Medical Smart Card System for Patient Record Management

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Executive Summary (Abstract)

Rising healthcare spending has led to an increase in calls for ways to reduce the cost of healthcare. Amid the debate on the best approach on cut costs in the healthcare system, one of the few bipartisan provisions is the need to integrate modern technology into the storage and transfer of medical records. Current attempts to establish such electronic medical records are challenged by concerns about patient privacy, issues with the incorporation of old records, and budget limitations. We propose the development of personal portable healthcare record smart cards and a corresponding framework to simplify maintenance and transfer of patient records as an incremental step towards a nationalized electronic records system. Our proposal is a feasible and cost-effective system that applies existing technology to address inefficiencies of the current paper based medical records system; simultaneously, it also serves as a transition system to facilitate the adoption of completely electronic medical records.

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1. Introduction

During the second half of the 20th century, the national expenditure on healthcare increased dramatically. As of 2005, over 16% of the US GDP is spent in the healthcare system, and at the current rate it could surpass 20%, or $4.3 trillion, by 2017[1]. Indeed, the United States spends on average six times as much per capita compared to other industrialized nations on healthcare administration[2]. A Harris Interactive Poll conducted in March 2009 reports that over two-thirds of *insured* US adults worry about the cost of healthcare[3]. The need to cut down on the costs of healthcare is widely acknowledged. Despite this urgent need, past efforts to reduce the amount of spending such as managed care organizations, perspective payment systems, and payment per capita have only effected temporary or marginal change[4]. Policymakers are investigating other approaches to mitigate the cost of healthcare, including a universal healthcare system, increased privatization, drug price regulation, and modernized medical recordkeeping. Of these proposals, adopting electronic medical records systems is widely favored as a solution to reduce expenditures[5], and studies suggest they also increase efficiency, minimize medical errors, and improve patient satisfaction[6]. In general, physicians who use electronic records report high levels of satisfaction[7]. It is reasonable therefore to investigate how government policy can aid healthcare providers in transitioning to electronic medical records.

2. Background on Medical Record Keeping

The Oxford Textbook of Primary Medical Care describes medical records as "the information that exists about a patient in a medical service"[8]. Record keeping assists doctors by retaining and communicating patient medical history in a portable, convenient format. Relevant information must be quickly available to allow rapid, effective decisions and reduce unnecessary repeat procedures.

The natural medium with which to record medical history is paper, since it is simple to use, low in cost, and reasonably durable. Information may be quickly added and readily shared amongst health professionals caring for a patient. However, problems arise due to the decentralized nature of the healthcare system; patients frequently visit different offices for dental work, cardiology, and primary care, impeding the necessary flow of medical information. Fragmented, incomplete patient records pose an obstacle to patient care[9]. It is generally agreed that administrative costs are a serious burden, and changes that can alleviate these costs are desirable[10]. An electronic medical records system has the potential to solve the problems of traditional paper records.

The concept of keeping electronic records has existed for nearly 50 years. As Dr. Henry J. Lowe from Stanford School of Medicine reports, institutions have experimented since the 60s and 70s with various forms of electronic recordkeeping. Examples of early electronic systems include Computer-stored Ambulatory Record (COSTAR), Health Evaluation through Logical Processing (HELP), and Multiphase Health Testing System (MHTS)[11]. These pilot programs were discontinued for various reasons ranging from difficulty processing data to inadequate computer technology and high costs.

Recently, electronic medical records have become more popular, but a clear plan remains to be undertaken. To encourage modernizing medical record keeping, President Obama signed the

American Recovery And Reinvestment Act of 2009, which provides healthcare providers up to $44,000 to make "meaningful use" of electronic health records by 2014, after which providers will be penalized in Medicare payments for lack of such systems[12]. There is pressure from the government to transition to electronic health records, yet the stated goal of "utilization of a certified electronic health record for each person in the United States by 2014" is unclear and fails to set explicit criteria. Hospitals acknowledge the inefficiencies of the traditional paper system, but adopting completely electronic medical records requires high upfront investments and it is difficult to quantify the benefits. The healthcare industry needs incremental, economically sound change that provides definite benefits.

