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COMPARATIVE ANALYSIS OF HEALTH LAW BETWEEN INDONESIA AND MALAYSIA REGARDING REPORTING OF PATIENT SAFETY INCIDENTS IN HOSPITALS

Irfan Setyo Nugroho [a*)], Adi Herisasono [a)] , Yeni Vitrianingsih [a)], Rommy Hardyansah [a)]

[a)] *Sunan Giri University Surabaya, Surabaya, Indonesia*

[*)]*Corresponding Author: datairfan33@gmail.com*

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Abstract. Patient safety incidents are unintentional events, an incident that can allow injuries that could have been avoided. When a patient safety incident occurs in a health facility, especially a hospital, a patient safety incident report must be made as a lesson so that it does not happen again in the future. Both Indonesia and Malaysia certainly have their own regulations in reporting patient safety incidents. So the purpose of this study is to find similarities and differences in reporting patient safety incidents in Indonesia and Malaysia. This type of research is a normative legal research with a comparative legal method approach and normative analysis. Legal sources obtained through secondary data through primary, secondary and tertiary legal sources. For the data validity technique, the data source triangulation technique is used, for data analysis techniques, secondary data is collected from primary sources and secondary sources, then the researcher studies and makes a summary. Based on the analysis, it can be concluded that there are similarities and differences regarding reporting of patient safety incidents in hospitals in Indonesia and hospitals in Malaysia. The author suggests that the Indonesian government should conduct a judicial review regarding the reporting of patient safety incidents in hospitals in a simpler way. For the hospital, it should always submit a report when a patient safety incident occurs so that it can be used as a lesson and not happen again in the future.

Keywords: *comparison laws; reporting of patient safety incidents; hospitals.*

I. INTRODUCTION

The statement is consistent with the Constitution of the Republic of Indonesia of 1945, hereinafter referred to as the "1945 Constitution of the Republic of Indonesia (UUD RI 1945)," as stipulated in Article 1 paragraph (3). Furthermore, every Indonesian citizen is entitled to recognition and legal certainty in accordance with the 1945 Constitution of the Republic of Indonesia, as stipulated in Article 28D paragraph (1). From this explanation, it can be concluded that Indonesia is a state in which all aspects are grounded in the rule of law, and through the existence of law, every Indonesian citizen has the right to obtain legal certainty and legal benefit from the law itself.

Hospitals are health service facilities operating within the service sector. Hospitals must strive to provide the best possible health services because they play a vital role in delivering healthcare services to the community [1]. In providing health services, healthcare facilities, particularly hospitals, must make continuous efforts to improve service quality [2]. The quality of healthcare services serves as a benchmark for the extent to which healthcare is delivered in accordance with established standards. Healthcare services provided to the public must comply with prevailing ethical, normative, legal, and social regulations within a given region [3].

Patient safety constitutes a guarantee of the continuity of integral values for every hospital as a provider of healthcare services [4]. Every healthcare provider must consistently prioritize safety in delivering services to prevent incidents that may adversely affect the quality of healthcare services [3]. A patient safety incident is an unintended condition or event that may result in patient injury and is, in fact, preventable [5]. As cited by the World Health Organization (WHO) in 2016, research on patient safety began in 2000. A prominent research report in the United States from the Institute of Medicine, titled "To Err Is Human," focused on improving the safety of healthcare systems and highlighted data on adverse events occurring in several hospitals in the United States. In its study, it was explained that (Kohn et al., 2000, p. 26) in the states of Utah and Colorado, the incidence of adverse events was recorded at 2.9 percent, with 6.6 percent resulting in death. Similarly, the incidence of adverse events in New York was

