and legal advancements now enable health consumers to have their medical records transmitted electronically, either to the web or to a personal device (e.g., smart card), ultimately resulting in a lifetime health record, many obstacles remain in the way of that vision. So who's afraid of electronic medical records (EMR)?

Healthcare providers would prefer that EMRs remain under their control. Many providers even claim to be the owners of those records and only submit copies of the records in accordance with a patient's bill of rights. Providers are also concerned by a potential increase in the number of lawsuits based on the data recorded in patient-held EMRs. In addition, providers have considerations regarding the process of creating unified EMRs. This process may be accompanied by strict guidelines, which would be detrimental to the more "artistic" parts of their work.

As for the consumers, each of us is considered a health consumer, but is it really so? Some people may be reluctant to get hold of their EMR because they prefer "not to know too much" or even to deny certain conditions, which could have been defined as medical conditions had they been examined.

What appears to be so natural, that is, managing your medical records in a "medical account" much like you manage your checking account, isn't really all that simple. This paper reviews different approaches and models for the availability of clinical information and envisions the establishment of independent entities that facilitate a new consumer-oriented model. This model focuses on the consumers' interests (where privacy is maintained by eliminating the need for a universal patient identifier), and at the same time proves advantageous to providers by reducing their costs.

Introduction

The use of Electronic Medical Records (EMR¹) within healthcare enterprises is already a common and well-appreciated practice. It facilitates the documentation process required for medico-legal reasons, administrative procedures, and bio-clinical research. It also increases the availability of clinical data at the point of care. This paper focuses on a lifetime EMR, which is different from an enterprise EMR in the sense that it aggregates recordings created by various healthcare enterprises from which the lifetime record owner has requested medical care throughout his/her life. This kind of entity does not exist yet. The advantages of a lifetime EMR are beneficial when a patient moves from one healthcare provider to another for various legitimate reasons, such as work relocation or just freedom of choice. Taking into account that the mobility of people throughout the world continues to increase (people are changing jobs, professions and places of living more rapidly than ever before), the availability of

personal medical data is becoming a high priority need for many people.

No single healthcare provider could probably maintain a lifetime EMR. So the following questions arise: What are the possible models of creating and maintaining lifetime EMRs? How does each model relate to ethical, legal, and technological issues?

One possible model is based on better connectivity between healthcare providers and the creation of a "virtual² health record" at the point of care 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 kept once the current encounter is over. Each provider continues to hold the records it created for its patients. This model can be seen as a provider-centered model.

On the other extreme, we would like to suggest another possible model, which is consumer-centered, and requires the establishment of new

¹ Also referred to as Computerized Patient Records (CPR) in the American literature or Electronic Healthcare Records (EHCR) in some European references [23].

² Also referred to as a "logical record," as opposed to a physical record, the items of which reside at the same physical location.

organizations that will solely deal with medical record keeping. We call such an organization an Independent Medical Record Bank (IMRB). IMRB organizations will be independent of medical providers or other players in the fields and operate in accordance with new laws that will have to be legislated. Their main customers will be health consumers, however they will serve the providers as well. A health consumer will be able to open an account with an IMB where all his/her medical records will be aggregated.

These models, as well as other possible models, offer different approaches to many important issues, such as autonomy, ownership, privacy, and patient-physician relationships. What are the interests of each party in the healthcare arena?

Healthcare providers would probably prefer that EMRs stay under their control. For example, the American Hospital Association has a Patient's Bill of Rights [3] but the patient has the right to merely review the records pertaining to his/her care. Another reason for their objection might be that many therapists feel that their work is partially artistic, in the sense that no algorithm 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 [24-27]. Recording all their actions in a **unified** EMR, 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's true that medical enterprises push their medical staff to document their actions as much as possible, in order to improve their management process. However the transfer of all records outside of the medical enterprise will put greater pressure on clinical documentation.

Human rights movements and patient's rights associations will probably prefer that each person has control over the information collected about him/her since it is personal information. However, psychological issues might work in the opposite direction; people might be reluctant to get hold of their EMRs because they may prefer "not to know too much" or may be emotionally affected or even hurt by the information recorded in their EMRs [22].

The following discussion gives more background on the ethical, legal, and technological issues relevant to the consideration of lifetime EMR models.

Ethical Issues:

American medicine is in the midst of a professional evolution driven by a refocusing of medicine's regard for the patient's viewpoint [4, 5]. A few decades ago none of the important medical schools had courses on medical 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 therapist and the patient. Four models of patient-physician relationship were suggested by Emanuel [6]: paternalistic, informative, interpretative, and deliberative. While most of the medical encounters in the past fit the paternalistic model, there are today physicians who have switched to the other extreme, i.e., 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.

