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Legal Study of Electronic Medical Records as a Tool of Evidence of Malpractice Claims in Indonesian Courts

Sobari[1], Henson Gunawan[2]
[1]Universitas Pembangunan Nasional Veteran Jakarta, Jakarta, Indonesia
[2]Universitas Pembangunan Nasional Veteran Jakarta, Jakarta, Indonesia
*sobari@upnvj.ac.id, drsobari987@gmail.com

ABSTRACT

Medical records are a form of administrative service provided by health facilities to patients that must be carried out by health workers who provide services. Various health facilities such as hospitals in big cities in Indonesia already use electronic medical records. In the case of medical malpractice in Indonesia, medical records play an important role in the evidence in court. Currently, there is no specific legal regulation that regulates the implementation of electronic medical record in Indonesia. Legislation in the form of a regulation of the minister of health only regulates medical records in general and there is no standardization and legislation regarding electronic medical record. Various lawsuits against health services or known as malpractice involve evidence in the form of medical records which are opened by court order. In practice, EMR which can be categorized as valid evidence in a medical malpractice case court is only based on the judge's conviction. For this reason, a normative study with a comparative approach was conducted to compare the legislation in other countries as a recommendation for the establishment of electronic medical record regulation in Indonesia in accordance with the rules for establishing legislation, so that they can be used as valid evidences in medical malpractice courts.

Keywords
Electronic medical record, regulation, medical malpractice.

Introduction (Times New Roman, bold, 12)

Health services in the form of medical services, nursing services, and or supporting services provided by health facilities to patients if they do not meet the standards in the regulations will have an impact on quality which leads to patient dissatisfaction. Patient dissatisfaction with the services provided by health facilities is prone to complaints, ranging from minor complaints to health facilities including hospitals, clinics, and community health centres (*Pusat Kesehatan Masyarakat*), complaints in electronic to filing legal claims for alleged medical malpractice.

The data states that 80 percent of malpractice cases occur in hospitals and 20 percent are cases that occur in doctors' offices. Malpractice that occurs in hospitals is not only related to doctors but also involves other services in patient handling procedures. Based on the data of medical malpractice cases that occur can be in the form of civil, criminal and administrative cases. Medical malpractice lawsuits that occur in Indonesia can go hand in hand both civil and criminal according to the legal system adopted [1].

In accordance with the regulations in the medical practice law, it is stated that every doctor or dentist in carrying out medical practice is required to make a medical record. Medical record documents are the property of doctors, dentists, or health care facilities, while the contents of medical records are the property of the patient. Medical records must be kept and kept confidential by doctors or dentists and leaders of health care facilities.

The regulation further states that doctors or dentists are required to make medical records while practicing medicine. Certain doctors, dentists and/or health workers are responsible for the records and/or documents made in the medical record. The medical record file is the property of the health service facility, but the contents of the medical record are the property of the patient. Based on these rules, legally the patient has the right to keep the contents of the medical record confidential and the hospital is obliged to maintain the confidentiality of the medical record data and the doctor in charge of the patient is obliged to make medical record data related to the patient's condition [2].

Medical records that are carried out by doctors, dentists and other health workers have requirements, namely they must be made in writing, complete and clear or electronically. It is stated that the administration of medical records using electronic information technology is further regulated in separate regulations. However, until now there is no legislation that specifically regulates the standard of electronic medical records (EMR) at health facilities in Indonesia that meets the requirements and legal principles in evidence in court. It is important to find out the role and mechanism of regulating electronic medical records as legal evidence in cases of malpractice lawsuits in courts in Indonesia

Literature Review

One of the services carried out by the hospital that is administrative in nature is the medical record service. This medical record service is the obligation of doctors and dentists in Indonesia in accordance with Article 46 of Law Number 29 of 2004 concerning Medical Practice. By this law, medical records are a form of legal protection for

patients as well as for officers who provide health services, including doctors, nurses, and other health workers involved, so that indirectly it is also the key to improving patient safety in these health facilities.

The definition of medical records contained in Indonesian law is a collection of files containing records and documents regarding identity, examination, treatment or therapy, actions and other services provided to patients. The obligation to make medical records carried out by doctors, dentists in carrying out medical practices that must be completed after the patient has finished receiving health services in Indonesia. In making notes in the medical record, the name, time, and signature of the health service provider or action must be included [3].