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3.7 percent, with a higher mortality rate of 13.6 percent. Studies conducted in several hospitals in Australia, the United States, New Zealand, Canada, and Europe indicated that the incidence of adverse events ranged between 3.2 percent and 16.6 percent (WHO, 2004, in Utarini, Ehry, & Hill, 2009, p. 81). In the United States alone, medical errors among hospitalized patients result in between 44,000 and 98,000 deaths annually out of a total of 33.6 million patients. This figure exceeds deaths caused by AIDS, breast cancer, and motor vehicle accidents (Utarini, Ehry, & Hill, 2009, p. 80). According to a report by the World Health Organization (WHO) on patient safety incidents, medical errors occur in approximately 8 percent to 12 percent of all hospitalized patients. In the European Union, 23 percent of residents reported experiencing significant medical errors in hospitals, while an additional 18 percent received incorrect prescriptions. Data indicate that 50 percent to 70.2 percent of these medical errors are actually preventable through a systematic and comprehensive patient safety approach [4].

Citing the Indonesian Ministry of Health (2020), Indonesia experienced 943 patient safety incidents. Of these, 33 percent were near-miss incidents, 29 percent were no-harm incidents, and 38 percent were adverse events. Among these incidents, 77.6 percent resulted in no injury, 12.9 percent resulted in minor injuries, 5.9 percent resulted in moderate injuries, 0.8 percent resulted in severe injuries, and 2.8 percent resulted in death [6]. This contrasts sharply with the number of incidents reported in Malaysia. As cited from the Malaysian Ministry of Health (2021), the Ministry reported that in 2021 there were 151,225 patient safety incidents in Malaysia [7].

Given the large number of incidents that occur, the quality of healthcare services in terms of patient safety must be given serious attention, particularly with regard to reporting, which is necessary as a learning basis for improving quality and patient safety [4]. Reporting patient safety incidents is crucial within the healthcare service system, as it is useful for identifying underlying risks and preventing the recurrence of similar errors [8]. In Indonesia, patient safety incident reporting has been regulated through Minister of Health Regulation Number 11 of 2017 concerning Patient Safety, which serves as an implementation of Law Number 17 of 2023 concerning Health. Other countries have their own reporting systems in accordance with their respective national guidelines. One such example is Malaysia, where the reporting of patient safety incidents is regulated through the Circular Letter of the Chairperson of the Malaysian Health Steering Committee, Draft Act Number q of 2017 concerning: Incident Reporting in Hospitals and Medical Institutions under the Ministry of Health Malaysia Using the Incident Reporting and Learning System (IRLS) 2.0.

The establishment of a patient safety culture in hospitals and the enhancement of hospital accountability to patients and the public constitute one of the primary objectives of patient safety incident reporting in hospitals [9]. The wide variety of incidents occurring across different countries, along with differences in national guidelines regarding patient safety incident reporting systems in hospitals, presents an interesting subject for study in order to compare and analyze legal certainty across countries. This includes examining how patient safety reporting systems are implemented in Indonesia compared to other countries, particularly Malaysia. Therefore, the researcher is interested in conducting a study entitled "A Comparative Analysis of Indonesian and Malaysian Health Laws Concerning the Reporting of Patient Safety Incidents in Hospitals.".

II. RESEARCH METHODS

This study is a normative legal research employing a comparative law approach and normative analysis. The data collection sources consist of secondary data comprising three types of legal materials: primary legal materials, secondary legal materials, and tertiary legal materials. Source triangulation techniques were applied to analyze the similarities and differences between Indonesian and Malaysian health law concerning the reporting of patient safety incidents in hospitals.

In the data analysis process, secondary data were obtained from primary, secondary, and tertiary sources. The collected data were then examined, after which the researcher formulated summaries or abstract explanations in order to achieve the research objectives.

Legal research can generally be divided into two research methods: normative research and empirical research, which employ deductive and inductive reasoning. Both research methods are equally important for legal researchers [10].

Dr. Serlika Aprita et al., in their book, explain that there are six types of legal science research approaches, namely: analytical methods, normative analytical methods, sociological methods, historical methods, systematic methods, and comparative methods [11].

Comparative law can be regarded as a branch of legal science that utilizes comparative methods to examine or study a legal institution within a legal system that is at least similar to or different from other legal systems [12].

