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Implementation of E-Medical Record Regulation: Issues and Challenges in Indonesia

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Abstract

Recently the Indonesian Ministry of Health issued a Regulation of the Minister of Health Number 24 Year 2022 concerning Medical Records, which requires all health service facilities in Indonesia to carry out Electronic Medical/Health Records (EMRs/EHRs) by December 31, 2023. This paper will discuss several issues and challenges that must be faced by health service facilities in Indonesia to adapt to their obligation to maintain EMRs. Considering the regulation, healthcare facilities that do not comply with this regulation will be subject to administrative sanctions. Furthermore, regarding EMR compliance, personal data protection violations can be subject to criminal sanctions. Are implementing EMRs a subtle policy, given Indonesia's geographic and demographic conditions, the need for massive infrastructure preparation, the lack of basic health facilities in several remote areas, and the lack of human resources? Are healthcare facilities and practitioners in Indonesia ready to use an EMR-mediated world? And would it be sufficient time to realize it?

Keywords: *E-medical records, personal data protection, the right to health*

BACKGROUND

In today's transformed world, information technology plays a pivotal role in every person's life. As a result, several new vocabularies related to IT developments recently are developing, such as social media, e-commerce, e-books, e-courts, e-health, e-doctors, etc. The health sector is one of the fields that has been significantly affected by IT developments. During the Covid-19 Pandemic, for example, worldwide, people used massive information technology to help those affected by Covid-19, purchase medicine, or help people get general health services, especially during the implementation of large-scale social restrictions. As a result, E-health services run by hospitals, doctors, midwives, and pharmacies also increased. Regarding health issues, IT can help ease the government's and healthcare's work in providing healthcare services and facilities.

Recently the Indonesian Ministry of Health issued a Regulation of the Minister of Health Number 24 of 2022 concerning Medical Records, which requires all health service facilities in Indonesia to carry out Electronic Medical Records (EMRs) by December 31, 2023. This regulation replaced the former Minister of Health Regulation Number 269 of 2008 concerning Medical Records. The primary consideration for issuing this regulation, among other things, is that the former law was considered incompatible with the development of science and technology and health service and facility development needs. The purpose of issuing this regulation is: (1) to improve the quality of health services; (2) to provide legal certainty in the implementation and management of Medical Records; (3) to actualize the implementation and management of digital-based and integrated Medical Records; and (4) to ensure the security, confidentiality, integrity, and availability of Medical Record Data¹.

What is a medical record? And why should it be maintained electronically? **A medical record** is a file that contains notes and documents regarding patient identity, examination, treatment, actions, and other services that have been provided to patients in healthcare facilities. Recording medical records are mandatory for every clinicians medical doctors (practitioners), dentists, midwives, and nurses who perform medical procedures on patients in accordance with the rules and laws elsewhere and in Indonesia. Consequently, there is no reason for them not to make patient medical records. Along with technological developments, many medical records are made electronically using Information Technology (IT) system. Several developed countries have long had policies for making electronic medical records to ease patient data access wherever they go for treatment.

An Electronic Medical Records (EMRs) or Electronic Health Record (EHRs)² is a computerized health information system where providers record detailed encounter information such as patient demographics, encounter summaries, medical history, allergies, intolerances, and lab test histories³. Electronic medical records offer the ability for health care providers to store and share health information without relying on paper-based documents.

Although in some countries EMRs are already being transferred to electronic ones, most of them today are still a hybrid collection of computerized and paper data. The efficient

¹ The Indonesia Ministry of Health Regulation Number 24 of 2022 on Medical Record

² EHRs are sometimes referred to as Electronic Medical Records (EMRs)

³ Vera Ehrenstein et.al. 2019. *Obtaining Data from Electronic Health Records*. in Richard E. Gliklich, 2019, *Registries for Evaluating Patient Outcomes: A User's Guide 3rd Edition, Addendum 2*, AHRQ Publication No. 19(20)-EHC017-EF. p. 52

20 management of manual medical record systems remains essential for the collection of complete and accurate data on health. The security of EMRs also remains 17 crucial obstacles for their acceptance. Patients, providers, and healthcare facilities continue to demand assurance that these records are securely protected. While EMRs 1 use has increased and clinicians are being prepared to practice in an EMR-mediated world, technical issues have been overshadowed by procedural, professional, social, political, and especially ethical issues as well as the need for compliance with standards and information security⁴.

