

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

Part 2

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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

Methods Inf Med 2006; 45: 498–505

1. Introduction

The introduction of this paper appears in part 1, which was published in Methods 3/2006 [1].

The next section provides 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 record banks) model. The latter was written so that it could be read separately for readers who only wish to understand the IHRB model.

2. EHR Sustainability Models

2.1 Provider-centric Model

A report of the US Committee on Maintaining Privacy and Security in Health Care [2] 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 need for information exchange mechanisms. Alice has no lifetime health record in place, nor can she access her medical records. From the point of view of the providers and other players, the important issue is real time connectivity between all parties involved in the different transactions. This connectivity is required to allow eligibility checkups, claim processing, managed care procedures, and the availability of clinical data at the point of care and to researchers and other interested parties.

The fundamental assumption in this model is that the medical records are kept by the enterprise that created them (as mandated by the current laws) and are made available on demand in response to authorized requests, preferably online. This might lead to a cross-institutional EHR created on the fly; however, the medical records remain in the legal custody of the provider that created them.

The provider-centric model is the emerging model today. For example, the USA Federal Government has recently launched a Health Information Technology program to foster the exchange of information between providers across local communities (LHII^a). At a later phase, this program will also involve the exchange of information across

^a LHII – Local Health Information Infrastructure

different communities (NHII^b) [3]. In the NHII-LHII approach, the current intention is to have each healthcare facility keep the medical records it created. A Regional Health Information Organization (RHIO) implements an LHII and holds metadata and points to the medical records while a National Health Information Network (NHIN) is built on the NHII.

The model's main advantages are: 1) better connectivity between all parties involved in the complex healthcare processes, possibly leading to higher quality of care [4] and 2) serving the managed care procedures that many healthcare organizations (e.g., HMOs) are trying to implement in order to cope with the increasing costs of medicine. This second goal can be achieved by increasing efficiency, for example, avoiding unnecessary testing.

This model has several disadvantages. First, the clinical data related to a single individual remains dispersed; therefore, a single patient record could only be achieved virtually. This "virtual record" is likely to be incomplete, for example, if a data source (e.g., a clinic) is inaccessible because its systems are down or if the clinic is out of business. Second, a lifetime patient record is hard to maintain since providers are not obligated to hold patient records more than a certain number of years^c. Third, the history of changes to a medical document within the healthcare provider's facility is not always maintained properly. Fourth, a unique patient identification mechanism might be needed to improve identification of patients who see different providers. This could eventually lead to a unique identifier at the country level, which would breach the individual's privacy^d [5]. If instead we use patient identification mechanisms, it is important to keep in mind that even though they have a relatively high accuracy, they are

based on heuristic algorithms^e and can still lead to mistakes.

The main drivers of this model are mainly economic and are different from the goals of creating a lifetime patient EHR. Due to the competitive market where each provider strives to provide better care with fewer expenses, providers try to achieve better efficacy by sharing resources via the healthcare industry's rapidly developing networking infrastructure. The two main examples of realizing the provider-centric model are the Integrated Delivery System (IDS) and the concept of LHII (Local Health Information Infrastructure).

An IDS generally uses one corporate umbrella to consolidate multiple types of healthcare providers serving different aspects of the care continuum such as hospitals and primary care clinics [6]. An IDS allows the exchange of information between its members and gives them better terms with insurers, thus increasing the providers' efficacy. 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. Naturally, an IDS is owned or under total control of the healthcare providers, which typically have one major ownership.

The LHII concept is part of the new NHII initiative in the USA and is in fact a broadening of the IDS concept. An LHII is a community-based operation backed by public-private partnerships and is not limited to healthcare providers, rather it encompasses all healthcare stakeholders in the community [7, 8]. During the past decade, the European Commission has funded numerous projects [9] aimed at developing regional health care networks, some of which have similar characteristics to IDS and LHII.

