Jurnal Eduhealth
Volume 15 , Number 02, 2024, DOI 10.54209/eduhealth.v15i02
ESSN 2808-4608 (Online)
https://ejournal.seaninstitute.or.id/index.php/healt

The Legal Analysis Of Electronic Medical Consent In The Inpatient Department Of RS PKU Muhammadiyah Petanahan

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Article Info
Keywords:
Electronic informed consent,
legality,
security,
privacy.

ABSTRACT
As technology advances, all fields are compelled to transition from manual to electronic processes, including informed consent. The implementation of electronic informed consent requires an examination of its execution and usage. Electronic signatures are used for verification and authentication in clinical information recording and documentation. From a legal perspective, medical records need validity to be used as legal evidence. RS PKU Muhammadiyah Petanahan has implemented informed consent using electronic signatures in the form of barcodes. This study aims to determine the validity of using electronic signatures on informed consent, as well as its security and privacy aspects. This research employs a qualitative method with an ethnographic design. The results show that the type of electronic signature used is a non- certified electronic signature in the form of a barcode. This signature was chosen because it facilitates healthcare workers in completing informed consent documents and its creation process is relatively easy and affordable. Currently, the regulation referenced for the use of electronic signatures in electronic medical records at RS PKU Muhammadiyah Petanahan is Law No. 19 of 2016 on Information and Electronic Transactions. In terms of security, electronic informed consent data is stored in a database on a computer server. Regarding privacy, there is a Standard Operating Procedure (SPO) that governs its use. Non-certified electronic signatures on medical records potentially pose a security risk. Therefore, based on the research results, it is recommended to change the type of electronic signature to a certified electronic signature.

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INTRODUCTION

Informed consent is an important document in a vital medical record and can be used as evidence in legal cases when there is a mistake or negligence in the implementation of medical actions in a hospital that is detrimental to the patient (Wulandari et al., 2019). Medical records can be manual, in written form, or electronic, as transcripts for each patient, and stored in Health Service Facilities in accordance with legislative provisions (Fitriyah, 2022). According to PERMENKES RI No. 24 Year 2022, electronic medical records are

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medical records created using electronic systems for the maintenance of medical records (Menteri Kesehatan, 2022). Electronic medical records are one of the subsystems of the Fasyankes information system and are connected to other information subsystems at the facility. From a legal standpoint, medical records need to be valid in order to be used as legal evidence. To maintain data security and protection, the maintenance of electronic medical records in Fasyankes can be accompanied by electronic signatures (Menteri Kesehatan, 2022). These signatures serve as tools for verification and authentication in the recordingand documentation of clinical information.

Security and privacy in the management of medical records in healthcare facilities are vital and are part of the effort to maintain quality service (Amir, 2019). Complete and accurate medical records are indicators of good quality healthcare. Ensuring the security and privacy of health information stored in healthcare facilities can reduce the risks that may cause problems for patients and hospitals in the future (Aini et al., 2022). Hospitals are healthcare institutions that provide comprehensive individual health services, including nursing care, outpatient care, and emergency services. Maintenance of healthcare in hospitals is heavily dependent on the role of medical records.

Technological advances have forced various fields to transition from manual systems to electronic systems, including hospitals that have begun to transform their services to be electronically based. This situation is problematic because there are no clear guidelines for healthcare facilities to implement electronic medical records, so each hospital has a different approach (Arimbi et al., 2021). Informed consent, which is often used as evidence in legal cases, is still generally made in paper form. Hatta (2017) states that the computerization of medical records or the use of electronic medical records (EMR) does not immediately make medical records paperless, but only reduces paper use. Some data, such as identity, informed consent, consultation results, radiological results, and permanent imaging, should be stored in paper form and printed if necessary.

Research on the application of electronic signatures to informed consent has been conducted by several researchers. Fikriya et al., (2016) conducted an analysis of the approval of medical actions (informed consent) in preparation for the accreditation of hospitals in the central surgical facility of RSUD Semarang. The study showed that the assessment standard related to informed consent had not yet reached more than 50%, as there were still regulations related to informed consent, and its use was not fully in accordance with hospital accreditation standards. Fitriyah, (2022) analyzed the level of readiness for implementing digital signatures for the authentication of electronic medical records in the medical facilities of RSUD Yogyakarta. The research indicated that in the execution of the electronic signature (scan), there were obstacles such as the signature being exchanged, not appearing, and concerns about validity. The readiness level of RSUD Yogyakarta was 81.83 and was in range II related to the application of digital signatures on informed consent in outpatient care installations (Fitriyah, 2022). Additionally, research on the security and privacy of the application of informed electronic consent was analyzed by Rijal Husni (2022) in the surgery unit of RSU Anna Medika Madura Bangkalan. From the security aspects, it still lacks a Standard Operating Procedure (SOP), but policies related

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to the anticipation of security threats have been implemented well. Regarding privacy aspects, it has generally been regulated in the hospital's SOP and implemented properly.

