Jurnal Hukum Prasada
Volume 11, Number 1, 2024, pp 16-24
ISSN (print) 2337-795X; ISSN (online) 2548-4524
https://doi.org/10.22225/jhp.11.1.2024.16-24

Original Article

OPEN ACCESS

Legal Approaches for Clinical Audits and Sanctions in Indonesian Health Service Facilities

Ida Ayu Sadnyini, David Christianto[1]*, I Gede Agus Kurniawan[1] & Made Jayantara[1]

1. *Master of Laws, Universitas Pendidikan Nasional, Bali-Indonesia*

Sadnyini, I, A., Christianto, D., Kurniawan, I, G, A., & Jayantara, M (2024). Legal Approaches for Clinical Audits and Sanctions in Indonesian Health Service Facilities. *Jurnal Hukum Prasada*, 11(1), 16-24

Abstract
Laws and regulations in Indonesia have regulated health law to ensure that every person has the right to safe, high-quality, and affordable health services. Article 21 of Law No. 36 of 2009 on Health stipulates that every Health Service Facility must have a good and responsible health service management and governance system. However, the regulation of clinical audits as an effort to reduce the risk of negligence in healthcare facilities and how the process and sanctions for unintended errors in handling patients are still unclear. The research method used is empirical legal research. This research was conducted using the Legislative Approach, Conceptual Approach, and Case Approach. The results show that the regulation of clinical audits as an effort to reduce the risk of negligence in healthcare facilities is still unclear, so an approach based on the principles of justice, legal certainty, and usefulness is needed to reduce the risk of negligence in healthcare facilities. Furthermore, the process of audit and the imposition of sanctions for unintended errors in handling patients in healthcare facilities are subject to civil and criminal lawsuits. The conclusion of this study is that in clinical audits in Indonesia, an approach that prioritizes the principles of justice, legal certainty, and usefulness is needed to reduce the risk of negligence in healthcare facilities, so that all parties are treated equally, sanctions for errors must be fair and proportional, and preventive sanctions should focus on improving the qualifications of health workers, improving systems, and developing policies to improve health services and provide patients with the right to claim compensation and file complaints both civilly and criminally.

Keyword: clinical audit; health service facilities; negligence.

Article History
Received: January 24, 2024
Accepted: March 26, 2024

Introduction

Health law is a set of rules that govern all aspects related to efforts and maintenance in the field of health (Soekidjo, 2016). Health law does not exist in a specific regulation form, but is spread across various regulations and legislation. Some are located in criminal law, civil law, and administrative law, whose application, interpretation, and assessment of facts are in the field of health or medicine (Ta'adi, 2013).

In Pancasila, health is implied in the Second Principle of Pancasila which states: "Justice and civilized humanity". Furthermore, Article 28H Paragraph (1) of the 1945 Constitution states that: "Every person has the right to live prosperously both physically and mentally, to reside, and to obtain a good and healthy environment as well as the right to obtain health services". Furthermore, Article 34 Paragraph (3) of the 1945 Constitution states that: "The State is responsible for providing health care facilities and decent public services." Starting from these, regulations and legislation that regulate all aspects related to efforts and maintenance in the field of health began to be made.

Correspondence regarding this article should be addressed to:
David Christianto, Universitas Pendidikan Nasional, Indonesia
Email address: dvidchristianto@gmail.com

One of the laws that is the main reference in health law is Law Number 36 of 2009 Concerning Health. The right to health services is clearly stated in Article 4 of Law Number 36 of 2009 Concerning Health, which states that: "Every person has the right to health". Furthermore, the right to health is clarified in Article 5 Paragraph (2) of Law Number 36 of 2009 Concerning Health, which states that: "Every person has the right to obtain safe, quality, and affordable health services"(DJPK, 2022).

