



MEDICAL AUDIT ARRANGEMENTS TO REALIZE HUMANE LEGAL PROTECTION IN MEDICAL PRACTICE

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Abstract

Medical audits are required in medical practice as a means of quality control and cost control so that the humanitarian principles and legal protections on which the basis and objectives of regulating medical practice in Indonesia can be achieved. Imperative rules are needed so that the conduct of a medical audit becomes a legal obligation. This is normative legal research with legal, conceptual, and comparative approaches. The study results concluded that the medical audit regulatory model in the Indonesian Medical Practice Law must be based on imperative legal norms and not contain vague (*vague norms*). This refers to reconstructing the norms of Article 49 and Article 79 of Law Number 29 of 2004 concerning Medical Practice by changing the word "may" to "mandatory," harmonization of regulations related to health service facilities in regulating medical audits by providing the concept of guidelines for the implementation of medical audits as a form of accountability and legal protection for doctors, health service facilities, and patients, adding sanctions norms for health care facilities that were not conducting medical audits, as well as strengthening the role of Professional Organizations in the implementation of medical audit functions.

Keywords: Medical; Audit Arrangements; Realize Humane; Legal Protection; Organizations

INTRODUCTION

Legislation in Indonesia, namely Article 1 of Law No. 29 of 2004 concerning Medical Practice (Law on Medical Practice), defines the medical practice as a series of health effort activities performed by doctors and dentists towards patients. The provision of this medical practice is the implementation of human rights as mandated by Article 28H paragraph (1) of the 1945 Constitution that everyone has the right to live a prosperous life physically and mentally, to re-side, and to get a good and healthy living environment and the right to health services. The derivation of human rights in the constitution stipulates explicitly that the practice of medicine is carried out based on scientific values, benefits, justice, humanity, balance, and patient protection and safety. Human Values are the central values that are upheld and have a close relationship with the purpose of regulating medical practice, namely to ensure patient protection and safety.

Medical action errors occur due to various things: competence, governance of medical service institutions, vested conflicts of interest, and sectoral egos on the part of healthcare providers when making policies. This is by individuals and corporations as private or government health service providers. Medical action errors are defined as failures of actions that are planned to be completed.⁴ Leape defines a mistake as an unintentional action or an action that does not achieve its purpose.⁵

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Research on medical errors is widely conducted in America and Australia.⁶ This study analyzed medical records and assessed them to find evidence of adverse events or negligence.⁷ Brennan et al. Of the 30,121 patients treated at 51 hospitals in New York in 1984, preventive adverse events occurred in 3.7% of cases (69% were medical errors).⁸ Australia's healthcare quality studies show adverse events in 16.6% of cases, permanent disability in 13.7%, and death in 4.9%. 51% of adverse events are considered preventable.⁹ Adverse events that occur can only be obtained when medical research or audit is carried out. This indicates the need for a medical audit in the hospital.

Some cases of medical error in Indonesia, including Ayu Tria case, in 2012 at RSAB Harapan Kita, Jakarta. His condition suddenly dropped, but he experienced a delay which was considered patient neglect, due to the hospital being shot for a feature film. However, in this case, the Indonesian Consumer Foundation stated that malpractice was not indicated. At that time, the perpetrator used a laser circumcision tool, which was known to the perpetrator did not have official permission.¹⁰

In October 2015, the victim named Falia Raafan Blegur died at Awal Bros Hospital Bekasi. The victim was admitted on Thursday, October 29, 2015, and died on Sunday, November 1, 2015, on suspicion of malpractice due to dehydration. In September 2019, a case of expired vitamin use was at one of the North Jakarta Health Centers.¹¹ Medical errors can occur due to negligence, new procedures, new diseases, doctors and dentists who are not up-to-date in medical services, and patient factors that, at the time of determining the diagnosis, some symptoms and conditions are not recorded by the doctor, so that they are not well documented. In January 2020, a lawsuit case against dr. Elizabeth, the doctor of Belle Beauty Care Makassar beauty clinic, allegedly caused the victim Agita Diola Fitri to experience permanent blindness after seeking treatment.¹² The case of a private hospital in Banyuwangi in November 2020, and the researcher, in this case participated as an observer to find a case of a patient's claim to one of the doctors, which was reported to the police for criminal

⁴ Institute of Medicine (US) Committee on Quality of Health Care in America, *To Err Is Human: Building a Safer Health System*, ed. oleh Linda T. Kohn, Janet M. Corrigan, dan Molla S. Donaldson (Washington (DC): National Academies Press (US), 2000), <http://www.ncbi.nlm.nih.gov/books/NBK225182/>.