Triangulation is a method used in qualitative research to examine and establish validity by analyzing data from various perspectives [13]. Techniques for testing data validity include method triangulation, investigator triangulation (if the research is conducted by a group), data source triangulation, and theory triangulation [14]. As cited from Alfansyur and Andarusni (2020), source triangulation refers to the process of searching for and testing information by utilizing various data or information sources [15].

III. RESULT AND DISCUSSION

Adaptive Comparison of Patient Safety Incident Reporting in Indonesia and Malaysia

According to Radbruch, legal certainty is defined as a condition in which law can function as a set of rules that must be obeyed [16]. Rules governing public order are often

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associated with prevailing legal norms or regulations. These norms function as guidelines for action, ensuring that individuals act in accordance with collectively agreed values. When clear rules exist and are enforced consistently, desired objectives such as order, justice, and harmony can be effectively achieved. Without rules, society loses direction and struggles to attain an orderly life. In the absence of norms or regulations that are enforced or validated as sources of law, a process or method may proceed blindly or become subject to dispute, as individuals tend to reinforce their own subjective opinions. Therefore, regulations or legal rules must be formulated, enforced, and validated as authoritative sources of law.

With the existence of legislation or legal sources in each country, the function of law becomes a crucial instrument of social control in regulating societal behavior, including that of healthcare facilities. Law does not merely serve as a set of rules to be complied with, but also as a mechanism to guide and encourage healthcare facilities to consistently adhere to prevailing legal norms and standards. This aims to ensure that healthcare services are delivered professionally, safely, and responsibly. Through such social control, healthcare facilities are expected to prevent violations, maintain service quality, and continuously enhance patient safety. Thus, law plays a vital role within the healthcare service system. It functions not only as guidance and binding rules, but also as an instrument of social regulation directing all parties to act professionally and responsibly. With clear legislation that is consistently enforced, the healthcare system can become safer, more transparent, and more trustworthy. Transparency and accountability supported by a legal framework enable patient safety incidents to be reported, analyzed, and followed up appropriately, thereby continuously improving healthcare service quality. Therefore, law constitutes a fundamental pillar in building a healthcare system that is not only efficient but also characterized by integrity and a strong orientation toward patient safety.

Through directives requiring the reporting of patient safety incidents in hospitals when incidents occur, law functions as a tool of social engineering. In other words, legal rules or sources in each country do not only serve as instruments of social control, but also as means to change behavior and systems within healthcare services. In the context of patient safety incident reporting, law aims to encourage positive change so that similar incidents do not recur in the future. Through this process, the healthcare system is expected to continuously improve service quality and enhance patient safety in a sustainable manner.

Concretely, law encourages healthcare facilities to implement systematic and transparent reporting procedures. For example, hospitals are required to establish internal incident reporting systems that are easily accessible to all healthcare workers, enabling any potential incident that may endanger patients to be promptly documented and analyzed. Subsequently, the results of these reports serve as the basis for evaluating and improving work procedures, retraining staff, and revising internal policies. In this way, law not only sets rules but also promotes the implementation of effective preventive measures, ultimately reducing the risk of similar incidents in the future and improving the overall quality of healthcare services.

For instance, patient safety incident reporting has helped identify the primary causes of medical errors, such as medication errors or nosocomial infections. With accurate reporting, healthcare facilities can take corrective actions, such as improving medication administration procedures and enhancing the sterilization of medical equipment. However, in practice, several challenges persist, including limited staff awareness of the importance of reporting, fear of sanctions or stigma, and inadequate technological systems to support reporting. Therefore, sustained efforts from governments and healthcare facility management are required to enhance reporting systems, provide protection for reporters, and strengthen reporting infrastructure so that the legal system can operate effectively and objectively, ultimately achieving patient safety.

