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Legal Aspects of Interoperability of Electronic Medical Records in Dentistry

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Abstract

Data interoperability of electronic medical records in dentistry in the present time is essential for ease and accuracy of health services. However, it also has the potential to cause ethical and legal problems in Indonesia if it is carried out without regard to the country's laws and regulations. This issue encourages the author to conduct a further research on the legality and the concept of data interoperability of electronic medical records in dentistry in Indonesia. Where to be able to analyze the subject matter well, the authors in conducting research adheres to the paradigm of post-Positivism Paradigm, using Normative-Juridical Research Method where the Research data consist of primary data sources from related Laws and secondary data sources from related literature and analyzed using qualitative descriptive analysis. The results of this study indicate that the data interoperability of electronic medical records in dentistry is legally valid if it meets the requirements contained in Law Number 11 of 2008 and the Regulation of the Minister of Health Number 269 of 2008. The requirement as mentioned are: patients give their consent, guaranteed data privacy security, and original documents of electronic medical records must be kept in the health facility where only medical resumes (medical data) can be exchanged.

Keywords: Legal Aspects, Interoperability Electronic Medical Records, Dentistry.

INTRODUCTION

The development of health information system has provided information support to the decision-making process at all levels of the health care administration. Health service facilities such as hospitals, health centers and clinics have the potential to implement information technology in their health service activities. One thing that can be integrated using information technology is management of medical records [1].

The legal basis for implementing electronic medical records is contained in the Regulation of the Minister of Health No. 269/MENKES/PER/III/2008 concerning Medical Records where in article 2 paragraph (2) explains that "*Medical records must be written, completely and clearly or electronically*". The problem that often arises in the implementation of electronic medical record is that there is no relationship between each hospital in terms of medical record data information as the information only adheres to the respective hospital. This Pose a problem as Information contained in a medical record data consists of several variables data that are very useful for patients, especially during their health treatment process. Currently, medical record data is only stored in one health facility, even though patients can carry out health checks at different hospitals or clinics. If there is no connection between health facilities that patients visit, their examinations will occur repeatedly and can cause a different result on patient health data which could create confusion [2].

The ownership of medical record is often debated among health workers. Doctors assume that they have a full authority over their patients while medical record officers insist on keeping medical record files in their work environment where on the other side, Patients insist on having or reading files that contain the history of their illness. This situation shows that medical records are very important for health facilities and patients. However, we must remember that data in medical records is confidential, sensitive and private for every patient and needs to be kept safe. This need must be considered because it does not rule out the

possibility that health information systems, especially the electronic medical records that have been implemented by health service providers, will have interconnectivity or interoperability with other health care providers everywhere, and not limited by region. With this system, patients can visit any health care provider with the same medical record number anywhere.

Medical record is a set of personal health data that must be brought by an individual wherever he or she goes. It is also called a record of patient's health history. Therefore, the availability of online and offline data interoperability models using web services or smart card technology can make it easy for both the patient and health facilities to obtain patient's medical record. This Technology provides the freedom to get medical record information without having to come directly to the health facility that stores the original source of medical record data.

Data sharing or interoperability of electronic medical record will indeed make it easier for patients to undergo health checks in several health services. However, in practice, the data interoperability of electronic medical record can cause problems. This is because the medical record can serve as legal evidence when there is a medical dispute between patients and doctors as the data interoperability of electronic medical record can potentially cause ethical and legal problems if it is carried out without paying attention to the laws and regulations.

Based on the explanation above, the author intends to conduct a further research on the existing problems, namely:

1. How is the concept of data interoperability of electronic medical record which is in accordance with the legal standards in Indonesia; and
2. How is the legality or legal aspect of data interoperability of electronic medical record in dentistry, Indonesia.

METHOD OF RESEARCH

In this study, the research method that the author uses is a normative-juridical method. With the method, researchers examine issues based on the juridical aspect, i.e. norms, regulations, legislation, legal theories, opinions of legal experts. The specification of research used in this study is descriptive-analytical: it provides a relevant description of the nature or characteristics of a problematic situation in research to be analyzed based on legal theories and general practices of implementing positive law on solving problems.