In the near future, it is foreseen that 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, as mentioned above, in the long run, the provider-centric model involves unresolved issues related to the lifelong sustainability of patient records.

2.2 Consumer-centric Model

Another model that is nowadays sparsely being implemented is the consumer-centric model, following the spirit of consumerism. Patients are perceived as the owners of their medical records and essentially as their custodian. Various Internet sites offer health consumers the ability to manage their EHR, typically by manually entering the data they received from their providers. These records are usually copies of summative records such as discharge summaries which are sometimes just the tip of the iceberg for the large amounts of data created during the provision of care. The main disadvantages of this model are 1) the incompleteness of the EHR; 2) the legal standing of the records, which might not be perceived as highly reliable by providers due the way they are kept, i.e., under the control of the patients; and 3) the difficulty in coping with the special situations of patients who could be harmed should they be able to access their records in a totally unrestricted manner.

An important article describing a consumer-centric type of model is the article "Bank of Health" [10]. The authors argue that "*These personal health records would not replace the physician's or the institution's records; rather they would function as personal records that consumers could control and share, all or in part, with whom they choose, and when, where, and how they choose*". This is a fundamental distinction between this type of bank and the independent health record bank proposed in this paper. The Bank of Health model lacks the replacement and independent principles and thus it will be hard to achieve an accurate and complete lifelong health record of an individual.

^b NHII – National Health Information Infrastructure

^c Depending on local regulations in each country

^d For example, see the USA congressional prohibition against creation of a national unique health care identifier which reflects the substantial concern in the general population that use of such an identifier would increase the risk of privacy violations.

^e Heuristics of comparing non-unique identifiers such as names and addresses of two persons in order to determine the probability that these identifier sets actually refer to the same person

2.3 National/Regional-centric Model

The national/regional/community-centric model is centered on the authority of a specific country or region which attempts to establish an authority-oriented operation to centralize its residents' EHRs. The essence of these models is the use of rich metadata in a central location so that queries could be posed to the registry, without necessarily approaching the data sources. For example, the entire header of each source clinical document could be stored in the registry (e.g., the Satakunta project in Finland [11]), or essential data items can be stored in a central repository (e.g., the UK NPfIT concept of a national "Spine" [12]). In any case, metadata sets like the CDA Header or the IHE XDS metadata definition [13] have clinical content and are not merely demographic data. This is fundamentally different than in the provider-centric approach, where the registries (sometimes called index serves) only include pointers to the patients' records. Advantages of the authority-centric model are in the power of the authority to push forward prototypical implementations based on public-private partnerships (with some seed money perhaps). In the regional-centric approach, the national infrastructure is being evolved in a bottom-up fashion in the sense that each region takes care of its tenure residents with the assumption that most of them don't move out of the area. The main disadvantages of the authority-centric approach are: 1) centralized operation that might lead to bureaucracy and inefficiency; 2) the 'big brother' concern, e.g., matching with other databases maintained by the authority; and 3) dependency on interested parties associated with the authority, which could lead to conflicts of interests.

The project health@net [14] is a regional project that strives, in the long term, to break the geographical boundaries and provides similar functionalities of a health record bank [15]. It is carried out in the region of Tyrol in Austria and currently allows sharing of clinical data between hospitals and general practitioners or specialists in that region. Such projects might be the forerunners of the model presented in the next section.

2.4 Non-centric IHRB Model

The models described so far are centered on a single stakeholder in healthcare, i.e., either on the providers, the local authorities, or the consumers. This model is non-centric in the sense that it is not centered on those stakeholders. It assumes the establishment of new entities that are called independent health record banks (IHRBs). These multiple competing banks will be solely responsible for one main task: managing the lifetime EHRs of individuals. They have only one interest – to provide an independent service to all parties that require the use of health records. The main role of an IHRB is to serve as the ultimate repository of lifetime records of its customers. Thus, providers will cease functioning as record keepers because the legal copies of the medical records will reside only in IHRBs. A fundamental principle in this model is that IHRB holders and operators do not have any control over other parties interested in the health records such as providers, payers, pharmaceutical companies, research institutes and government agencies, as it might lead to conflicts of interests.