Law in a country aims to ensure order and security for society. Such order is maintained when society complies with applicable laws [17]. Function, in this context, refers to duties whereby law operates to ensure that everything proceeds in an orderly and structured manner, as law clearly defines the rights and obligations of each individual [18]. Sources of State Administrative Law refer to rules, principles, or guidelines that form the basis for the administration of government. These sources are divided into formal and material legal sources. Formal legal sources include all positive laws in Indonesia, such as statutes, MPR decrees, government regulations, regional regulations, ministerial regulations, government regulations in lieu of law, and others. These sources are directly binding and possess legal force that must be complied with by government institutions and the public. Material legal sources, on the other hand, are not written rules that directly bind society, such as administrative customs, general principles of law, and jurisprudence [19].

According to the American Hospital Association (1974, cited in Azwar: 1996), a hospital is defined as an organized institution consisting of professional medical personnel and medical facilities that provide medical services, continuous nursing care, diagnosis, and treatment of patients' illnesses [20]. Hospitals provide various types of services, including medical services, medical support services, nursing services, rehabilitation, prevention, and health promotion [21]. Every hospital is required to establish a patient safety team and implement patient safety programs that include incident reporting [22].

Healthcare service processes inherently involve various potential risks; therefore, systems are required to ensure patient safety. These efforts include the development of reporting systems to manage risks effectively. Patient safety incident reporting constitutes the core of service quality and

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is used for informed decision-making as well as a learning tool in evaluating patient safety incident reporting [23]. Such reporting is essential for understanding the causes of incidents, which serve as the basis for improving patient safety [24]. Types of incidents that must be reported include "unexpected incidents, no-harm incidents, near-miss incidents, and potential injury conditions affecting both patients and visitors" [25].

Patient safety incident reporting in hospitals is one of the key benchmarks for evaluating the extent to which healthcare service processes are implemented in accordance with applicable standard operating procedures (SOPs). Moreover, such reporting can be regarded as a form of quality assurance demonstrating a healthcare facility's commitment to patient safety. Beyond risk identification, incident reporting is an integral component of continuous quality improvement efforts, particularly within hospital settings. In Indonesia and Malaysia, healthcare facility leaders play a central role in ensuring the effective operation of reporting systems. They are responsible for fostering a culture of safety, providing effective reporting systems, and professionally and transparently following up on every incident report. With active leadership involvement, incident reporting becomes not merely a formality, but a genuinely effective tool for continuous improvement in healthcare services.

Every patient safety incident must be reported and analyzed by healthcare service units. Reporting should not only document the incident itself but also include analysis to prevent recurrence. Hospitals must facilitate efficient patient safety reporting without imposing sanctions. Reports should be made without fear of punishment. This is essential for identifying, analyzing, and managing patient safety. Information technology should be utilized to support patient safety, such as patient identification systems, electronic medical records, and incident reporting systems. These technologies are used to prevent errors and enhance service efficiency [26]. In general, the objective of patient safety incident reporting is to improve service quality by reducing the number of patient safety incidents, including adverse events, near misses, no-harm incidents, and potential injury incidents. Specifically, the objectives include identifying root causes of patient safety incidents, improving patient care to prevent similar incidents in the future, and mapping adverse events, near misses, and no-harm incidents [27].

As cited from Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017, the term patient safety incidents includes "potential injury conditions, for example, ventilator malfunction; near-miss conditions, where the incident has not yet reached the patient, such as when a healthcare worker is about to administer medication but later realizes the medication is incorrect; no-harm incidents, where the patient is exposed to an incident but does not suffer injury, such as medication errors without adverse effects; unexpected incidents, where the patient is exposed to an incident resulting in injury, such as adverse drug reactions causing nausea, vomiting, poisoning, and others; and sentinel events, where unexpected incidents result in serious or permanent injury requiring life-sustaining intervention, unrelated to the patient's underlying condition, including wrong-site surgery, baby swaps, infant abduction, rape, or violence against patients" [27].

