# Integration of Electronic Medical Record and SATUSEHAT’s Platform: Patient’s Legal Protection Perspective

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## Abstract

SATUSEHAT’s platform has been implemented as a form of digital transformation in health services in Indonesia. This platform includes features that facilitate data integration from medical records, medical resumes, and various similar health platforms with the concept of interoperability and data sharing between healthcare facilities in Indonesia. Data sharing and ownership of patient data raises various ethical and legal issues in its application, especially concerning the right to patient data in electronic medical records (EMR) in health services. However, in the guidelines for the implementation of EMR, there is no general consent regarding the release of the data. This study aims to analyze legal issues that can occur and to construct the recommendations related to the implementation of SATUSEHAT which is integrated with EMR of health care facilities. The method used was a normative legal study with a statutory and conceptual approach. General consent regarding the release of EMR data to be integrated with SATUSEHAT needs to be applied. Several issues may arise regarding the implications of refusing or approving the integration of EMR with SATUSEHAT such as security, confidentiality, and data usage. Healthcare facilities should include general consent regarding the integration of the data as a separate option in the clause in the general consent which is preceded by information regarding the risks and benefits obtained. Guarantees regarding the security and privacy of patient data by both health facilities and the SATUSEHAT’s platform also need to be strengthened so that they do not harm patients. In addition, guidelines regarding data access and ownership need to be developed, and clarification on the responsible party and the sanctions to be imposed in the event of a data leakage need to be further defined.

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**Keywords:** SATUSEHAT’s platform, Electronic Medical Records, legal protection, data interoperability
Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic has spread all over the world including Indonesia and affected the resilience of the existing health system. Various problems arise related to the availability of resources and access to health services (Hadibroto et al., 2022). This also strengthens the need for Indonesia’s health transformation which includes 6 pillars including the transformation of primary services, secondary services, health security, health financing system, health human capital, and health technology (Indonesian Ministry of Health, 2023).

To connect these various pillars, the Ministry of Health has released the Regulation of the Minister of Health of the Republic of Indonesia Number 21 of 2020 to change governance which includes health development related to the integration of information systems, research, and health development in the Indonesia Health Services (HIS) platform (Indonesian Ministry of Health, 2020). The platform is a digital health platform that enables linkage or interoperability of data, analysis, and services for various health applications in Indonesia. The integration of the resulting data is expected to be able to be used in formulating evidence-based policies in every health agency (Indonesian Ministry of Health, 2022a).

One of the platforms developed to bridge digitalization in health services in Indonesia is known as the SATUSEHAT platform. The platform realizes data integration starting from medical records, medical resumes, and various similar health platforms with the concept of interoperability and data sharing between healthcare facilities in Indonesia (Indonesian Ministry of Health, 2022a). The concept of interoperability and data sharing is supported by the obligation to implement electronic medical records in all service facilities. Health based on Minister of Health Regulation Number 24 of 2022 concerning Medical Records (Indonesian Ministry of Health, 2022b).

Data sharing procedure, security, confidentiality, and ownership are crucial issues in the legal aspects of applying this concept. In the Decree of the Minister of Health of the Republic of Indonesia Number HK.01.07/Menkes/1423/2022 concerning Guidelines for Variables and Meta Data in the Implementation of Electronic Medical Records, there is an aspect of general consent as a form of patient consent before obtaining health services (Indonesian Ministry of Health, 2022c). General consent is a statement of willingness or general approval obtained from the patient and the patient’s family before receiving health services (Yulia & Nurazizah, 2018). The application of general consent is often done when a patient is being treated by an administrative officer regarding the patient’s rights and obligations during the registration process. However, the policy does not yet contain general consent items regarding the release of Electronic Medical Record (EMR) data which will be integrated with SATUSEHAT’s platform.

The application of general consent regarding the release of data and the extent to which medical record data is integrated is crucial to determine a form of protection of human rights to health, namely the right of self-determination. However, various implications can raise issues related to legality in approving or refusing the general consent. The previous study showed that the use of cloud electronic medical records (EMR) can lead to many ethical and legal issues such as data security, data sharing, interoperability, and medical secrets issues (Budiyanti, Arso, & Herlambang, 2018). Other studies also showed that the implementation of electronic health records (EHR) in healthcare can affect physician-patient care and relationship, patient autonomy, privacy, and confidentiality (Sulmasy., et al, 2017). Hazin et al. (2013) show that the use of EHR in genomic information can raise the risk to patient’s privacy and security (Hazin et al., 2013). However, no research discuss the related integration of electronic medical record and SATUSEHAT’s platform, especially based on a legal perspective. This study aims to analyze legal issues that can occur and construct legal concepts related to the integration of SATUSEHAT’s platform with a patient’s EMR, especially regarding the application of general consent so that it does not conflict with the existing law.