3 Today, efficient health information systems are not only important to hospitals and clinicians, but also for the government as they provide information about the health of the people in a country. The collected information is used by governments in the planning of health facilities and programs, for the management and financing of health facilities as well as medical research.

PROBLEM

This paper will discuss several issues and challenges that must be faced by health service facilities in Indonesia to adapt to their obligation to maintain EMRs. Considering the regulation, health service facilities that do not comply with this regulation will be subject to administrative sanctions. Furthermore, personal data protection violations can also be subject to criminal sanctions. Problems are limited to the availability of healthcare facilities to comply with or carry out the obligation to use EMRs, considering the general condition of health facilities in Indonesia. Moreover, several vital issues concerning protecting personal data have also become crucial.

METHODS

This paper uses a legal and qualitative approach. The data used are various regulations and policies issued by the Indonesian government. Empirical data regarding Indonesian general health facilitation and condition are collected by literature studies, especially from government report studies. Data is analyzed qualitatively.

DISCUSSION

7 As human beings, our health and the health of our loved ones are our daily 7 concerns. Regardless of our age, race/ethnicity, gender, lifestyle, socio-economic or socio-cultural background, we always consider our health to be the most basic and essential asset. Therefore, the right to health 12 to enjoy the highest attainable physical and mental health standards is a fundamental part of our human rights. Meanwhile, international, regional, 6 and national human rights instruments also recognize the right to privacy as a fundamental human right. The right to privacy plays a pivotal role in the balance of power between the State and the individual. It is also a foundational right for a democratic society, expressing human dignity and protecting human autonomy and personal identity⁵.

⁴ R. S. Evans. 2016. *Electronic Health Records: Then, Now, and in the Future*. Intermountain Healthcare & Biomedical Informatics, University of Utah School of Medicine, Salt Lake City, USA. IMIA Yearbook of Medical Informatics. p. 551

⁵ Human Rights Council. 2021. *The Right to Privacy in the Digital Age*. Report of the United Nations High Commissioner for Human Rights A/HRC/48/31. New York: UN General Assembly. p. 3

A. The Right to Health

The right to health or to enjoy the highest attainable physical and mental health standards is fundamental to human rights. Therefore, states have the primary obligation to protect, promote and realize every possible effort, within available resources, to better protect and promote the right to health. The Art. 25, 1948 Universal Declaration of Human Rights and 1966 International Covenant on Economic, Social and Cultural Rights mentioned health as part of the right to an adequate standard of living. Since then, other international human rights treaties have recognized or referred to the right to health or elements of it, such as medical care. Moreover, states must commit to protecting this right through domestic legislation, policies, guidelines, etc.

Many international conferences and declarations, such as the International Conference on Primary Health Care (resulting in the Declaration of Alma-Ata), the United Nations Millennium Declaration and Millennium Development Goals, and the Declaration of Commitment on HIV/AIDS, also clarify various aspects of public health relevant to the right to health and reaffirm commitments to its realization. For example, the Alma-Ata Declaration of 1978 article VII affirms the crucial role of primary health care, which addresses the leading health problems in the community, providing promotive, preventive, curative, and rehabilitative services accordingly. Article V also stresses that access to primary health care is the key to attaining a level of health that will permit all individuals to lead a socially and economically productive life and contribute to the realization of the highest attainable standard of health⁶.