All incident reporting guidelines refer to policies and procedural stages within healthcare facilities as well as national-level guidelines. Reporting is carried out by the first witness of the incident, and reports must not include personal names. This requires a positive work culture that avoids blame and judgment during the reporting process, allowing reporting to proceed smoothly without obstacles. The reporting process begins with the occurrence of an incident, followed by digital reporting within 2 × 24 hours. The report form includes patient data, incident chronology, risk assessment results, and investigation outcomes presented in a simple manner. Data must be accurate, timely, complete, and reliable. These data serve as the basis for problem analysis, evaluation, and comparison of service systems or methods [25]. In Indonesia, patient safety incident reporting refers to the Regulation of the Minister of Health Number 11 of 2017.

The flow of handling patient safety incidents in Indonesia, in accordance with national legal sources, is as follows: (a) when an incident occurs, it must be immediately addressed and reported to the direct supervisor within a maximum of 2 × 24 hours; (b) the supervisor determines the risk grading and conducts a simple investigation; (c) investigation results and incident reports are submitted to the Hospital Patient Safety Committee (KPRS); (d) the KPRS prepares reports and recommendations for submission to hospital directors; (e) reports of investigation results, root cause analysis (RCA), and recommendations are then submitted to the National Committee for Patient Safety (KKPRS/KNKP) via anonymous e-reporting through the official website www.buk.depkes.go.id [28].

Patient safety incident reporting in Malaysia is based on the Circular of the Director-General of Health Malaysia Bill Q 2017 on Incident Reporting in Hospitals and Medical Institutions under the Malaysian Ministry of Health, using the Incident Reporting and Learning System 2.0, as described in the Implementation Guidelines for Incident Reporting (IR) & Learning System 2.0 of the Ministry of Health Malaysia [29].

A circular is defined as an official letter concerning a particular matter distributed for public awareness or specific actions. This circular, issued by the Director-General of Health Malaysia, aims to announce directives for incident reporting using the Incident Reporting and Learning System 2.0 in hospitals and institutions under the Ministry of Health and Malaysian Medical Services [29].

The IR 2.0 form is a two-page form used to report all patient safety incidents, including what happened and near-miss incidents. Its scope is limited to incidents related to patient safety, near misses, or patient safety-related issues. Other incidents, such as accidents or chemical poisoning

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involving staff, staff harmed by patients, and similar events, must not use this form, but instead use other relevant reporting mechanisms, such as Accident Notification, Dangerous Occurrence, Occupational Poisoning and Occupational Disease forms (WEHU). For workplace violence, a specific Workplace Violence Notification form must be used. Administrative issues, such as detecting damaged equipment during routine monitoring, cannot use this form. Individuals authorized to report incidents using the IR 2.0 form include staff involved in the incident, staff who witnessed the incident, and staff who detected errors or near-miss events [30].

Similarity refers to having the same or identical meaning. In the Indonesian Dictionary (KBBI), this is often referred to as synonymy [31]. Patient safety incident reporting can be defined as the process of reporting incidents that have occurred with the aim of preventing recurrence. Hospitals are healthcare facilities provided by the government or private sector, consisting of medical personnel, health workers, and other staff. In Indonesia and Malaysia, incident reporting in healthcare facilities, particularly hospitals, is common and shares the same meaning and objectives in terms of patient safety incident reporting.

Every healthcare facility, particularly hospitals, is required to prepare and submit reports of adverse events when incidents occur. Each incident report prepared by healthcare facilities in both Indonesia and Malaysia must follow technical guidelines stipulated in their respective national regulations. Both countries have legally binding rules and guidelines that ensure legal certainty.

Legal regulations in both Indonesia and Malaysia serve the same function and operate as intended, namely as instruments of social control. In other words, legal rules or sources in each country function to guide and encourage healthcare facilities to comply with existing legal norms. Through directives to report patient safety incidents in hospitals when incidents occur, law also functions as a tool of social engineering, driving change in patient safety incident reporting so that the desired outcome—prevention of similar incidents in the future—can be achieved.