An important issue in medical ethics is how much and what exactly to tell patients with serious illnesses. If these patients hold full copies of their records, this issue becomes somewhat obsolete. However, even without giving the records, physicians today tend to simply tell the truth. Furthermore, court rulings in this subject are usually in favor of telling the truth.

The issue of facilitating a second opinion is still problematic because the request for a second opinion often involves the "first opinion" physician. Once the latter realizes that his/her opinion is not enough for the patient, s/he sometimes reacts in an irrational way, such as limiting the availability of data collected on the case. Making the medical records available to the patient technically solves this issue. However, it is more effective if the two physicians cooperate and exchange views.

In a seminar on bio-medical ethics [7] it was claimed that the principle of patient autonomy has been widely accepted in the West and that arrogance and patronization have decreased among part 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.

Legal Issues:

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

The patient's bill of rights has not been accepted well by many physicians who feel that society lacks confidence in the medical community, despite the fact that most of them are devoted to their patients and do hard work 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 [8], 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 patient's 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 that are 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 get to court. Thus, in the eyes of many physicians, not only has the patient's bill of rights not contributed anything useful, but it has also decreased the quality of the self-monitoring processes that physicians used to have when the quality 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 and 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 [9], the physicians association reported to its members that it strongly objected to and regretted the final version of this article and that perhaps this item would remain declarative only. 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.

Technological Issues:

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 [10] 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 that enhance medical care. HL7 (Health Level Seven) is a messaging standard that has been developed to accommodate transactions that takes place within a medical enterprise, between different enterprises, and between the medical enterprise and other players, such as the insurers or HMOs. The new IHE (Integrating the Healthcare Enterprise) standard aims to provide a framework for both DICOM and HL7.

EMRs could contain codes taken from different medical taxonomies such as ICD, LOINC, SNOMED and ReadCodes.³ The National Library of Medicine in the USA has developed the UMLS [11] – a meta-thesaurus of medical taxonomies.

³ ICD- International Classification of Diseases; LOINC- Logical Observation Identifiers Names and Codes; SNOMED- Systematized Nomenclature of Medicine.

Thus it is now possible to translate medical code from one taxonomy to another. Eventually this will lead to the acceptance of a single taxonomy with optional extensions for local customization.

Another important standard now under development is the CDA (Clinical Document Architecture) standard [12], which is aimed at offering a standard way to represent a medical document for the purpose of exchange. The mechanisms for dealing with issues of authentication and versioning of documents are already built into this standard and its acceptance could lead to higher integrity of the medical record, especially when the history of events is under investigation. Also, the CDA standard dictates that every medical document be represented as an XML document. Because the XML standard is human-readable [13] it makes the CDA potentially easier for patients to comprehend (using a standard browser), which in turn could facilitate the realization of the patient's right for informed consent, as well as making the medical practice more transparent.

In the medical enterprise 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's common to see several kinds of CISs in a single hospital. For example, one kind of CIS in the cardiology department and another in the urology department. Each department defines different needs and perceives differently the notion of an electronic medical record. Furthermore, some CIS systems allow the department to change the record structure dynamically whenever physicians in the department choose [14]. Issues with legal implications, such as authentication, digital signature, and versioning of documents, are treated differently in 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 systems conform to the new standards such as HL7. However, the number of standard-compliant CIS systems is expected to increase as medical enterprises use networks more frequently and network connectivity requires better conformance to standards.

Models of Lifetime Record Management

Although lifetime records do not exist yet, we would like to present the different possible models for managing such records. Figure 1 illustrates two extreme models of such management. It is important to indicate at this point that a model for the structure of a lifetime record has not been defined even by the new emerging standards. The