PKU Muhammadiyah Petanahan Hospital is a class D hospital that performs medical procedures, both moderate and minor. It must inform the patient or the patient's family about any medical action to be taken and requires their consent or refusal. Proof of such information and consent or refusal is documented in the informed consent form, which includes information/education and a declaration of refusal for surgery/medical procedures/diagnostic actions. PKU Muhammadiyah Petanahan Hospital offers several types of services, including inpatient care categorized into classes I, II, III, and VIP. The hospital is known to use both manual (paper-based) and electronic methods for the implementation of informed consent.

Based on the above description, this study aims to determine the validity of using electronic signatures on electronic informed consent at PKU Muhammadiyah Petanahan Hospital and to examine the implementation of electronic medical records in the form of electronic informed consent from the aspects of security and privacy. This research is expected to serve as a benchmark for the development of regulations related to electronic signatures in hospitals and the implementation of Electronic Medical Records (EMR).

METHODS

The research was conducted at PKU Muhammadiyah Petanahan Hospital in April 2024. This research method adopts a qualitative approach with an ethnographic design. The study aims to produce clear and detailed descriptions and obtain in-depth data related to the legality of electronic medical consent actions, accompanied by security and privacy at PKU Muhammadiyah Petanahan Hospital.

The stages of qualitative research are: (1) The description or orientation stage, where the researcher describes what is seen, heard, and felt. Initially, the researcher briefly describes the information obtained; (2) The reduction phase, where the researcher reduces all the information acquired in the first phase to focus on a particular problem; (3) The selection phase, where the researcher delineates the focus that has been set to be more detailed and then conducts an in-depth analysis of the problem. The result is a theme constructed based on the data obtained, leading to new knowledge, a new hypothesis, or even a new theory.

In this study, data was collected through interviews and field observations. The interviews were conducted with two respondents: the Head of the Medical Records Working Unit and Electronic Data Processing (EDP) staff at PKU Muhammadiyah Petanahan Hospital. There are nine questions that form the basis of the data collection, which then evolve as the interview progresses. The researchers also observed medical records and electronic signature processes through an electronic medical record application. The interview data is processed and analyzed by the researchers.

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RESULTS AND DISCUSSION

PKU Muhammadiyah Petanahan Hospital has implemented an electronic informed consent system for hospital services since April 2024. This system is integrated into the SIMRS application of PKU Muhammadiyah Petanahan Hospital within the medical record module. The process of creating an electronic signature is carried out by an Electronic Data Processing (EDP) officer, who uses a barcode signature.

The use of electronic informed consent still requires adherence to the Standard Operating Procedure (SOP). However, currently, only SOPs related to electronic data access, particularly in connection with E-Medical Record applications, are in force. Although the implementation of e-informed consent services generally aligns with the SOP, there are still some obstacles, especially regarding the means of delivery, such as hardware limitations like touchscreen computers for electronic signatures.

In terms of security, electronic informed consent data is stored electronically in a database on a computer server in the IT unit, managed by a single IT officer serving as the database administrator. Each officer is given a username and password to access the electronic system according to their service unit. In terms of privacy, only officers with access rights specified by the administrator (IT team) can access electronic informed consent. The determination of access rights is carried out by the IT team according to the service unit, by assigning a username and password to the user to enter the system through the RME module in SIMRS. The IT team is also obligated to maintain the confidentiality of medical data through an oath, which is a condition of employment at PKU Muhammadiyah Petanahan Hospital.

PKU Muhammadiyah Petanahan Hospital has begun implementing electronic informed consent, while still using two methods: manual (paper-based) and electronic (paperless). According to Article 184 (1) of the Criminal Procedure Law (KUHP), a medical record is considered valid proof in the form of a letter. However, under the KUHP, only a physical letter is recognized as a valid proof tool. Therefore, it is important to have a medical record in physical form, signed by the doctor responsible for examining the patient's medical history. The selection of barcode-shaped signatures as electronic signatures at PKU Muhammadiyah Petanahan Hospital is due to their ease of use in the system. The barcode stores the identity data of the healthcare provider serving the patient and assists in completing the medical record file. This indirectly improves the availability of patient medical records and enhances the efficiency of services at PKU Muhammadiyah Petanahan Hospital.

Moreover, the use of barcode-shaped signatures is more practical because it does not require special equipment. This aligns with research findings that show the benefits of implementing electronic signatures in electronic medical records include ease and speed of use, as well as reduced costs for paper, printer ink, and hardcopy document storage (Amir, 2019).