Methods

This research was normative legal research with statutory and conceptual approaches. Normative legal research is the research study of law as an object and removes any non-legal material from the scope of this research (Christian, 2016). The statutory approach used legal material in this study i.e. Minister of Health Regulation Number 24 of 2022 concerning Medical Records, Indonesian Minister of Health Decree Number HK.01.07/Menkes/1423/2022 concerning Guidelines for Variables and Meta Data in the Implementation of Electronic Medical Records, Minister of Health Regulation Number 4 of 2018 concerning Hospital Obligations and Patient Obligations, and Law Number 27 of 2022 concerning Personal Data
Protection. The aspect of the normative study was the regulation related to general consent of integration EMR and SATUSEHAT’s platform in Indonesia.

Then, the conceptual research method was built to find the legal issues and conceptual framework of general consent of integration EMR and SATUSEHAT’s platform in Indonesia. The conceptual legal approach is legal research that describes and analyzes research problems that can raise issues or gaps that occur due to the vacuum of legislation. This method is used if no law applies to a matter being studied in a country. By using this method researchers can develop valuable recommendations to improve existing legal systems (Negara, 2023). Legal material that was used in this study was primary legal materials i.e. laws and regulations, secondary legal materials were obtained from journal articles and books related to general consent law, as well as secondary legal materials were derived from articles, journals, and books related to legal issues of electronic medical records and the integration of the SATUSEHAT’s platform. This research was conducted from January to March 2023.

**Results**

In the integration of electronic medical records in health services with the SATUSEHAT’s platform, general consent is required regarding patient rights and obligations. General consent is characterized by providing information to the patient which is then followed by the approval of the consent form (Yulia & Nurazizah, 2018). If the patient accepts, the patient will continue to get health services at the health care facility. Meanwhile, if the patient refuses, then the patient has the right to choose another healthcare facility.

In its application, general consent is often not preceded by the provision of complete information, or if the information is provided in writing, the patient often does not read or understand the information provided (Mahriati, 2022). In research conducted by Yulia and Nurazizah (2018), it was stated that the application of providing information or explanations to general consent at Medika Permata Hijau Hospital had not been carried out optimally. Often the patient or the patient’s family is in a hurry to sign without reading or understanding the information submitted first written on the consent form (Yulia & Nurazizah, 2018). The number of queues at registration and limited service time are often the limitations of the information conveyed and patients pay less attention to the information provided before signing the agreement (Rozali, 2023).

This condition has the potential to create misinformation and is prone to conflicts or disputes between patients and health services. Especially in the integration of EMR with the SATUSEHAT’s platform. Therefore the application of general consent in a data release and the extent to which data is integrated needs to be conveyed in general consent. However, two conditions cause several implications that need further attention both in refusing and accepting general consent regarding the integration of EMR with SATUSEHAT’s platform.

1) Implications in the General Consent’s Refusing regarding the Integration of EMR and SATUSEHAT’s platform

General consent is given to patients before patients get general health services at healthcare facilities (Irwansyah et al, 2021). It usually contains information about identity, rules and requirements, confidentiality and disclosure of information, approval for personal property liability, consent for the release of information, information about patient and family rights, information about costs, information on education and research agreements, and special regulations that apply to service facilities. Items in general consent are often in the form of points which are then combined into one and the patient is expected to agree and sign all the points or clauses mentioned so that they can be processed further to obtain health services. With this method, of course, there will be an all-or-none mechanism, especially if there are points that are rejected by patients, such as those related to data exchange or data sharing and data utilization for research.

This of course becomes a dilemma for the patient, having to sign an existing general consent or otherwise not getting health services. On the other hand, the application of general consent related to data sharing and utilization of data for research can be an option that is not required to be fulfilled by patients based on Article 17 paragraph (3) of the Minister of Health Regulation Number 4 of 2018 concerning Hospital Obligations and Patient Obligations which reads "patients has the right to obtain privacy and confidentiality of the illness, including medical data as referred to in paragraph (2) letter (i), including access to the contents of the medical record. Furthermore, paragraph (4) of a similar article states that "the patient has the right to give approval or refuse actions taken by health workers for the disease they are suffering from as referred to in paragraph (2) letter (k) including the right to give approval or refuse to be part of a study” (Indonesian Ministry of Health, 2018). So, in this case, it is clear that patient data sharing and
utilization of patient data for research is an option, not an obligation that must be fulfilled by patients and patients can still have the right to receive health services.