⁵ L. L. Leape, "Error in Medicine," *JAMA* 272, no. 23 (21 Desember 1994): 1851–57.

⁶ S. N Weingart, "Epidemiology of Medical Error," *BMJ* 320, no. 7237 (18 Maret 2000): 774–77, <https://doi.org/10.1136/bmj.320.7237.774>.

⁷ Troyen A. Brennan dkk., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I," *New England Journal of Medicine* 324, no. 6 (7 Februari 1991): 370–76, <https://doi.org/10.1056/NEJM199102073240604>.

⁸ Brennan dkk.

⁹ L Pietra dkk., "Medical errors and clinical risk management: state of the art," *Acta otorhinolaryngologica Italica : organo ufficiale della Società italiana di otorinolaringologia e chirurgia cervico-facciale* 25 (Januari 2006): 339–46. hlm. 342

¹⁰ Okezone, "Mantri 'Khitan Berdarah' di Pekalongan Terancam Penjara 5 Tahun: Okezone News," <https://news.okezone.com/>, 11 September 2018, <https://news.okezone.com/read/2018/09/11/512/1948889/mantri-khitan-berdarah-di-pekalongan-terancam-penjara-5-tahun>.

¹¹ "Soal Vitamin Kedaluwarsa di Puskesmas Kamal Muara, BPOM Bantah Kecolongan," diakses 30 Januari 2021, <https://health.detik.com/berita-detikhealth/d-4675243/soal-vitamin-kedaluwarsa-di-puskesmas-kamal-muara-bpom-bantah-kecolongan>.

¹² "Miris... Kasus Malapraktik Penyebab Korban Buta Permanen Terancam Tanpa Kabar – FAJAR," diakses 30 Januari 2021, <https://fajar.co.id/2019/03/21/miris-kasus-malapraktik-penyebab-korban-buta-permanen-terancam-tanpa-kabar/>.



proceedings. In this case, it is suspected that in a tooth extraction operation, the patient suffered a lower jaw fracture, which led to a lawsuit and demands from the patient. A medical audit was conducted, there was no fault on the doctor's part, and the case was settled through mediation.

The record of the above incident illustrates the injury to the patient's human value so patient protection and safety deserve attention. Not all patients experience problems and types of diseases that are precisely the same as what is written in the medical literature. Medicine is like an art, including investigating whether patients are honest in communicating symptoms and complaints so that diseases can be diagnosed appropriately.

Related to the Honorary Council of Medical Ethics (MKEK) of the Indonesian Medical Association (IDI) defines medical dispute as namely "Disagreement between the doctor and the patient/client or his family (both referred to as parties) in or after the doctor-patient/client relationship in the form of the doctor's complaint to health facilities, IDI, MKEK or other disciplinary and judicial institutions."¹³ Customary laws of proof cannot answer about quality control and cost, which affects patient safety. The medical audit is an activity that can minimize quality and costs that need to be more responsive to changes in health services.

The formulation of Article 49 and Article 74 of the Law on Medical Practice regarding medical audits contains vague norms (vague normen). This legal problem must be further examined by evaluating, critiquing, and resolving medical disputes. A medical practice requires legal certainty for the implementation of medical audits, along with its function and position as one of the documents and evidence that medical practice is protected from malpractice and maladministration. There has been an injury to human values, patient protection, and safety when there is a suspicion or potential for malpractice and maladministration. At this level, the practice of medicine is dehumanized.