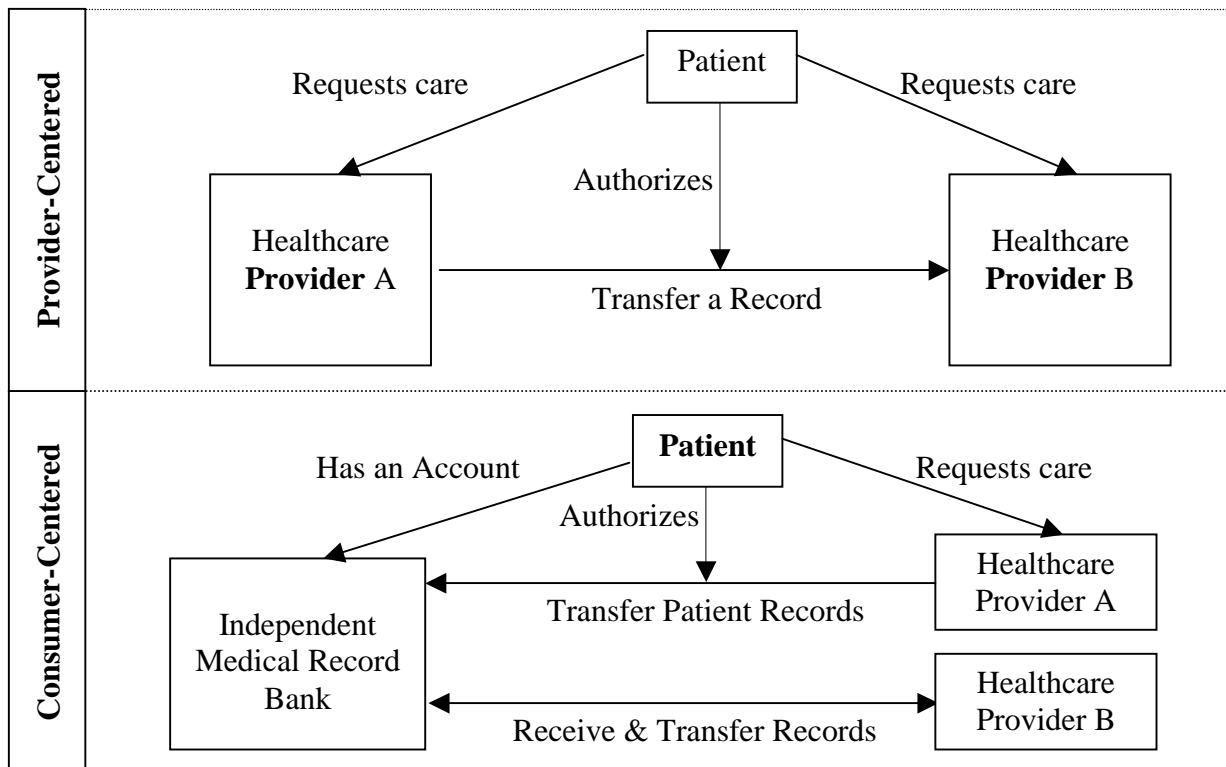


Figure 1: The two extreme models of EMR management: Provider-Centered vs. Consumer-Centered.

CDA standard developers suggest that the collection of all medical documents related to a patient could lead to the patient lifetime record. However, there are many issues that still need to be resolved. For example, the representation of personal genomic data, which is crucial for personalization of treatment in general and medications in particular.

The intensive development of local networks and their interconnection through the Internet is crucial to healthcare because it enables different applications and enterprises to communicate in standard ways, while in the past each enterprise was a kind of closed world and information was communicated via paper-based documents, sometimes hand-written. If medical enterprises, small clinics, insurers and others can connect and exchange information (which mainly relates to their patients/customers), why not connect the health consumers as well?

Connecting patients/health-consumers to the 'medical net' can be done in different ways, two of which are illustrated in Figure 1.

The figure shows two extreme models: The provider-centered model involves connectivity between providers. Provider A transfers the record it created for a patient to provider B, where that patient is now requesting medical care. On the other hand, the consumer-centered model involves an Independent Medical Record Bank (IMRB) that functions as a keeper of lifetime patient records. It serves both the patients and the providers. In this figure, provider B receives the patient record directly from the IMRB where provider A has previously deposited records relating to that patient.

The following sections describe the two models in detail. We start with the provider-centered model that seems to be emerging these days, and proceed to the alternative model that this paper suggests – the consumer-centered model.

The Provider-Centered Model

The provider-centered model is the emerging model these days, due to the rapid development of networking infrastructure in the healthcare industry and the competitive market in which each provider strives to provide better care with fewer expenses. Figure 2 shows a model in which the central role is performed by networking mechanisms, which serve as a hub for exchanging information about

patients between all interested parties. Providers can exchange information directly (if they are on the same network), through an IDS (Integrated Delivery System) that provides connectivity services to several enterprises, or over the Internet.

Currently, the best forerunner of the provider-centered model is the Integrated Delivery System (IDS). An IDS generally consolidates under one corporate umbrella multiple types of healthcare providers serving different aspects of the care continuum (such as hospitals and primary care clinics) [15]. An IDS allows the exchange of information between its members and gives them better terms with insurers, thus increasing the providers' efficacy.