3. Criteria for Proposed Solutions

a. Patient Privacy

The Health Information Portability and Accountability Act (HIPAA) establishes national standards for electronic health care transactions and addresses security and privacy of health data[13]. Patient medical records are considered protected health information under federal and any changes or accessions of medical records must comply with HIPAA to maintain patient privacy. Medical information needs to remain accessible to qualified professionals yet inaccessible to unauthorized persons to prevent identity theft or compromise of confidential patient medical history.

b. Accountability

Medical records including physician orders as well as exam and test reports are considered legal documents and must be kept in unadulterated form. Doctors or other professionals may make errors, so it is important to maintain truthful, accurate information regarding patients.

c. Impact on Efficiency

Medical records systems play a fundamental role in healthcare because they communicate patient information between professionals. A bottleneck in this critical process will slow down overall patient care; medical information flow is especially prone to delays because it involves personnel who must physically examine and transcribe data. Optimizing data management reduces costs by increasing throughput.

d. Cost Impact

Healthcare institutions cite "return on investment unclear" and "maintenance costs" as some of the major issues with electronic records systems[14]. To alleviate costs, medical record systems must be interoperable. Existing paper systems must be taken into consideration when adopting any new system to minimize the inefficiencies of conversion between formats. Healthcare providers come from a large range of backgrounds and have access to varying amounts of resources. To be administratively feasible on a national scope, any changes to the status quo must increase long-term savings and have an affordable initial cost barrier.

e. Policy Considerations

Electronic medical records have gained bipartisan support as well as the endorsement of healthcare professionals[15]. Legislation to mandate electronic medical records has already been passed, however lawmakers may seek policies to assist healthcare providers in the transition, perhaps by providing financial incentives, defining achievable criteria for medical records, or deciding on data storage format standards.

4. Option #1 – Status Quo, Traditional Paper Records

Today, medical records are being kept in a variety of formats ranging from folders in cabinets to modern electronic databases. It is common to see computers in healthcare facilities, where many instruments are electronic. A June 2008 study by the non-profit Healthcare Information and Management Systems Society reports that over half of all hospitals have a form of electronic clinical documentation or a data repository[16]. However, this same study notes that about 20% of facilities are at the most basic form of IT usage, and no facilities have reached fully electronic records.

The majority of healthcare providers continue to use the traditional paper based records system. This system has existed for longer than most of our doctors have practiced medicine, and professionals are accustomed to it. The current system is built to maximize patient privacy issues and accountability. The only substantial recent change in criteria is HIPAA, and traditional records are commensurate with this because they are portable (faxable, can be copied), private (lockable, only allow authorized individuals access), and accountable (conspicuous when tampered). Since paper records are already in place, the status quo is inherently the most feasible of alternatives and requires no action.

The problem with the current system lies in the lack of efficiency. Because records are stored in so many formats, and because patients often go to more than one provider, records are often fragmented and the transfer of information between providers is limited. The fragmentation of information leads to higher risk of medical errors, duplicate procedures, and time wasted obtaining information. Consider *Health Affairs*' 2005 report that interoperable electronic record systems could produce savings of $142-$371 billion (see reference 5). Maintaining the status quo beyond 2015 will also lead to Medicare payments loss, 1% for 2015, 2% for 2016, etc. as per ARRA (see reference 12). Paper records place unreasonable burdens on the healthcare industry.

5. Option #2 - Directly Adopt Electronic Medical Records

A system of electronic health records provides an infrastructure where all medical records are digitized, then stored and transferred electronically. Popular companies vendors are fond of publishing reports in favor of using electronic medical records and some like Hewlett-Packard even offer to have lunch with healthcare directors to advertise their products[17]. Big names like Google or Microsoft have offered to handle all the logistics and security. With bipartisan support in congress and the support of industry to digitize patient records (ref. 7), this measure has high political feasibility.