A comparative study with the United Kingdom states in its regulations states that hospital medical audits must be carried out. Medical audit includes assessment of medical and managerial service responsibilities, organization, recording, and evaluation.¹⁴ The medical audits are structured as systematic, quantified, and formal documents rather than traditional clinical ward rounds, meetings, and case presentations but share the goal of better patient care and education.¹⁵ The Health Office carries out supervision of the implementation of medical audits. Medical audits are conducted with a systematic, peer-reviewed approach to ongoing medical treatment. Different from Indonesia, this systematic approach is necessary, not just an option that makes medical audits legally uncertain.

Guidance and supervision of medical practice carried out through medical audits is a means of legal protection and an instrument of behavioral control. This shows that the constitutional rights of doctors and patients must be fulfilled so that the legal facts are seen from the right point of view, based on the coherence of scientific thinking, and can be accounted for scientifically in medicine with the paradigm of *evidence-based* medicine.¹⁶ Previous research on medical audits conducted by

¹³ Organisasi dan Tata Kelola Majelis Kehormatan Etik Kedokteran Ikatan Dokter Indonesia Tahun 2018

¹⁴ "Developing Clinical Audit Patient Panels," HQIP, 4 Januari 2016, <https://www.hqip.org.uk/resource/developing-clinical-audit-patient-panels/>. hlm. 5

¹⁵ C. D. Shaw dan D. W. Costain, "Guidelines for Medical Audit: Seven Principles.," *BMJ* 299, no. 6697 (19 Agustus 1989): 498–99, <https://doi.org/10.1136/bmj.299.6697.498>.

¹⁶ Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. Izet Masic, Milan Miokovic, dan Belma Muhamedagic, "Evidence Based Medicine - New Approaches and Challenges," *Acta Informatica Medica* 16, no. 4 (2008): 219, <https://doi.org/10.5455/aim.2008.16.219-225>.



Pasquale Esposito and Antonio Dal Canton in 2014 showed how continuous quality improvement is sustained by clinical or medical audits focusing on specific issues.¹⁷

The medical audit is a means of legal protection for doctors, patients, and healthcare facilities because a medical audit can reveal everything doctors do against reference standards (professional standards, professional service standards, and standard operating procedures) and apply corrective actions to improve individual and system performance.¹⁸

Normative problems cause uncertainty, and legal uncertainty raises fundamental problems in achieving the essence of humanity. The value of humanity that lives and make humans genuinely human need the basis of ratio legis crystallized in the form of humane legal protection. With continuous quality improvement, it is expected that health services that are human rights achieve their essence, namely healthy living achieved by the entire community.

RESEARCH PROBLEM

This legal research analyzes how the norms of Medical Audit rules Realize Humane Legal Protection in Medical Practice.

RESEARCH METHODS

This research is normative legal research with a statutory, conceptual, and comparative approach. The statutory approach is carried out on primary legal materials, namely the Medical Practice Law. The conceptual approach is used to examine existing principles and doctrines to find a medical audit model that provides humanitarian legal protection in the implementation of medical practice and a comparative approach is used as a tool by comparing medical audits in other countries, in this case, comparisons are made with the implementation of audits Medical in the United Kingdom has used the seven principles guidelines for medical audit since 1989 and Singapore.

ANALYSIS AND DISCUSSION

The Medical Audit

The definition of medical audit in the Medical Practice Law is listed in the explanation section: efforts to professionally evaluate the quality of medical services provided to patients using their medical records carried out by the medical profession." Editorially, Article 49 paragraph (1) states that every "Doctor and dentist in carrying out the practice of medicine or dentistry must carry out quality control and cost control." Furthermore, in paragraph (2), a medical audit can be carried out to carry out activities as referred to in paragraph (1). Law Number 44 of 2009 concerning Hospitals emphasizes that hospitals carry out medical and performance audits.