A few technology companies specialize in establishing the technological infrastructure of IDSs, such as WebMD [16]. Although the technological infrastructure of an IDS allows patients to be connected as well and potentially access their medical records, the focus of an IDS is to serve the healthcare providers and make the connectivity between them as smooth and efficient as possible. Obviously these IDS are owned or under total control of the healthcare providers.

A report of the US Committee on Maintaining Privacy and Security in Health Care [17], presents a representative case study of a couple, Alice and Bob, who are insured by a health benefits plan offered by Bob's employer (a self-insured large firm). Alice is diagnosed with hypertension and mild anemia. When Alice becomes pregnant, she develops a condition that her primary care provider wishes to discuss with another physician. At some point the organizations that hold clinical information about Alice are as follows: her primary care physician's practice, a clinical laboratory, the local pharmacy, the pharmacy benefits provider, the consulting physician's practice, the local hospital, the state bureau of vital statistics, the hospital accrediting agency, Bob's employer, Alice's life insurance company, the Medical Information Bureau, the outcomes researcher, and various lawyers. Most of the information was transmitted electronically, some with Alice's explicit consent and some without. This case study shows the complexity of the healthcare processes with regard to the number of entities involved and the importance of connectivity based on networking. Alice has no lifetime medical record, nor can she access her EMRs. From the point of view of the providers and other players the important issue is real time connectivity between all parties involved in the

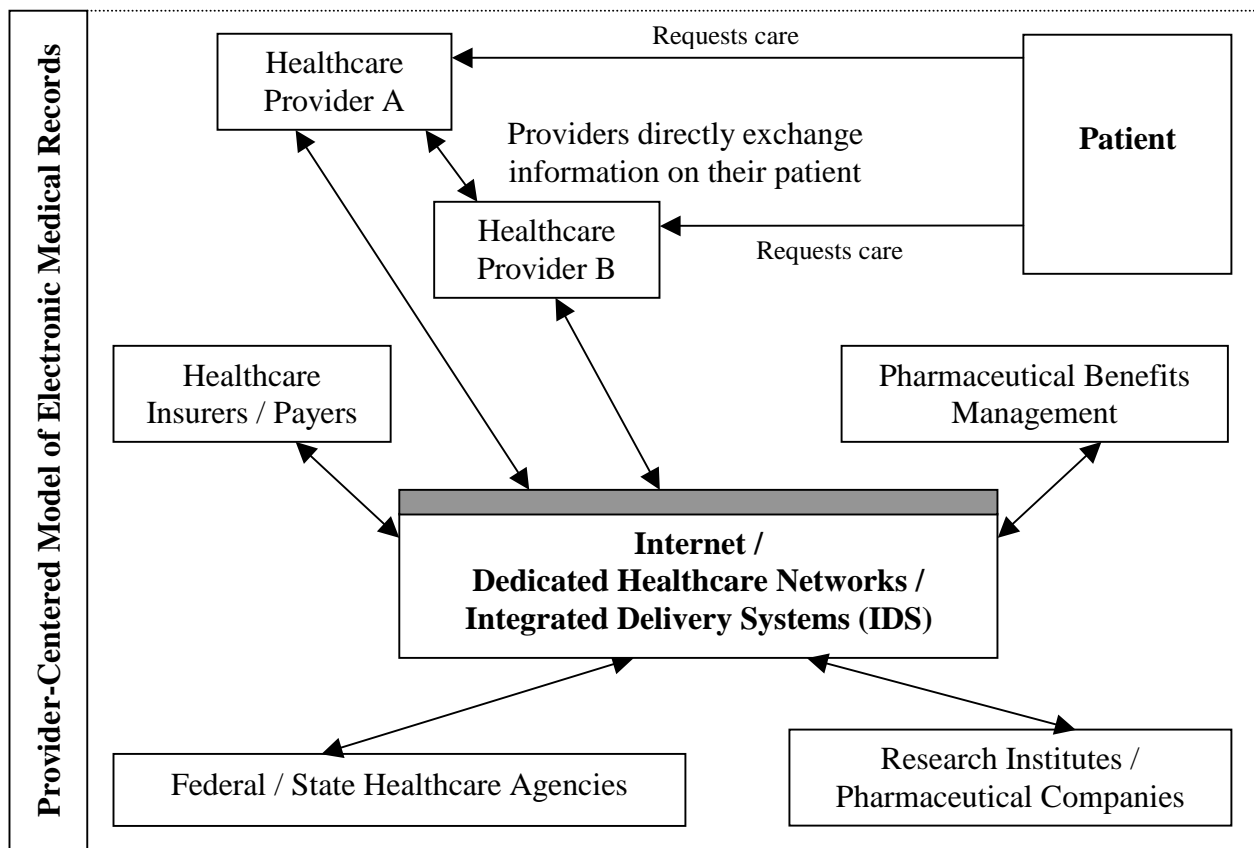


Figure 2: The provider-centered model focuses on the connectivity capabilities of all parties interested in patient records. The clinical information for a single individual remains dispersed.

different transactions, to allow eligibility checkups, claim processing, managed care procedures, and the availability of clinical data at the point of care as well as to researchers and other interested parties. These are the kinds of goals that the provider-centered model is aimed at realizing for the benefit of the various healthcare organizations.

