

A Long March to Implement the Legally Accepted Electronic Medical Record in Taiwan

An-Jim Long^{a,b}, Polun Chang^b, Da-Wei Wang^c, Yu-Chuan Li^d

^a*Institute of Public Health, Yang-Ming University, Taiwan*

^b*Institute of Health Informatics and Decision Making, Yang-Ming University, Taiwan,*

^c*Institute of Information Science Academia Sinica, Taiwan*

^d*Graduate Institute of Medical Informatics, Taipei Medical University, Taiwan*

Abstract

This paper describes the status and a process review of electronic medical record and its legal issue in Taiwan. The surveys showed electronic signature law is insufficient to legalize the current electronic medical record and emendation of law appears to be a difficult and ineffective task. The feasible temporarily approach and technical framework is also discussed.

Keywords:

Electronic Medical Record; Legal; Electronic Signature; Taiwan

Introduction

In the late 1990's, due to medical record exchanges and referrals, medical information technology and electronic medical records became an important health policy in Taiwan. However, the underdevelopment of related legal issues has obstructed the progress of medical informatics. The Department of Health (DOH) conducted a poll in 2002 pointing out that up to eighty percent of the interviewed hospitals believed that the major obstacles for hospital digitization are immature regulations and vague policies. That is, governmental policies and regulations have the most influence on the implementation of information systems in hospitals.

All hospitals in Taiwan have implemented electronic medical record (EMR) systems of various scopes after the national health insurance was put into practice. However, the administrative order issued by DOH required hospitals and clinics to provide paper medical records signed or stamped by the medical staff involved and these printed papers have to be reserved for seven years. Therefore, hospitals and clinics have to print out paper medical records and sign or stamp the records after the digital information has been saved, which costs a lot of extra time and money.

According to related electronic medical record regulations recently issued by the DOH, electronic medical records, legalized by the Electronic Signature Law, still have to be electronically signed by all medical staff involved, and a time stamp is also required for validating medical records. According to statistics, up to one million records in any one medical center need to be signed each day. The system requirements of legal medical records are much higher than that is required for dealing with the year 2000 (Y2K) crisis; hence, this might be the strictest Electronic Signature regulation in the world. The purpose of this article is to discuss some major issues based on the experience of promoting legally accepted electronic medical records.

Process Review

The electronic signature applied in healthcare can be traced back to 1997, when the Ministry of Economy outsourced studies of implementation and the impact of electronic signature regulations. The application of Electronic Signature Law (ESL) in healthcare can be divided into three major stages (see Figure 1), which are labeled as the Beginning, Preparation, and Campaign.

The Beginning

Before the passage of the Electronic Signature Law marks the Beginning. The DOH and major medical associations held conferences in 1999 to discuss related issues about medical law. One of the resolutions was to reform Medical Treatment Law to facilitate the promotion of Electronic Signature Law. That was the first time the medical field had a formal conference about the legal issues of electronic medical records.

In that year, a poll was conducted to collect public opinions. The result of the poll pointed out that 85% of interviewees supported the use of electronic medical records and 8.2% are against their use. Of those polled, 50% did not trust the security of electronic documents, 47% did not trust the security of paper documents, and 26% did not trust the

security of either. From the result of the poll, the public is still uncomfortable about saving their health data and other private information electronically. Obviously, the government has to consider public opinion to successfully promote the use of electronic medical records.

In a word, the Electronic Signature Law is still a major impact on electronic medical record development.

