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Legal Analysis of Incident Reporting Against the Patient Safety Management System in Hospitals

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Abstrak

Keselamatan pasien di rumah sakit masih menjadi isu utama, dengan berbagai macam pelayanan yang memiliki risiko yang mengancam keselamatan pasien. Insiden keselamatan pasien (IKP) merupakan kejadian dan kondisi yang tidak disengaja yang mengakibatkan atau berpotensi mengakibatkan cedera pada pasien yang sebenarnya dapat dicegah. Menurut Peraturan Menteri Kesehatan No. 11 Tahun 2017, keselamatan pasien merupakan suatu sistem yang menjadikan perawatan pasien lebih aman, meliputi penilaian risiko, identifikasi dan pengelolaan risiko pasien, pelaporan dan analisis insiden, kemampuan belajar dari insiden dan tindak lanjutnya, serta penerapan solusi untuk meminimalkan timbulnya risiko dan mencegah cedera yang disebabkan oleh kesalahan karena melakukan suatu tindakan atau tidak melakukan tindakan yang seharusnya dilakukan. 2014, meliputi rasa takut disalahkan, kurangnya komitmen dari manajemen dan unit terkait, tidak ada reward dari rumah sakit jika melapor, tidak mengetahui batasan atau hal yang harus dilaporkan, serta sosialisasi insiden keselamatan pasien yang kurang efektif. Oleh karena itu, rumah sakit harus meningkatkan kesadaran dan kemampuan sumber daya manusia kesehatan dalam menganalisis, menangani, dan melaporkan insiden keselamatan pasien. Dengan demikian, pelaporan insiden keselamatan pasien di rumah sakit sangat penting untuk meningkatkan keselamatan pasien. Rumah sakit harus memastikan bahwa sistem pelaporan insiden keselamatan pasien dilakukan secara efektif dan efisien.
Kata kunci: Keselamatan pasien; Pelaporan medis; Analisis hukum; Tanggung jawab rumah sakit

Abstract

Patient safety in hospitals is still a major issue, with a wide range of services that have risks that threaten patient safety. Patient safety incidents (PSEs) are unintentional events and conditions that result in or have the potential to result in preventable harm to patients. According to the Minister of Health Regulation No. 11 of 2017, patient safety is a system that makes patient care safer, including risk assessment, identification and management of patient risks, incident reporting and analysis, the ability to learn from incidents and their follow-up, and the implementation of solutions to minimize the incidence of risk and prevent injury caused by errors due to carrying out an action or not taking action that should be taken. 2014, includes fear of being blamed, lack of commitment from management and related units, no reward from the hospital if reporting, not knowing which boundaries or what to report, and ineffective socialization of patient safety incidents. Therefore, hospitals must increase the awareness and ability of health human resources in analyzing, handling, and reporting patient safety incidents. Thus, patient safety incident reporting in hospitals is essential to improve patient safety. Hospitals must ensure that the patient safety incident reporting system is carried out effectively and efficiently.
Keywords: Patient safety; Medical reporting; Legal analysis; Hospital liability

Introduction

Patient safety is a fundamental aspect of healthcare in modern hospitals. In this increasingly complex era, patient safety management is not only a moral responsibility, but also has significant implications in the legal realm. Hospitals as

institutions that provide health services are obliged to maintain patient safety throughout the treatment process. However, the implementation of patient safety management is often faced with complex challenges, including issues such as underreporting of incidents, lack of safety culture, incomplete filling of medical record files, and so on.

In Indonesia, patient safety issues began to be discussed in 2000, followed by the first study in 15 hospitals with 4500 medical records. The results showed that the rate of KTDs varied widely, with 8.0%-98.2% for misdiagnosis and 4.1%-91.6% for medication errors. Since then, evidence on patient safety in Indonesia has been spreading, although there has been no national study to date. We should be envious of countries in Latin America that have the Iberoamerican study of adverse events (IBEAS) in 58 hospitals from 5 countries (Utarini & Djasri, 2012).

Hospital patient safety is a system by which hospitals make patient care safer, which includes risk assessment, identification and management of patient risk, incident reporting and analysis, learning from incidents and follow-up, and implementation of solutions to minimize the incidence of risk and prevent injuries caused by errors due to performing an action or not taking an action that should be taken (Ministry of Health, 2011).