The current paradigm where each healthcare enterprise holds a legal archive of its medical records should change into the new constellation of regulated independent health record banks, serving as the sole holder of medical records. The change within each healthcare provider is that there is no need to maintain an archive of medical records, thus this component is essentially eliminated in the information systems of healthcare enterprises. Instead, the standard-based communications module has a significant place within the provider information systems. A few providers already use standard-based communications within the enterprise, mainly to bridge between applications deployed by different vendors. After the proposed transition, the communications subsystem will continue to deal with internal transactions, but will deal with the outside world much more intensively and will relentlessly comply with the required international standards.

A common scenario in the new constellation includes IHRBs as new players in the healthcare field. The following steps de-

scribe that basic scenario as well as other possible data exchanges using the IHRBs services:

- 1) A patient has an account in the IHRB of his/her choice.
- 2) The patient requests care from healthcare provider A.
- 3) Provider A transfers the medical records created during that care to the patient's IHRB account upon patient's request and authorization.
- 4) At a later time, the patient requests care from healthcare provider B. Provider B needs the medical history of the patient, who authorizes the transfer of his EHR (optionally embedding the raw medical records) from the patient's IHRB account to provider B.
- 5) Provider B transfers the medical records created during the provision of care to the patient's IHRB account upon the patient's request and authorization. The IHRB updates the patient's lifetime EHR by embedding the newly submitted medical records to the EHR, and more importantly, updates the summative^f (non-temporal) parts of the EHR.
- 6) If the provider claims reimbursement from the patient's insurer and the insurer requires more information – it could be obtained from the patient's IHRB with prior patient authorization. Such an authorization can be limited by time, type of data, level of detail, and so forth.
- 7) Pharmaceutical companies, research institutes, and government agencies that need access to the clinical data, will be able to do it upon patient authorization and in line with local regulations.

IHRBs could be the vehicle used by the society to achieve the goal of a lifetime patient record controlled by the patient. The establishment of IHRBs should be preceded by appropriate legislation^g as well as the creation of an ethical code for their operation.

^f For example, current diagnoses/medications etc.)

^g In June 2006, an "Independent Health Record Banks" legislation bill was introduced in the USA Congress [16].

We could think of IHRBs similar to the way we perceive financial banks. Just as most people have a chequing account to which they can request a wire transfer of money, each healthcare consumer could have a private health record account possibly opened for her/him at birth and the “birth record” will be the first record “wire-transferred” to their newly created account (this record could include essential data from the pregnancy as well).

A number of IHRBs will compete for the benefit of healthcare consumers, which could lead to better services in terms of reliability and responsiveness. Additionally, IHRBs could offer advanced services like telemedicine infrastructure and the summarization of the patient’s medical records within the summative part of the EHR. The latter service is extremely important considering the short encounters (typically several minutes) where the patient is new to the physician in scenarios such as specialist visits, switching to a new general practitioner, ER visits, second opinions and so forth.

The manner in which the longitudinal EHR is continuously updated could be depicted through an EHR Production Cycle: providers send clinical data to the IHRBs, which then update the appropriate EHR based on new incoming data. The next time the IHRB is queried for the patient’s EHR, a current and updated EHR will be returned to the querying provider.

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

Another source of clinical data is the individual. Consumers will be able to add self-

documentation reflecting on unreported events as well as their own perspective of a medical encounter, expanding the account to consist of health records^h 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 practices. This portion of the data is also known as the PHR (personal health record) [15], which is now part of the USA NHIN initiative as well of other national efforts [17].

There is a need for comprehensive legislation to enable the legal and business operation of IHRBs. Considerations for such legislation are described below.