The implementation of medical audits is regulated in PMK Number 755 of 2011 concerning the Implementation of Medical Committees in Hospitals, namely in Chapter 1 Article 1 paragraph (11), which states that a medical audit is an effort to professionally evaluate the quality of medical services provided to patients using their medical records carried out by the medical profession. This medical audit aims to regulate good clinical governance so that the quality of service and patient safety in medical practice are constitutionally protected. The next goal is that medical audits obtain a basis to

¹⁷ Pasquale Esposito dan Antonio Dal Canton, "Clinical Audit, a Valuable Tool to Improve Quality of Care: General Methodology and Applications in Nephrology," *World Journal of Nephrology* 3, no. 4 (6 November 2014): 249–55, <https://doi.org/10.5527/wjn.v3.i4.249>. Hal. 249

¹⁸ Germana Montesi dan Alessandro Lechi, "Prevention of Medication Errors: Detection and Audit," *British Journal of Clinical Pharmacology* 67, no. 6 (Juni 2009): 651–55, <https://doi.org/10.1111/j.1365-2125.2009.03422.x>.



spur the renewal of human resources in the health sector. This aligns with what Keogh put forward in his research, which shows that methodology in medical auditing needs improvement to achieve effective medical auditing.¹⁹

At the praxis, Medical Audit is updated to Clinical Audit. Referring to the system in the United Kingdom, there are the Principles for Best Practice in Clinical Audit, which emphasizes that medical audit is a quality improvement process that tries to improve patient care and its results, which is realized through systematic service review activities compared with clear criteria.²⁰ In Singapore, Medical Audits are not conducted to prove or to look for any doctors or medical personnel's fault. The implementation of medical audits is based on laws and regulations, which are carried out as the implementation of clinical management functions in the context of implementing good clinical governance in hospitals.

Evaluation in medical audits aims to achieve the interests of patient safety. In medical audits, the data sources used are personal data and evidence of the competence of doctors, dentists, and health workers; medical records, both outpatient and inpatient; and patient personal data.

Humanity Legal Protection in Medical Practice

Fulfilling constitutional rights in the health sector includes 3 (three) components: medical practice providers, doctors and dentists, and patients. Medical practice providers are Health Service Facilities. Health Service Facilities in Government Regulation Number 47 of 2016 concerning Health Service Facilities is a tool and/or place used to carry out health service efforts, both promotive, preventive, curative, and rehabilitative by the central government, regional governments, and/or the community.

The types of Health Service Facilities are regulated in Article 4 of Government Regulation Number 47 of 2016 concerning Health Service Facilities, which consist of independent practices of Health Workers, community health centers, clinics, hospitals, pharmacies, blood transfusion units, health laboratories, optics, medical service facilities for legal purposes, and public health service facilities.

Analysis based on Joseph Raz's theory shows that there is still a need for the formulation of norms that make medical audits facilitators, which can be used as evidence at the level of medical dispute resolution. The humane legal protection in medical practice that the author initiated in this dissertation is divided into 4 (four) principles: harmonious law, imperative law, the law that protects human dignity and dignity, and law that meets the fundamental principles of biomedical ethics.

According to Joseph Raz, legal protection prioritizes the function of law as a rule, facilitator, and protection in resolving disputes. All forms of health services are integrated and cannot be separated. A study conducted by Netsanet Fetene et al., shows that services in Addis Ababa, Ethiopia, have yet to carry out these services in an integrated manner routinely. The opportunity for patient presence in health facilities needs to be more utilized.²¹ Humane legal protection is the protection of

¹⁹ James Y Paton, Rita Ranmal, dan Jan Dudley, "Clinical Audit: Still an Important Tool for Improving Healthcare," *Archives of Disease in Childhood - Education & Practice* Edition 100, no. 2 (April 2015): 83–88, <https://doi.org/10.1136/archdischild-2013-305194>. hlm. 85

²⁰ Ross Scrivener dkk., ed., *Principles for Best Practice in Clinical Audit*, repr (Abingdon: Radcliffe Medical, 2004).

²¹ Netsanet Fetene Wendimagegn dan Marthie C Bezuidenhout, "Integrating Promotive, Preventive, and Curative Health Care Services At Hospitals And Health Centers In Addis Ababa, Ethiopia," *Journal of*



human dignity and dignity in a responsive manner carried out by all communities to achieve quality, humane, and fair health services.

Quality control and cost control are forms of a doctor's responsibility in fulfilling the Indonesian people's human rights, namely the right to get health services. These health rights include:

1. The right to makes decisions independently for himself

This right aligns with one of the fundamental principles of biomedical ethics, namely, respect for autonomy. As Beauchamp and Childress, this principle is first described besides nonmaleficence, beneficence, and justice.