To fulfill the right to safe, quality, and affordable health services, therefore the provision of health services must be carried out responsibly, safely, with quality, and evenly and nondiscriminatory, in accordance with Article 54 Paragraph (1) of Law Number 36 of 2009 Concerning Health. Therefore, the government is obliged to establish quality standards for health services, because the government is also responsible for the availability of all forms of quality, safe, efficient, and affordable health services. This is in accordance with Article 19 and Article 55 Paragraph (1) of Law Number 36 of 2009 Concerning Health. Furthermore, in Article 94, Article 126 Paragraph (3), Article 144 Paragraph (4), and Article 153, it is explained that the Government and local governments are obliged to guarantee the availability of personnel, service facilities, equipment, and drugs in order to provide safe, quality, effective, affordable, and evenly distributed health services for the public.

To provide safe, quality, effective, affordable, and equitable health services to the public, the government regulates the planning, procurement, utilization, development, and quality control of healthcare workers in the provision of healthcare services, as stipulated in Article 21 Paragraph (1) of Law Number 36 of 2009 concerning Health. Article 21 of Law Number 36 of 2009 concerning Health mandates that every Healthcare Facility (Faskes) must have a good management and clinical governance system to be able to provide safe, quality, and affordable healthcare services. Good Clinical Governance (GCG) is an important concept in clinical governance aimed at ensuring patient safety, treatment effectiveness, and healthcare service efficiency. One way to implement GCG is through clinical audits.

Based on the Kamus Besar Bahasa Indonesia (KBBI), an audit is a periodic examination of financial books (of companies, banks, and so on) or an evaluation of the effectiveness of the inflow and outflow of money and the reasonableness of the resulting reports (KBBI Daring, 2022). Although most audits are related to financial matters, clinical audit is used by healthcare professionals (particularly care providers) to systematically evaluate, estimate, and improve the quality of healthcare services (Samiran, 2022). Care providers may include medical personnel (doctors, dentists, specialists, and dental specialists), nursing personnel, midwifery personnel, pharmaceutical personnel, nutrition personnel, physical therapy personnel, and other healthcare personnel who directly provide care to patients (MenKes, 2022).

Auditing clinical care is not well-defined in the Indonesian Health Law No. 36 of 2009. The law only implies clinical audit in Article 21 Paragraph (1) stating that "the government regulates the planning, procurement, utilization, development, and quality control of health workers in the implementation of health services", and in Article 182 Paragraph (1) stating that "the Minister supervises the public and any organizer of activities related to health resources and health efforts." Furthermore, according to Articles 183, 184, 186, and 189, the supervision can be carried out by supervisors appointed by the Minister or the head of the department to oversee everything related to health resources and health efforts.

The National Institute for Clinical Excellence (NICE) defines clinical audit as a process that aims to improve the quality of patient care and outcomes by systematically analyzing the services provided using predetermined criteria and then implementing necessary changes (Cowan, 2002). Clinical audits can be performed internally or externally. Clinical audits can provide feedback to the government and healthcare facility administrators about the quality of healthcare services provided by healthcare workers (Sidharta, 2020). This is in line with Article

49 Paragraph (2) and Article 74 of the Republic of Indonesia Law No. 29 of 2004 on Medical Practice, which uses medical audits as a professional evaluation of the quality of medical care provided to patients using medical records carried out by medical professionals (UU PKedokteran, 2004).

Unfortunately, the effort to evaluate the quality of healthcare services professionally is limited to the establishment of clinical audit as one of the assessment elements in Patient Safety and Quality Improvement Standards point 7 used for hospital accreditation in the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1128/2022 Regarding Hospital Accreditation Standards. In this assessment, only the assessment element is mentioned, namely, "The hospital has conducted clinical and/or medical audits on the application of priority medical service standards in the hospital." There is no recommendation for how often clinical audits should be conducted. The existing regulation also only refers to Article 40 of Law Number 44 of 2009 concerning Hospitals which requires hospitals to undergo accreditation at least once every 3 (three) years. Hospital accreditation can be carried out by an independent institution either from within or outside the country based on applicable accreditation standards.

This is regrettable, considering that clinical audits can compare patient care provided in healthcare facilities by healthcare workers with standard healthcare protocols (Nundy, 2020) Healthcare facilities can minimize the risk of errors and improve the quality of healthcare services they provide. The risk of errors in healthcare services is very important to consider because it can impact patient safety and health, as well as cause losses to healthcare service consumers.