The Consumer-Centered Model

This model includes new entities that we call Independent Medical Record Banks (IMRB), which we foresee will be solely responsible for one main task: managing lifetime EMRs on behalf of their individual customers, i.e., healthcare consumers. They have only one interest – to provide an independent service to all parties who are interested in lifetime EMRs. Figure 3 describes the basic relationships between a consumer/patient, an IMRB where the patient has an account, healthcare providers from which the patient requests medical care, and other interested parties such as insurers, payers, or research institutions. The main role of an IMRB is to serve as the ultimate repository of lifetime patient records. It is very important that an IMRB not have any business stakes in any parties interested in the patients' lifetime record, other than the patients

themselves. Such stakes might lead to conflicts of interests.

Figure 3 illustrates a common scenario in which a patient requests care from one healthcare provider (A) then from another healthcare provider (B). Provider A transfers the records⁴ to the patient's account at the IMRB at the patient's request and authorization. Such an authorization can be issued at the beginning of a series of hospitalizations, for example, and there is no need for the patient to authorize each transfer. Provider B needs the medical history of the patient, who authorizes the transfer of his records to Provider B. In this case, the old record is sent by the IMRB to the provider and the provider sends new records to the IMRB, which in turn updates the patient's lifetime record. If the provider claims reimbursement from the patient's insurer and the insurer requires relevant information from the patient's IMRB, then the patient needs to authorize that access as well. An

⁴ The term "medical record" usually refers to any recording of medical care given to a patient. Since this paper deals with lifetime medical records, we assume that the lifetime record of a patient aggregates all medical records created to describe the care this patient received.