"Respect for the autonomous choice of a person... primarily to examine patients', subjects', and surrogates' decision making in healthcare and research". It is respect for an autonomous decision or choice.²² However, autonomy is not merely individualistic, rationalist without ignoring emotions, nor legalistic without making social practices one of the calculations. One person's right to autonomy must not degrade another's right to a healthy life. Autonomy still pays attention to social responsibility and common goals in society.²³

2. The right to obtain information

The right to obtain information, as referred to in the Law on Medical Practice, is interpreted in the Approval of Medical Measures. This consent is absolute for doing or not performing medical actions. This is faced with disclosing information without teleological nuances.²⁴ However, prioritizing the process is a complete explanation accepted and understood by the patient. Positive law regulates the minimum points of coverage explanations/information patients obtain.

Reconstruction of norms on Medical Audit that realize humane Legal Protection

The powerlessness of the rules on medical auditing philosophically, juridically, and sociologically, and on the touchstone of biomedical ethics full of human values, makes it necessary to reform in terms of norms in positive law at the level of legal dogmatics. As a result of a comparative study in the United Kingdom - UK, detailed medical audit arrangements were made in the form of guidelines that have been carried out since 1989. *Guidelines* or guidelines for conducting medical audits are based on the following principles, namely:²⁵

- 1) Health authorities (Ministry of Health) and medical staff should explicitly define their respective responsibilities for the quality of patient care
- 2) Medical staff must organize themselves to fulfill audit responsibilities and to take action to improve clinical performance
- 3) Each Hospital must agree to a regular audit program with all doctors in various fields participating

Multidisciplinary Healthcare 12 (5 April 2019): 243–55, <https://doi.org/10.2147/JMDH.S193370>. Hal. 254.

²² CB Kusmaryanto, *Bioetika Fundamental* (Jakarta: Gramedia Pustaka Utama, 2022). Hal. 180.

²³ Kusmaryanto. Hal. 182.

²⁴ The end goal comes first

²⁵ C. D. Shaw dan D. W. Costain, "Guidelines for Medical Audit: Seven Principles," *BMJ* (Clinical Research Ed.) 299, no. 6697 (19 Agustus 1989): 498–99, <https://doi.org/10.1136/bmj.299.6697.498>.



- 4) The audit process is carried out in a relevant, objective, robust, and repeatable manner and can affect appropriate changes in the organization and clinical practice

Singapore uses four connected and integral cycles in medical audits, namely: setting standards (sets of standards), observing implementation in standard practice (observing practice), conducting assessments by comparing with standards (comparing with standards), and implementing changes (implementing change). In Singapore's quality control context, payment based on costs incurred for procedures or administration should be subject to an extra investigation where the justification for the procedure constitutes a violation. The British Medical Journal has since January 1990 conducted medical audits as a form of "Audit in Practice," which shows. One section in medical audits is "Audit in Person." For example, in hospitals, general practitioner performance audits are carried out.

Singapore's efficiency efforts use of hospitalization quality index of medical care is done with regular statistics to assess outcomes. Suitable clinical service quality parameters relate to process rather than results. Buyers need outcome indicators if they have to choose between hospitals based on quality and cost, and providers want similar information about the effectiveness and efficiency of their services. Indicators relate more to processes than outcomes. They tell us little about what is achieved for patients and their health.

The rule reconstruction model in Indonesia is based on norm testing: (1). Norm testing against imperative legal principles. (2). Testing norms against laws that meet the fundamental principles of biomedical ethics.

- 1) Testing norms against imperative legal principles.

Testing norms against imperative legal principles is carried out by harmonization of several rules. The attachment of doctors to practicing in a healthcare facility increasingly shows inharmony.

The Regulation on the Place of Independent Practice of Health Workers, as stipulated in Government Regulation Number 47 of 2016, is "Health Service Facilities organized by Health Workers who have the authority to provide direct services to patients/clients." A doctor who practices in a health care facility as an Independent Practice Place for Health Workers is not bound to conduct a medical audit, considering that the Regulation regarding this independent practice place is only limited to permits for implementation, not regulating the obligation to conduct audits.