2) Implications in General Consent Acceptance regarding the Integration of EMR and SATUSEHAT’s platform

When patients agree to general consent regarding data sharing and integration of data into the SATUSEHAT’s platform, legal challenges can occur regarding the security and protection of patient data which also includes patient confidentiality, use, and deletion of patient data, and management related to sensitive health data.

Security and protection of patient data

Data security is crucial in the provision of electronic medical records. This has been regulated in Minister of Health Regulation Number 24 of 2022 concerning Medical Records (Indonesian Ministry of Health, 2022c). In the implementation of electronic medical records in healthcare facilities, there are several challenges related to data security. This is because EMR organizing activities include several things such as patient registration, distribution of electronic medical record data, filling in clinical information, processing electronic medical record information, inputting data for financing claims, electronic medical record storage, electronic medical record quality assurance, and transfer of record contents. electronic medical.

Each of these stages involves various resources and technical implementation. So there is the potential for data leakage, either internal or external (Esposito et al, 2018). Indonesia already has Law Number 27 of 2022 concerning Personal Data Protection, where according to Article 4 paragraph (2) health, genetic, and biometric data are included in specific personal data (Indonesian Government, 2022). So health data includes data that must be kept secure.

The existence of interoperability and data sharing between health facilities and the Ministry of Health, or one health facility with another health facility, further increases the risk of data security. This is because it will involve more parties in data management as well as tiered or connected technicalities which will increase the risk of data leakage if it is not balanced with strong and qualified data security. One aspect of health facilities that experiences security weaknesses can affect data security at other health service facilities. In addition, the responsibility of health care facilities and the government is quite large in this regard.

Ownership of electronic medical record data

In the electronic medical record, document ownership belongs to the health care facility. Therefore, health facilities are responsible for loss, damage, falsification, or use by irresponsible parties (Indonesian Ministry of Health, 2022d). The contents of the medical record are the property of the patient and can be conveyed to the patient, the patient’s family, or other parties who have obtained the patient’s consent. All parties in the health facility, including health workers, medical staff, students working at the health facility, and administrative and non-administrative staff, are responsible for the confidentiality and existence of medical record documents. Data storage in electronic medical records is carried out for at least 25 years from the date of the patient’s last visit and can be destroyed through certain procedures (Indonesian Ministry of Health, 2022d). Unless there is further data required, the data can be maintained.

In the opening, the contents of an EMR can be done in writing or electronically but requires patient consent. Nonetheless, based on Ministry of Health Regulation Number 24 of 2022 concerning Medical Records, EMR can be opened without the patient’s consent in certain cases but must obtain the approval of the Minister of Health of the Republic (Indonesian Ministry of Health, 2022d). In this case, further guidance is needed regarding the procedures stages, and conditions under which the data can be disclosed by the Ministry of Health.

Disclosure of medical records can also be done without the patient’s consent if it is done based on a court order. In addition, if the patient or family informs the contents of the medical record to the public, it is deemed to have waived the right to the contents of the medical record related to confidentiality (Indonesian Ministry of Health, 2022d). With the implication that the health facility can disclose EMR as the health facility’s right to answer.

Disclosure of medical records in Article 15 paragraph 1(c) of Law Number 27 of 2022 concerning Protection of Personal Data states that personal data can be disclosed if it is used for public purposes in the context of administering the state and 1(e) related to statistical and scientific research purposes (Indonesian Government, 2022). In this case, further specific guidance is needed regarding the extent to which health-related personal data can be disclosed.
In addition, in the integration of EMR with the SATUSEHAT's platform, patients can view their resume or medical history through the SATUSEHAT application. This is in accordance with Article 7 of Law Number 27 of 2022 concerning Personal Data Protection, which states that personal data subjects have the right to gain access to and obtain copies of personal data about themselves by statutory provisions (Indonesian Government, 2022).