Previous studies, such as those conducted by Susanto & Handiyani (2023) on the determinants of patient safety incident reporting by nurses in hospitals, Suwandy et al. (2023) on the factors that influence patient safety culture, Verawati (2021) who analysed the causes of incomplete filling of medical record files, and Gabriella et al. (2023) who examined the effect of electronic medical records on improving quality and patient safety, provide important insights in understanding the dynamics and challenges in patient safety management in hospitals. However, there are still research gaps that need to be explored further, such as factors that lead to underreporting of patient safety incidents (Lestari & Fitriani, 2021; Rombeallo et al., 2022; Tarigan et al., 2024), barriers to the use of telenursing on patient safety (Yulianti et al., 2024), and the implementation of patient safety in drug administration related to the incidence of medication errors (Handoko et al., 2023).

As a concrete example of the case experienced by victim S for the removal of vital organs carried out by Bangil Regional Hospital, the chronology is as follows: Victim S came to the emergency room of the hospital on May 7, 2024 in an unstable condition with complaints of anemia, low hemoglobin, etc. for examination. Three weeks later, on May 31, 2024, the victim returned to the hospital to find that S had prostate cancer, and the hospital advised him to have his testicles removed to prevent it from spreading to other vital organs. One week after the surgery, the victim S went to the orology clinic and said that he had never returned to the hospital. Victim S found out that his testicles were removed after he noticed stitches on his vital organs after he pulled the thread. Victim S admitted that he had come to the hospital four times to ask about this matter because he felt aggrieved. Victim S only received approval for laser prostate surgery, not for testicular removal.

In this context, this study aims to conduct a legal analysis of patient safety management in hospitals, using a literature review as a theoretical foundation. Through this approach, it is expected to find a deeper understanding of how legal aspects affect the implementation and success of patient safety management in hospitals. The implications

of this study are expected to make a significant contribution to the development of more effective policies and practices in ensuring patient safety and well-being as a top priority in healthcare.

Research Method

The research method used is a normative juridical approach, which emphasizes the use of secondary data obtained through library research. The research specification used is descriptive analytical, which is to obtain a comprehensive and systematic picture of the problem under study. Data analysis is carried out descriptively, where researchers identify, describe, and explain the findings that arise from the selected literature study. This analysis process involves synthesizing and interpreting the information contained in relevant literature sources. by looking at the existing problems associated with regulations as positive law, to then be analyzed qualitatively.

Results and Discussion

The Importance of Patient Safety in Hospitals

The hospital's attention to Patient Safety is due to the inconvenience and losses suffered by patients as well as the legal responsibility it causes, potentially becoming a legal dispute. Hospitals must be responsible for overseeing policies on patient safety, which are regulated in Law Number 36 of 2009 concerning Health and more detailed patient safety is regulated in Law Number 44 of 2009 concerning Hospitals.

This law explains that the hospital is legally responsible for the harm caused by the negligence of health workers in the hospital. Legal protection of patients in the form of legislation is very important considering that patients have been positioned as the weakest party. Hospital legal protection is basically related to the interests of hospitals and patients. Law No. 44 of 2009 Concerning Hospitals regulates the balance between the rights and obligations of hospitals and the rights and obligations of patients. Patient Safety Arrangements Based on Law Number 44 of 2009 Concerning Hospitals, are closely related to the purpose of organizing hospitals.

Incident Handling is very important because no matter how small the incident, delays in handling incidents can result in losses that can be material or immaterial, in the form of disability or death. All hospital human resources work in accordance with professional standards, hospital service standards, applicable standard operating procedures, professional ethics, respect for patient rights and prioritize patient safety. The implementation of patient safety in hospitals cannot stand alone, it involves health workers and non-health workers who work in accordance with patient safety standards.

Patient Safety Related Issues

Hospital patient safety is a system where hospitals make patient care safer by including risk assessment, identification and management of things related to patient risk, incident reporting and analysis, the ability to learn from incidents and prevent injuries caused by errors due to carrying out an action or not taking the action that should be (Ministry of Health, 2011).

Based on Minister of Health Regulation No. 1691 of 2011 concerning Hospital Patient safety, patient safety incidents consist of:

1. Unexpected Event, an unexpected event that results in injury to a patient because of performing an action or not taking an action that should have been taken, and not due to the underlying disease or condition of the patient.
2. Non-Injury Event, an incident that has been exposed to the patient but does not result in injury.