2.5 Legal and Ethical Considerations

This section presents guidelines for the new legislation needed for IHRBs to be established and function. Ideally, the legislation should be international and consistent across different countriesⁱ. Practically, it could be that each country will have its own variation of the IHRB legislation, but still follow the same guidelines presented below.

2.5.1 The Medico-legal Copy

Legally, the IHRB record will be considered the most updated source of data and thus, if there are other sources with contradicting details, the content of the IHRB record will be taken as the accurate one. This legal standing of the IHRB record will actually enforce all interested parties to properly communicate with the IHRBs.

2.5.2 Auditing

IHRBs will have to adhere to very strict rules to prevent unauthorized changes and accesses to the attested medical records. For example, a medical record transferred to an IHRB account by a healthcare provider would be signed by the IHRB in such a

way that no one else could change it. This signing process will be conducted independently of any other electronic signatures created by the originator of the record/document. Such records should be clearly distinguished from self-documented records entered by health consumers.

2.5.3 Legal Dispute

If a patient sues a provider because she/he thinks that the provider caused him/her damages, then the patient’s IHRB is obligated to provide the patient’s EHR to both sides – the healthcare provider being sued and the patient. The IHRB will also provide the complete audit trail of that EHR.

2.5.4 Transfer Timing

The transfer of a medical record to the appropriate patient’s IHRB account should happen as close as possible to the time the record is made available for patient care. For example, if a patient is hospitalized^j for two weeks and an operation took place on the fourth day of hospitalization, the operative note should be transferred to the IHRB as soon as that record is made available^k and not only when the patient was discharged. Nevertheless, while records have not been transferred to the IHRB they are considered the legal copies. Furthermore, as long as the patient is under the authority of the healthcare provider (e.g., is still hospitalized), the local copies of the medical records are considered legal copies as well, even if they have already been transferred to an IHRB. This will allow providers to have the data they created available for patient care, without necessarily accessing IHRBs. This would probably be more important to large providers like hospitals than to small clinics that could significantly cut the costs of short-term storage by always accessing IHRBs.

^j ...and assuming that the patient requested upfront that all medical records created during the hospitalization will be sent to his/her IHRB account.

^k Available for patient care, e.g., is not in edit or creation mode or waiting for the legal authenticator attestation

^h Other examples of health records could be lifestyle data and personal preferences.

ⁱ It is foreseen that international agreements will enable persons who live temporarily in (or immigrate to) other countries to transfer their records to an IHRB in the country of their current residence.

2.5.5 Multiple Accounts

Individuals could choose the IHRB they prefer but would be advised not to open a number of accounts at different IHRBs. Nevertheless, consumers with privacy concerns might still want to have multiple accounts where there is one main account and the others serve confidential information relating, for example, to psychiatric or infectious diseases. Such a situation should be further explored but it is clear that privacy concerns could drive people to open accounts under a false identity. This is the case today with sensitive treatments and operations that people undergo in distant locations and with false identity in order to maintain their confidentiality. In any case, each signed medical record^l will reside in only one IHRB account, because providers will be obligated to send a record only once and only to one account. Nevertheless, the summative^m information in the multiple EHRs might contain similar information as there is typically an overlap in the content of medical recordsⁿ. It is assumed that critical data such as diagnoses, sensitivities/allergies, and current medications will be part of the summative information of the EHR in the main account.

It is important to note that while dispersed medical records are inherent in the current paradigm, in the IHRB model it is foreseen that the number of patients holding more than one account will be negligible. The patient's insurance plan would probably fund only one account so multiple accounts will cost the consumer more charges and eventually may harm the person's own health.

2.5.6 Changing Accounts

A patient will be able to move from one IHRB to another and the entire lifetime record should then be transferred to the new account. Each EHR transfer will always be

conducted in such a way that the transferred EHR will eventually reside only at the target IHRB and thus will be erased from the source IHRB. No duplications will be allowed and the regulator should take care that the information exchange between the IHRBs is conducted properly.