With this convenience and integration, it is beneficial for patients to be able to find out their medical history, but challenges in its implementation are related to patient awareness of the security of their medical data stored in mobile applications. Strengthening the security for logging into the SATUSEHAT application is needed so that only the owner can access the application.

Accountability in the event of data leakage

In the interoperability and data-sharing models that involve the integration of electronic medical records and electronic health records between health service facilities and ministries, the potential for data leakage will increase because it involves various parties (Kayes et al, 2020). The thing that needs to be considered is that if the health facility also uses cloud-based EMR managed by a third party, it is necessary to pay attention to the responsibilities and ownership of and access to the contents of the medical record. Clear agreements regarding responsibilities, access rights, and data storage need to be made between cloud service providers and health facilities.

The types of data that can be shared with health facilities or ministries need to be clarified because health data is sensitive data that must be kept confidential. Legal protection for patients is needed so that patients can continue to receive health services that are safe, confidential private, and of good quality (Kayes et al, 2020).

Discussion

Based on various legal issues that can occur in the integration of EMR with SATUSEHAT's platform, patient legal protection is needed including general consent, security guarantees, data protection, guidelines regarding procedures for use, accessibility, deletion, data ownership, and management of sensitive data, as well as responsibilities in the event of a data leakage.

General consent as an option

To provide legal protection and patient's human rights in determining the desired health service (the right of self-determination) as well as the right to choose and obtain quality health services, it is necessary to apply general consent regarding the release of medical record data and the extent to which the data is integrated with the SATUSEHAT’s platform. Article 11 of Law Number 27 of 2022 concerning Personal Data Protection states that personal data subjects have the right to delay or limit the processing of personal data according to the purpose of processing (Indonesian Government, 2022). In addition, in Article 22 paragraphs (1), (2), and (3) of Law Number 27 of 2022 concerning the Protection of Personal Data it is stated that to process personal data, approval from the owner of personal data is required, both electronically and non-electronically. Furthermore, in paragraph (4) it is stated that the agreement must meet the conditions, namely that it can be clearly distinguished from other matters, made in a format that is understandable and easily accessible, and uses simple and clear language (Indonesian Government, 2022). If the agreement does not meet these conditions, it will be declared null and void.

Based on these regulations, patients have the freedom to accept the sharing of their EMR data on the SATUSEHAT’s platform, and they also have the right to refuse it. To be able to adopt these freedoms or rights, the general consent model needs to be structured in such a way as to provide flexibility for the patient as an option in determining points that are approved and not agreed upon and not incorporated into one clause that is all or none. With this option, patients who refuse to integrate their medical data with the SATUSEHAT's platform can still get the health services they need.

Guarantee of data security and protection of health care facilities and government agencies

Data leakage due to cyber attacks can be minimized by increasing cyber security and cyber hygiene (Coventry& Branley, 2018). Evaluation and testing of network security can be carried out periodically with penetration testing, the use of user passwords, and periodic data backups (Argaw et al, 2020). Meanwhile, behavioral focuses more on user habits such as in accessing the EMR system or web and restrictions on things accessed. Access restrictions are necessary, because the fewer parties that can access the service, the less the risk of leakage (Kioskli et al, 2023).
The application of blockchain can be done to minimize data leakage in EMR. With this model, not only can user privacy protection be maintained but patients can manage their medical data independently (Zhao et al, 2019). There are several stages in implementing cyber hygiene, namely awareness, situation analysis (analysis), planning, implementation, evaluation, and follow-up (European Union Agency for Cybersecurity, 2019).

The awareness stage is crucial as the initial implementation of cyber hygiene related to EMR’s security. There is a need for health facilities and users to understand the urgency of cybersecurity, risks, and implications that can occur in the implementation of EMR (European Union Agency for Cybersecurity, 2019). After there is awareness of the importance of cyber security, it is necessary to analyze the appropriate methods to analyze existing problems or weaknesses. Several combinations of methods can be used to solve this problem (Zhao et al, 2019). For example, in the analysis, it is known that the level of awareness of health workers regarding cyber security is still low. So an alternative solution is needed to overcome it.

The next stage is planning based on alternative solutions that will be implemented (European Union Agency for Cybersecurity, 2019). For example, a low level of awareness will be overcome by implementing training or applying internal health facility regulations. The implementation of behavior change requires an organizational culture which is a long-term program. Several techniques and approaches can be carried out with results that may vary depending on the readiness of the health facility organization. In the final stage, it is necessary to evaluate the results of these interventions, regarding the effectiveness and the resulting implications.