Organizing medical records is an activity process that begins when the patient is received at the hospital and then continues with the activity of recording the patient's medical data as long as the patient receives medical services at the hospital. Furthermore, the handling of medical record files also includes the administration, storage and release of medical record files from storage areas to serve requests for certain purposes.

Based on the form, there are two types of medical records, namely written medical records or known as conventional medical records, and electronic medical records (EMR). Since the last two decades, the international community has experienced rapid progress in the field of digital technology where the manual filing and documentation administration system has been replaced by a computerized system. The Developed countries such as the United States, the European Union, Australia, New Zealand, Japan, Hong Kong, Malaysia, Singapore, and Taiwan have implemented an EMR system that is integrated into the health information technology system [4]. The EMR system is increasingly important and closely related to the implementation of the national health insurance system and has become a mandate in legislation in developed countries such as the United States that is integrated in the Electronic Health Record (EHR) system. The EHR system is built with standard clinical data collected in the provider's office in order to get a broader picture for the benefit of patient care. The benefits of EHR are easier access to evidence-based tools that providers can use to make decisions about patient care, as well as automating and simplifying provider workflows. By using EHR, errors that occur due to failure to order diagnostic tests or lack of a follow-up plan can be minimized. IT supports clinical decision support and avoids possible omissions or diagnostic errors [5].

In 2009, the United States Congress passed the Health Information Technology for Economic and Clinical Health Act (HITECT Act) that encouraged the conversion of manual medical records to electronic medical records. The rules regarding RME became clearer with the issuance of the Patient Protection and Affordable Care Act (PPACA) which reformed health services and was strengthened by the Health Insurance Portability and Accountability Act (HIPAA) in 2014 [6].

Regulation of Medical Record in Indonesia

Currently still in use is the Regulation of the Minister of Health Number 269 of 2008 concerning Medical Records, which previously replaced the Regulation of the Minister of Health Number 749a of 1989 concerning Medical Records. This rule states the obligations, types and contents of each medical record, procedures for organizing medical records, obligations of health service facilities, the confidential nature of medical records and the benefits of medical records. However, the explanation of electronic medical records which in Article 2 paragraph (2) states that medical records using electronic information technology are further regulated in separate regulations, which until now have not been a specific law (*lex specialis*).

In the case of medical records whose contents become the rights of patients, it is stated in the Act Number 29 Year 2004 concerning Medical Practice. In accordance with the rules in this law, it is stated that every doctor or dentist in carrying out medical practice is obliged to make a medical record. Medical record documents are owned by doctors, dentists, or health care facilities. The contents of the medical record are the rights of the patient. Medical records must be kept and kept confidential by doctors or dentists and leaders of health care facilities. This rule regarding medical confidentiality is of particular concern in

Indonesian law because it is closely related to civil and criminal dispute cases.
Furthermore, regarding medical secret, it is regulated in Government Regulation Number 10 of 1966 on Mandatory Keeping Medical Secrets and Minister of Health Regulation Number 36 of 2012 concerning Medical Confidentiality.