Patient safety incident reporting in hospitals serves as a benchmark and assurance of the extent to which service processes are implemented in accordance with established standards. It is also part of healthcare quality improvement efforts, particularly in hospitals. Leaders of healthcare facilities play a crucial role in managing and reporting patient safety incidents in hospitals.

The explanation above clearly demonstrates similarities in the process of patient safety incident reporting in hospitals. Healthcare facilities, particularly hospitals in Indonesia and Malaysia, are required to report patient safety incidents. In implementing patient safety incident reporting processes, each country adheres to legal principles. Patient safety incident reporting is a key component of hospital quality assurance, with the primary objective of preventing future incidents. Healthcare facility leadership plays a vital role in the reporting and management of patient safety incidents..

Table 1. Similarities in the Regulation of Patient Safety Incident Reporting in Hospitals in Indonesia and Malaysia

No	Indonesia vs Malaysia
1	According to legal sources in Indonesia and Malaysia, patient safety incidents are adverse events that should be preventable..
2	According to legal sources in Indonesia and Malaysia, when an incident occurs, healthcare facilities, particularly hospitals, must prepare a patient safety incident report
3	In preparing patient safety incident reports in hospitals, both Indonesia and Malaysia have guidelines or legal certainty..
4	The objective of patient safety incident reporting in hospitals in Indonesia and Malaysia is the same, namely to prevent similar incidents from recurring in the future..
5	Patient safety incident reports in hospitals in Indonesia and Malaysia serve as benchmarks of hospital healthcare facility quality..
6	There is involvement of healthcare facility leadership in the reporting and management of patient safety incidents.

Comparison of Patient Safety Incident Reporting in Indonesia and Malaysia

Menurut kamus KBBI, perbedaan berarti suatu kegiatan atau According to the Kamus Besar Bahasa Indonesia (KBBI), "difference" refers to an activity or condition characterized by differing factors, resulting in divergence or separation [32]. There are differences in the regulations governing patient safety incident reporting in Indonesia and Malaysia. These differences arise from the distinct governmental systems adopted by the two countries. Indonesia adheres to a presidential system in which sovereignty rests with the people, whereas Malaysia adopts a parliamentary system with a supreme monarch.

In Indonesia, ministers serve as assistants to the President in carrying out presidential duties. In performing their functions, ministers are responsible for formulating, stipulating, and implementing policies within their respective sectors. Ministers are also authorized to issue laws and regulations to implement existing legislation.

One of the statutory regulations directly enacted and signed by the Indonesian Minister of Health is Minister of Health Regulation Number 11 of 2017 on Patient Safety (hereinafter referred to as MoH Regulation No. 11 of 2017). This regulation serves as an implementation of Law Number

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17 of 2023 on Health (hereinafter referred to as Health Law No. 17 of 2023).

MoH Regulation No. 11 of 2017 outlines the procedures for reporting patient safety incidents in hospitals, the roles of leadership in managing patient safety incidents, and the procedures for handling incidents occurring within healthcare facilities, including incidents with wide-ranging or national impact.

The types of patient safety incidents in Indonesia include adverse events, no-harm incidents, near-miss incidents and potential injury conditions, as well as sentinel events resulting in death, all of which are required to be reported. When an incident occurs in an Indonesian hospital, it must be reported within 2 × 24 hours using a manual reporting form and subsequently reviewed by the hospital patient safety team. If the assessment outcome is categorized as blue or green, resolution is sufficient through a simple investigation conducted by the head of the unit related to the incident. However, if the assessment outcome is yellow or red, a Root Cause Analysis (RCA) must be conducted by the hospital patient safety team. Based on the RCA results, the patient safety team is required to provide recommendations for improvement. The next stage involves reporting the incident to the National Committee for Patient Safety (Komite Nasional Keselamatan Pasien—KNKP).