2.5.7 Closing an Account

A patient will not be able to close an account unless he asks for the transfer of his entire EHR to another IHRB. Closing an account will merely involve its deactivation in a way that no data can go in or out. It will be the legal responsibility of an IHRB to keep records even after the death of its customers.

2.5.8 Defaulting

When a patient chooses not to transfer a copy of a record created by a healthcare provider to her IHRB account, the provider must still keep that record according to local regulations (this is also valid in case the account is not available or does not exist). The patient can ask for a copy at a later time as long as it is still kept by the provider. As noted, if a provider sends a record to an IHRB, it is always available for retrieval by that provider, and thus the provider could perceive the IHRB as its own long-term storage. Consequently, it is anticipated that once the IHRBs become ubiquitous, the local regulations will shorten the mandatory period required by healthcare providers for long-term storage of medical records that were not sent to an IHRB. The 'tipping point' will occur when most of the records can be sent to IHRBs and only a small number of records should be persisted. This will be the moment when the burden of medical records archiving will be removed from the healthcare providers.

2.5.9 Access Control

In principle, patients will have access to their EHR and to each of the medical records embedded in the EHR. There will be an option to restrict the access to certain medical records such as the psychiatric ones. This might be needed in two main scenarios: 1) statutory ethical committees

decide that specific information might harm the patient, and 2) the patient would like to keep part of the information confidential. In the latter scenario, the provider receiving the EHR will be notified that not all data items in the EHR are available and the provider will then be entitled to inform the patient that the care provided might not be as good as it could be if the entire EHR was available and that some testing procedures might be repeated unnecessarily.

Healthcare providers will always be entitled to retrieve the medical records they created and transmitted to the various IHRBs. However, they will not be allowed to keep the patient's EHR sent from the patient's IHRB, beyond the time limits of providing care to that patient. Keeping the EHR will be illegal but could also result in using an outdated EHR as the most current EHR will always reside in the patient's IHRB account.

2.5.10 Privacy

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 individuals' health information have to do 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" [18].
- Individual privacy concerns 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 [19] that predicts the probability of an individual to get sick and potentially have high claim rates^o.

^l Created and signed by a healthcare provider

^m Summative information is generated from the medical records by means of extraction, summarization, or topical encapsulation.

ⁿ For example, a discharge summary can describe an operation conducted

^o 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 [5].

These concerns might increase once all health records are aggregated in one place, as proposed by the IHRB vision. However, the concerns should be weighted against the benefits of the availability of complete medical history in general and in scenarios such as emergency, relocation, second opinion, and telemedicine in particular.

Individuals with high privacy concerns might want to have their records reside on a personal computer or a smart card [20], rather than in an online repository such as an IHRB. On the other hand, this might make the records less available as those devices are much more vulnerable and the patient might easily lose or damage them unintentionally.

Keeping records on personal devices [21] is a risk that an individual has the right to take if it seems to that individual that his privacy is better protected in this way. Individuals should make the choice between the approaches after they have been informed of the advantages and disadvantages of each choice, much as the informed consent^p notion is realized when the patient has to choose one of a few alternative treatments.

Another controversial issue regarding privacy is the potential use of genetic differences between individuals and other biometric methods as a way to uniquely identify an individual. Matching these kinds of identifications across systems in various sectors could possibly lead to the abuse of genetic information against individuals. Nevertheless, the vision of IHRBs also eliminates the need for any type of unique identifier since only the IHRB account number^q will be required for identification.

2.6 Business Considerations

The immediate business incentive to move to the IHRB model is reduced costs in long-term archiving of medical records for healthcare providers. The design of the pro-

viders' IT systems will change and focus on operational systems with decision support and other care-oriented components instead of investing in the long-term archiving of medical records for all patients who visited their facility, as required by the current law. Those costs are embodied today in the charges that providers claim. Therefore, the main business transformation is to move those costs to other entities and enable providers to invest more in healthcare rather than in archiving. Those costs will be covered against added value provided by the IHRBs through the availability of lifetime EHRs for the benefit of the consumers and payers.