One example is the case of Dr. Wida Parama Astiti, who was convicted by the Supreme Court for malpractice resulting in the death of a 3-year-old patient, and sentenced to 10 months in prison. According to expert testimony, the administration of KCL injection should have been done by mixing it with an infusion so that the KCL fluid could enter the patient's body slowly. In this case, there was negligence in following the standard protocol of health care services, leading to the death of a patient. This could have been prevented if the risk of negligence had been identified earlier and corrective action taken.

Clinical audit is an important tool to help health care facilities minimize such risks. However, there is a regulatory gap in the regulation of clinical audits, as identified in Law No. 36 of 2009 on Health, which lacks provisions on clinical audit, including its definition, frequency, supervision and control, as well as sanctions for health care providers who fail to comply with clinical audit standards or participate in clinical audits.

Therefore, this article explores the following research questions; whether the regulation of clinical audits is clear as an effort to reduce the risk of negligence in healthcare facilities and how the process and sanctions are if there are unintentional errors in handling patients.

Method

The research method used is empirical legal research. This research was conducted using the Legislative Approach, Conceptual Approach, and Case Approach. Referring to the type and approach of research used, the main data used in this study are secondary data in the form of legal materials. Primary legal materials include the 1945 Constitution, the Criminal Code, Law Number 36 of 2009 on Health, Law Number 29 of 2004 on Medical Practice, Law Number 44 of 2009 on Hospitals, Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1128/2022, and various sources of secondary and tertiary legal materials. The legal materials collected through literature review were then processed by conducting inventory, identification, classification, and systematization. After the legal materials were systematically arranged, the next step was to conduct a juridical analysis. Juridical analysis was conducted by examining legal materials that can be contested, criticized, supported, added, or provided legal comments or arguments. Then, the results of the analysis will be used as a basis for making conclu-

sions with one's own thoughts, supported by the theory that has been prepared beforehand (Zainal & Tjoa, 2006).

Discussion

Clinical Audit Regulation as an Effort to Reduce Errors Risk in Health Service Facilities

The interpretive approach can be used to address the gaps in regulations for clinical audits in Indonesia by interpreting existing norms and referring to general legal principles (Shidarta, 2000). Generally, the regulation of clinical audits in Indonesia is governed by the Health Law No. 36 of 2009. However, this regulation does not explicitly regulate clinical audits in detail, resulting in gaps in the regulation of clinical audits in Indonesia (Asmara, 2020). In this case, interpretation of existing norms can be done by referring to general legal principles (Paul, 2015). For example, legal principles related to clinical audits such as fairness, legal certainty, and usefulness can be used as a reference to form new legal rules to fill these gaps in regulations.

To address the gaps in regulations for clinical audits in Indonesia, an interpretive approach can be used by referring to legal theory, specifically the principles of fairness, legal certainty, and usefulness (Moreso, 2018). By referring to these general legal principles, it is possible to interpret existing norms and address the gaps in regulations for clinical audits in Indonesia. Therefore, the authorities need to create clear and definitive regulations regarding clinical audits, including defining the frequency and supervision of clinical audits, as well as establishing sanctions for healthcare providers who do not meet clinical audit standards or fail to participate in clinical audits.

The interpretive approach using the principle of justice emphasizes the importance of equal treatment for all parties involved in clinical audits. In this regard, it should be noted that clinical audits are carried out to improve the quality of healthcare services provided to the public. Therefore, fair treatment must be given to all parties involved in clinical audits, including healthcare providers, the public, and those involved in the supervision and control of clinical audits (Katharina & Peter, 2015). Healthcare providers must be provided with adequate and non-discriminatory legal protection. (Efa, 2019). linical audit regulations must clearly define the rights and obligations of healthcare providers in clinical audits (Efa, 2019). In addition, mechanisms for resolving disputes or complaints that are fair and transparent should also be regulated in case of disputes between healthcare providers and those involved in the supervision and control of clinical audits (Ash & Gunn, 2003).