Medical Records as Medical Malpractice Evidences in Indonesia

Medical records play an important role and function in law enforcement efforts, especially in the context of proving medical malpractice as a means of legal protection. The power of legal evidence for medical malpractice cases using the patient's medical record must be on a court order in fulfilling the request of law enforcement officials in the context of law enforcement, as stated in Article 10 paragraph (2) b of Ministry of Health Regulation Number 269 of 2008.
In Article 14 of Government Regulation Number 46 of 2014 concerning Health Information Systems states that “Health data and information sourced from Health Service Facilities obtained from electronic and non-electronic medical records are carried out according to with the provisions of the legislation, but there is no technical regulation regarding electronic medical record which is in accordance with the mandate of Act Number 15 Year 2019 Amendment to Act Number 12 Year 2011 concerning the Establishment of Legislation.
In general, electronic documents can be considered as legal evidence based on Act Number 19 Year 2016 concerning Amendments to Law Number 11 of 2018 concerning Electronic Information and Transactions (EIT Act). It states that information and/or electronic documents and/or their printouts are legal evidence and have legal consequences.
In reality in the trial of medical malpractice civil lawsuits, EMR as legal evidence in court is considered not to have binding legal force and only depends on the judge's conviction [7]. One of the reasons is that the explanation of electronic documents has not been listed in the Civil Procedure Code (*Kitab Undang-Undang Hukum Acara Perdata*). In Indonesian civil procedural law, the type of evidence is mentioned in Article 164 of the *Herziene Inlandsch Reglement* (HIR) or Article 1866 of the Civil Code which states that "So what is called evidence, namely: documentary evidence, witness evidence, suspicion, confession, oath."[8]. The law also states that written evidence is legal and primary evidence.
It has been said that electronic documents as legal evidence and the expansion of legal evidence in accordance with the applicable procedural law in Indonesia. In the explanation of Article 20 of EIT Act, it is stated that electronic transactions occur when there is an agreement between the parties which can take the form of checking data, identity, personal identification number (PIN) or password (password). Electronic medical records are documents made using electronic information technology and it is stated that the obligation to sign can be replaced by using a personal identification number which is explained in the elucidation of Article 46 paragraph (3) of Act Number 29 Year 2004 concerning Medical Practice, but it is not clearly stated in the article of the Act.
Article 11 paragraph (1) of the EIT Act states that “Electronic signatures” (ES) have legal force and legal consequences as long as they meet the requirements : (a) for the existence of related ES, making data only to the Signer, (b) the ES creation data at the time of the electronic signing process is only available in the power of the Signatories, (c) all changes to the ES that occur after the signing time can be known, (d) all changes to the electronic information related to the ES after the signing time can be known, (e) there are certain methods used to identify who the Signer is, and (f) there are certain ways to show that The Signer has given his/her approval to the related Electronic Information.” Regarding electronic signatures, the arrangements, in accordance with Article 11 paragraph (2) of EIT Act, do not yet exist because they are waiting for provisions in Government Regulations.
The provisions of Article 5 paragraphs (1) and (2) of EIT Act have clearly regulated the position of electronic information and/or electronic documents as legal evidence. It states that “(1) Electronic Information and/or Electronic Documents and/or their printouts are legal evidence, (2) Electronic Information and/or Electronic Documents and/or their printouts as referred to paragraph (1) is an extension of valid

evidence in accordance with the applicable procedural law in Indonesia.

In general, the obligation to write, sign and maintain data confidentiality remains in effect. The authentication of the person who inputs the data must be clearly and quickly identifiable. In the discussion of the international health sector, it is in accordance with the requirements of the Joint Commission International (JCI) as an international hospital accreditation body and the application of the Electronic Code of Federal Regulations (e-CFR) Beta Test Site [9].

It is important to draw up a legal regulation regarding EMR so that it can provide legal certainty in terms of proving medical malpractice cases using evidence, one of which is EMR.

Research Method

The research uses a normative legal method which referred to library research by secondary data materials which are the laws, regulations, and legal theories. It is also using a comparative approach to assess legal regulations regarding electronic medical records in various countries, including the United States, Singapore, and Malaysia. The descriptive-prescriptive writing techniques which has a systematic explanation in order to provide recommendations for the establishment of standardized electronic medical record regulations. There are several limitations in this study, especially in understanding legal foreign languages and the differences in legal systems between countries will have an impact on the formation of legal regulations issued.

Results and Discussions

In Indonesia, there are no standard rules for EMR, although it belongs to the term of “electronic documents”. This causes many hospitals in Indonesia, especially big cities, to develop their own EMR only based on their respective perceptions, according to information technology system vendors, without any clear boundaries as a minimum standard in accordance with applicable law in Indonesia. In terms of the legality of EMR until now there is no regulation that regulates EMR as mandated in Article 2 paragraph (2) of the Regulation of the Minister of Health Number 269 of 2008 concerning Medical Records which states that "The implementation of medical records using electronic information technology will further regulated by separate regulations.” Until now, there is no legal rules or regulation that provides a detailed description and standardization in implementing EMR in all health facilities. It should be noted that the legal rules that are drawn up are in accordance with the hierarchy of laws and regulations, as stated in Article 7 and Article 8 of Act Number 15 Year 2019 Amendment to Act Number 12 Year 2011 concerning the Establishment of Legislation. In the formation of laws and regulations, ministerial regulations should not state the arrangements according to matters. The mention of regulation should be in higher laws and regulations, in this case government regulations or presidential regulations.

Electronic information phrases and/or electronic documents as evidence are carried out in the context of law enforcement at the request of the police, prosecutors and/or other law enforcement institutions stipulated by law as stipulated in Article 31 paragraph (3) of EIT Act, which had been declared as The Constitutional Court Decision Number 20/ PUU-XIV/2016) before. In accordance with the content of the petition at the Constitutional Court, the decision is directed to a criminal legal process and not a civil legal process [10].