In Indonesia, the right to health is protected by the constitution (UUD RI 1945) and some legislations (Acts). Article 28H UUD 1945 stated, “Every person has the right to live in physical and spiritual prosperity, have a place to live/reside, have a good and healthy living environment, and receive health care/services.” Apart from being stated in the Economic, Social, and Cultural Rights Covenant, which Indonesia has ratified in Law Number 11 of 2005, the right to health is also regulated in Article 9 (3) of Law Number 39 of 1999 on Human Rights. It is stated in Article 9 (3) that “Everyone has the right to a good and healthy environment.” Furthermore, the right to health is also mentioned on Law No. 36 of 2009 on Health in Article 4-8, stated that: “Everyone has the rights to health, access to health resources, access to health care, health care self-determination, healthy environment, health information and education, obtain information about their health condition, including action and medication received or will receive from health workers etc.”

The right to health has economic, social, and also cultural aspects. This right has an economic and social character because it seeks to protect that individuals do not suffer social and economic injustice concerning their health as much as possible. Furthermore, this right has a cultural character because it aims to ensure that the available health services are sufficient to adapt to one’s cultural background⁷.

OHCHR mentioned some critical (key) aspects of the right to health⁸. According to their 31 factsheets, they are: **(1) The right to health as an inclusive right.** The right to health is

⁶ Office of the United Nations High Commissioner for Human Rights. 2008. *The Right to Health*. Geneva: OHCHR & WHO. p. 10

⁷ KontraS, JKN, *Hak atas Kesehatan dan Kewajiban Negara*, Buletin KontraS, downloaded on 19 December 2022 from <http://kontras.org/backup/buletin/indo/bpjs.pdf>

⁸ Office of the United Nations High Commissioner for Human Rights. 2008, *Ibid.* p. 3-4

⁹ usually associated with access to health care and the building of hospitals. It extends further. It includes a wide range of factors that can help someone lead a healthy life, which The Committee on Economic, Social and Cultural Rights called “the underlying determinants of health.” They include: safe drinking water and adequate sanitation, safe food, adequate nutrition, and housing, healthy working and environmental conditions, health-related education and information, and gender equality; **(2) The right to health contains freedoms**, including the right to be free from non-consensual medical treatment, such as medical experiments and research or forced sterilization, and to be free from torture and other cruel, inhuman or degrading treatment or punishment; **(3) The right to health contains entitlements**. These entitlements include the right to a system of health protection providing equal opportunity for everyone to enjoy the highest attainable level of health, the right to prevention, treatment, and control of diseases, and access to essential medicines. It also includes maternal, child, and reproductive health; equal access to essential health services, the provision of health-related education and information; and participation of the population in health-related decision-making at the national and community levels; **(4) Health services, goods, and facilities must be provided without discrimination**. Non-discrimination is a critical principle in human rights and is crucial to the enjoyment of the right to the highest attainable standard of health; **(5) All services, goods, and facilities must be available, accessible, acceptable, and of good quality**. It includes, among other things functioning public health and healthcare facilities, goods and services that must be available in sufficient quantity within a State, physical accessibility to all of the population (including children, adolescents, older persons, persons with disabilities, and other vulnerable groups) as well as financially and based on non-discrimination. This accessibility also implies the right to seek, receive and impart health-related information in an accessible format. It does not still impair the right to have personal health data treated confidentially. The facilities, goods, and services should also respect medical ethics, be culturally appropriate, and be medically and culturally acceptable. Last but not least, it must be scientifically and medically appropriate and of good quality⁹.