Meanwhile, the public must also be given equal legal protection in clinical audits. Clinical audit regulations should consider the interests of the public in receiving quality healthcare services. Therefore, clinical audit regulations must clearly define the rights and obligations of the public in the clinical audit process, including the right to obtain clear and transparent information on the results of clinical audits and the resolution of disputes or complaints in case of dissatisfaction with healthcare services (Desy, et al, 2023). The principle of justice should also be applied to those involved in the supervision and control of clinical audits. Clinical audit regulations must clearly define the obligations and rights of those involved in the supervision and control of clinical audits, including the right to monitor and oversee the clinical audit process and take appropriate action if violations or non-compliance are found in clinical audits (Mirelle Hanskamp-Sebregts et al , 2020).

By consistently applying the principle of justice in the regulation of clinical audits, it is hoped that a fair and transparent clinical audit system will be created for all parties involved. This will help improve the quality of healthcare services provided to the public and provide adequate legal protection for all parties involved in the clinical audit process (Shivansh & Srivastava, 2020).

The interpretative approach using the principle of legal certainty emphasizes the importance of clear and strict regulation of clinical audits in Indonesian law. The aim is to create legal certainty for all parties involved in the clinical audit process. In this regard, regulations on clinical audits must be clearly and specifically defined, including the definition, frequency, supervision, and control of clinical audits, as well as sanctions for healthcare providers who do not meet clinical audit standards or do not participate in clinical audits. Additionally, clear and measurable procedures for conducting clinical audits need to be established (Nicole & Daniel, 2021).

Regulations on clinical audits must also be predictable and consistent so that all parties involved can understand what is expected of them during the clinical audit process. This will make it easier for

healthcare providers, the public, and stakeholders involved in clinical audit supervision and control to comply with and understand clinical audit regulations. Furthermore, the regulations on clinical audits need to include clear and measurable mechanisms for resolving disputes or complaints. This will provide legal certainty for all parties involved in the clinical audit process, so that if disputes or dissatisfaction arise during the audit process, clear and measurable mechanisms for resolving them can be followed to address the problem (Nicole & Daniel, 2021).

By consistently applying the principle of legal certainty in the regulation of clinical audits, it is hoped that a predictable, clear, and consistent clinical audit system can be established for all parties involved. This will help improve the quality of healthcare provided to the public and create legal certainty for all parties involved in the clinical audit process (Nicole & Daniel, 2021).

The interpretive approach using the principle of utility emphasizes the importance of regulation that ensures clinical audits can provide optimal benefits for all parties involved, including healthcare providers, patients, and the wider community. In this regard, regulations concerning clinical audits should be based on the goal of improving the quality of healthcare services and patient safety, as well as enhancing the effectiveness and efficiency of the healthcare system as a whole. Regulations should ensure that clinical audits not only focus on the technical aspects of healthcare services, but also consider patients' experiences, quality of life, and broader social impact ((Nicole & Daniel, 2021).

Regulations concerning clinical audits should also consider the benefits for stakeholders, such as healthcare providers, hospital management, and the community. Clinical audits should benefit healthcare providers in improving their competence and skills in providing quality healthcare services. Clinical audits should also benefit hospital management in improving the overall effectiveness and efficiency of the healthcare system. Furthermore, clinical audits should benefit the community in improving the quality of healthcare services provided(Johnston, 2021).

In regulating clinical audits, patient needs and expectations must also be considered. Clinical audits should benefit patients in improving safety, service quality, and overall patient experience. Regulations should ensure that patients have the right to know and participate in the clinical audit process, as well as provide feedback and suggestions to improve healthcare service quality (Cowan,2002).

Consistently applying the principle of utility in regulating clinical audits is expected to create an effective and efficient clinical audit system that can benefit all parties involved. This will help improve the quality of healthcare services and patient safety, as well as enhance the effectiveness and efficiency of the healthcare system as a whole (Samanta, 2003).

