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PATIENT SAFETY CULTURE IN HOSPITALS: A LITERATURE REVIEW ON THE IMPLEMENTATION OF SAFETY STANDARDS, ACCOUNTABILITY, AND LEGAL PROTECTION FOR PATIENTS AND MEDICAL PERSONNEL

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Abstract

Patient safety culture in hospitals is a very important aspect in ensuring the quality and safety of health services. This study is a literature review that aims to analyse the implementation of patient safety standards, the responsibilities of hospitals and medical personnel, and legal protection for patients and medical personnel. Data was obtained through a review of literature from scientific journals, books, and relevant laws and regulations. The results of the study show that the implementation of safety standards such as patient identification, effective communication, safe use of medicines, infection prevention, and fall risk management still faces various obstacles, including organisational culture and resource constraints. In addition, legal responsibility for hospitals and medical personnel is crucial in maintaining fairness and professionalism, while adequate legal protection is a prerequisite for creating a safe working environment and supporting incident reporting. This study emphasises that the synergy between the implementation of standards, legal responsibility, and legal protection is the main foundation for building a sustainable patient safety culture. These findings can be used as a basis for further policy development and empirical research in the context of healthcare in Indonesia and other countries.

Keywords: patient safety culture, safety standards, legal responsibility, legal protection, hospitals, medical personnel.

Introduction

Patient safety is one of the most crucial issues in modern healthcare, whether at the local, national, or global level. In hospital practice, patient safety encompasses all efforts made to minimise the risk of injury arising from the medical service process. The World Health Organisation (WHO) emphasises that *patient safety* is the most important foundation in a quality healthcare system (Ananda, 2022) . Without safety guarantees, the quality of services provided by hospitals cannot be accounted for, thus directly impacting public trust. The phenomenon of high rates of *adverse events* in hospitals is an important alarm that the development of a patient safety culture cannot be delayed any longer (Masic, 2014) .

Patient safety in hospitals is not only about safe medical procedures but also involves a comprehensive system, from regulations and managerial policies to the

integrity of healthcare workers. Since 2008, the Indonesian Ministry of Health has launched *Hospital Patient Safety Standards* in line with the Joint Commission International (JCI), covering aspects of patient identification, effective communication, safe medication administration, anaesthesia and surgical services, infection prevention, and fall risk management (Masic, 2014) . All of these standards require interprofessional collaboration, management support, and supervision of implementation in the field. Without such collaboration, the standards will only remain on paper (Zhelev, 2025c) .

In Indonesia, patient safety issues still face various challenges. WHO reports indicate that patient safety incidents remain high, particularly in developing countries, including Indonesia. Cases such as medication errors, patient misidentification, medical procedures performed without clear *informed consent*, and failures in controlling nosocomial infections are still recorded as serious problems. This situation shows that the implementation of a patient safety culture in Indonesian hospitals still requires considerable effort, particularly in terms of healthcare worker compliance and strengthening hospital management systems (Reis, 2020b) .

Another issue that exacerbates the implementation of patient safety culture is the organisational culture within the hospital itself. Many studies have found that there is still a tendency towards a "*blaming* culture" when medical incidents occur. This makes medical personnel more likely to cover up mistakes rather than report them for the sake of system improvement (Reis, 2020b) . In fact, according to patient safety principles, every *near miss* or incident must be reported openly so that it can be analysed, corrected, and prevented from recurring. Without a culture of openness, hospitals will struggle to improve safety quality and instead become trapped in a cycle of recurring errors (Mistri, 2023b) .

In addition to safety standards, another important dimension is the hospital's responsibility towards patients. This responsibility includes the professional responsibility of medical personnel as individuals, as well as the institutional responsibility of hospitals as healthcare providers. Law No. 44 of 2009 concerning Hospitals stipulates that hospitals are obliged to provide safe, high-quality, non-discriminatory, and effective healthcare services (Zhelev, 2025b) . This means that if negligence or errors occur that cause harm to patients, both medical personnel and the hospital institution can be held accountable. In the context of health law, this responsibility can take the form of moral, ethical, administrative, civil, or even criminal liability (Chilukuri, 2024) .