Office of the United Nations High Commissioner for Human Rights noted that sometimes some common misconceptions about the right to health arise. They are: **(1) The right to health is not the same as the right to be healthy**. Having good health is influenced by several factors outside the direct control of States, so it is a bit different than the right to health. The right to health refers to the right to enjoy a variety of goods (i.e., access to medicine, vitamins, etc.), facilities, services, and conditions necessary for its realization. It is more accurate to describe the right to health as the right to the highest attainable standard of physical and mental health rather than an unconditional right to be healthy; **(2) The right to health is not only a programmatic goal to be attained in the long term**. OHCHR mentioned that the fact that the right to health should be a tangible programmatic goal does not mean that no immediate obligations on States arise from it. On the contrary, it implies that States must make every possible effort, within available resources, to realize it and to take steps in that direction without delay, including developing specific legislation and plans of action or taking other similar steps toward the full realization of it; **(3) A country’s difficult financial situation shall not prevent it from taking action to realize the right to health**, meaning that no State can justify a failure to respect its commitments because of a lack of resources. States

⁹ Ibid

must guarantee the right to health to the maximum available resources, even if these are tight¹⁰. How about preparing a very sophisticated technology like EMRs, as it is obligatory regarding the new law issued by the Ministry of Health? Is the provision of these facilities, i.e., infrastructure and tools, the responsibility of the state or the responsibility of health service facilities, considering that many private health service facilities do not receive subsidies from the government? Is the government ready to facilitate, build infrastructure, and implement EMRs in all healthcare facilities in Indonesia? Have various challenges already been seriously considered, bearing in mind that in some remote, outermost, and under-developed areas, even basic health facilities are difficult to be fulfilled? Furthermore, what about data security, considering that, under the law, medical records must be kept confidential, as stated in Law Number 23 of 2006 jo. Law Number 24 of 2013 on Administration of Population Article 79 (1) says that “Population (including an individual) data and documents must be stored and protected by the state.”?

B. The Right to Personal Data Protection

Article 12 of the Universal Declaration of Human Rights, Article 17 of the International Covenant on Civil and Political Rights, and several other international and regional human rights instruments recognize the right to privacy as a fundamental human right. In an increasing world of data-centric growth, every person needs to enjoy and exercise personal data protection online and offline, as it is linked to protecting human autonomy and personal identity. Aspects of privacy that are of particular importance in the use of artificial intelligence include informational privacy, information that exists or can be derived about a person and their life, the decisions based on that information, and the freedom to make decisions about one’s identity¹¹.

In Indonesia, the right to personal data protection is protected by the constitution (UUD RI 1945) and some legislations (Acts). Article 28G (1) UUD 1945 stated that “Every person shall be entitled to a personal, family, honor, dignity, and property under his/her control protection, as well as be entitled to feel secure and be entitled to safeguard against the threat of fear to do or omit to do something being his/her fundamental right. Besides being stated in Article 28G (1) of the Indonesian Constitution or UUD 1945, Personal Data Protection in Indonesia is regulated in some laws/acts.

Law Number 23 of 2006 jo. Law Number 24 of 2013 on Administration of Population article 1 Point 22 stated that “Personal Data is certain (specific) individual data that is stored, maintained, and confidentiality protected.” As already mentioned, Article 79 (1) also stated that “Population (including an individual) data and documents must be stored and protected by the state.” Article 26 (1) Law Number 11 of 2008 jo. Law Number 19 of 2016 on Information and Electronic Transaction also mentioned that “unless otherwise stipulated by Laws and Regulations, the use of any personal data information through electronic data media needs the consent of the person concerned.” A (Civil) lawsuit could be imposed if this article is violated, as stated in the same law, Article 26 (2).

Recently, the newest law in protecting Personal Data was promulgated. It is the Law Number 27 of 2022 on Personal Data Protection. In Article 65 (1), it is stated that “Everyone is prohibited from obtaining or collecting Personal Data for their own or others’ benefit,

¹⁰ Ibid. p. 5

¹¹ Human Rights Council. 2021. *Op.Cit.* p. 3

which can result in the loss (damage/harm/ disadvantage) of Personal Data Subjects; and Article 65 (2) stated that “Everyone is prohibited from disclosing Personal Data that does not belong to him.” Article 12 (1) also stated, “The Personal Data Subject has the right to sue and receive compensation/restitution for violations of processing Personal Data about her/himself in accordance with the provisions of the regulations/ legislations.”