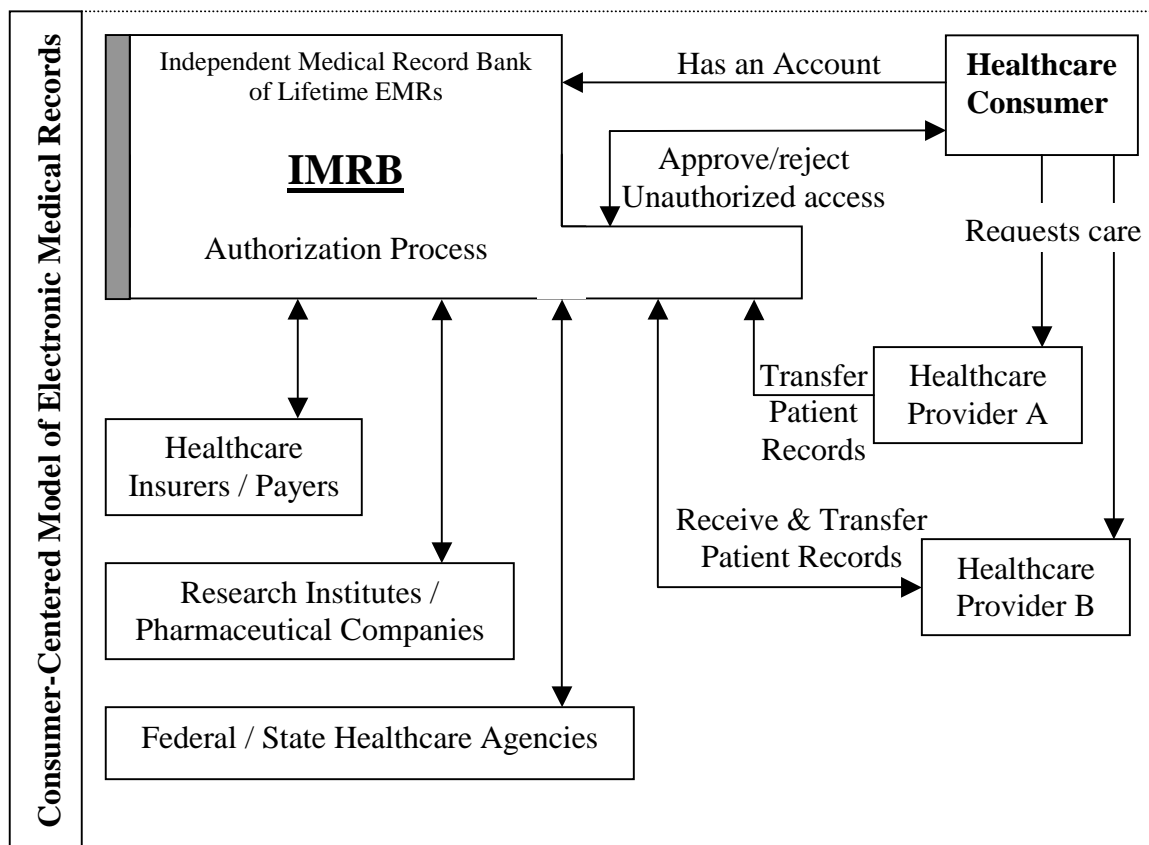


Figure 3: The consumer-centered model focuses on enabling access to lifetime EMRs for the healthcare consumer as well as for all other interested parties.

authorization can be limited by time, type of data, level of detail, and so forth.

IMRBs will have to adhere to very strict rules to prevent unauthorized changes to the medical records. For example, a medical record transferred to an IMRB account by a healthcare provider would be signed by the IMRB in such a way that no one else could change it. This signature could be added on the top of other electronic signatures created by the originator of the record/document. Such records should be clearly distinguished from self-documented records entered by consumers to reflect unreported events or his/her own perspective of a medical encounter where s/he was treated by healthcare professionals⁵.

If a patient sues the provider because s/he thinks the provider caused him/her damages, then the patient's IMRB is obligated to provide the signed record to the healthcare provider being sued as well.

⁵ Adding self-documentation and possibly a personal will, insurance data, and so forth, expands the account to consist of health records and not only medical records. The term 'health record' has a broader meaning that relates to all health issues not necessarily confined to results of medical practice.

There is a need for comprehensive legislation to enable the legal operation of IMRBs. Possible guidelines for such legislation are described below.

Legally, the IMRB record will be considered the most updated source of data and thus, if there are other sources with contradicting details, the content of the IMRB record will be taken as the accurate one. This status of the IMRB record will enforce all interested parties to get their data in line with the IMRB record.

Patients should realize their right to receive copies of their medical records (according to the patient's bill of rights) immediately after a medical document is created. For example, if a patient is hospitalized for two weeks and an operation took place on the fourth day of hospitalization, then the operation record should be transferred to the IMRB immediately after that record was created, i.e., right after the operation was completed. This will ensure that any changes that the provider might want to make in existing documents will not override the original documentation and can be coordinated with the patient.

A patient will be allowed to open a number of accounts in different IMRBs (although this is not recommended because of coherence and

performance issues). However, each signed medical record/document should reside in only one IMRB account. For example, a patient can request that all of his psychiatric records be transmitted to his account at one IMRB and all other records to another account at a different IMRB, but all critical data – such as diagnoses, sensitivities/allergies, and current medications – should be kept in the same account.

A patient will be allowed to move from one IMRB to another and the entire lifetime record should be transferred to the new account upon the patient's request. Each transfer between two IMRBs will always be conducted in such a way that the transferred item will eventually reside only at the target IMRB and thus will be erased from the source IMRB. In this way it is assured that each item resides in only one IMRB.

The availability of the records could be done over the Internet [1] or through a mobile device capable of holding the entire record or only certain parts of the record. For example, a patient can choose to use a mobile hand-held device (e.g., palm device with cellular connection) to make all transactions. Upon a visit to her gynecologist, she could beam the doctor the parts of her record that are relevant for that visit (“the gynecology capsule”), and receive a visit summary from the doctor at the end of the visit. In this case, access to the patient's IMRB account is done through her mobile device and not through the doctor's network. The update of the account is done automatically and a backup is always maintained, which is another important goal of an IMRB. This optional mechanism gives the patient better control over what is revealed to the provider at the point of care, and thus facilitates the patient's right to privacy.

When a patient chooses not to receive a copy of a record created by a healthcare provider, the provider must keep that record according to the local regulations. The patient can still ask for a copy at a later time. If a provider sends the record to an IMRB it is always available for retrieval by that provider. Thus, the provider could use the IMRB for long-term storage. If the patient does not authorize a provider to retrieve the record created by that provider then the provider can refuse care for that patient. As mentioned previously, if there is a legal dispute, the provider is eligible to retrieve the records without patient authorization.

A patient will not be able to close an account unless he asks to transfer his entire record to another IMRB. Closing an account will always be

merely its deactivation in a way that no data can go in or out. It will be the legal responsibility of an IMRB to keep records even after the death of record owners.