Clinical Audit Process and Sanctions for Unintentional Errors in Patient Care

Unintentional errors occur when a medical action is not carried out with adequate skill, knowledge, or experience or due to environmental factors that do not support it (Jeffrey, 2005). The term "medical negligence" is used in the field of medical law to describe such unintentional errors. These errors are usually not intended to harm the patient and are made unintentionally by healthcare professionals (Dirjen Pelayanan Kesehatan, 2022). Unintentional errors can occur in various healthcare service situations, such as errors in administering the wrong dose of medication, errors in diagnosis, errors in surgery, or errors in patient care. Environmental factors such as a lack of healthcare equipment, time, or fatigue can affect the occurrence of unintentional errors. Although unintentional, such errors can have serious consequences for the patient. These errors can cause injury, organ damage, infection, or even death (Jennifer & Brit, 2017) (Rohan, et al, 2019).

According to Article 58 Paragraph (1) of the 2009 Health Law, every person has the right to claim compensation from an individual, healthcare professional, and/or healthcare provider who causes harm due to errors or negligence in the healthcare services received. Medical confidentiality breaches are included as a "loss" due to healthcare services.

Furthermore, Article 66 Paragraph (1) of the 2004 Medical Practice Law states that: "Any person who knows or whose interests are harmed by the actions of a doctor or dentist in carrying out medical practice may file a written complaint with the Chairman of the Indonesian Medical Discipline Honorary Council." Those who cannot file a written complaint may still do so verbally. In addition, Paragraph (3) of the 2004 Medical Practice Law confirms that complainants may still report alleged criminal acts to the authorities and/or sue for civil damages in court.

However, according to Article 29 of the 2009 Health Law, if a healthcare professional is suspected of negligence in carrying out their profession, such negligence must first be resolved through mediation. Mediation is carried out with the aim of resolving disputes outside of court by a mediator agreed upon by the healthcare professional providing healthcare services and the patient as the recipient of healthcare services. In addition, healthcare professionals who perform life-saving actions or prevent disability in an emergency cannot be sued for damages.

After a complaint has been filed, if found guilty, the Indonesian Medical Discipline Honorary Council will impose disciplinary sanctions regulated in Article 69 Paragraph (3) of the 2004 Medical Practice Law, namely written warnings, recommendations to revoke registration certificates or practice permits, and obligations to attend education or training at medical or dental education institutions.

This is in accordance with Article 71 and Article 72 of the 2004 Medical Practice Law, which states that the central government, the Indonesian Medical Council, local governments, and professional organizations must nurture and supervise medical practice in accordance with their respective functions and duties. Development and supervision are aimed at improving the quality of healthcare services provided by doctors and dentists, protecting the public from the actions of doctors and dentists, and providing legal certainty for the public, doctors, and dentists alike (Ismail & Erwin, 2021) (Yusuf, 2023).

There are several theories of sanction application that can be adjusted according to each specific case, such as absolute sanction theory, relative sanction theory, preventive sanction theory, and restorative sanction theory. In the context of healthcare, absolute sanction theory may not be relevant because excessively severe sanctions can hinder healthcare professionals' ability to provide good service and have negative impacts on patients. Furthermore, restorative sanction theory may also be less relevant because negligence reported in the context of healthcare often has serious consequences and significant negative impacts on patients (disability or death), making efforts to rectify the mistake, repair damaged relationships with victims, and restore the situation as much as possible very difficult or impossible (Robertson, 2018).

Therefore, this study uses relative sanction theory and preventive sanction theory to analyse sanctions in the event of unintentional errors in patient care (Walesa, 2022). Relative sanction theory considers that sanctions should be adjusted according to the level of error committed and the specific circumstances of the case. In the context of healthcare, this theory can be useful in ensuring that the sanctions imposed are fair and proportional to the error committed, and consider contextual factors and conditions that occur in the case. In cases of unintentional errors in patient care, relative sanctions may include several factors, such as the level of error committed, whether the error could have been prevented, the impact of the error on the patient, and whether the error occurred due to a lack of training or knowledge, or due to system failure. For example, if the error is not too serious and does not have a significant negative impact on the patient, the sanction imposed may be a reprimand or retraining. However, if the error is serious and preventable, more severe sanctions such as dismissal or legal sanctions may need to be imposed. Additionally, if the error occurs due to system failure or lack of training, the sanction imposed may be training or system improvement. By applying relative sanction theory, it can ensure that the sanctions imposed are fair and not too excessive or lenient. This can help improve practices and improve the quality of healthcare, as well as provide a deterrent effect on offenders and prevent similar errors in the future (Puteri, 2016).