Once IHRBs are established, their business model will be somewhat similar to that of financial banks. The revenue model of an IHRB will be based on account charges per number of transactions and capacity of storage. It is foreseen that insurers and health plans will include coverage for the basic account charges as it improves the quality of care and thus reduces the cost of claims. Perhaps, there will be extra charge paid by the patient or through complementary health insurance plans when demands are beyond a certain amount of transactions and storage capacity. Another possible coverage for IHRB account charges might be provided by research facilities directly to patients in return for their authorization to make use of their EHRs.

Other optional sources of revenue for IHRBs might include the following:

- IHRBs will charge other interested parties such as pharmaceutical companies, research institutes, and government agencies for providing them with data. Grid services will be developed by consortiums of IHRBs or by other entities to mine and process IHRBs data using the emerging Grid technologies.
- Special services might be provided by IHRBs to their individual customers, such as linking their actual data to relevant educational materials or telemedicine services.
- IHRBs could offer healthcare providers support in transforming their proprietary data to standard representations, as this will be required by the new legislation (i.e., any participant in health informa-

tion exchange should comply with international standards of medical informatics).

2.6.1 Enterprise Data

Healthcare providers will be entitled to retrieve data they sent to different IHRBs at any time and at no cost, for their own enterprise needs (e.g., quality control, clinical research, etc.). However, they will be also entitled to keep the data (or any part of it) in their own repositories, bearing the costs of this storage not as part of the care charges, rather as part of a funded research for example.

2.7 Technological Considerations

An IHRB will be able to receive medical messages or documents that were formatted using any of the internationally recognized information exchange standards such as HL7, CEN, and DICOM.

A provider's clinical information system [22] may have a proprietary structure to represent the clinical data of its patients. If that format does not map to one of the standards, the provider is obligated to attach all details that were not mapped to the medical standard using a more generic data exchange standard [23]. IHRBs will notify their customers when they get proprietary data from healthcare providers, and allow them to look for healthcare providers that comply with internationally recognized standards. Once IHRBs become ubiquitous, it will be impossible for healthcare providers to send proprietary data; therefore, these issues characterize a transition state which could last a few years in order to let providers adjust their IT systems to produce standard-compliant data.

Another important role of the IHRBs will be to communicate effectively with health ontologies in order to map and reconcile medical records that were sent from various sources and comply with different standards, terminologies and templates/archetypes^r. Better use of medical in-

^p The notion of 'informed consent' is one of the fundamental principles of the patient's bill of rights.

^q An IHRB account no. is unique within a specific IHRB (similarly to a checking account no. which is unique in a specific financial bank) but at the same time could be replaced very easily and is not used in any other sector.

^r Templates and archetypes are the means by which the major standardization bodies are trying in these days to express domain-specific data [25].

Table 1 Comparing the centric models of EHR sustainability against the non-centric model of independent health record banks

Model \ Criterion	Independent health record banks	Providers with national infrastructure	Government-operated repositories	Regional metadata registries	Patient-held records (consumer)
Socioethical	Private, regulated, independent	Government-centric	Government-centric	Government control	Patient full control, regulated (?)
Business model	Similar to financial banks Providers cut costs	Government budget	Government budget and medical taxes	Regional operation	Patients pay for holding their records
Custody of legal copies	Legal copies reside in the banks only	Legal copies – in the providers repositories	Legal copies – in various repositories	Legal copies – in the providers repositories	Legal copies – in the providers repositories
Government role	Regulator only	Responsible for the infrastructure	Government operation and budget	Oversees the regional operations	No role
Providers role	Provide health and attested medical records	Provide long-term record keeping of their medical records	Continue to keep records' site-specific data	Provide metadata and long-term record keeping of medical records	Provide copies of the records they created on demand
Patients role	Control the access rights		Review their records and suggest modifications		Responsible for their record
EHR completeness	Potential for completeness	Incomplete a.l.a providers are record keepers	Potential for completeness practically – incomplete	Incomplete as long as providers are record keepers	Incomplete a.l.a providers are record keepers
Privacy – need for unique id	no need for unique id – only account number	Need a patient-unique id	Need a patient-unique id	Need a-patient unique id	No need for unique id
International standard	Highly dependent on international standards	Government could mandate national standards	Government could mandate national standards	Regions could mandate regional standards	Highly dependent on international standards
Feasibility	Need radical preemptive legislation	National priority	National prioritization – big budget	Regional budget	Private – consumer empowerment