The legal requirement for electronic documents is that they use an electronic system in accordance with the provisions stipulated in the EIT Act especially in Article 6, namely "Electronic information and/or electronic documents are considered valid as long as the information contained can be accessed, displayed, guaranteed for its integrity, and can be accounted for thus explaining a situation.” However, there are also specificities in the implementation of electronic certification and electronic systems as well as electronic transactions [11].

There are no rules on how to submit electronic documents as legal evidence in court. In this case, there is a vacuum in the procedural law, because the EIT Act and other laws do not regulate the procedure for submitting it in court. The method of submission is important because it concerns whether or not the civil procedure law is applied and in order to meet the element of "guaranteed its

integrity" as stated in Article 6 of EIT Act. Guaranteed integrity means that the form has not been changed since the electronic document was ratified.

In addition, electronic documents containing electronic signatures must meet a number of criteria in Article 11 of the EIT Act, so that they have legal force and legal consequences, and contain security aspects of electronic documents as mandated in Article 12 paragraph 1 of the EIT Act including authenticity, integrity and non-repudiation.

The replacement of the signature by using a PIN on the recording of the EMR in the explanation of Article 46 paragraph (3) of Act Number 29 Uear 2004 concerning Medical Practice is legally not clearly stated in the article of the Act. It is necessary to pay close attention to the justification of the PIN so that it is equated with the validity of the signature and can be juxtaposed as proof of authentication such as the original signature as in conventional medical records.

The replacement of a signature by using a PIN in the EMR recording is legally still having doubts about the PIN can be proof of authentication from the signer because it cannot be categorized as unique and inherent which reflects a person's authentication function. This authentication function must be able to ensure that only the person concerned owns/uses it, so that the PIN cannot be used as authentic evidence in proving EMR [12]. The legal aspect of implementing EMR actually lies in the electronic signature, namely as evidence of authentication for medical data contained in the EMR and must be affixed to every record. This is in accordance with the statement in Article 1 number 12 of EIT Act concerning electronic signatures, which states "Electronic signature is a sign which consists of Electronic information that is attached, associated or related to other Electronic Information that is used as a means of verification and authentication." The validity and authentication of EMR is very important, as one of evidence in law enforcement cases related to medical malpractice.

In relation to the evidence in the Draft Civil Procedure Law (*Rancangan Undang-Undang Hukum Acara Perdata*), which has been drafted since 1987, it does not explicitly regulate or mention electronic evidence, it is only implied in the open arrangement of evidence in Article 98 paragraph (1) of Draft Civil Procedure Law which is stated that "Proof can be done with all kinds of evidence." In terms of proving evidence using electronic documents, it is considered not to have binding legal force but only becomes the judge's belief [13].

Electronic Medical Records as a Tool of Malpractice Evidences in USA and Singapore

The United States of America (USA) has been establish Electronic Health Record (EHR) system that refers broadly about patients' medical information, including information on health and lifestyle beyond episodic medical encounters. It has been developed since 1992. Nowadays EHR are web/client-server-based, by using relational databases, data access and entry screens. Electronic medical records have become parts of the EHR [14].

This process must be defined in a written policy within the Health Information Management (HIM) and there are procedures that support authentication of entries in legal proceedings. The original entry must be viewed, along with date and time stamp, the name of the person who made the change, and the reasons for the change of entry [15].

For EMR authentication, as attestation it must be able to show authorship and assign responsibility for an action, event, condition, opinion, or diagnosis wherein each entry in the health record must be authenticated and traceable to the author of the entry. The Evidence Rule indicates that the author of an entry is the only one with knowledge of the entry. This is in accordance with Federal Regulations/ Guidelines for Interpretation for Hospitals (482.24(c)(1)(i) requiring that there be a method for determining that authors authenticated entries. Where permitted under state, federal, and reimbursement rules, the electronic signature is acceptable as authentication. Electronic signature technology must provide specific verification of the author's identity. In addition, Health Records Certification should be present when requested in legal process of malpractice cases. The certification process verifies that the copy provided is an appropriate duplicate of the original. This certification can be granted by using a written certification letter, stating that the copy

provided is the precise copy of the original. Any State laws may differ in terms of the certification requirements. Generally, a statement and signature of the archivist will suffice. However, some states may require a witness or notary signature as well [16].

In 2006, the Supreme Court approved amendments to the Federal Rules of Civil Procedure, which reflect changes in the discovery process governing the handling of electronically stored information and apply to all litigation in the federal court system. The regulation fundamentally changes the trial preparation process from pre-trial conference through the disclosure process and includes the introduction of new sanctions [17].