The theory of preventive sanctions suggests that sanctions should be given as an effort to prevent future mistakes or undesirable actions. In the context of healthcare, this theory can help ensure that the services provided always meet high standards and reduce the risk of errors that could harm patients. In cases of unintentional mistakes in patient care, preventive sanctions may involve several factors, such as the cause of the error, the level of error, and the potential impact of the error on the patient and healthcare services in general. For example, if an error occurs due to a lack of training or knowledge, then preventive sanctions may involve training or improving the qualifications of the relevant healthcare personnel. Additionally, if the error is caused by system failure, then preventive sanctions may involve improving the system or procedures to ensure that similar errors do not occur in the future. Preventive sanctions may also involve the development and implementation of stricter and clearer policies or guidelines related to healthcare practices. This can help improve the quality of healthcare services and minimize the risk of future errors. By implementing the theory of preventive sanctions, the sanctions given can help prevent errors that could harm patients and ensure that healthcare practices always meet high

standards. Additionally, this theory can help improve healthcare systems and procedures, thus minimizing the risk of future errors and increasing patient confidence in healthcare services (Dananjaya, et al, 2019).

Not only can complaints about healthcare services provided by healthcare personnel be reported, but Article 32 of Law Number 44 of 2009 Regarding Hospitals also guarantees the right of patients to file complaints about the quality of services received, sue and/or demand both civilly and criminally, and complain about hospital services that do not meet service standards through print and electronic media in accordance with the provisions of laws and regulations.

In Indonesia, criminal regulations for malpractice are found in Article 359 of the Criminal Code (KUHP). This article states that any doctor or other healthcare worker who performs medical treatment that harms the patient, resulting in severe injury or death, may be subject to criminal sanctions. The criminal sanctions that can be applied include imprisonment for up to 9 years and/or a fine of up to 1 billion rupiah. In addition, the doctor or healthcare worker may also be subject to administrative sanctions such as revocation of their practice license.

In the context of justice theory, sanctions must be considered proportional to the wrongdoing committed and based on the principle that everyone is responsible for their actions. In this case, the sanctions given to healthcare workers who commit negligence due to the absence of clinical audit regulations in their healthcare facilities should consider their contribution and responsibility for the negligence. If healthcare workers have a responsibility to carry out clinical audits and fail to do so properly or ignore the results of clinical audits, the sanctions imposed should include patient compensation and appropriate administrative sanctions based on their role and responsibility.

However, if there are no clear clinical audit regulations and healthcare workers have no specific role or responsibility in this regard, the sanctions imposed should include the development and implementation of better policies and practices to prevent future negligence. In this case, the sanctions imposed should focus on improving the system and practices, rather than just correcting individual mistakes. For example, this can be done by improving the effectiveness of clinical audit systems and ensuring that healthcare workers have the knowledge and skills needed to carry out clinical audits properly. Therefore, the sanctions imposed can help improve healthcare practices and prevent future negligence, providing long-term benefits to patients and society.

If the negligence committed by the healthcare workers leads to disability or even death of the patient, the sanction imposed must be more serious and firmer. This is because the negligence has had a serious impact on the patient, their family, and the community served by the healthcare facility. In the context of justice theory, the sanction imposed should consider the mistakes made and be based on the principle that every person should be responsible for their actions. In this case, healthcare workers who commit negligence that leads to disability or death of the patient must be held accountable for their actions, and the sanctions imposed should include recovery of damages for the patient and their family, as well as appropriate administrative and criminal penalties. However, the sanctions imposed should also consider the context and mitigating factors that may affect the actions of healthcare workers. For example, if negligence occurs due to a lack of resources or support in a poor work environment, the sanctions imposed should include improving the work environment and providing the necessary resources to prevent negligence in the future. In all cases, the sanctions imposed should focus on improving systems and better practices rather than just fixing individual mistakes. Effective sanctions should help prevent future negligence and provide long-term benefits for patients and the community as a whole.