Law Number 14 of 2008 on Public Information Disclosure in Article 54 stated, “Every person who deliberately and without the right to access and/or obtain, provides information ..., shall be subject to imprisonment”. Furthermore, the National Criminal Code also stated in Article 322 that “Whoever intentionally discloses a document that is obliged to be kept by him because of his position and occupation, both current and former ones, is punishable by imprisonment and a fine.” The right to privacy and personal data protection also goes within the health information data. Law No. 36 of 2009 on Health, Article 57 (1), mentioned, “Everyone has the right to confidentiality regarding their health conditions...etc.”

C. Medical Record-Health Information and Confidentiality Law

Following are some laws governing the obligation to keep and maintain medical or e-medical records and the obligation to preserve someone’s health information confidentiality in Indonesia.

Law Number 29 of 2004 on Medical Practice Article 46 (1) stated, “Physicians (and dentists) are required to record certain information in their patients’ records.” Article 47 (1) also said, “Medical records are the property of the patient – while the documents belong to the physician or health care unit.” Article 47 (2) states, “Patient records must be kept confidential.” Law Number 36 of 2014 on Health Workers also mentioned in Article 70 (4) that “Health workers and head of health service facilities have to maintain and protect the confidentiality of medical records.” Law Number 44 of 2009 on Hospitals in Article 29 (1) point h mentioned that “All hospitals are obliged to maintain medical records.”

Article 23 (1) (b) Government Regulation Number 46 of 2014 on Health Information System stated that “Security of health information is carried out to ensure that health information confidentiality is maintained primarily for specific secure health information.” While Ministry of Health Regulation Number 36 of 2012 on Medical Privacy (Secrecy/Confidentiality) in Article 4 (1) also stated, “All parties involved in medical services and/or using the patient’s data and information must maintain medical confidentiality.”

The newest Medical Record Law is The Ministry of Health Regulation No. 24 of 2022 on Medical Records, issued on August 31, 2022. It repealed The Ministry of Health Regulation No. 269 of 2008 on Medical Records. This new regulation intends to replace the entire paper-based medical record system with an electronic one, which will be very useful for compiling health data for all Indonesian. Article 45 states that All Health Service Facilities have to organize Electronic Medical Records following the provisions regulated in this Ministerial Regulation by December 31, 2023. Thus, nationally, the Government can factually better formulate health insurance policies because the data collected can be used as a database connected to the national health insurance system, which the Government is still building. The writer also believes that healthcare facilities management, doctors, dentists, midwives, and pharmacies may have also understood the need for better medical records management. However, limited time, budget, and human resources preparedness may be the most concerning issue, especially for small private healthcare facilities and private practitioners.

D. ISSUES AND CHALLENGES

1. Lack of Basic Health Conditions Due to Demographics and Geographical Conditions

One of Indonesia’s most significant challenges in realizing and implementing EMRs are demographics and geographical conditions. Indonesia is the 5th largest country and the 4th most populous population in the world. The total population: ± 276 million(s). Indonesia is also the largest archipelagic country in the world. The country has more than 17,500 islands, which only around ± 920 has been permanently inhabited. The total land area is 1,904,569 km², and the total size with the ocean/sea is 7,900,000 km².

This geographical and demographic condition especially raises the issue of equitable distribution of development. Development in Indonesia is generally centralized in big cities and industrial areas, not in remote areas. As Indonesia is an archipelagic country, the terms used for these less developed regions are outermost, frontiers, remote and disadvantaged regions. Disadvantaged regions are classified as areas that still need assistance in various sectors, including primary education, basic health, and economic condition. It is happened due to ineffective decentralization processes. It becomes very ironic when the government talks about the health facilities obligation to implement EMRs; meanwhile, many areas in Indonesia are still not covered by the internet, lack basic communication infrastructure, lack education, and lack essential health conditions.