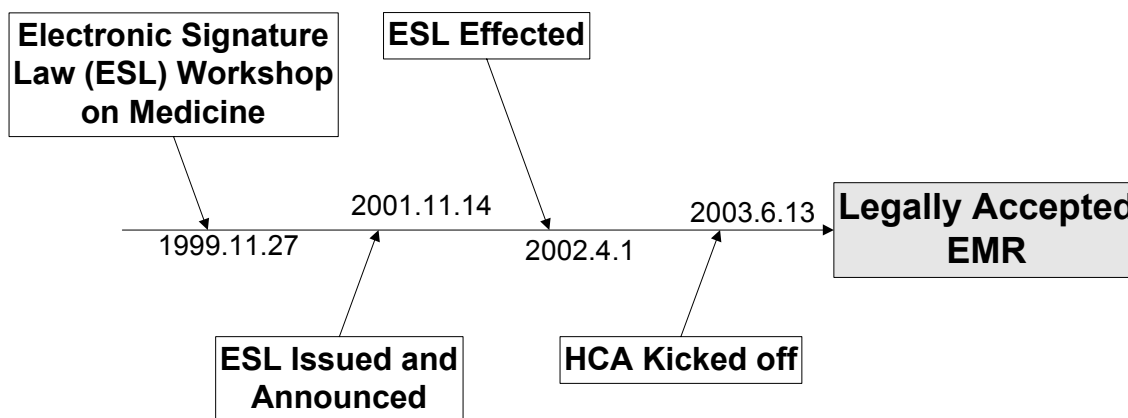


Figure 1 Timeline for promoting the legally accepted EMR

The Preparing

The time between the issuing of the Electronic Signature Law and its adoption is the Preparing stage. During that time, the DOH held several professional workshops and conferences to discuss related issues about applying electronic signature laws to electronic medical records. The following conclusions were arrived at:

- 1) For governmental organizations, a favorable legislation would be to restrict falsification of medical records.
- 2) For hospitals and owners, a less strict and more feasible regulation of hardware and software requirements is favorable.
- 3) In the conferences and workshops, many professionals referred to the Health Insurance Portability and Accountability Act (HIPAA) of the United States as a reference for Taiwan. However, most of the professionals felt that HIPAA mainly covers general issues and has a lack of verifiable regulations, making it an unsuitable reference for Taiwan.

Because the Electronic Signature Law and Medical Treatment Law cover too many professional issues, medical professionals in each session spent too much time clarifying concepts such as the liability of loss or damage of electronic records, the consenting party, and the relationships between doctors and patients (commission or untypical contract).

In the end, the DOH did not establish any regulations. In addition, according to a poll conducted last year, up to 85.0% of those interviewed said that there is no sufficient legal support to promote the use of electronic medical records. Although the Electronic Signature Law has been adopted, 59.4% of those interviewed in the poll did not

believe that it is complete enough to regulate electronic medical record use.

The Struggling

The adoption of the Electronic Signature Law is the beginning of the Campaign stage. Around this period, the Bureau of National Health Insurance began advocating the Health Smart Card. Under the articles of the contract, the contractor voluntarily provided 45,000 free RSA cards. The DOH was planning to utilize those cards and issue 200,000 RSA-based Health Smart Cards covering all healthcare professions, and rename them as Healthcare Professional Cards (HPCs). A Healthcare Certification Authority (HCA) will be established to administer the management of related affairs. The Authority is entitled to read and write information in patient records such as serious illnesses, allergic medications, prescriptions, and related personal private information recorded in the NHI Health Smart Card, and to certify medical information transferred between hospitals and clinics.

In addition, the DOH also sponsors medical centers to invite ancillary hospitals to organize a hospital alliance, in which hospitals may exchange medical records and refer patients to one another, and put HPCs and the HCA into practice. Finally, the DOH outsourced a study called "Establishing and promoting a policy for security and privacy protection on medical information" to study the possible administrative decrees to enact electronic medical record and to prepare for reforming the Medical Treatment Law.

Because of the impact brought by severe acute respiratory syndrome (SARS), most officers and professionals appealed for electronic medical record use and exchange to optimize contagious disease surveillance. Moreover, the governmental sponsorships on implementation and promotion of EMR also advanced the related infrastructure

and technologies. However, the related legal basis for electronic medical records is still absent, and the public is still uncomfortable about the security and privacy of electronic medical records, both of which have become the primary obstacles of promoting the widespread use of electronic medical records.

Remarks

After reviewing the above observations and discussions, the breakthroughs needed to achieve the promotion of electronic medical records can be broke into two aspects: legal and technical. Recommended practices are as follows:

Legal Breakthrough

The agreement reached by legal professionals is that the Electronic Signature Law alone cannot be a legal basis for electronic medical record processes; it can only be a legal basis for managing medical record electronic signatures. The only avenue for legalizing electronic medical records is the Medical Treatment Law, which is under examination for reformation in the Legislative Yuan. The technology neutrality principle described in the Electronic Signature Law refers to any technology that is able to ensure the integrity of information transferred on the Internet, and is able to verify that the user ID can be used as an electronic signature not limited to asymmetric encryption. Therefore, whether electronic signatures and documents can be empowered with the same validity as paper documents with signatures or stamps will be the focus of the Electronic Signature Law.