The Regulation of Community Health Centers stipulated in Government Regulation Number 47 of 2016 is "Health Service Facilities that carry out public health efforts and first-level individual health efforts, by prioritizing promotive and preventive efforts, to achieve the highest degree of public health in their work area." No law mandates that a physician practicing in a health care facility in the form of a Community Health Center is not bound to conduct a medical audit.

The Regulation on Clinics in Government Regulation Number 47 of 2016 is "Health Service Facilities that provide individual health services that provide basic and/or specialist medical services." A doctor who practices in a health service facility in the form of a clinic will have an obligation to conduct or at least participate in a medical audit organized by the clinic with the obligation to conduct a medical audit, based on the obligation to conduct a medical audit in the Minister of Health Regulation Number 9 of 2014 concerning Clinics. Medical audits are regulated internally and externally. Periodically required to conduct internal medical audits at least 1 (once) time each year, while external medical audits are declared "can" be carried out by professional organizations. At least this arrangement shows concern about the need for medical audits. Guidance and supervision are carried



out by the Minister of Health, Governor, Head of the Provincial Health Office, Regent / Mayor, and Head of the District / City Health Office. They can include professional organizations and associations/associations of clinics. This guidance and supervision is carried out by being directed to improve the quality of service, patient safety, and community protection.

Law Number 44 of 2009 concerning Hospitals indicates the obligation of doctors' obligation to conduct audits, but there needs to be no clarity on sanctions if they do so. Medical. It is stated in Article 39 of Law Number 44 of 2009 concerning Hospitals that the audit obligation can be in the form of performance audits and medical audits. The implementation of medical audits is delegated to the determination of the Minister, regulated in the Regulation of the Minister of Health Number 755 / 2011 concerning the Implementation of Medical Committees in Hospitals. In the Regulation, it is stated that the role of the medical committee in the Hospital as a tool to implement clinical governance to maintain the professionalism of the medical staff (doctors). This professionalism is maintained through the existence of a credential mechanism. Hospital bylaws regulate Hospital Governance.

A pharmacy is not a healthcare facility a doctor uses to practice his profession. Minister of Health Regulation Number 9 of 2017 explains that pharmacies are a means of pharmaceutical services, becoming a "vehicle" for practicing pharmacy for a Pharmacist.

Blood Transfusion Unit as a type of health service facility is one of the community's needs regarding access to blood transfusion services." Regulation of the Minister of Health Number 91 of 2015 concerning Blood Transfusion Service Standards stipulates that doctors are responsible for donor safety and the safety of blood components distributed. However, the Medical Practice Law does not explicitly regulate the authority of doctors in terms of practicing or being responsible for the function of the Blood Transfusion Unit. Therefore, it requires an audit to achieve services that are in their implementation per standards. Audits in the Blood Transfusion Unit are carried out through internal and external audits, hoping to continuously improve services to achieve service standards.

The laboratory as a unit that carries out measurement, determination, and testing for the determination of the type of disease, cause of disease, health conditions or risk factors that can affect individual and/or community health" is regulated explicitly in the Minister of Health Regulation Number 14 of 2021 concerning Business Activity and Product Standards in the Implementation of Health Sector Risk-Based Business Licensing. Regulations related to health laboratories in the Regulation are standard as a reference for business licenses. In this case, the laboratory comprises a stem cell processing laboratory and a medical laboratory. Specific arrangements related to medical audits are not regulated in the Regulation but regulate quality control. There is no specific mention of the assignment or responsibility of quality control given to doctors.

Optics is "a Health Care Facility that provides refraction services, optical services, and/or contact lens services," not a doctor's practice and therefore is not the object of norm testing.

The Medical Services Facility for Legal Purposes (Fasyandokum) provides medical services for legal purposes, including clinical forensic medicine services, forensic pathology, forensic laboratories, and law enforcement support. Detailed arrangements related to Fasyandokum are regulated in the Minister of Health Regulation Number 38 of 2022 concerning Medical Services for Legal Purposes. Fasyandokum is not directly bound by medical audits, considering that the nature of its services is for legal purposes, not in order to carry out doctor-patient therapeutic contracts.