An IMRB will be able to receive medical documents or messages that were formatted using any of the common medical standards such as DICOM, HL7, IHE, and CDA. A provider's CIS may have a proprietary structure to represent the clinical data of its patients. If that format does not map to one of the standards, then the provider is obligated to attach all details that were not mapped to the medical standard using a more general data exchange standard.

A lifetime record stored in an IMRB is likely to consist of medical documents created by different healthcare providers. In the case of a legal dispute a provider could retrieve only the documents that it sent to the IMRB. However, the court could order the IMRB to reveal other documents or even the entire record during the trial.

Other Models

A special type of medical provider is the HMO (Health Maintenance Organization). HMOs are entering this market [18] by offering to serve as their customers' record keepers as well as being their insurer and healthcare provider. For example, a major HMO in Israel is now offering its customers access to their records through the Internet and an option to add data to these records from clinics outside of the HMO [19]. The problem here could be that HMOs have contradicting interests and might not act in the best interest of the health consumers [20]. HMOs need to take care of their customers, but at the same time they have to reduce costs as much as possible and protect their employees (i.e., physicians and other healthcare professionals).

Another model that could evolve is one that offers both options – a consortium of medical providers would assure global connectivity and thus the availability of medical records on demand, and consumer medical record banks would keep “copies” of records that their customers received from the providers. The main disadvantage here is that a lifetime record of all the documents regarding a single individual might not be feasible.

Privacy vs. Availability

Privacy is certainly the main concern of health consumers with regard to electronic medical

records. Privacy concerns are raised at the individual level as well as at the public level.

Public concerns about the privacy of individual health information deal with inappropriate use of individual genetic information encoded in the lifetime health record, as well as about aggregation of such information that could be utilized by immoral efforts such as “ethnic cleansing” [28].

Individual concerns about privacy mainly relate to potential misuse of personal information by insurance companies, employers and other organizations that have access to personal health information. Examples include genetic information that predicts the probability of an individual to get sick and potentially high claim rates. For example, a self-insured employer seeking to reduce expenses might not renew an employment contract for an employee whose spouse has been recently diagnosed with a chronic disease and is expected to have a high rate of health claims [17].

All of these concerns should be weighted against the benefits of lifetime records availability. The most common example is the benefit derived in an emergency situation: an individual is injured in a car accident while traveling abroad. She is unconscious and must undergo surgery. Information about drug sensitivities and medical history is crucial to the success of the operation. The availability of her lifetime health record by means of electronic transmission, for example, is essential [21]. Other scenarios include relocation, a request for a second opinion, and telemedicine.

Privacy could be better protected, perhaps, if records reside on a personal computer at the patient’s home or even on a smart card [2], rather than in a central repository such as an IMRB. However, this might make them less available. The different approaches to striking a balance between privacy and availability are:

- (1) Lifetime health records are kept on home devices (e.g., personal computers), which are online at the owners decision. Each lifetime record is completely separate and secured.
- (2) Lifetime health records are kept on home devices (e.g., personal computers), where records of household members are secured within “domestic privacy.” Access rights are based on a domestic unit such as a family. A problematic scenario in this approach is pressure to disclose information that could evolve between husband and wife.

- (3) Lifetime health records are kept at independent entities, such as the medical record banks suggested in this paper and strict personal privacy is kept by the banks. These banks are totally independent of the other players in the field (i.e., healthcare providers, insurers, and so forth) and thus health consumers could perceive these banks as loyal agents, similar to the way we perceive financial banks concerning equally sensitive personal information.

It is important to make these approaches available for health consumers to choose from. The right to have your health information collected is just as important as the right not to have it. Keeping records on home devices, which might not be available when needed, is a risk that an individual has the right to take if protecting his/her privacy is more important to that individual. Furthermore, an individual should have the right not to have a lifetime record and thus each healthcare provider will keep that individual’s records according to its own regulations and local laws (which is the common practice today). On the other hand, if an individual chooses to have all of his/her information maintained in a medical record bank account, s/he should be aware that such a record can not be totally deleted, especially if the healthcare providers (which transmitted the records to his/her account) might need to retrieve that information.

The choice between the approaches should be made by the individual after s/he has been informed of the advantages and disadvantages of each choice, much as the ‘informed consent’ notion in the patient’s bill of rights is implemented when the patient chooses an alternative therapy.

Another unresolved issue regarding privacy is the potential use of slight genetic differences between individuals (e.g., mitochondrial DNA) to replace regular identifiers such as name, address, ethnic information, and so forth. This molecular “bar code” enables personalized medicine for each individual, thus improving the quality of care. In addition it can be used in place of human-readable identifiers, thus better protecting the individual’s privacy. The disadvantages of this molecular identification are mainly focused on the possible abuse of genetic information against an individual or a group of individuals (e.g., an ethnic group [28]).