Supposing there was a way to instantly switch to interoperable electronic records, the most evident change reflected on the system would be greatly increased efficiency of recording and transferring data. A valid concern is that working with data would be easier for not only legitimate users but also malicious users. Fortunately, security technology is sufficiently strong, protecting sensitive transactions such as bank transfers, all electronic since 2004[18], and US e-commerce, which rose over $175 billion in 2007[19]. Thus, privacy and accountability are ensured as long as users practice good habits. In regards to cost impact, the $19 billion ARRA package suggests that the government has faith that electronic records will benefit the economy. The only remaining question is integration, a key part of feasibility, because organizations will likely adopt electronic systems at different times.

The current process healthcare providers must undertake to transition to electronic records is long and arduous. An institution needs to select a desirable electronic record system, install information technology infrastructure, train users, and migrate data. An enormous task in itself, transitioning is further impeded by lack of coordination among other institutions. Paper records will exist at least until 2015, the deadline set by ARRA. The need to collaborate with different healthcare services creates roadblocks when patient data systems are incompatible. An article in the American Health Information Management Association's journal is aptly titled "Record Limbo: Hybrid Systems Add Burden and Risk to Data Reporting"[20]. A fully electronic system readily functions within an institution, but causes inefficiencies when dealing with incoming or outgoing information. As such, the electronic-paper connection is necessarily preserved; managing this burden is key to adopting digital records. Even amongst electronic systems the existence of over 38 different record systems[21] surely impedes information flow.

6. Option #3 – Personal Medical Smart Cards

A novel proposal to apply existing technology to an imminent problem

a. Summary of Proposal

We propose developing a personal medical smart card system for maintaining and transferring patient health records. Each patient, if he or she elects to do so, will carry a credit-card shaped personal smart card containing his or her medical records. The data on these cards will not be accessible unless the card is inserted into a special card reader regulated by the government and distributed to registered healthcare providers. When read, the provider will be able to access the patient's medical records and convert the information into the preferred format with which the provider stores patient files. Providers will be responsible for updating the card with any relevant changes. Our proposal of using smart cards as the medium of patient record transfer between healthcare organizations does not depend on the type of database organizations use internally to store information, and it requires no centralized medical record database. Individual patients will possess their records in a convenient form, and professionals can be certain all available records are present. In addition, implementing such a system will effectively begin converting all current paper based medical records into electronic format, serving as a key intermediate step towards transitioning into fully nationalized electronic medical records. We assume an industry-standard level of encryption where it is necessary, and a system of checks to ensure patient privacy. It is suggested that financial incentives be in place to encourage adoption of this system.

b. Technology Discussion

A smart card is defined as a "card incorporating one or more integrated [electronic] circuits within its thickness"[22]. The simplest smart cards are much like the familiar USB pen or thumb drive in a card form factor - a piece of memory on plastic. The smart cards we are interested in are those with microcontrollers that encrypt all information on the card, are tamper proof, and securely communicate with a reader. In regards to reader interfaces, there are two major types of cards: contact cards, where there is physical contact with a reader; and contactless cards, which are read wirelessly with radio frequency identification (RFID). The interface is not particularly important for our application.

In terms of capacity, it is feasible to store medical records on a smart card. As explained by the Medical Board of California, there is no umbrella law on how long medical records should be stored however they are generally retained for at least 7 years[23]. As such, medical record files contain perhaps 50 pages of handwritten text. Assuming 5 letters per word, 8 words per line, 25 lines per page, we require 50,000 letters. A unit of digital storage is the byte, which stores one letter; we require therefore 50 kilobytes. Images, such as X-rays or scan results, require more space depending on resolution; a 6" by 4" color photo at 150 dots per inch requires a little bit over 100 kilobytes[24]. A typical smart card holds 256 kilobytes of data[25], and new high capacity cards hold 4 to 256 megabytes without compromising security. The former, more common smart card is more than sufficient for holding all non-image medical record data and supplementary information. With the newer high capacity cards, many diagnostic procedures like CT scans or X-rays can also be stored (short of video or audio, which consume large amounts of storage).