3. Near-Injury Event, the occurrence of an incident that has not yet been exposed to the patient.
4. Potentially Injurious Event, a condition that has the potential to cause injury but has not yet occurred.
5. Sentinel Event Is an unexpected event that results in death or serious injury. Usually used for events that are very unexpected or unacceptable.

There are six goals of patient safety in hospitals, namely correct identification, improving effective communication, improving the safety of drugs that need to be watched out for, ensuring the right location, the right procedure, the right operation patient, reducing the risk of infection related to health services, reducing the risk of patient falls. These six aspects are very important to be implemented in every hospital. However, it must be recognized that the activities of hospital institutions can run if there are patients. Patient safety is a top priority to be implemented and it is related to quality issues and hospital image. Patient safety in hospitals (KPRS) is a service system in a hospital that provides safer patient care, including measuring risk, identifying and managing risks to patients analyzing incidents, the ability to learn and follow up on incidents and implementing solutions to reduce risk. Therefore, commitment and ethics in nursing are required. Patient safety is a system that is needed and with this system it is expected to minimize errors in patient handling both in emergency patients, inpatients and polyclinic patients.

Building awareness of the value of patient safety is a way for the hospital to create leadership and a culture of openness and fairness, which means that the hospital has a policy on what staff should do immediately after an incident, how to take steps to gather facts and what support is provided to staff, a culture of reporting and learning from incidents and conducting patient safety assessments. Engaging and communicating with patients is an action where the hospital has a policy to clearly outline ways of open communication about incidents with patients and their families, prioritize notification to patients and families when an incident occurs and immediately provide them with clear and correct information in an appropriate manner. Good communication between medical staff and patients will have a positive impact on the quality of health services in a hospital and may reduce misunderstandings in the event of accidents, negligence and or malpractice.

The Importance of Patient Safety Incident Reporting in Hospitals

A patient safety incident is an event or situation that can cause or potentially cause injury that should not have occurred. Patient Safety Incidents in hospitals have different types consisting of: Potentially Injurious Events, Nearly Injurious Events, Non-Injurious Events, Unexpected Events or adverse events and Sentinel Events (sentinel events) (Ministry of Health, 2017). The hospital has a Hospital Patient Safety Team (TKP¬RS) which is incorporated in the Quality and Patient Safety Committee, which is a non-structural organization and is responsible for carrying out tasks, one of which is to report directly to the Hospital Director. TKP-RS carries out the task of recording, reporting incidents, analyzing incidents including conducting Root Cause Analysis (RCA) / Root Cause Analysis and developing solutions to improve patient safety.

In the event of a patient safety incident, the PST-RS follows the flow of handling patient safety incidents as follows: (1) every incident must be reported internally to the Patient Safety Team (PST) no later than 2×24 (twice twenty-four) hours using the report format, (2) The report is verified by the PST-RS to ensure the truth of the incident, (3) after verifying the PST-RS report, the hospital conducts an investigation in the form of interviews and document examination, (4) based on the results of the investigation, the patient safety team determines the degree of the incident (grading) and conducts Root Cause Analysis

(RCA) with standardized methods to determine the root cause of the problem, (5) The patient safety team must provide patient safety recommendations to the leadership of the health service facility based on the results of Root Cause Analysis (RCA).

Various countries report the number of hospital safety events each year with detailed figures for each hospital. National Patient Safety Agency 2017 reported in January - December 2016 the number of patient safety events reported from the United Kingdom was 1,879,822 events. Ministry of Health Malaysia 2013 reported the number of patient safety incidents in the span of January - December as many as 2,769 events and for Indonesia in the span of 2006 - 2011 KPPRS reported there were 877 patient safety events. Factors of low reporting of patient safety incidents according to the results of Iskandar et al 2014 research, there are several factors that influence the low reporting of patient safety incidents, namely: (1) fear of being blamed, (2) lack of commitment from management and related units, (3) no reward from the hospital if reporting, (4) do not know which limits or what to report, (5) socialization of patient safety incidents has not been thorough to all staff, (6) have not participated in training on patient safety for all hospital staff. According to research by Widodo & Harijanto 2015 conducted in hospitals in Central Java which caused the low reporting of incidents, namely: (1) lack of understanding of officers to report patient safety incidents, (2) less than optimal implementation of the patient safety incident reporting system, (3) fear of reporting and high HR workload. Reporting patient safety incident data is very important because valid and accurate patient safety incidents will determine the evaluation of subsequent safety-based health programs and services and underlie service system improvements and prevention of recurrent patient safety incidents (Hwang et al., 2012).