Summary

A wide variety of organizations hold clinical data in many formats. Most of the clinical data are, in fact, parts of patient records or derivations from that information. It is widely accepted that a lifetime patient record is an important goal to achieve. The main questions that this paper raises are where should such a lifetime record be maintained, who should own it, and who should have control over its accessibility? Two main models were described: the consumer-centered model and the provider-centered model.

The provider-centered model is the emerging model today. Its main advantages are: (1) smooth connectivity between all parties involved in the complex healthcare processes, which could lead to more efficient and higher quality care and (2) it serves well the managed care procedures that many healthcare organization (e.g., HMOs) are trying to implement in order to cope with the increasing costs of medicine. Its main disadvantages are: (1) the clinical data related to a single individual remains dispersed, therefore a single patient record could only be achieved virtually and this “virtual record” is likely to be incomplete; (2) a lifetime patient record is hard to maintain since providers are not obligated to hold patient records more than x^6 years; (3) the history of changes to a medical document within the healthcare provider’s facility is not always maintained properly; and (4) providers may have to develop a “universal patient identifier” to improve patient identification throughout a consortium of healthcare organizations, eventually leading to a unique identifier at the country level, which could lead to breaches in privacy.

The consumer-centered approach involves the establishment of new players in the field: independent medical record banks (IMRBs). IMRBs should be the vehicle used to achieve the goal of a lifetime patient record controlled by the patient. The establishment of such organizations should be preceded by appropriate legislation as well as the creation of an ethical code for the IMRBs. These processes would probably be time-consuming and resource intensive.

We could think of IMRBs similar to the way we think of financial banks. Imagine employees who are told by their employer that their salary is being kept for them within the enterprise in a special account according to their employee ID. They can

withdraw money from that account but cannot receive the entire salary elsewhere. If an employee works in two workplaces then he has two separate salary accounts. Sounds weird... doesn't it? That's the current situation of the healthcare world. The consumer-centered approach could lead to a different situation in which healthcare providers will no longer hold medical records beyond the reasonable scope of a series of visits, hospitalization, medical procedure, and such. Just as most people have a checking account to which they can request a wire transfer of money, each healthcare consumer will have a private medical account opened for them at birth and the “birth record” will be the first record “wire transferred” to their newly created medical account.

A number of IMRBs will compete for healthcare consumers, which will lead to better service; for example, offering an advanced service of interpreting medical records or serving as a loyal and discrete liaison between consumers who might have similar records.

An argument against the consumer-centered approach is that providers are unlikely to cooperate with the IMRBs and this process will be stuck right from the beginning. Indeed, we foresee that in the near future, providers will continue to maintain control over medical records, but begin to exchange patient records on demand. The medical records remain dispersed but, thanks to improved connectivity and widespread agreement between providers, some data related to a person seeking medical care can be located and gathered at the point of care. However, in the long run, there are lifetime issues that remain unresolved in the provider-centered model. For example, according to local laws a medical provider should keep medical records for a certain number of years. What happens afterwards? Who will be responsible for keeping a lifelong record from birth to death and even after death, in cases where cause of death requires investigation? For example, a case in which sensitivity to specific medication was discovered by a medical provider, but this information was not available at the point of care of another provider, where inappropriate medication was given and resulted in death. Also, what if a provider closes its business (mainly a risk with small clinics) – who will handle the records they kept for their patients?

A real chance to solve the dispersed record problem and the need for lifelong sustainability is by moving medical record maintenance out of the providers' hands into a single anchor that belongs

⁶ Depending on local regulations in each country.

to the consumer and is maintained by third-party banks that function objectively and adhere to strict country-level laws⁷. While these independent banks will serve the consumers, they will serve the providers as well by saving them the costs of record keeping and by providing a lifelong record for any person who requests their medical care, thus improving the quality of their care.

IMRBs may also serve the needs of researchers for anonymous medical records. Researchers could more effectively mine an IMRB repository and IMRBs could offer a retrieval service based on records of their customers who grant permission for such access. Independent organizations such as IMRBs are likely to better preserve the anonymity of their customers than the medical providers. More importantly to the researchers, IMRBs will provide lifetime records, whereas other organizations are likely to have only partial views of clinical data.

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⁷ We foresee international agreements (or even treaties) so that persons who live temporarily in other countries (or immigrate) will be able to transfer their records to a local IMRB in such a way that the transferred record will be considered a legal medical document.