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# ELECTRONIC MEDICAL RECORD, A MEDICAL SERVICE CHALLENGE IN 4.0 ERA AND ITS LEGAL ASPECT

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#### **ABSTRACT**

**Background**: All people need health services. As a concequences of that, we found great number of patients queue in public healh services. To reduce the patients queue, technology implemented. Electronic medical record is one of technology aplication that able to solve the problem of queueing. Indonesia has no special regulation on electronic medical record. Considering that background, author try to explore problems in implementation of electronic medical record, 1) is the electronic medical record valid as an evidence in litigation process (ethics and law) and 2) is electronic medical record able to provide information needed in patient management.

**Objective**: Justification proofing of ethicolegal judgement in technology implementation of medical record documentation.

**Methods**: This research uses mixed methods design: Quantitative method leading to in-depth ethically reflective method after coherent qualitative result. Populations of the research are outpatients, and the subject of this research are health workers of hospital that use electronic medical record.

**Results**: Electronic medical record used is "computerized" or "automated" medical record. There are some paperless documents, combining with conventional record in implementation.

There is significant difference on accessability and completeness between electronic

medical record and conventional medical record. Electronic medical record able to improve the service quality, in beneficence and non-maleficence principle. There is no significant difference on legal quality between electronic medical record and conventional medical record.

Implementation of automated medical record is an inter phase, before a hospital successfully implement fully electronic medical record.

**Conclusion**: Automated medical record able to improove quality of medical record, based on beneficence and non-maleficence ethics principle. It's needed further investigation to conclude autonomy and justice principle nowadays.

Keywords: electronic medical record, quality, legal quality, ethics.

## **BACKGROUND**

All people need health services<sup>1</sup>. As a concequences of that, we found great number of patients queue in public health services. According to the Medical Praactice Act article number 1, medical services means are places with means of giving medical care which can be used for medical practices or dental practices. Meanwhile, medical practice is activities that is done by doctors and dentists to their patients in the means of giving medical attention<sup>2</sup>. According to the form, there

are two kinds of medical practice: solo practice and collaborative practice. Collaborative practice can be a clinic or a hospital.

Every medical practice in Indonesia is practiced based on Pancasila value and based on scientific, utility, justice, humanity, and balance value; and also protection and safety of patients (article no. 2 UU Medical Practice). Those make a unique relationship in medical practices. This unique relationship between doctors and patients differs itself from any other service recipients and providers. This unique relationship is called therapeutic transaction. The regulation of medical practice is made to regulate a good relationship in this therapeutic transaction between doctors and patients, and to assure the rights and obligations between doctors and patients. This regulation is made to give protection to patients, to maintain and improve the medical service quality given by doctors and dentists, and also to give legal certainty to the community, the doctors, and dentists (article no 3 Medical Practice)<sup>2</sup>.

Medical services in its implementation do not only involve doctors as health workers, but also involves other health workers. Health workers are everyone that serve themselves in medical field and also have the skill and knowledge from formal education of medicine, that for some requires authority to give medical attention (article no 1 Health Act)<sup>3</sup>. Many research proofed that there is a gap between cities and countryside and also between areas, which means that medical services isn't well distributed<sup>4</sup>.

Quality of health care service depend to many indicators. Some incicators refer to patient safety, patient satisfaction, fast response in patient management, length of stay in-patient, and medical goals achievement.

Considering the condition in Indonesia, it's not rare to find a long queue in public medical service places. The public medical service places in this context are ones that is mostly owned by the government, that gives services using universal coverage of national health system or national health insurance. Meanwhile, according to a research covering patients' dissatisfaction of government maintained hospitals, one of the causes of patients' dissatisfaction is that it takes too long for a patients in a polyclinic to go from registration to entering the examination room<sup>5</sup>. The researcher said that patients' dissatisfaction means that improvement on medical services quality needs attention in the form of new innovations to make the public medical service better, one of which being implementing electronic medical record that is already being implemented in several areas in Indonesia according to World Health Organization (WHO)<sup>6</sup>. The implementation of medical record is not only to satisfy patients more by shortening the waiting time for them, it can also make the medical record quality better medically and legally, considering that medical record function is also very significant in giving medical services.