The issue of responsibility does not only apply to patients, but also to healthcare workers. Medical personnel are at the forefront of hospital services, so their safety must also be guaranteed. Many lawsuits ultimately drag doctors or medical personnel into the criminal realm, even though mistakes can arise due to weaknesses in the hospital system. Without clear legal protection, medical personnel will work with fear, anxiety, and stress every time they have to make clinical decisions. The impact is that it disrupts the quality of health services and has the potential to increase the risk of incidents to patients (Su, 2025b) .

Legal protection for medical personnel is an integral part of strengthening patient safety culture. The Medical Practice Act No. 29 of 2004 provides a dispute resolution mechanism through the Indonesian Medical Disciplinary Council (MKDKI), which assesses whether there has been a disciplinary violation (Su, 2025b) . This type of protection is important so that medical issues are not immediately criminalised without professional analysis. At the same time, this legal protection should not diminish patients' rights to receive safe healthcare services and obtain justice if they suffer harm. Thus, the balance between patients' rights and the protection of the medical profession is key to the healthcare system (Ministry of Health of the Republic of Indonesia, 2017) .

An effective patient safety culture is fundamentally built on a strong legal foundation and a healthy organisational culture. Regulations alone are insufficient without internal hospital commitment to prioritise patient safety. On the other hand, a good organisational culture without strong regulatory support will not result in adequate legal protection for all parties. Therefore, integrating the application of safety standards, legal responsibility, and the protection of patients and medical personnel is an agenda that cannot be separated in the development of a patient safety culture.

Research Method

The research method used in this study is a descriptive-analytical literature review. Research data was obtained from various secondary sources, including national and international scientific journals, reference books related to patient safety, and laws and regulations such as the Health Law, Hospital Law, Medical Practice Law, and Ministry of Health regulations (Snyder, 2019) . The data collection process was carried out through systematic searches using scientific databases (PubMed, Scopus, and Google Scholar) and official government documents. Data analysis was conducted using a thematic approach, which involved grouping literature based on main themes such as the implementation of safety standards, hospital responsibilities, and legal protection for patients and medical personnel, which were then synthesised to produce a comprehensive understanding that answered the research questions (Snyder, 2019) .

Results and Discussion

Implementation of Patient Safety Standards

The implementation of patient safety standards is one of the fundamental pillars of the hospital healthcare system, which aims to minimise the risk of adverse events during the medical treatment process. These standards are compiled based on widely recognised international guidelines, such as those issued by the World Health Organisation (WHO) and the Joint Commission International (JCI). In Indonesia, the Ministry of Health has also adopted and adapted these standards in the form of national standards that must be implemented by all healthcare facilities. This implementation covers various aspects, ranging from patient identification, communication between medical personnel, safe use of medicines, infection prevention, to the management of medical complications(Sijabat, 2025) .

One of the key elements in implementing patient safety standards is accurate patient identification. Patient identification errors are often the main source of adverse medical events, ranging from incorrect medication administration to incorrect medical procedures. Therefore, hospitals are required to systematically verify patient identity using at least two unique identifiers each time a medical interaction occurs(Sijabat, 2025) . This procedure must be carried out repeatedly at every stage of care, from registration and examination to the administration of therapy. The use of technology such as barcodes and electronic medical records is also increasingly being adopted to ensure the accuracy of this identification (Oberlander, 2018) .

In addition to identification, effective communication between medical personnel is a crucial aspect of patient safety standards. Poor communication between healthcare workers has been identified as a major cause of medical errors and patient complications. Safety standards emphasise the importance of structured *hand-off communication*, such as the SBAR (Situation, Background, Assessment, Recommendation) method, to ensure clear and accurate information exchange during shift changes or between units. Strengthening communication also includes providing comprehensive explanations to patients and families as part of informed consent and health education (Oberlander, 2021) .

Safe medication use is the next focus in patient safety standards. Medication errors are one of the most common incidents in hospitals with the potential for fatal outcomes. Therefore, the standard requires a strict medication management system, from planning, storage, administration, to monitoring medication side effects (Zhelev, 2025a) . Clear medication labelling, re-checking by medical personnel before administration, and monitoring of patient medication interactions are mandatory parts of this protocol. The role of pharmacists integrated with the medical team is also crucial to the successful implementation of safe medication use (Reis, 2020a) .