Figure 1. Number of Government Primary Health Facilities

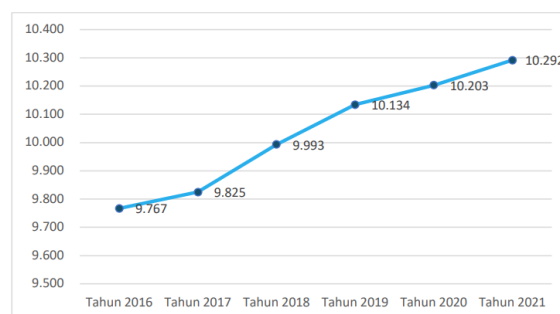


Figure 2. Number of Hospitals

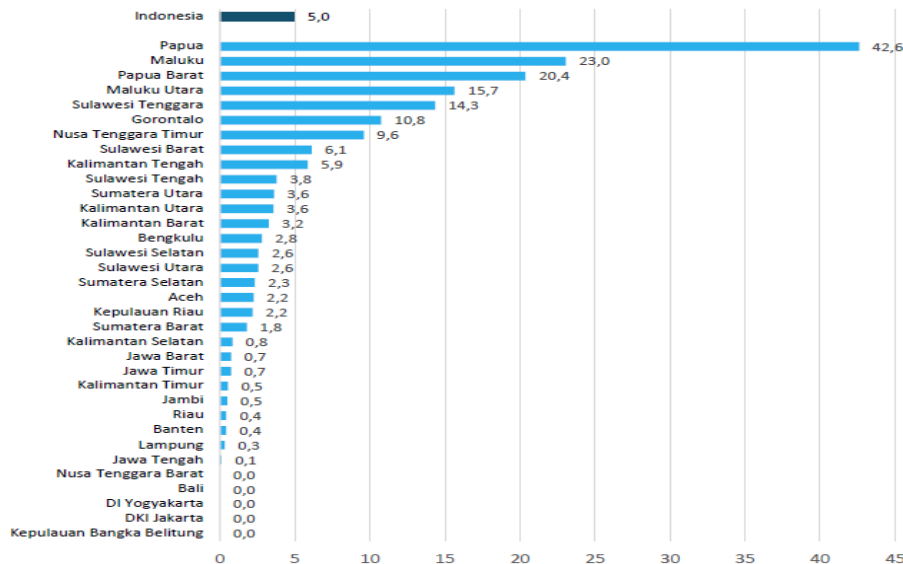
No	Penyelenggara	2017	2018	2019	2020	2021
PEMERINTAH PUSAT						
1	Kementerian Kesehatan	14	15	18	19	19
2	TNI/POLRI	164	158	159	160	164
3	Kementerian Lain dan BUMN	62	55	51	51	53
PEMERINTAH DAERAH						
1	Pemerintah Provinsi	87	91	92	97	96
2	Pemerintah Kabupaten/Kota	585	614	640	676	694
SWASTA		1.286	1.336	1.384	1.445	1.496
Total Keseluruhan		2.198	2.269	2.344	2.448	2.522

Source: Directorate General of Health Services Ministry of Health, 2022

Figure 1 shows the total number of Government Primary Health Facilities in Indonesia, while Figure 2 shows the total number of Hospitals in Indonesia in 2021. Total 236 hospitals are owned by the Central Government operated by Ministry of Health, Police Department/Army and State-Owned Enterprises, while 790 are owned by Local Government, and 1,496 are owned by private sector. Even though the number of health facilities is quite

large, Figure 3 shows the lack of physicians in several government primary health facilities due to Indonesia’s geographic and demographic conditions. The most significant number of physicians absent is in Papua Province, which lies in the eastern part of Indonesia.

Figure 3. Number of Government Primary Health Facilities without Physician



Source: SISDMK by Secretariat of the Directorate General of the Ministry of Health, 2022

Considering that several hospitals in remote areas are still struggling, i.e., with the absence of a physician, is it wise to push a very sophisticated modern system like implementing EMRs in Indonesia? Isn't it better or more valuable for the government to provide essential health services by completing the necessary infrastructure and providing the physicians and medical equipment needed for society?