Analysis of norm testing on the harmony or harmony of rules with one another shows that it is urgent to clarify the obligation to conduct medical audits because healthcare facilities as "vehicles" for practicing doctors require legal certainty over control through medical audits.

The existing medical audit arrangements in Article 49 paragraph (2) of Law Number 29 of 2004 concerning Medical Practice are regulated with the norm operator "may". The norm operator "can" is an alternative. It can be done, and it can not be done. The norm operator "can" does not provide a binding, does not coerce, and does not oblige. The complexity of legal norms is not reduced to a complete norm of behavior, as in Bentham's imperative theory of law.

The extrinsic value of a doctor (without distinguishing and overriding the dignity of the human person as a whole) is the existence of attributes as healers and professionals inherent in a doctor. The fulfillment of the best effort is reflected through medical audits as a means of sustainable professional culture development, maintaining the dignity and dignity of doctors as well as patients as subjects receiving health services provided by doctors. The norms of medical audit in Law Number 29 of 2004 concerning Medical Practice do not meet legal principles that protect human dignity and dignity, potentially injure them.

2) Testing norms against laws that meet the fundamental principles of biomedical ethics.

The fundamental principles of biomedical ethics proposed by Beauchamp and Childress consist of respect for *autonomy, nonmaleficence, beneficence, and justice*.²⁷ Autonomy is a principle where patients are free to choose what is best for them. In their health efforts, patients have considerations inseparable from the cultural and social context. Patients may choose different management with the best guideline in current medical science. This is only known by the Audit "Deviation" standard and criteria categorized as "acceptable" when this is a request from the patient himself. The problem of fulfilling this principle arises because the medical audit cycle is only regulated in its implementation at the Hospital. Even the arrangement does not detail the patient's choice in choosing the health services he receives. The setting only regulates whether there is a deviation or not. Healthcare facilities in other forms are not regulated by positive law on conducting a standardized medical audit cycle.

The principle of nonmaleficence is closely related to the principle of *primum non nocere*, above all (or the first) do not harm. This is a manifestation of the Hippocratic Oath, which interprets that the doctor should use his knowledge entirely for the patient.²⁸ The problem of fulfilling this principle arises because this medical audit cycle is only regulated in its implementation in hospitals. The setting only regulates whether there is a deviation or not. Healthcare facilities in other forms are not regulated by positive law on conducting a standardized medical audit cycle.

The principle of beneficence has implications for a doctor to provide the best health services.²⁹ This is the moral standard of doctors as an obligation to provide the most significant benefit and

²⁶ Richard L Cruess, Sylvia R Cruess, dan Yvonne Steinert, ed., *Teaching Medical Professionalism* (New York: Cambridge University Press, 2009).

²⁷ Tom L Beauchamp dan James F Childress, *Principles of Biomedical Ethics*, 7 ed. (New York: Oxford University Press, 2013).

²⁸ the Hippocratic oath incorporates both an obligation of nonmaleficence and an obligation of beneficence: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them." Beauchamp dan Childress. Hlm. 150.

²⁹ Beauchamp dan Childress. Hlm. 203



expediency for improving the patient's health status. The best justification for health services can be seen from the portrait of the results of medical audits. Conformity to standards and criteria can indicate whether or not this principle is met.

The principle of justice is not only a fundamental moral principle in biomedical ethics but is also inherent to the purpose of the law. Fairness in the doctor-patient relationship is proportional to justice so that quality control can stand alone and in the context of financing control. It becomes an injustice when the best size of doctor services is from the quality perspective. However, costs are not controlled, let alone become a burden for delivering health services, such as healthcare facilities. Quality control and financing formulation are framed in professional and professional service standards that produce standard operational procedures in healthcare facilities. Doctors with the same competence as their colleagues who have the authority to practice in the same healthcare facility are expected to have a consensus with patient management framed in a standard operating procedure implemented by every doctor who practices in the healthcare facility. The problem of fulfilling this principle arises because this medical audit cycle is only regulated in its implementation in hospitals. The setting only regulates whether there is a deviation or not. Healthcare facilities in other forms are not regulated by positive law on conducting a standardized medical audit cycle.