Durability of smart cards must also be considered. England's official Identity & Passport Service conducted a survey in 2006 that addressed durability questions[26], and the report concludes that frequent-use cards are anticipated to last at least 10 years. Because smart cards are a mature technology, working systems are available as models. 5 year durability of 12 uses/week cards has already been achieved by programs such as Hong Kong's government ID card.

Inherent security of the smart card platform is strong. Smart cards are used worldwide to secure sensitive information. International standards such as ISO 7816 exist that specify physical and electronic implementations of smart cards, and other standards serve to define security interoperability like RSA's Public Key Cryptography Standards. Sophisticated smart cards exist which are extremely tamper-resistant, thwarting unauthorized reading or modification of data or hardware[27]. In addition, integrated circuits ensure mutual authenticity of smart card and reader[28].

An evaluation of smart cards should consider the international use of smart cards for medical applications. France, Germany, and Taiwan are all rolling out smart cards with varying levels of information from healthcare insurance identification to medical records, prescriptions, and hospital admissions[29]. US institutions such as Mount Sinai Medical Center[30] and the University of Pittsburgh Medical Center[31] have adopted similar smart card medical information systems, suggesting that smart card technology is at a state ready to handle sensitive healthcare information.

c. Information to be stored

Each card will contain a photo (also printed on the card), birth date, blood type, allergies, prescriptions, and any other medical information. The data structure can be a modular container to allow addition of new or atypical data fields if it becomes necessary, much as the structure of ID3 tagging allows for appending any data to audio files[32]. Finally, a security log will be kept to record all card activity (see Section e).

d. Improved Maintenance, Upkeep, and Transfer of Data

The card will be a portable, complete source of medical information. If a healthcare provider already has an electronic records system, it is possible to synchronize data on the card with the hospital records every time the card is scanned; any new tests or reports can be uploaded both ways. This also has the benefit of backing up data in case of card loss (see Section e), because it will be easy to recharge all data onto a new card.

To ensure compatibility with paper systems, complete medical record information can also be printed and stored in traditional paper medical record files. These records may be kept alongside the medical card record, and this way a healthcare provider can choose to transition to electronic records when it is ready to do so. Since all records will be on the medical card, transitioning to electronic patient records only requires scanning the patient's medical card.

In case a patient only frequents medical offices that do not support the card, the patient need not take any action; the medical card is optional and designed to only provide convenience. However, a patient might change providers from one which uses the card to one that does not. The patient can have the new provider periodically fax changes to the previous provider, which will update the medical card for a fee. In truth, it may simpler to cease updating the medical card until the primary facility a patient uses supports the medical card.

As a side effect, having a complete medical information record in a wallet provides critical information in case of a medical emergency. Perhaps a patient has an allergy which causes symptoms suggestive of other ailments. Without specific, comprehensive knowledge of an incapacitated patient, doctors may treat the patient with numerous techniques to cover all potential problems and in the process exacerbate the patient's condition. With a card that can quickly be scanned, any ER doctor has all relevant information and can make effective choices for patient care.

e. Privacy, Security, and Accountability

Perhaps the most serious concern with any system designed to manage confidential information is how securely the information will be protected. Fortunately, it is possible to render security compromise highly unlikely by making it unfeasible to steal cards or readers or otherwise compromise the system.

Cards and readers can be regulated and solely distributed through the government. Each organization that purchases a reader can be given an ID number and can be password protected for users in the organization. Besides medical record information, each card can include log of every time data was read, modified, or added. This can be done with a microcircuit in the card

which automatically creates data when a reader scans it, so malicious users with card readers cannot secretly scan a card. The same microcircuit can also prevent deletion of data. On the healthcare provider side, each scan is logged. Therefore, a reliable record will be kept of who scanned what and when, thus maintaining accountability.