formatics will be practiced by IHRBs [24]. For more information about the technological aspects of the IHRBs operation, see the section on Technological Background in the Introduction (in part 1).

3. Discussion

Typically, disparate healthcare organizations hold clinical data relating to the same patient. It is widely accepted that an integrated, longitudinal and cross-institutional health record is an important goal to achieve [26]. According to an ISO definition proposal [27, 28], an EHR is “a longitudinal collection of personal health information concerning a single individual, entered or accepted by healthcare providers, and stored electronically. The information is organized primarily to support continuing, efficient and quality healthcare and is stored and transmitted securely”. A natural extension of this definition could lead to making a lifetime EHR available at the point of care. The main question that this paper raises is

how should such a record be sustained over the lifetime of an individual? Three main models were described, centered on the provider, government/region and consumer stakeholders, respectively. These models were compared to the non-centric model of IHRBs (independent health record banks). Table 1 summarizes the comparison of the models using various criteria such as social, ethical, legal, and business issues along with the role each stakeholder has in each model. The table may help policy makers in countries and regions that consider the development of health information infrastructure, in comparing these models of large-scale EHR implementations. It is strongly recommended that such a comparison be brought up to public discussion before deciding on one model or the other.

4. 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 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 healthcare 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 thoroughly discussed and explored.