# **OBJECTIVE**

The brief explanation of the background above gives basis for researcher to propose research questions as follows:

- 1. How is the implementation of electronic medical record in hospital?
- 2. How is justification proofing of ethicolegal judgement in technology implementation of medical record documentation?

The first question is explored using quantitative research. The second question is explored using qualitative research and reflective study.

#### **METHOD**

This research uses mixed method design approach. Mixed method design is quantitative method leading to in-depth ethically reflective. This research consists of three phases with three designs that is designed to strengthen one another.

Quantitative study is performed use observational research design. Researcher takes measurement without doing intervention. Measurement is performed once (cross sectional) to see the general description of electronic medical record implementation.

The population in quantitative study of this research is patients that got treatment in government maintained medical service place that can be reach by all members of the community. The population of this research is divided by two. First one is from the hospital that had implemented electronic medical record (Dr. Soetomo Hospital) and the second one is from the hospital that is still using conventional medical record (Dr. Sardjito Hospital).

Sample is taken from outpatient unit in surgical section and pediatric section. The reason of choosing outpatient unit is because the electronic medical record is still only implemented in outpatient unit in the place where the research is being done. Sample is chosen by computerized random sampling.

The instrument in quantitative study of this research is questionnaire. The questionnaire being used in this research is dichotomy, with "yes" or "no" as the answers. The questionnaire is medical record quality questionnaire which is being filled by the health worker, completed with checklist for document analysis filled by the researcher.

Qualitative study of this research uses phenomenology as the qualitative research design. This design is considered right for researches based on four truths, which is sensual empiric truth, logical empiric truth, ethical empiric truth, and transcendental empiric truth.

Research is done in Dr. Soetomo Hospital Surabaya East Java for electronic medical record and DR. Sardjito Hospital Yogyakarta for conventional medical record. Those two are chosen because both hospitals are type A hospital and main educational hospital, which is about ideal. The research is done in 18 months.

The last step of this research is reflective study, which consists of thought framework and researcher's opinions, ideas, and concerns.

#### RESULT

To measure the medical record quality, the parameter is according to the legal basis of medical record which is Medical Practice Act and Indonesia Ministry of Health (MoH) Regulation number 269/MENKES/PER/III/2008 regarding medical record<sup>7</sup>. The questionnaire is dichotomy with "yes" or "no" as answer because the variable is discreet, also known as nominal variable or categorical variable because it can only be categorized as "yes" and "no".

In accordance with the data achieved from this research which is medical record, the approach being used is content analysis. Content analysis is any technic to get conclusion by trying to get the message characteristic, performed objectively and systematically<sup>8</sup>.

The next step, the data from the quantitative study is coded and scored to later be made into tabulation and be tested with normality test. Then, the data is analyzed with t-test and Mann-Whitney test <sup>9,10</sup>.

Electronic medical record documentation covers the software model of the electronic medical record and the institution that developed it, medical record input time, paper based file presence, periodic back up file presence, inputter staffs, written delegation for inputter staffs who

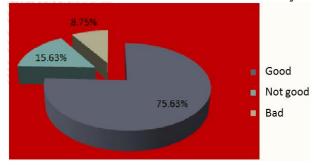
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is not a doctor. Conventional medical record documentation covers medical record input time, inputter staffs, written delegation for inputter staffs who is not a doctor, medical record saving model.

There are two kinds of medical record, electronic medical record and conventional medical record<sup>7,11</sup>. Electronic medical record develops along with science and technology advancement in medical field. Computerization process is also developed, one of which is in medical documentation field in form of electronic medical record.

There are several kinds of medical record: electronic health record, automated health record, electronic medical record, and computer-based patient record. Automated health record is conventional health record that is scanned and saved in optic disks. Electronic medical record contains patient detail identity, procedures, receipts, lab results, and all health information of the patient that is recorded by the doctor each visit. In some countries, such as Korea, patient's clinical information is being inputted by health workers in the treatment place. Computer based patient record is a compilation of medical information for each patient that is linked with administration officers, which consists of patient's registration, admission, finance, treatment record, laboratory, radiology, pharmacy, that can be made from one visit or a certain period of inpatient. Electronic health record contains all medical information of someone, that can be inputted and accessed by medical care providers for as long as the patient lives, consist of all of the treatment that had been received by the patient<sup>6</sup>.