Not all patient safety incidents are reported, generally patient safety incidents go unnoticed by health workers because only patient safety incidents that are found by chance are reported. Challenges faced There is a commitment to enforce the Minister of Health Regulation Number 11 of 2017 concerning Hospital Patient Safety needs to be adjusted to the development and needs of services in health care facilities, demanding that the central government, local governments and public and private hospitals are responsible for ensuring that patients have the right to get quality health services and get comprehensive and responsive action to unwanted events in health care facilities and demands from the public about safe health services this has become a public concern and is an urgent policy issue, including the need to review the Minister of Health Regulation to ensure that health services in hospitals are health services based on patient safety.

Alternative Policy Options To answer these challenges, a public policy program is needed to improve the quality of patient safety incident reporting in hospitals. Policy alternatives can be, making derivative regulations from the Regulation of the Minister of Health of the Republic of Indonesia No. 11 of 2017 concerning patient safety, which is specifically about reporting patient safety incidents, such as making regulations to protect the reporter by not publishing the personal data of the patient safety incident reporter, then developing a reporting module for patient safety incidents so that it can be a guide for health human resources in reporting patient safety incidents, it can also be by making regulations for rewarding health human resources who are able to carry out risk assessment, identification and management of patient risk, incident reporting and analysis, ability to learn from incidents and their follow-up, and implementation of solutions to minimize the incidence of risk and prevent injuries caused by errors due to carrying out an action or not taking action that should be taken.

Recommendations Conducting a review of the Minister of Health Regulations and existing modules related to patient

safety incident reporting needs to be done, then requiring socialization and evaluation by the Hospital Patient Safety Team to all health HR related to analysis, handling and technical procedures for reporting patient safety incidents in this hospital is very helpful for the implementation of patient safety incident reporting and with socialization can also improve the ability of health HR in analyzing, handling and reporting patient safety incidents, giving rewards to health HR who are able to analyze, handle and report patient safety incidents properly and protect the reporter by not including the name and personal data of the reporter this will be a motivation to report all patient safety incidents in the hospital. to improve the quality of sustainable health services and become a learning process for patient safety-oriented service improvement. So that it can improve the quality of health services continuously and become a learning process for service improvement oriented to patient safety.

Hospital Responsibility in Reporting Patient Safety Incidents from a Legal Perspective

Hospital legal liability in the practice of health services and medical practice in hospitals should be applied without deviating from Law Number 44 of 2014 concerning Hospitals, Law Number 36 of 2009 concerning Health, Law Number 36 of 2014 concerning Health Workers, Law Number 29 of 2004 concerning Medical Practice and Law Number 38 of 2014 concerning Nursing. This is because the legal liability of hospitals in resolving medical service disputes in Indonesia requires expediency according to the principles.

In practice, several times the legal responsibility of hospitals in the provision of health services cannot be implemented optimally. This can be seen from the quality of service in the Hospital Emergency Unit which cannot run excellently. The Hospital Emergency Unit is the forefront or spearhead of the hospital in providing health services, so that the good or bad quality of service in the Hospital Emergency Unit can be a mirror of the quality of hospital services.

In several instances, services at the Hospital Emergency Unit could not run properly due to the absence of the person responsible for the patient's costs. (Decision of Tanjung Karang District Court Number 381/Pid/2014/PN.Tk). In fact, Article 32 of Law Number 36 of 2009 on Health has mandated health care facilities, both public and private, to prioritize saving the patient's life and preventing disability and override advances when providing patient assistance in an emergency.

The legal responsibility of hospitals often cannot be fully implemented due to the strong paternalistic relationship between providers and recipients of health services. The paternalistic relationship pattern is a relationship pattern between superiors and subordinates. In this paternalistic relationship pattern, doctors are positioned as superiors and patients are positioned as subordinates. Patients do not realize that they have rights, including the right to information, so doctors often perform medical actions without providing adequate information to patients.

According to J Guwandi in his book entitled "Doctors and Hospitals" states that, basically, hospitals are responsible for three things namely, responsibilities related to duty of care (obligation to provide good service); responsibility for facilities and equipment; and responsibility for personnel. Duty of care can be interpreted as the obligation to provide good and reasonable service. The implementation of the obligation to provide good service is related to various matters, among others related to personnel, because the hospital as an organization can only act through the personnel it employs. The provision of health services in hospitals is carried out both by health workers and non-health workers. Services provided by hospital personnel, especially health workers, must be in accordance with professional standards. Hospitals should be held

responsible if there is a substandard provision of health services by their personnel that causes undesirable consequences for patients.