The type of data used in this research is secondary data, obtained from laws and regulations, official documents, textbooks, academic papers concerning with the research problems. The secondary data in the field of law consists of [3]:

1. Primary legal materials, or main legal materials. They are authoritative, i.e. legal materials that have authority. They include statutory regulations and official documents that contain legal provision.
2. Secondary legal materials. They are documents or legal materials that provide explanations for primary legal materials such as textbooks, articles, scientific journals, research results, scientific papers which are relevant to the research topics, i.e. electronic medical records, data interoperability of medical records, legal aspects of electronic medical records and data interoperability of medical records.
3. Tertiary legal materials. They provide instructions or explanations for primary and secondary legal materials, such as dictionaries, encyclopedias, and cumulative indexes.

RESEARCH RESULT AND DISCUSSION

1. Concept of Data Interoperability of Electronic Medical Records in Dentistry

Along with the development of information and communication technology, physical office documents, including medical records, have gradually been shifted into electronic media or so-called office-documents. Exchanges in office-documents are carried out through electronic transactions using computers, computer networks and/or other electronic media. Exchange of data through electronic transactions can be called interoperability. In the Regulation of Minister of Communication and Information Technology No. 7 of 2013, interoperability is defined as the ability of two or more systems or components to exchange information and use that information [4]. According to the Interoperability Working Group, interoperability requires unlimited access and implementation, including time.

The framework of interoperability aims to define a set of specifications that facilitates electronic systems when interacting with other, both in internal and external environment, efficiently and effectively. Using the framework of data interoperability on medical records will provide benefits as follows [5]:

a) It facilitates health service agencies to cooperate in electronic environment;
b) It creates systems that enrich knowledge and experience sharing among health facilities;
c) It reduces the complexity of processes for establishing online linkages among health facilities using a consistent approach;
d) It reduces dependence on traditional media in data exchange according to respective security policies;
e) It anticipates developmental needs to respond to increasingly diverse services in the future.

In the conventional system, there is no medical record information service among hospitals. Therefore, a more flexible service system needs to be developed. By using the framework of interoperability, we can model an integrated medical record service system. This interoperability model of medical records can be presented in online or offline formats, such as:

a. Web Service

Most researches regarding interoperability and integration between systems within hospitals, or among organizations in health services in Indonesia, use web service technology and XML messages that allow systems to communicate with each other. Amin's research[6] for example, uses a web service in designing a broker that is used for the integration process of medical record data. His research produces a software that is built in a client/server environment with a visual/desktop application model. The system is limited to recording outpatient's medical record.

According to Fehlmann [7], web services are different from websites. Websites are built to have attractive appearances or user interfaces while web services only provide interfaces. Web services are applications that can be called or accessed by other applications via internet or intranet using XML as a message delivery architecture. Web services simplify the application integration process. Web services integrate applications over the internet. Therefore, the user can build web services with .NET Runtime with a little understanding of XML, SOAP, and WSDL [8].

b. Smart Card

It is possible to develop an application that utilizes smart cards as its medium for storing patient's medical record information. With this application, smart cards can be used as a medium for identifying patient's identity as well as a storage for medical record. They can be carried anywhere because they are as small as credit cards. Smart cards have several advantages in terms of reliability, the ability to store a big amount of information, portability, and harder to counterfeit. In addition, smart cards are easier to program, making them possible to be further developed in applications. The use of these applications is expected to speed up the process of patient analysis and diagnosis by doctors. A medical record application utilizing smart cards was developed with the Visual Basic programming language. The application is able to process the data of doctors, patients, and patients' medical records in the database server and execute the reading and writing patient's data and patient's medical record in smart cards [9].

A smart card is a simple card made of plastic, has the size of a credit card, equipped with a microprocessor and a built-in memory. Despite its small size, it has a wide variety of applications for storing data, telephone cards and personal digital identification. Examples of its applications are customer identification, library cards, door locks, and storage for patient medical records.

There are several versions of smart cards that can be used to store data: Microprocessor and Memory. The difference between the two systems lies in the presence or absence of a microprocessor chip in a smart card. In term of reading process, there are also two versions, Contact and Contactless. In the contact smart card system, a smart card reader is used to read the card directly while the contactless smart card uses radio waves (Radio Frequency ID) as its communication technology.