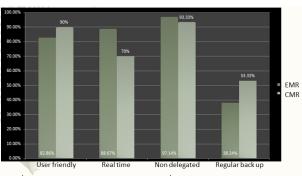
Medical record availability covers medical record searching difficulty and speed, which is measured with questionnaire. Availability of electronic medical record is 100% good. The documents are ready in the real time access. Figure 1 show that availability of conventional medical record only 75.63% include in good category. Conventional medical record need time to collect from the storage. Mostly of them can be found but time consuming. Thirty percent of medical record in Surgery department and 18.75% in Pediatric department cannot be found real time.



**Figure 1.** Conventional Medical Record Availability

Medical record documentation is measured with checklist and questionnaire. Figure 2 show medical record documentation. There is significant difference between electronic medical record and conventional medical record in overall documentation. More doctors did not agree that electronic medical record is user friendly. Electronic medical record has benefit in real time documentation and non-delegated documentation. To fulfill the medical record is doctor's obligation. It must be real time, before doctor manages another patient. Electronic medical records push the doctors to do in real time by themself.

Figure 2. Medical Record Documentation



Kolmogorov-Smirnov p = 0,016, Mann-Whitney test p = 0,0008

Research found that 68,86% EMR still non paperless. Doctors make back up in conventional medical record for legal protection reason. They do double medical record for patient who get high risk procedure. Some sub divisions also make paper additional data for some specific/more detail examination. This data documented in sub division office conventionally.

Document analyses show that completeness of medical data in electronic medical record is better than conventional medical record, and there is significant different between EMR and CMR (Mann-Whitney test p=0,0000, normality test K-S p=0,0000). Document analyses also proof there is no significant different between EMR and CMR in legal quality (Mann-Whitney test p=0,5226, normality test K-S p=0,0000).

Essentially, medical record is a data source that can be used for many concerns. Considering that the data is a very private and confidential, the usage of medical record is strictly regulated. According to Indonesia MoH Regulation number 296/MENKES/PER/III/2008, medical record can be used as a basis for patient's medical care and treatment, as evidence in a law enforcement process, medical and dentistry discipline, for enforcement of medical and dentistry ethic, for research and education purposes, as a basis for medical service payment, and as a data source for medical statistics<sup>7</sup>. Medical record has the same function in medical and law concerns. If a medical record is not created and saved adequately, it will bring difficulty in patient treatment that ultimately disadvantages the patient which is a negligence<sup>10</sup>. The usage of patient's medical record must be of patient's consent<sup>12,13</sup>.

Medical record will do its function only if the document easily access, available anytime it's needed, and can give valid real time information. Figure 3 show how is the medical record can be read obviously, so every health worker can get valid information from that document, and the medical record give its function to medical service properly. Less than 50% conventional medical record can be read obviously by another health worker.

According to Waters and Murphy, medical record definition is a compendium filled with information about patients' condition during their treatment or during medical care. According to Indonesia Medical Doctor Association (Ikatan Dokter Indonesia), medical record is a record in form of writings or description of service activity which is given by the medical service provider to a patient<sup>14</sup>. According to Medical Practice Act and Indonesia MoH Regulation number 269/MENKES/PER/III/2008 about medical record, medical record is a file filled with notes and documents about patient's identity, examination, treatment, procedure and any other services that had been given to the patient<sup>2,7</sup>.

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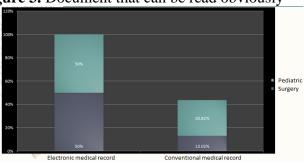


Figure 3. Document that can be read obviously

Phenomenological research tries to unveil concept's meaning or experience phenomenon that is based by some individual consciousness. This research is performed in a natural situation so that there is no limit in giving meaning or understanding the phenomenon that is being studied <sup>8</sup>. According to Creswell, phenomenological approach delays any judgement about natural attitude up until certain basis is found. This delay is usually called epoche (suspension). This epoche concept differs data (subject) with researcher's interpretation. Epoche concept becomes the center in which researcher constructs and groups initial guess about phenomenon to understand what is being said by the respondents <sup>15</sup>.