Prevention of nosocomial infections, or infections acquired in hospitals, is an equally important part of patient safety standards. Uncontrolled infections can increase morbidity, mortality, length of hospital stay, and treatment costs. Therefore, standards regulate hand hygiene protocols, sterilisation of medical equipment, use of personal protective equipment (PPE), and isolation of patients with infectious diseases. Routine audits and continuous training for all hospital staff are also key to maintaining compliance with these infection prevention standards(2024b) .

Fall risk management for patients, especially those who are vulnerable such as the elderly and patients with mobility impairments, is also a serious concern in safety standards. Falls can cause serious complications ranging from physical injuries to permanent disabilities. Therefore, hospitals are required to conduct comprehensive fall risk assessments and develop prevention strategies such as installing handrails, close supervision, and patient and family education. In addition, the use of patient monitoring technology is also being implemented to improve supervision of patients at high risk of falling (Han, 2017b) .

The implementation of patient safety standards does not only depend on written regulations, but is also greatly influenced by the organisational culture within the hospital. A strong safety culture encourages all elements of the hospital to play an active role and work together in creating a safe environment for patients. This includes an attitude of openness towards incident reporting without fear, management support for safety initiatives, and the continuous development of medical personnel competencies. This culture must be built systematically through training programmes, regular communication, and performance evaluations related to safety (Su, 2025a) .

Common obstacles in implementing patient safety standards in Indonesian hospitals include limitations in human resources and infrastructure, as well as a lack of awareness and compliance with safety protocols among healthcare personnel. Many hospitals, especially those that are less advanced, still face difficulties in providing consistent training and adequate supporting facilities. Additionally, high workloads and time pressures also influence healthcare workers' compliance with strict safety standards(, 2020) .

To overcome these obstacles, various efforts have been made, including the implementation of scheduled training and workshops, the development of an internal patient safety audit system, and the implementation of an easy and transparent incident reporting system. Hospitals that have implemented ISO-based quality management systems and JCI accreditation have shown positive developments in patient safety culture. This approach involves all staff, from top management to medical personnel in the field, so that improvements can be made comprehensively and sustainably(Tandry, 2024a) .

In addition, technology also plays an important role in facilitating the implementation of patient safety standards. For example, electronic medical records (EMR) systems help to ensure the completeness and accuracy of patient data, reduce the risk of identification and medication errors, and speed up communication between units. The use of other technological tools such as barcode scanning for medicines and medical devices, digital patient monitoring, and alarm systems for early warning of critical risks further increases the effectiveness of implementing these standards in hospitals (Amallia, 2025) .

A comparison of the implementation of patient safety standards between hospitals in Indonesia and developed countries shows a significant gap, particularly in terms of organisational culture and regulatory support. In developed countries, in addition to strict technical standards, a culture of reporting and learning from incidents has become a widely accepted norm without stigma. Meanwhile, in Indonesia, there is still a tendency to be protective and afraid to report errors, which is a major obstacle to improving the system (Camacho-Rodríguez, 2022b) . However, efforts to raise awareness continue to be promoted through various seminars, campaigns, and the integration of patient safety topics into health education.

The involvement of hospital leaders is crucial to the successful implementation of patient safety standards. Visionary leadership and a strong commitment to patient

safety can create an organisational climate that supports and empowers all staff. Leaders must actively facilitate resources, oversee the implementation of standards, and provide constructive feedback to encourage continuous improvement. Without strong leadership support, initiatives to implement safety standards will be difficult to optimise because there is no main driver within the organisation (Kadivar, 2017) .

Regular monitoring and evaluation are essential elements to ensure that safety standards are properly implemented. Internal audits, patient satisfaction surveys, and incident report analyses are instruments used to measure the effectiveness of standard implementation. From the results of this evaluation, hospitals can develop more targeted improvement strategies that focus on critical areas that pose risks to patient safety. This data-driven approach also supports a risk management model that is adaptive to changes in hospital conditions (Mistri, 2023a) .