To legalize electronic medical records with the Electronic Signature Law, reformation of the Medical Treatment Law is the final direction. Due to the statutory sessions in the Legislative Yuan and competition between legislations, the process for reforming the Law requires two to four years. However, the Electronic Signature Law has provided legal power for electronic documents, and related organizations may apply administrative orders to dodge the restrictions of the current regulations. We recommend that the DOH take the following measures:

1) Issue an administrative order to override the regulation of printing signatures when the medical record is issued. The Electronic Signature Law does not regulate that each record should be signed immediately after it is recorded. Therefore, any technologies that provide integrity and identity may be used for authenticating electronic medical records. Securing medical information via the login and access control process, integrating several medical records into one complete record set, and signing the record with an electronic signature might be a legally accepted approach.

2) Establish a cross functional organization to manage electronic medical records and related affairs. In other countries, cross functional organizations will be established to manage regulations dealing with professional technologies such as electronic signatures; these organizations have to be independent and professional. Similar organizations are the Fair Trade Commission

(Taiwan), Federal Communications Commission (USA), and Digital Integration Pattern (Germany).

3) Establish an electronic medical record commission similar to the original medical record commission. Information technology changes rapidly; therefore it is difficult to regulate the technology with traditional regulations. It is appropriate to establish an organization and a flexible mechanism to manage this fast-changing technology. An electronic medical record security administrator should also be trained and authenticated.

Technical Breakthrough

Legally introduce electronic medical records into each hospital and clinic while minimizing the burden resulting from encryption. Apply an encryption mechanism that conforms to electronic signature law without adversely influencing the daily hospital routine. It is recommended to apply standards such as offline encryption mechanisms and Clinical Document Architecture (CDA) or eXtended Markup Language (XML) to marshal an integrated medical treatment record. With the signing of a time stamp, a standard document will become a validated electronic medical record document. All storage, amendment, and reorganization process will automatically be audited and recorded by the system.

Credibility Breakthrough

To make the credibility breakthrough, it is important to assuage public doubts about security and privacy. The recommended practices are:

1) Establish third party authentication organizations to verify and store signed medical record summaries. By doing so, the credibility of electronic medical record verification will be elevated.

2) Select a few hospitals to be exemplary hospitals. A favorable choice would be regional hospitals with a mature information infrastructure and a willingness to implement the electronic medical record system.

3) Eliminate public doubt about electronic medical records by organizing a peer review committee. The peer review committee regularly or occasionally publishes educational information about encryption/decryption, digital forgery tracing technology, and the integrity of electronic medical records. A symbol will be designed to represent hospitals that meet the requirements of electronic medical record laws. Introductory hospitals can provide electronic medical records for people to download on the premise that security and privacy are fortified.

Conclusion

It is a long march for promoting legal electronic medical records in Taiwan. The sluggish lawmaking process is a

major issue, and the Electronic Signature Law is unable to meet different requirements. To promote acceptance of electronic medical records in the society, another important issue is to destroy public doubts about information security and privacy protection.

Acknowledgments

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Address for Correspondence



Dr. Polun Chang. Major in the Decision Analysis, Simulation, Economic Evaluation, Health Information Management; interested in Nursing Informatics, Consumer Health Informatics, and Intelligent Agents; and working on projects of establishing mobile support systems in the ED, building up the mobile Nursing diagnosis support systems, evaluating the quality of health information on the webs, and developing the Post-SARS Public Health Emergency Response Systems. Correspondence address to: 155, Li-Long St., Sec. 2, Taipei 11221, Taiwan/ROC; 886-2-2826-7238; polun@ym.edu.tw.



Mr. An Jim Long, executive director of Taiwan Association for Medical Informatics; major in Electronic Medical Record and its legal issue, Exchanging Standard; interested in Natural Language Processing and working on projects of establishing Semantic-based Intelligent Interactive Knowledge Architecture for the Health Education, building Taiwan Healthcare Information System Guideline. 886-920483196 jimlong@tmu.edu.tw