This system uses a memory card with a contact smart card type that uses the ISO/IEC 7816 and ISO/IEC 7810 standards. The standard determine as follows:

1) Physical form of smart card
2) Position and shape of electrical connector
3) Electrical characteristics
4) Communication protocol
5) Format of commands that are sent and responded by smart card
6) Reliability of smart card
7) Functionality

The existence of the standards in this system means that a smart card that contains patient data can be read anywhere by a smart card reader that has the same standards. Smart cards are able to store data up to 256 kb. This amount is better than the magnetic tape technology used in the past. In addition, the stored data can be protected from unauthorized access and manipulation [10].

The working principle of the system as a whole is that medical record process only connects communication between doctors and patients. A medical record process begins when a smart card reader is connected to a smart card. A light indicator will turn on, indicating there is a card being connected. Next, the microcontroller instructs the smart card reader to read the data contained in the smart card. The data, in form of ID cards and treatment code that have been read by the smart card reader, will be sent to the database on a computer. The data will be compared first according to the ID cards and treatment code in the computer's database. Once the data in the smart card and the database are synchronous, the Delphi program will display the patient data form according to the ID cards and treatment code. A data writing process is carried out after the patient is examined. Data on the results of the patient's health examination will be stored in the hospital's database. Then, the computer converts the data from the last examination according to the sequence code in the database. Next, the computer

instructs the microcontroller to send the data in form of code to the smart card reader to be rewritten on the smart card.

2. Legality of Data Interoperability of Electronic Medical Record

In its implementation, data interconnectivity or interoperability of electronic medical records has the potential to cause ethical and legal problems. This is also caused by the absence of specific regulations regarding electronic medical records or the data interoperability of electronic medical records in Indonesia. However, there are several laws and regulations related to the issue so that the implementation of data interoperability of medical records can have a fairly strong legal basis.

Provisions regarding the integration of electronic medical records can be seen in Government Regulation No. 46 of 2014 concerning Health Information Systems. In Article 40 where it is stated that:

1. *Each Health Service Facility must operate its own electronic medical record system.*
2. *The electronic medical record system as referred to in paragraph (1) is not integrated with the electronic medical record system of other Health Service Facilities.*
3. *The electronic medical record system as referred to in paragraph (1) and paragraph (2) must be capable of interconnectivity with health electronic systems and other electronic systems.*

The Government Regulation above emphasizes that electronic medical record systems in health care facilities are not allowed to be integrated with electronic medical record systems of other health service facilities. However, contents of medical record data or medical resume can be exchanged with other health facilities with patient's consent or permission. This is done, of course, for the sake of patient's treatment. This is regulated in Article 12 paragraph (2) and paragraph (3) of the Regulation of the Minister of Health Number 269/MENKES/PER/III/2008 concerning Medical Records. This article states that content of medical record is the property of the patient which is made in form of a summary of their medical record.

Further provisions regarding the data interoperability of contents of medical record can be seen in Government Regulation No. 46 of 2014 concerning Health Information Systems Article 61 paragraph (4) which states that:

"*The dissemination of Health Data and Information is carried out using electronic media, including the use of standard technology in form of Electronic Data Interchange, and/or non-electronic media through activities of provision of access, distribution and exchange*."

In the Regulation, it is emphasized that the interoperability of health and information data can be implemented through the provision of access, distribution and exchange. In addition to regulating interoperability, the Government Regulation also regulates the prohibition and permission of data dissemination. The Government Regulation No. 46 of 2014 concerning Health Information Systems Article 63 states that:

1) Everyone is prohibited from disseminating Health Data and Information to the public in form of:

a. A copy of the Health Service Facility user card or other identity proof;

b. Medical history;

c. Invoices and proof of payment of fees for using Health Service Facilities;

d. Diagnostic examination results;

e. Data and information related to research activities, including:

1. *Identity data of research subjects, both an individual or a group of individuals/society;*
2. *Data and information on research and/or study results which, if open to the public, will harm the subjects, disturb the public and/or threaten the state's security;*
3. *Data and information on research results that are ethically, or as a result of an agreement with research subjects, confidential or kept secret; and*
4. *Data and information that are still in the process of research, procession and/or completion;*

f. Data and information on research results that are still in the process of filing intellectual property rights.