Thus, the implementation of patient safety standards in hospitals is a complex process that not only depends on compliance with technical procedures but also requires organisational cultural change, management support, and improvements in resources and technology. Hospitals that successfully build a strong safety culture and prioritise safety standards have greater potential to reduce medical incidents and improve overall healthcare quality. Therefore, efforts to implement patient safety standards must be consistently and comprehensively promoted by all stakeholders in the healthcare system.

Responsibility and Legal Protection for Patients and Medical Personnel

Responsibility in healthcare is a fundamental aspect that forms the ethical and legal basis binding all service providers, including hospitals and medical personnel. This concept of responsibility includes the obligation to ensure that services are provided safely, with quality, and in accordance with established professional standards. In the context of patient safety culture, responsibility is not only related to the prevention of medical errors, but also to corrective and reparative measures if an incident occurs that harms the patient. Thus, this responsibility includes preventive, curative, and compensatory dimensions in the implementation of healthcare services (Han, 2017a) .

Legally, the responsibilities of hospitals and medical personnel are regulated in various regulations, such as Law No. 44 of 2009 concerning Hospitals, Law No. 36 of 2009 concerning Health, and Law No. 29 of 2004 concerning Medical Practice. These regulations emphasise that hospitals and healthcare personnel are obliged to provide services that meet patient safety standards and can be held accountable in the event of negligence or malpractice. This makes the legal aspect an important instrument in maintaining justice and protecting patient rights as well as ensuring the professionalism of medical personnel (Camacho-Rodríguez, 2022a) .

The responsibilities of hospitals cover various aspects, ranging from administrative and ethical to legal. Administrative responsibilities include hospital management to ensure the smooth implementation of safety procedures, while ethical responsibilities require medical personnel to act with integrity and commitment to

patient safety. Legally, if a violation of service standards causes harm, the hospital may be subject to civil or criminal sanctions. This emphasises that negligence not only affects patients but also has serious consequences for the institution (Chance, 2024a) .

In the context of medical personnel responsibility, the main principles that must be upheld are *non-maleficence* and *beneficence*, which encourage them to avoid actions that could harm patients and always strive to provide the best possible benefits. However, medical personnel are also often faced with professional dilemmas where the risk of error cannot be completely eliminated. Therefore, the responsibility of medical personnel is not only technical, but also communicative and emotional in treating patients, including obtaining valid consent before medical procedures are performed (Chance, 2024b) .

Medical negligence or malpractice is a serious violation in healthcare services that has the potential to result in legal action. Malpractice can take the form of misdiagnosis, actions that do not follow procedures, incorrect medication, or disregard for safety standards. If proven, malpractice can result in civil liability in the form of compensation, as well as criminal liability depending on the level of error and the consequences for the patient (Hamdani, 2007) .

Legal protection for patients is crucial in ensuring their right to safe and quality care. Patients have the right to receive complete information about their condition, risks, benefits, and alternative medical treatments, as well as protection from harmful treatment. In the Indonesian legal system, patients' rights are also guaranteed through various regulations, including the Health Law, which requires hospitals to provide compensation if there are service errors that result in losses(Azyabi et al., 2021) .

On the other hand, legal protection for medical personnel must also be given serious attention to maintain the continuity of the profession and the quality of health services. Without adequate legal protection, medical personnel will be in a vulnerable position against excessive lawsuits or disproportionate criminalisation for mistakes that occur. Therefore, medical practice laws regulate the mechanism for supervision and resolution of disciplinary disputes through the Medical Disciplinary Council (MKDKI), which serves to ensure the enforcement of the code of ethics without eliminating the right of defence for medical personnel(Basra Hospital, 2010) .

Legal protection for medical personnel is not limited to internal aspects of the profession, but also includes protection against unfounded legal actions that can disrupt the psychological well-being and performance of doctors and other health workers. Several countries, including Indonesia, have developed professional liability insurance or *medical malpractice insurance* models to assist medical personnel in facing legal risks arising from the practice of their profession. This scheme serves as a form of safety net that helps maintain trust and professionalism in healthcare services (Ananda, 2022) .

The relationship between responsibility and legal protection is also a crucial foundation for building a sustainable patient safety culture. When all parties understand and accept their responsibilities and receive fair legal protection, the risk of medical

errors can be minimised through a proactive and collaborative approach. This creates a conducive working environment, where medical personnel dare to report incidents and near misses for improvement without fear of receiving disproportionate sanctions (Masic, 2014) .