Although electronic signatures provide legal support for electronic medical record files, specific regulations governing their use in such files are not yet available. Therefore, PKU Muhammadiyah Petanahan Hospital adheres to general regulations related to the implementation of electronic systems in medical record services, such as PERMENKES RI No.

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24 Year 2022 on Medical Records and Act No. 19 Year 2016 on Electronic Information and Transactions (Undang-Undang Republik Indonesia Nomor 19 Tahun 2016, 2016). In implementing electronic systems in medical records, PKU Muhammadiyah Petanahan Hospital has developed SOPs in compliance with existing regulatory constraints. It requires both software and hardware to realize the implementation of these electronic systems.

In PKU Muhammadiyah Hospital, electronic informed consent is implemented through the use of personal computers (PCs) equipped with touchscreens to produce electronic signatures in applications. According to PP No. 71 Year 2019 on Electronic Transaction and System Maintenance, electronic signatures are divided into two types: certified and uncertified (PP, 2019). In the context of electronic medical records, where digital information lacks a signature or proof of authentication, it can reduce the validity of information generated by electronic systems, especially on electronic forms that often serve as evidence in legal cases. Therefore, conducting electronic authentication through electronic signatures on crucial information, such as informed consent, which is often evidence in cases of malpracticein healthcare, is important.

From a security perspective, PKU Muhammadiyah Petanahan has implemented a series of policies to maintain system security. These include performing regular data backups, installing antivirus software, strengthening the security system with a firewall to control unsafe network access, using racks as physical protection for server computers, adjusting the temperature and humidity of server rooms with air conditioning according to standards, regulating access to server space with lock security, providing fire extinguisher tools, setting up the genset as a backup resource, performing routine monitoring on system usage, and installing surveillance cameras in server rooms to prevent hardware theft.

Regarding privacy, PKU Muhammadiyah Petanahan Hospital has implemented several security measures on electronic systems in electronic informed consent services to maintain the confidentiality of data and health information. In addition to the security measures described above, the hospital also imposes access restrictions for officials and non-officials who are not authorized to access health information in electronic systems through internal rules specified in the form of Standard Operational Procedures (SOPs). Privacy is defined as the right of an individual to maintain his or her privacy, including freedom from supervision or observation of personal affairs and control over personal information as well as health information (Hatta, 2017).

In the digital era, transactions that were previously conducted manually using paper have evolved into electronic transactions through computerized systems, including in the field of medical records and health information. Computerizing medical records must be accompanied by systems capable of addressing the potential privacy violations of patient data, where electronic information can be easily accessed and disseminated without proper authorization. To prevent this, every user responsible for patient data and health information must be provided with a username and password to access limited menus according to their service responsibilities.

In addition to the option of using usernames, there are other alternatives such as smart cards, fingerprints, or iris patterns to identify users. Medical data must be classified

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according to user access limitations in carrying out their duties. The system should also be able to detect user identities and access times to health data, facilitating administrators in addressing privacy breaches or issues related to data and health information access (Hatta, 2017). Regulations regarding access to electronic medical records also need to be carefully drafted and regulated to restrict access for unauthorized parties to modify, edit, or even delete health data stored therein, for example by designating the type of data access as read-only.

According to MIRM 11 assessment elements in SNARS 1, hospitals are required to establish and implement policies to prevent unauthorized access to electronic medical records, ensuring that electronic medical records are not disrupted by unauthorized access and usage, and regulating the storage location of medical records, both in paper and electronic forms, to ensure protection against unauthorized access from unauthorized parties(SNARS, 2018).

The electronic informed consent service at PKU Muhammadiyah Petanahan Hospital has been implemented across various services, including outpatient care, inpatient care, emergency installations, and operating rooms. Access rights to access electronic informed consent are granted to authorized personnel by the administrator (IT team) to use the application. The process of determining user access rights in the electronic informed consent service is carried out by the IT team according to the unit providing informed consent services, by providing usernames and passwords. Users can then access the system through the RME module in SIMRS by accessing the informed consent menu. Personnel with access rights include nurses responsible for service implementation and medical record personnel responsible for reporting. In this study, the researchers observed inpatient care while providing services using informed consent and interviewed operating room nurses and medical record personnel. The electronic informed consent service is still not regulated in the SPO, but only in the form of SPO regarding Data Access to E-Medical Record Applications(Document No: 510.07/001.5/35.04.14/A/2023).