References

1. Shabo A. A Global socio-economic-medico-legal Model for the Sustainability of Longitudinal Electronic Health Records. Part 1. *Methods Inf Med* 2006; 45: 240-5.
2. US Committee on Maintaining Privacy and Security in Health Care: For the Record: Protecting Electronic Health Information, part one. (1997). Available at: <http://www.nap.edu/books/0309056977/html/index.html>. Accessed February 28, 2005.
3. Brailer D. Report to the President by the USA Office of the National Coordinator for Health Information Technology (2004). Available at: <http://hhs.gov/healthit/>. Accessed February 28, 2005.
4. Li YC, Kuo HS, Jian WS, Tang DD, Liu CT, Liu L, Hsu CY, Tan YK, Hu CH. Building a generic architecture for medical information exchange among healthcare providers. *Int J Med Inform* 2001; 61 (2-3): 241-6.
5. Yasnoff WA, et al. A Consensus Action Agenda for Achieving the National Health Information Infrastructure. *J Am Med Inform Assoc* 2004; 11: 332-8. DOI 10.1197/jamia.M1616.
6. Rovinson JC, Casalino L. Vertical Integration and Organizational Networks in Health Care. *Health Affairs* 1996; 15 (1): 7-22.
7. Middleton B. The Value of Healthcare Information Exchange and Interoperability. Cornerstones for Electronic Healthcare, 2004. Washington DC, July 20-23, 2004.
8. Karp S. Santa Barbara County Care Data Exchange. Cornerstones for Electronic Healthcare, 2004. Washington DC, July 20-23, 2004.
9. PICNIC – Professionals and Citizens Network for Integrated Care. National and Regional Health Portals: Content – Web-services – Technology – Organisation. (A European Commission funded project in the fifth framework program. Available at: <http://www.medcom.dk/picnic/>. Accessed February 28, 2005.
10. Ramsaroop P, Ball MJ. The Bank of Health: A Model for More Useful Patient Records. *MD Comput* 2000; 17 (4): 45-8.
11. Horsch A, Itälä T, Mikola T, Leonhardt P, Tobman M, Nätscher C, and Sußmann H. CDA-based Integration of a Teleconsultation Service into a Regional Electronic Patient Record System. MIE 2003. Proceedings of the Medical Informatics Europe Congress, May 4-7, 2003, St Malo, France.
12. Spronk R. The NPfIT Spine, an English national programme. 2003. Available at http://www.ringholm.de/docs/00970_en.htm. Accessed February 28, 2005.
13. IHE (Integrating the Healthcare Enterprise) XDS (Cross-Enterprise Clinical Documents Sharing) Profile. Available online at http://www.rsna.org/IHE/tf/ihe_tf_index.shtml. Accessed February 28, 2005.
14. Machan C, Ammenwerth E, Schabetsberger T. Evaluation of the electronic transmission of medical findings from hospitals to practitioners by triangulation. *Methods Inf Med* 2006; 45: 225-33.
15. Kim MI, Johnson KB. Personal health records: evaluation of functionality and utility. *J Am Med Inform Assoc* 2002; 9 (2): 171-80.
16. Independent Health Record Banks Act introduced in the USA Senate and Congress. Available at: <http://thomas.loc.gov/cgi-bin/query/z?c109:S.3454>. Accessed July 4, 2006.
17. Duftschmid G, Wrba T, Gall W, Dorda W. The Strategic Approach of Managing Healthcare Data Exchange in Austria. *Methods Inf Med* 2004; 43: 122-32.
18. Hubbard R, Wald RE. Exploding the Gene Myth: How Genetic Information Is Produced and Manipulated by Scientists, Physicians, Employers, Insurance Companies, Educators, and Law Enforcers. Boston: Beacon Press; 1993.
19. Sax U, Schmidt S. Integration of Genomic Data in Electronic Health Records – Opportunities and Dilemmas. *Methods Inf Med* 2005; 44: 546-50.
20. Aubert BA, Hamel G. Adoption of smart cards in the medical sector: the Canadian experience. *Soc Sci Med* 2001; 53 (7): 879-94.
21. QuickMedical, Personal Health Card. Available at: http://quickmedical.com/LifeStream/smart_card.html. Accessed February 28, 2005.
22. Wendt T, Häber A, Brigl B, Winter A. Modeling Hospital Information Systems (Part 2): Using the 3LGM² Tool for Modeling Patient Record Management. *Methods Inf Med* 2004; 43: 256-67.
23. Bludau HB, Wolff A, Hochlehner AJ. Presenting XML-based Medical Discharge Letters According to CDA. *Methods Inf Med* 2003; 42: 552-6.
24. Ammenwerth E, Shaw NT. Bad Health Informatics Can Kill – Is Evaluation the Answer? *Methods Inf Med* 2005; 44: 1-3.
25. Beale T, Heard S, Kalra D, Lloyd D. The Open-EHR Technical Roadmap. 2003. Available at: <http://www.openehr.org/>. Accessed February 28, 2005.
26. The Good European Health Record (GEHR): Ethical and Legal Requirements, Deliverable 8, October 1993. Available at: <http://www.chime.ucl.ac.uk/Health/GEHR>. Accessed February 28, 2005.
27. Health Informatics – Electronic Health Record Definition, Scope, and Context. ISO Draft Technical Report 20514, Second Draft, August 2003. Available at: http://secure.cihi.ca/cihiweb/en/downloads/infostand_ihisd_isowg1_mtg_denocnt_contextdraft.pdf. Accessed February 28, 2005.
28. Schloeffel P, Jeselon P. Standards Requirements for the Electronic Health Record & Discharge/Referral Plans. ISO/TC 215 EHR ad hoc Group, Final Report, July 2002. Available at: http://secure.cihi.ca/cihiweb/en/downloads/infostand_ihisd_isowg1_finalreportJan03_e.pdf. Accessed February 28, 2005.

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