Data in this study is achieved by in-depth interview and focus group discussion. The population in qualitative study of this research is grouped into two, health workers group and IT officer group. The sample being used is judgement sample, also known as purposeful sampling, which is sample selection according to sample's capability on giving relevant information and sufficient on answering research questions. The basis of the sample selection considered to be able to give relevant information to answer the research question are practical knowledge of the researcher of the research area, according to literatures, and also the preliminary data for the research itself <sup>16</sup>.

The instrument of this research is interview guideline in the form of open questions related with more operational explanation of things that had been studied quantitatively. The data from this qualitative study is processed with data transcription, data codification, data categorization, temporary inference, triangulation, and final conclusion<sup>17</sup>.

In a research, important notes from the whole research process consist of two important matters. First one is the descriptive part which consists of descriptions about observation background, people, actions, and talks. Second one is the reflective part which consists of thought framework and researcher's opinions, ideas, and concerns<sup>8</sup>. The first part which is descriptive part is reviewed in quantitative and qualitative study, while the second part which is reflective part needs in-depth thinking (reflective study).

That research that highlights the implementation decision problem of a policy for the community is loaded with ethical content and should be accommodated in legal space to ensure the fulfillment of that need and the protection towards every part that is involved in that interaction. Reflection study of electronic medical record implementation ethical decision is done with considering its benefit for patients in Indonesia.

Basic moral principles in medical record implementation also include respect for patient autonomy, beneficence, non-maleficence, and justice. Respect for patient autonomy principle requires health workers to respect patient rights in taking choices and also ensuring patient confidentiality. In making medical choices, patient should be involved and the choice must be

made by considering patient's needs, wishes, capability, and also safety <sup>18, 19</sup>. In medical record implementation context, medical record should be a tool to help ensuring patient safety and should also be kept confidential.

Beneficence principle requires every health worker to act for patient welfare, for others' benefit and not their own benefit <sup>18, 19</sup>. According to this principle, doctors should give the best service according to patient's needs.

Non-maleficence principle requires all health workers to keep their patient from everything that could harm the patient. For that, doctors should apply the right knowledge and skill in treating patients, including updating their knowledge and developing medical knowledge in accordance with the current development <sup>18, 19</sup>.

Justice principle requires health worker to treat everyone justly. Justice in this context includes fairness, rightness, equity, and integrity. Justice is not only about equity but also take account on priority in accordance with each importance <sup>18, 19</sup>. In medical record context, medical record should be beneficial for the community as a source of plague condition, and should also function optimally and has authenticity so it can be used as evidence in law enforcement.

Data shows that electronic medical record offers many benefits to us in improving health service. Fast access and valid information can make shorter long line of patient avoid patients from nosocomial infection. Data pool and easy access of valid data make faster all the process, since the admission to the patient release. Fastest process and shorten long line of patient will improve quality of service and patient satisfactory. Basic moral principles were accommodated in implementation only by strict regulation and willingness all team that has access to the medical record to follow highest standard of morality.

### **CONCLUSION**

- There is significant difference on accessability and completeness between electronic medical record and conventional medical record.
- Electronic medical record able to improve the service quality, in beneficence and non-maleficence principle.
- There is no significant difference on legal quality between electronic medical record and conventional medical record.
- Implementation of automated medical record is an inter phase, before a hospital successfully implement fully electronic medical record.

## **Ethical Clearance**

The ethical problem of this research is more on the institutional ethic, because this research involves policy implementation in public service. This research is not experimental and intervention towards individuals. Before this research is done, an ethical agreement is made by Medical Faculty of Universitas Gadjah Mada's Ethic Committee and Dr. Soetomo Hospital. The hospital is asked for written consent before taking data, and the data taken is kept confidential within applicable limits<sup>20</sup>.

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