This is relevant for doctors because state courts, which handle health care litigation such as malpractice claims, follow, using federal e-discovery rules as a foundation. More than half of the states have enacted or are in the process of changing their rules to address e-discovery. The fact that the role of e-discovery and metadata in health care litigation involving clinical care may be underreported, as cases settled out of court [18].

In addition to increasing the risk of lawsuits, EMR affects the litigation process by increasing the availability of data and documentation to defend or prove malpractice claims. Documentation in electronic form is often organized, detailed and easier to read. Under Federal Law, EMR metadata consisting of all electronic transactions such as clinical activity time stamps and order entries found in civil proceedings is subject to the respective state laws governing most malpractice litigation [19].

In Singapore, public healthcare providers are required to use the 'National Electronic Health Record' (NEHR). Private health care providers may use voluntarily. Under the draft Health Services Bill, all health care license holders will be required to provide information to the NEHR system. Individual health data is uploaded to the system by health care providers, but an opt-out mechanism is created to allow patients to choose not to access their health data, or to upload it entirely to the system [20].

The NEHR becomes a tool of better coordination to perform continuity of care and patient safety. It supports better judgment and decision-making among healthcare professionals through access to patient medical histories including in emergencies. This bill will protect data or limit the circumstances under which data uploaded to the NEHR can be accessed, including the provision of access logs to patients and regular audits of NEHR access, will be implemented to protect against unauthorized access. Penalties will be imposed for unauthorized access. Under the new law, licensing will be service-based taking into new and emerging healthcare models and businesses that are not based in a physical location, such as mobile medical services and telemedicine services [21].

Electronic Medical Record Exchange (EMRX) is an initiative of the Ministry of Health for sharing electronic medical records (EMR) across healthcare companies since 2004 with two public healthcare clusters namely Healthcare Singapore and The National Health Group thus allows sharing in all public hospitals and polyclinics in Singapore including private parties [22].

However, admission of electronic records as evidence in a Singapore court is governed by the Evidence Act (Chapter 97). Article 116A states that it contains certain presumptions, where a party wishes to use electronic records as reliable evidence in court. In particular, courts will consider the authenticity of electronic records if certain conditions are met and if not, there is no evidence to the contrary. Using a certified imaging system (known as an “approved process” under this Act) that has been certified by an independent body appointed by the Ministry of Law (known as a Certification Authority under the Act) to ensure accurate conversion of physical documents to images electronic for those who have a higher risk of litigation. Electronic record-keeping system to be certified as an “approved process” as per Section 116A (6) of the Act. This is not a mandatory requirement, but it will be relevant and helpful if the electronic record system to be certified as an "approved process" by a Certification Authority (commonly known as an Evidence Act certificate), as evidence in Singapore courts [23]. (See table 1).

Table 1. Application of Electronic Medical Records as Legal Evidence for Courts in Several Countries

Specification	USA	Singapore	Indonesia
Law and Regulation	Health Information Technology for Economic and Clinical Health Act (HITECT Act), Patient Protection and Affordable Care Act (PPACA), Health Insurance Portability and Accountability Act (HIPAA)	Evidence Act (Chap 97) Healthcare Service Bill (2018)	Law Number 11 of 2008 concerning Electronic Information and Transactions, updated in Law Number 19 of 2016 Government Regulation Number 46 of 2014 concerning Health Information Systems
Health Information System	Medicaid (National Health Insurance)	Hospital Information System, Telemedicine, e-Health Applications	Hospital Information system, P-care (National Health Insurance)
Electronic Health/ Medical Records	Various EMRs	National Electronic Health Record (NEHR) EMR Exchange (EMRX)	Various EMRs
Electronic Medical records (electronic documents) authentication in courts	May use electronic signature, Health Record Certification,	Evidence Act Certificate (approved process)	Personal Identification Number, electronic signature (not familiar)

Conclusion

With the growing use of information technology in the health sector, there is a need for standardization of authentication of electronic documents, especially electronic medical records which are supported by civil law regulations in Indonesia. So that when legal cases such as civil medical malpractice occur, there is no doubt in proving evidence in court, including the procedure for submitting it in court. A rule regarding Health Records Certification can be drawn up for the legal process. The author also recommends making a Presidential Regulation that oversees the establishment of an Integrated National Electronic Health Records System, including setting standardization of electronic medical records in Indonesia in order to bring greater benefits to public health, especially supporting the quality of health and patient safety services.

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