These stages can not only be implemented in healthcare facilities but can also be implemented by parties related to the integration of EMR and SATUSEHAT’s platform. In addition to EMR, strengthening the SATUSEHAT's security system also needs to be carried out. Cyber hygiene patients also need to be socialized, especially in protecting their medical resumes in the SATUSEHAT’s application. Strengthening the security for logging into the SATUSEHAT’s application needs to be strengthened so that only the owner can access the application.

The need for procedural guidelines regarding the use, accessibility, deletion, data ownership, and management of sensitive data

Protection regarding personal data and patient privacy needs to be considered in implementing RME integration with SA’USEHAT’s platform. Even though data sharing can make it easier for patients to obtain health services, this needs to be done with the patient’s consent (Perera et al, 2011).

Guidelines regarding procedures for use, parties who can access, delete, own data, and management of sensitive health data such as diagnoses related to sexually transmitted diseases, history of genetic diseases, and so on need to be prepared so that patients can obtain protection and legal certainty regarding data in electronic medical records (Otjacques et al, 2007). Guidelines regarding health facilities that use cloud-based RME also need to be developed, especially regarding the period of continuation of the collaboration, medical record data managed by third parties, and so on (Budiyanti et al, 2018).

In article 15 paragraph 1(c) of Law Number 27 of 2022 concerning the Protection of Personal Data, it is stated that personal data related to health which is included in specific data can be disclosed if it is used for public purposes in the context of administering the staff and in (e) related to statistical and scientific research (Indonesian Government, 2022). In this case, further specific guidance is needed regarding the extent to which health-related personal data can be disclosed.

Legal protection in the event of a data leakage

Data leakage (data breach) in health services is a major form of failure for managers and data storage in maintaining security and access control (Kayes et al, 2020; Budiyanti et al, 2018). Policies related to responsibility for data leakage need to be developed based on the level of data leakage. Was the data breach at the health facility level, on ‘SATUSEHAT’s platform, or was it the result of the patient’s own mistakes in maintaining the security of their data? The flow of service complaints and those responsible for data leakage need to be clarified.

Apart from that, strict sanctions also need to be developed as a form of guaranteeing legal protection for patients who are willing to submit their health data and personal data in EMR which is integrated with the SATUSEHAT’s platform. In Law Number 27 of 2022 concerning Personal Data Protection, most of the sanctions given are administrative sanctions. Furthermore, in Article 67 paragraphs (1), (2), and (3) and Article 68 of Law Number 27 of 2022 concerning the Protection of Personal Data, criminal sanctions are
given to parties/subjects who collect, use, disclose, and intentionally falsify data person who is not his (Indonesian Government, 2022).

However, the regulation has not yet stated sanctions for the negligence of healthcare facilities providing EMR, cloud third parties, and data integration platform providers in maintaining the security and confidentiality of patient data. So in this case, patient protection and legal certainty are still not fully guaranteed.

**Conclusion**

In implementing the integration of electronic medical records (EMR) in health facilities with the SATUSEHAT’s platform, consent from the patient is stated in the general consent. However, there are ethical and legal challenges related to the implementation of this integration. Patients who refuse the integration of EMR with SATUSEHAT’s platform in general consent have the potential to be denied health services because the general consent form is often an all-or-none clause. Ethical and legal issues can also develop as implications regarding patient consent in the integration of EMR with SATUSEHAT’s platform such as security, confidentiality, and data use. Therefore, healthcare facilities should provide a separate option for clauses in general consent which is preceded by information regarding the risks and benefits obtained in the integration of EMR and the SATUSEHAT’s platform so that the patient’s right to make decisions can be guaranteed. Guarantees regarding the security and privacy of patient data by both health facilities and organizers of the SATUSEHAT’s platform also need to be strengthened so that they do not harm patients. In addition, guidelines regarding data access and ownership need to be developed, and clarification on the responsible party and the sanctions to be imposed in the event of a data leakage need to be further defined. This study has limitation because just use the literature approach to develop the conceptual approach. Further research can use a comparative approach to compare the regulation related to the interoperability of EMR and can do the empirical research related to the need analysis of EMR’s interoperability regulation.

**Author Contributions**

RTB: research article concept, research, correspondence and author, PMH: research and author, AF: research and author, WK: author and proofread.

**Acknowledgments**

None

**Conflicts of Interest:**

None

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