Conclusion

The clinical audit arrangement to reduce the risk of negligence in healthcare facilities is still unclear, therefore an approach is needed with principles of fairness, legal certainty, and utility to reduce the risk of negligence in healthcare facilities. The fairness approach ensures that all parties in clinical audits are treated equally. Performance evaluations are carried out with a clear and objective assessment system, including medical and non-medical staff, as well as patients. The legal certainty approach emphasizes that clinical audit arrangements must have a strong and clear legal basis. The government can issue regulations regarding clinical audits, their procedures, and who is responsible. The utility approach ensures that clinical audits provide the greatest benefit to those involved, especially patients. The goal is to improve

healthcare services and reduce the risk of negligence in healthcare facilities.

The process of clinical audit and sanctions for unintentional errors in handling patients in healthcare facilities are provided by ensuring that the sanctions given are fair and proportional to the mistakes made, and prevent mistakes from happening in the future. The relative imposition of sanctions must consider several factors such as the level of error, the impact of the error on patients, and the cause of the error. Meanwhile, preventive sanctions should focus on improving the qualifications of healthcare workers, improving systems, and developing policies or guidelines. Patients have the right to demand compensation, file complaints about the quality of healthcare facilities, and sue both civilly and criminally.

References

Ameratunga, R., Hilary, K., Jenny, V., Alan, M., & Jonathan, C.(2019).Criminalisation of Unintentional Error in Healthcare in the UK: A Perspective from New Zealand. *BMJ*, March 7, l706. https://doi.org/10.1136/bmj.l706.

Amiruddin, A. Z. (2006). Pengantar Metode Penelitian Hukum Jakarta: Raja Grafindo Persada. *Cet. Ke-1*.

Asmara, G. Y. P., Hartiwiningsih, H., & Isharyanto, I. COMPARING MEDICAL AUDIT SYSTEMS AND REGULATING: A SYSTEMATIC REVIEW. In *The 4th Legal Internasional Conference and Studies* (Vol. 4, No. 4). Boghossian, Paul. "Rules, Norms and Principles: A Conceptual Framework," 3–11, 2015. https://doi.org/10.1007/978-3-319-09375-8_1.

Brown, G. C., Brown, M. M., & Sharma, S. (2000). Health care in the 21st century: evidence-based medicine, patient preference-based quality, and cost effectiveness. *Quality Management in Healthcare*, *9*(1), 23-31.KBBI Daring. "Audit," 2022. https://kbbi.kemdikbud.go.id/entri/audit.

Cowan, P. J. (2002). The role of clinical audit in risk reduction. *British Journal of Clinical Governance*, *7*(3), 220-223.

Dananjaya, A. N. D., Dewi, A. A. S. L., & Suryani, L. P. (2019). Sanksi malpraktik dan resiko medik yang dilakukan oleh dokter. *Jurnal Analogi Hukum*, *1*(1), 6-10

Direktur Jenderal Pelayanan Kesehatan.(2022) Keputusan Direktur Jenderal Pelayanan Kesehatan Nomor HK.02.02/I/0522/2022 Tentang Pedoman Pelaksanaan Audit Klinis di Rumah Sakit.

DM, M. Y., Yunis, H., Hasibuan, H., & Saragih, G. M. (2023). Analisis Yuridis Terhadap Tindakan Malpraktik Yang Dilakukan Oleh Tenaga Medis. *Jurnal Pendidikan dan Konseling (JPDK)*, *5*(1), 84-91.

Hanskamp-Sebregts, M., Robben, P. B., Wollersheim, H., & Zegers, M. (2020). Transparency about internal audit results to reduce the supervisory burden: A qualitative study on the preconditions of sharing audit results. *Health Policy*, *124*(2), 216-223..