Medical personnel working at PKU Muhammadiyah Petanahan Hospital are required to adhere to established competency standards and have a responsibility to maintain the confidentiality of medical information in accordance with applicable laws. This includes doctors, dentists, nurses, or midwives who have taken professional oaths. The same applies to medical record personnel. When becoming new employees at PKU Muhammadiyah Petanahan Hospital, employees will undergo a reaffirmation oath ceremony according to the hospital's internal policy. The IT team is also required to take an oath to maintain patient data confidentiality, which is one of the requirements for employment at PKU Muhammadiyah Petanahan Hospital. Additionally, vendors or third parties assisting in securing digital health information at the hospital are also required to take an oath at the beginning of their contract, and they must sign the document with a stamp as a guarantee that they will maintain the confidentiality of health data and will not disclose information about PKU Muhammadiyah Petanahan Hospital patients to any external party outside the hospital.

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CONCLUSION

Based on the data analysis results, the use of electronic signatures in the form of barcodes at PKU Muhammadiyah Petanahan Hospital has been legally recognized due to compliance with Law No. 19 of 2016 concerning Electronic Information and Transactions as well as Government Regulation No. 71 of 2019 concerning the Implementation of Electronic Systems and Transactions. However, the use of uncertified electronic signatures on medical record files has potential weaknesses in data security. With the development of services at PKU Muhammadiyah Petanahan Hospital, a change in the type of electronic signature to certified ones is needed. The implementation of electronic informed consent at PKU Muhammadiyah Petanahan Hospital in terms of security still lacks a Standard Operating Procedure (SOP), but policies to anticipate security threats have been well implemented, covering both software and hardware security. In terms of privacy, the implementation of electronic informed consent has generally been regulated in the applicable hospital SOPs and has been executed effectively.

REFERENCE

Aini, R. N., Rosiandini, R., Angelica, P., Kusumadewi, A. F., & ... (2022). Legalitas Tanda Tangan Elektronik pada Rekam Medis di RS PKU Muhammadiyah Gamping. Jmiki.Aptirmik.or.Id, 9–13. https://doi.org/10.33560/jmiki.v12i1.536

Amir, N. (2019). Perlindungan Hukum Kerahasiaan Data Pasien Dalam Rekam Medik Elektronik. Seminar Nasional Paperless Healthcare System In Indonesia, 1–18. http://repository.ubaya.ac.id/id/eprint/35220

Arimbi, A. D., Muflihatin, I., & Muna, N. (2021). Analisis Kuantitatif Kelengkapan Pengisian Formulir Informed Consent Rumkital Dr. Ramelan Surabaya. J-REMI : Jurnal Rekam Medik Dan Informasi Kesehatan, 2(2), 221–230. https://doi.org/10.25047/j-remi.v2i2.2009

Fikriya, K., Sriatmi, A., & Jati, S. P. (2016). Analisis Persetujuan Tindakan Kedokteran (Informed Consent) Dalam Rangka Persiapan Akreditasirumah Sakitdi Instalasi Bedah Sentral RSUD Kota Semarang. Jurnal Kesehatan Masyarakat, 4(1), 1–23.

Fitriyah, Y. (2022). Analisis Tingkat Kesiapan implmentasi Tanda Tangan Digital Untuk Autentikasi Dokumen Rekam Medis ELektronik di Instalasi Rawat Jalan RSUD Kota Yogyakarta. Journal of Information Systems for Public Health, 7(2), 53. https://doi.org/10.22146/jisph.73666

Hatta, G. (2017). Pedoman Manajemen Informasi Kesehatan di Sarana Pelayanan Kesehatan

(Edisi Revi). UI Press.

Menteri Kesehatan. (2022). Peraturan Menteri Kesehatan RI No 24 tahun 2022 tentang Rekam Medis. Peraturan Menteri Kesehatan Republik Indonesia Nomor 24 Tahun 2022, 151(2), 10–17.

PP. (2019). Peraturan Pemerintah Republik Indonesia Nomor 71 Tahun 2019 Tentang Penyelenggaraan Sistem Dan Transaksi Elektronik. In Peraturan Pemerintah Republik Indonesia.

Undang-Undang Republik Indonesia Nomor 19 tahun 2016, 287 (2016).

Rijal Husni, M. A. (2022). Aspek Keamanan Dan Privasi Penerapan Informed Consent Elektronik Di Unit Kamar Bedah Rsu Anna Medika Madura Bangkalan. Jurnal Rekam Medis Dan Informasi Kesehatan, 5(2), 72–80. https://doi.org/10.31983/jrmik.v5i2.8376 SNARS, E. 1. (2018). Standar Nasional Akreditasi Rumah Sakit Edisi 1. Standar Nasional

Akreditasi Rumah Sakit, 1, 421.

Wulandari, M., Wasono, H. A., Lestari, S. M. P., & Maitsya, A. N. (2019). Analisiskelengkapan Pengisian Informed Consent Tindakan Beedah Di Rumah Sakit Pertamina Bintang Amin Tahun 2018. Jurnal Ilmu Kedokteran Dan Kesehatan, 6(2), 98–104. https://doi.org/10.33024/jikk.v6i2.2296