Medical audits in the Medical Practice Act, a vague norm (vage normen) lie in the word "may". There is no binding force in the form of obligation, no imperative (imperative), for medical audits to be carried out or not to conduct medical audits. The word "may" does not contain the allure of obligation, no imperative power for medical audits to be carried out or not to be carried out. This differs from the provisions in paragraph (1) stipulating, "Every doctor or dentist in carrying out the practice of medicine or dentistry must carry out quality control and cost control."

In The Command of Law theory, John Austin, in his book the command of the law, that law is an order, with the concept of sanctions applied to ensure that the order is always followed. Sanctions provide an essential role in controlling people's behavior, with the hope that in their application, they will provide happiness for society.³⁰ The words "mandatory" and "must" constitute commands.

Medical audit as a report on activities related to evaluation. With evaluation, deviations can occur. To quote Lord Acton, "*Power tends to corrupt, and absolute Power corrupts absolutely. Liberty is not a means to a higher political end. It is itself the highest political end. Liberty is not the Power of saying what we like, but the right to do what we ought.*"³¹

The research problem of sanctions must exist as a form of guidance and supervision of quality control and cost control in the implementation of medical practice. Law Number 29 of 2004 concerning Medical Practice has not formulated this, so a new norm is proposed in Article 74: "Sanctions for doctors and dentists who do not carry out medical audits are imposed in the form of reprimands and administrative sanctions."

The implementation of Medical Audit has yet to be regulated in detail in Law Number 29 of 2004 concerning Medical Practice. However, in Law Number 44 of 2009 concerning Hospitals, it is carried out by a medical committee at the Hospital. Medical Audit conducted by the medical committee through

³⁰ Monarch Mittal, "John Austin's Theory of Command Law: Its Practicality in Today's World," SSRN Electronic Journal, 2022, <https://doi.org/10.2139/ssrn.4157659>.

³¹ Christopher Lazarski, *Power Tends To Corrupt: Lord Acton's Study of Liberty* (Cornell University Press, 2012), <https://doi.org/10.1515/9781501757426>.



the professional quality subcommittee is carried out as a form of responsibility of the Hospital as a health service facility. Professional organizations need more space to guide and supervise the implementation of medical audits by healthcare facilities, including hospitals.

What is urgent in protecting humane law in medicine is the need for professional organizations (in this case, IDI) to conduct guidance and supervision, especially when there are complaints against allegations of malpractice and maladministration by doctors or dentists. A medical action is called an artist's lege if the action has been carried out following the medical profession's standards, namely the medical profession, namely the so-called standards of the medical profession (proportional), compared to the definite purpose of the medical action. The quality of medical action is measured by standardization made by all medical associations or peer groups based on the scientific standards they have.³²

Medical audit in the new norm should mention forming a team of experts within the Medical Audit Mechanism. In the context of public and criminal law, a medical audit is a legal document that serves as evidence. The medical audit is an instrument of protection in the event of alleged violations of ethics, discipline, and law.

CONCLUSION

The medical audit assesses and evaluates the quality of medical services. Regulations in the form of the Medical Practice Law aim for patient protection and safety. However, this has not expressly regulated the obligation to conduct medical audits, so the rules do not have legal certainty.

The humane model of medical audit arrangements contains principle a. The law must be harmonious; b. Existence of binding Sanctions; c. Respect for human dignity and dignity; d. Meet the Fundamental Principles of Biomedical Ethics; and e. Achieve justice, expediency, and legal certainty. This is done by reconstructing articles 49 and 74 of the Medical Practice Law by explicitly mentioning: (1) the obligation to carry out medical audits, (2) sanctions for not carrying out medical audits, (3) the involvement of the auditor team in the medical audit mechanism, (4) placing medical audit documents as one of the valid evidence in resolving alleged violations of ethics, discipline, and law.

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³² Hamdani Abubakar, "Kedudukan Audit Medis dalam Penegakan Hukum Tindak Pidana di Bidang Medis," *Jurnal Lex Renaissance* 3, no. 2 (1 Juli 2018): 263–83, <https://doi.org/10.20885/JLR.vol3.iss2.art2>. hlm. 275



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