Hikmawati, P. (2017). Pidana Pengawasan Sebagai Pengganti Pidana Bersyarat Menuju Keadilan Restoratif (Criminal Conditional Supervision As a Substitute of Probation Sentence Towards Restorative Justice). *Negara Hukum: Membangun Hukum Untuk Keadilan Dan Kesejahteraan*, *7*(1), 71-88.

Kieslich, K., & Littlejohns, P. (2015). Does accountability for reasonableness work? A protocol for a mixed methods study using an audit tool to evaluate the decision-making of clinical commissioning groups in England. *BMJ open*, *5*(7), e007908.

Khanna, S., & Srivastava, S. (2020). Patient-centric ethical frameworks for privacy, transparency, and bias awareness in deep learning-based medical systems. *Applied Research in Artificial Intelligence and Cloud Computing*, *3*(1), 16-35.

Made, W. P. I. (2022). Ideologi Pancasila Sebagai Dasar Tujuan Pemidanaan dalam Pembaharuan Hukum Pidana Nasional. *Vyavahara Duta*, *17*(1), 55-64.

Mannasa, Y. A., & Fakhriah, E. L. Legal Protection of Doctors as Health Services Providers: Implementing the Balance Principle in Indonesia. *International Journal of Innovation, Creativity and Change*, *10*.

Koto, I., & Asmadi, E. (2021). Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik Tenaga Medis di Rumah Sakit. *Volksgeist: Jurnal Ilmu Hukum dan Konstitusi*, 181-192.

Menteri Kesehatan Republik Indonesia. Keputusan Menteri Kesehatan Republik Indonesia Nomor HK.01.07/MENKES/1128/2022 Tentang Standar Akreditasi Rumah Sakit (2022).

Moreso, J. J., & Chilovi, S. (2018). Interpretive Arguments and the Application of the Law. *Handbook of legal reasoning and argumentation*, 495-517.

Ningsih, Desy Kartika, Dey Ravena, and Agus Hadian Rahim. "Settlement of Medical Crimes by the Medical Committee and Medical Audit." *International Journal of Law and Society (IJLS)* 2, no. 3 (July 20, 2023): 189–205. https://doi.org/10.59683/ijls.v2i3.37.

Nundy, S., Kakar, A., & Bhutta, Z. A. (2022). *How to Practice Academic Medicine and Publish from Developing Countries?: A Practical Guide* (p. 465). Springer Nature.

Presiden Republik Indonesia.(2004) Undang-Undang Nomor 29 Tahun 2004 Tentang Praktik Kedokteran.

Robertson, J. J., & Long, B. (2018). Suffering in silence: medical error and its impact on health care providers. *The Journal of emergency medicine*, *54*(4), 402-409.Rose, Nicole, and Daniel S J Pang. "Review Article Compte Rendu A Practical Guide to Implementing Clinical Audit." *Canadian Veterinary Journal* 62, no. 5 (2021): 145.

Rothschild, J. M., Landrigan, C. P., Cronin, J. W., Kaushal, R., Lockley, S. W., Burdick, E., ... & Bates, D. W. (2005). The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care. *Critical care medicine*, *33*(8), 1694-1700.Samanta, Ash, Jo Samanta, and Michael Gunn. "Legal Considerations of Clinical Guidelines: Will NICE Make a Difference?" *Journal of the Royal Society of Medicine* 96, no. 3 (March 23, 2003): 133–38. https://

doi.org/10.1177/014107680309600310.

Shidarta, S. (2020). Bernard Arief Sidharta: Dari Pengembanan Hukum Teoretis ke Pembentukan Ilmu Hukum Nasional Indonesia. *Undang: Jurnal Hukum*, *3*(2), 441-476.

Siswati, Sri.(2013). *Etika Dan Hukum Kesehatan Dalam Perspektif Undang-Undang Kesehatan*. Jakarta: Rajawali Pers.

Soekidjo, N. (2010). Etika dan hukum kesehatan. *Jakarta: Rineka Cipta*, *44*.

Ta'adi, N., & Angelina, B. (2013). Hukum Kesehatan Sanksi dan Motivasi Bagi Perawat. *Penerbit Buku Kedokteran EGC, Jakarta*.