The role of regulation in maintaining this balance is vital. Legislation must be able to provide clarity regarding the rights and obligations of patients and medical personnel, fair dispute resolution mechanisms, and sanctions that educate rather than merely punish. Clarity in regulation will strengthen compliance with safety standards and prevent perceptions of injustice that are detrimental to either party. Regular regulatory updates are also necessary to keep pace with developments in medical practice and dynamic legal protection needs (Zhelev, 2025c) .

In practice, many medical disputes can actually be resolved amicably through mediation or alternative dispute resolution outside of court if effective communication mechanisms and procedures are implemented. This restorative dispute resolution also better ensures the continuity of the relationship between medical personnel and patients and reduces the burden on the judicial system. Therefore, training in communication, complaint handling, and mediation is an important part of hospital policies that support a culture of patient safety (Reis, 2020b) .

Legal responsibility and protection also apply to hospitals as institutions. Hospitals are required to provide adequate facilities, implement strict standard operating procedures, and operate an effective risk management system. Failure to fulfil institutional responsibilities can result in administrative or civil legal action and a decline in accreditation. Therefore, hospitals must proactively conduct periodic evaluations to ensure that all aspects of service meet patient safety standards (Mistri, 2023b) .

Legal protection for medical personnel and patients should be combined with an educational approach, namely providing an understanding of the rights and obligations of each party from the outset of the service interaction. This education aims to build a shared awareness of the importance of cooperation in maintaining the safety and quality of health services . With good education, the potential for conflict can be minimised and a positive culture that supports transparency and accountability can be effectively realised (Zhelev, 2025b) .

In the context of patient safety culture, responsibility and legal protection serve as key drivers for hospitals and medical personnel to continue innovating and improving service quality. Those who know that there is fair legal protection will feel motivated to apply patient safety standards more consistently and boldly make clinical decisions in accordance with procedures. Conversely, patients who feel their rights are protected will also be more trusting and active in the care process, which ultimately strengthens the overall patient safety culture (Chilukuri, 2024) .

Overall, legal responsibility and protection for patients and healthcare professionals are two complementary aspects in building an effective and sustainable patient safety culture. Clear regulations, fair dispute resolution mechanisms, and an

organisational culture that supports incident reporting and evaluation are essential elements that must be implemented simultaneously. In this way, hospitals can become safe, fair, and professional places that ensure patient safety while protecting the dignity of healthcare professionals in carrying out their noble duties.

Conclusion

Patient safety culture in hospitals is a crucial aspect that not only emphasises the implementation of technical safety standards, but also requires the support of organisational culture, management, and adequate technology so that its implementation can be effective and sustainable. This literature review confirms that patient safety standards such as accurate patient identification, communication between medical personnel, safe use of medicines, infection prevention, and risk management are clearly regulated by various guidelines and regulations, but practice in the field often encounters obstacles such as a lack of competent human resources, high workloads, and an organisational culture that does not fully support openness and incident reporting. Therefore, raising awareness, continuous training, and strengthening leadership are key to building a strong patient safety culture.

On the other hand, the responsibility of hospitals and medical personnel in maintaining patient safety is multi-dimensional: ethical, administrative, and legal, requiring clear regulations and the implementation of fair protection mechanisms. Patients have the right to be protected from malpractice and to receive safe services, while medical personnel must also receive legal protection so that they do not experience unreasonable criminalisation that could hinder their professionalism. This study emphasises the importance of balanced legal protection as a driver for creating a conducive working climate, where incident reporting is carried out without fear of disproportionate sanctions that are not , so that a patient safety culture can develop properly and sustainably.

Overall, patient safety culture is not merely a technical medical matter, but also a product of the synergy between the implementation of safety standards, the strengthening of institutional and individual responsibilities, and adequate legal protection for all parties involved. The combination of these three aspects is the main foundation that must be built and continuously improved by hospitals and policy makers in order to create safe, effective, and high-quality health services. This study opens the door for further empirical research to evaluate the effectiveness of implementing a patient safety culture and legal aspects in the context of hospitals in Indonesia and other countries.

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