Regulations related to this obligation include the Regulation of the Minister of Health of the Republic of Indonesia No. 11/2017 on Patient Safety, which defines patient safety as a system that makes patient care safer, including risk assessment, identification and management of patient risks, incident reporting and analysis, learning from incidents and follow-up, and implementation of solutions to minimize the incidence of risks and prevent injuries caused by errors due to carrying out an action or not taking an action that should be taken.

Hospitals must ensure that the existing infrastructure functions properly and continuously. Broadly speaking, the facilities in the hospital can be divided into non-medical facilities and medical facilities. Non-medical facilities include the provision of rooms complete with beds, mattresses, lighting, water, electricity, and other facilities. The nature and function of non-medical facilities are very important because the malfunction of non-medical facilities results in obstruction of service functions in the hospital. Medical facilities include all medical supplies and equipment needed in the hospital. Given that the hospital is an institution that is dense in facilities and equipment and is a concentration of medical equipment ranging from simple to high-tech. The type and amount of provision depends on the type of hospital, except for the minimum basic equipment that must be available in every hospital such as equipment and supplies in the emergency room.

The legal responsibility of the hospital towards its health workers implies that the hospital must be responsible for the quality of the health workers who work. The legal relationship between hospitals and doctors is basically divided into two patterns, namely the pattern of labor relations in which doctors become employees or permanent employees of the hospital (commonly referred to as doctors in) and the pattern of agreement or partnership relations in which doctors work independently and act as hospital partners (commonly referred to as doctors out). The embodiment of this partnership relationship pattern includes Part Timer Doctors; Visiting Doctors or Guest Doctors; Doctors who work full time in a hospital but are not permanent employees of the hospital. Whatever the form of relationship between doctors and hospitals, doctors are a profession that has independence and independence in carrying out their profession and applying their knowledge.

The majority of Indonesians assume that medical failures constitute malpractice and even equate medical failures with criminal offenses. This is not entirely correct because in criminal acts, the emphasis is on the consequences of the criminal act. Whereas in medical action, the emphasis is on the process. Therefore, the characteristic of medical action is inspanningsverbintennis (an obligation that focuses on maximum effort) and not resultaatsverbintennis (an obligation that focuses on results). However, in applying maximum effort, there are parameters that must be adhered to, namely the Standards of the Medical Profession.

Hospital liability in Indonesia is regulated in Article 46 of the Hospital Law which states that hospitals are legally responsible for all losses caused by negligence committed by health workers in hospitals. There are two meanings contained in this arrangement. First, hospitals are only liable for negligent errors and not intentional errors. This is because intentional wrongdoing is an act that is classified as criminal because there is mens rea (the inner attitude of the perpetrator when committing a criminal offense) and actus reus (an act that violates criminal law).

Second, negligence is committed by health workers when or in the context of carrying out the duties assigned by the hospital. Hospital-centered liability is also emphasized in Article 32 (q) of Law Number

44 of 2009 concerning Hospitals which states that every patient has the right, one of which is to sue and / or sue the Hospital if the Hospital is suspected of providing services that are not in accordance with standards either civilly or criminally.

The pattern of legal liability as stipulated in Article 46 of the Hospital Law does not cause legal problems when applied to non-physician health workers but has the potential to cause legal problems when applied to doctors. This is because the status of doctors in hospitals varies. The result is that several times there have been inconsistencies in court decisions in addressing the pattern of legal liability of hospitals against their doctors. The regulation of the pattern of hospital legal liability stipulated in Law Number 44 of 2009 concerning Hospitals in its implementation can lead to various interpretations.

IV. CONCLUSION

Legal responsibility in handling and reporting medical incidents in hospitals is essential for patient safety management. Understanding healthcare regulations and standards ensures actions are in line with established safety and quality, building public trust in the healthcare system. The implementation of legal responsibility increases transparency and accountability, enabling the identification of problems and corrective actions to prevent similar events. Building a culture of patient safety is also important, creating a work environment that supports collaboration and communication between health workers, so that the risk of medical incidents can be minimized. Support and active participation from the government, hospitals, health workers, and the community are needed to improve the quality and safety of health services. In conclusion, by complying with regulations, building a culture of safety, and collaborating, hospitals can create a safe and quality environment for patients, maintaining integrity and public trust in the health system.

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