To address the issue of lost cards, a central database should be kept of active cards, and nothing more. If a card is lost then a patient will report it and obtain a replacement card. If a lost card is scanned, the card will be deleted. There should also be a central database for valid card readers. Each reader is registered to a specific organization and it must revalidate itself every day from a specific location or else it will shut down and could emit loud noises. This makes theft of cards or readers unlikely, and only unauthorized use of readers at healthcare providers will pose a problem. Suspicious scanning can be identified such as doctors examining patients who do not belong to them, etc.; this is much like the existing problem of personnel reading patient files they are unauthorized to examine.

If it is desirable to let patients view their own record, a special read-only reader can be sold and a PIN implemented into each card. If too many failed scans occur then the card will delete itself.

f. Cost of Implementation

A potential candidate for a medical record smart card which possesses on-card security and authentication is the ASECard[33], which comes with 72 kilobytes of storage and sells for 27 USD/unit (50 card order). A compatible reader costs 41 USD in single quantity orders[34]. With larger quantities and competition amongst vendors, the price should be reasonable for an item with a useable life of up to 10 years.

Besides hardware, it is difficult to estimate software and training costs. However, it is likely that upfront costs will be strongly offset by the savings from simplified data administration. In support of medical smart cards, Paul Contino, VP of Information Technology at Mount Sinai Medical Center, cited a hospital using traditional medical records found 200,000 duplicate records – estimated to cost $60 to $100 per patient[35]. Smart cards as an electronic medical record system can alleviate these problems. In addition, it is not necessary to convert all old records into digital formats because the cards can coexist with existing systems as all institutions gradually ease into electronic records. Detailed records only need to be kept for at least 7 years, so 7 years after adoption of the smart card system, participating patients will each possess a practically complete electronic record of medical information. Coupled with the time savings of electronic records and this reduced need to convert old records, it becomes evident smart cards are very cost-effective.

g. Future Prospects for Smart Card Technology

Although in a mature state, smart card technology will improve. Security methods to protect against attacks are already robust today, but smart cards are likely to become even more secure. The most likely future development is increased storage capacity. Recently the Secure Digital Association has introduced its smartSD product[36], which offers the security features of a smart card but adds 1 gigabyte or more of storage. In the future, holographic media, which allows

volumetric storage (compare to surface area storage as in a CD or DVD), may provide an even cheaper, more efficient storage means. Optware plans to produce 30 gigabyte credit card-sized media for 1 USD each[37]. If industry can couple modern storage media with security microcircuits, medical record cards may one day contain images like X-rays or CT scans or even video like echocardiograms or ultrasound.

Recommendation

The status quo delivers excellent accountability and patient privacy to the healthcare system, but the current state of uncoordinated incompatible internal databases for each healthcare provider is a source of inefficiency. A fully electronic, nationalized, health records system can deliver the same accountability and reasonable privacy as well as increase efficiency. While the system is politically feasible, implementing and administrating such a system is a costly and consuming challenge. We recommend investment into our proposal, a personal medical smart card system, to be implemented in the short term with the long-term goal of transitioning into a fully electronic health record management system. The required technology is available and robust, our system coexists well with the traditional system of healthcare record management as well as a potential electronic medical record management system, is cost effective to implement, and allows institutions to gradually ease into electronic medical records. We recommend government regulated, standardized personal medical cards as part of a portfolio of strategies to ameliorate the burgeoning of United States healthcare expenditures.

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Changrui Xiao and Arthur Yu are both third year undergraduate students at the University of California – Berkeley projected to graduate in the fall of 2009. Changrui Xiao is majoring Molecular and Cell Biology with an emphasis on Biochemistry and Molecular Biology while minoring in public policy. In addition to his studies, he is a member and the armourer of the Cal Fencing Club. Arthur Yu is also a Molecular and Cell Biology Student, emphasizing in Cell and Developmental Biology. Outside of class, Arthur is the founder of Electonic, the electronic music club on campus. Both authors have been volunteering at the Chinese Hospital in Chinatown, San Francisco and are familiar with the medical record management systems in place there. It is through this experience that they realized the need and potential for information technology to make an immediate impact on patient record storage and transfer.

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