2) The prohibitions as referred to in paragraph (1) do not apply if:

a) A written approval is obtained from an individual regarding the usage of his/her Health Data and Information;

b) They are conducted to fulfill an institution request for research purposes in accordance with the provisions of the legislation; and/or

c) *They are conducted for the sake of law enforcement in accordance with the provisions of the legislation*.

From this regulation, it can be ensured that health service facilities (hospitals, health centers or clinics) are allowed to exchange medical record data on a condition that there must be a written consent and permission from the patient (Article 63 paragraph (2) point a). In addition, the important thing in implementing data interoperability of electronic medical record is the protection of personal data or data privacy. According to Article 2 paragraph (1) of the Regulation of the Minister of Communication and Information Technology Number 20 of 2016

concerning Protection of Personal Data in Electronic Systems, protection of personal data in electronic systems includes protection against the acquisition, collection, processing, analysis, storage, appearance, announcement, transmission, dissemination, and destruction of personal data.

Provisions regarding the data interoperability of medical records are supported in Law No. 29 of 2004 concerning Medical Practice Article 47 paragraph (1) which states that:

"*Medical record documents as referred to in Article 46 paragraph (1) of the PK Law are the property of doctors, dentists or health service facilities while the contents of the medical records are the property of the patients*".

The reinforcement of the legal basis for data interoperability of medical records with patient's permission can also be seen in Article 12 of the Regulation of the Minister of Health Number: 269/MENKES/PER/III/2008 concerning Medical Records which states that:

1. *Medical record files belong to health service facilities.*
2. *The contents of the medical records are the property of the patients.*
3. *The contents of the medical records as referred to in paragraph (2) are presented in form of a summary of medical record.*
4. *The summary of medical record as referred to in paragraph (3) may be given, recorded, or copied by the patients or authorized individuals or with patients' written consent or patients' family member who is entitled to it.*

In paragraph (4) it can be seen that the contents of the medical record data which is a summary of the main medical record may be copied and brought home by the patients themselves. Enabling full interoperability within and between population-based patient- registry domains would open up access to a rich and unique source of health data for secondary data usage. Previous attempts to tackle patient-registry interoperability have met with varying degrees of success, but a unifying solution remains elusive. it must be noted that one important feature motivating the use of this framework is that it can be implemented gradually and independently within each patient-registry domain. By employing linked open data principles, the framework extends the ISO/IEC 11179 standard to provide both syntactic and semantic interoperability of data elements with the means of specifying automated extraction scripts for retrieval of data from different registry content models. The examples provided above are able to demonstrate the feasibility of the approach [11].

New technology is being introduced in hospitals and labs at an ever-increasing rate. The need for "plug-and-play" interoperability – the ability to take a medical device out of its box and easily make it work with one's other devices – has attracted great attention from both healthcare providers and the industry [12].

Increasingly, medical devices like incubators, imaging (MRI, CT, ultrasound, and others) are driven by sophisticated software that must integrate at the point of care and with electronic systems, such as electronic medical records. At the 2016 Regulatory Affairs Professionals Society (RAPS) meeting, experts in the field like Angela N. Johnson with GE Healthcare and representative of the United States Food and Drug Administration provided practical seminars in how companies developing new medical devices, and hospitals installing them, can work more effectively to align interoperable software systems. Therefore, to maintain the current technological advancement, it is possible to implement a medical record resume in form of a smart card. However, the main, original physical form of the medical record belongs to the health facility and must be kept in it.

CONCLUSION

1. The concept of data interoperability of electronic medical records in dentistry meets the regulations in Indonesia which can be presented in form of web service (online) and smart card (offline).
2. The data interoperability of electronic medical records in dentistry has a legal basis if it meets the requirements stated in Law Number 11 of 2008 and Regulation of the Minister of Health Number 269 of 2008. These requirements are: patients give their consent, data privacy security is guaranteed, original documents of electronic medical records must be kept in the health facility and only medical resumes (medical data) can be exchanged.

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