2. Infrastructure, Human Resources Development Cost and Ethical Issues

Disruptive innovations are a double-edged sword, bringing both opportunity and risk. The EMR, for example, simultaneously facilitates and complicates the delivery of health care¹². Growing documentation requirements add time pressures on direct patient care. The complexity of routine primary care visits today—and the tasks to be accomplished—has increased, but visit time has not¹³. EMRs also encourage “copy-and-paste” (C&P)—copying previous entries into the current note. This might save time, but may not reflect current thought processes, leading to unhelpful, repetitive entries¹⁴.

Implementing a sophisticated and modern system such as EMRs in Indonesia may relatively be easy for some hospitals in big cities. Still, this policy will be challenging for hospitals or primary health care located far away in remote areas.

The first question is, who will finance and bear the infrastructure and construction cost? For government hospitals, it will likely be funded by the government. What about private hospitals? Will there be subsidies from the government to finance it? EMRS needs an

¹² Lois Snyder Sulmasy, Ethical Implications of the Electronic Health Record: In the Service of the Patient, *Health Policy: JGIM Crossmark*. p. 935-939

¹³ Linzer M, Bitton A, Tu SP, Plews-Ogan M, Horowitz KR, Schwartz MD, et al. The end of the 15–20 Minute Primary Care Visit. *J Gen Intern Med*. 2015;30: p. 1584–6

¹⁴ Lois Snyder Sulmasy. Op.Cit. p. 937

internet network/connection, not to mention a server, router, NAS (network attached storage), wireless card, LAN Card, USB Wi-Fi Adapter, Modem, Bridge, etc., and human resources to be educated to store and maintain the data. What about network and data security? Who will take responsibility when something goes wrong?

The second question is more related to human resources ethical issues. Many Indonesians still need more digital index literacy for technology and information system, as all data in EMRs are considered confidential.⁸ Ozair et.al (2015) mentioned that security breaches threaten patient privacy when confidential health information is made available to others without the individual's consent or authorization. Keeping records secure is a challenge physicians, public health officials, and regulators must understand.¹⁹ Cloud storage, password protection, and encryption are all measures healthcare providers should take to make EMRs more secure. Ozair et.al (2015) also mentioned that mobile devices are for individual use and are not designed for centralized management by an IT Department. Mobile devices can easily be misplaced, damaged, or stolen, so emphasis must be placed on encrypting mobile devices that transmit confidential information. The government should serve specific policies and procedures to maintain patient privacy and confidentiality and to protect data integrity. It should also include security measures policies like firewalls, antivirus, and intrusion detection software¹⁵.

The third question concerned administrative and criminal sanctions imposed on healthcare and person who violated the law. Making policies that bind healthcare facilities to use EMRs and state that violators can be subject to administrative sanctions might improper if it is not followed by the government's duty to facilitate and educate all related stakeholders. Another thing to think about is the imposition of criminal sanctions, as one wrong 'click' can bring someone subject to criminal sanctions, leading to criminalization.

CONCLUSION

Before its implementation, things to be prepared to use EMR are many, i.e., especially infrastructure and human resources literacy. Creating an EMR system requires expertise. Government, physicians, administrative personnel, technology professionals, ethicists, and patients must be ready before establishing the new system.²¹ Although EMRs offer many remarkable benefits, the future of healthcare requires that their risks be recognized and adequately managed. Due to Indonesia's geographic and demographic conditions, the government cannot trivialize the situation just by saying that hospital or healthcare unit omission complying with this regulation will be subject to administrative sanctions. Furthermore, regarding EMR compliance, one should also be well informed, as personal data protection violations can be subject to criminal sanctions.

¹⁵ Ozair FF, Jamshed N, Sharma A, Aggarwal P. 2015. Ethical Issues in Electronic health records: A General Overview. *Perspect Clin Res* 2015; 6: p. 73-76

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