There are also specific procedures for handling hospital incidents with wide-ranging or national impact. In Indonesia, these procedures are described in detail, and there is a clear distinction between reporting systems for incidents with wide-ranging impact and those without such impact. For incidents with wide-ranging impact, a very short reporting timeframe is stipulated. As stated in Article 23 paragraph (1), a sentinel event must be reported no later than one hour after occurrence. Healthcare facilities are required to respond promptly by following up on the report, taking immediate action to prevent widespread impact, securing evidence, stabilizing the situation, and establishing communication with the National Committee for Patient Safety (KNKP). At a minimum, these actions aim to mitigate the impact of the sentinel event, ensure the security of evidence, maintain safety at the incident site, manage media coverage, and alleviate anxiety among patients, patients' families, and healthcare workers.

For large-scale handling and investigation, the Director General establishes and appoints a special investigation team. This team consists of representatives from the Ministry of Health, the National Committee for Patient Safety, and relevant professional organizations. Healthcare facilities are also responsible for securing facilities and infrastructure at the incident location. Investigation results, including both preliminary and final reports, are compiled and submitted to the Director General. A summary incident report must be submitted within 3 × 24 hours after the sentinel event is reported. The head of the investigation team submits the report to the Director General no later than four months after the preliminary report is delivered. If the sentinel event contains elements of a criminal offense, the Director General will recommend investigation by civil servant investigators (Penyidik Pegawai Negeri Sipil—PPNS). If subsequent investigation reveals new information that further clarifies the sentinel event, the investigation will be conducted again by the same or a follow-up investigation team appointed by the Director General.

This approach differs from that of Malaysia. Malaysia also has a Minister with authority to issue directives or regulations; however, such directives or regulations are conveyed through an authorized Director General. In the health sector, the Director General of Health holds the authority to issue health-related directives or regulations.

With regard to patient safety incident reporting in Malaysian government hospitals, the Director General of Health Malaysia issued the Health Malaysia Circular Letter of 2017 on Incident Reporting in Hospitals and Medical Institutions of the Ministry of Health Malaysia Using the Incident Reporting and Learning System 2.0. In the Kamus Besar Bahasa Melayu, a pekeliling (circular) is defined as an official letter concerning a particular matter circulated for general information or for action by specific parties. This circular provides instructions on how patient safety incidents must be reported in Malaysian hospitals.

The circular is accompanied by a procedural guideline in the form of a book entitled "Guidelines for the Implementation of the Incident Reporting and Learning System 2.0 for Ministry of Health Hospitals, 2017." This guideline can be accessed through the website https://www.patientsafety.moh.gov.my/v2/?page_id=56 and is signed by the Head of Health Malaysia. The guideline book further elaborates in detail on incident management, including the types of patient safety incidents in Malaysian hospitals, leadership roles, and the processes or procedures for reporting patient safety incidents. In Indonesia, there are five categories of patient safety incidents, whereas the situation in Malaysia differs. Malaysia recognizes only one overarching category of incidents, with two reportable types: Actual Patient Safety Incidents (incidents that occur and reach the patient) and near-miss incidents (incidents that do not reach the patient). There are significant differences in the handling of patient safety incidents between Indonesia and Malaysia. In Malaysia, hospital incidents must be reported within 48 hours to the risk/quality manager from the onset of the incident. The risk/quality manager then provides feedback to the head of the ward or department involved, containing comments or instructions to be implemented, which are documented in the form of a "prescription slip" as a learning tool. The report must be submitted within five working days after the incident, after which the quality manager signs and stamps the manual form. The incident report (IR) prescription slip is confidential, and document security is strictly ensured. In addition to issuing prescription slips, the quality manager may conduct investigative actions such as RCA, Mini-RCA (MIRCA), and other methods, as indicated by the checklist in Section B of the IR form. In cases of uncertainty, RCA is recommended. At the final stage, the quality manager submits the report online through the e-IR 2.0 system.

Another difference relates to the reporting of incidents with wide-ranging impact. Malaysian hospitals report such incidents using the e-IR system, and the reporting process is the same as that for incidents with less extensive impact. To enhance or investigate incidents occurring in hospitals, Malaysia has established specific processes. If an incident

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results in death, a near miss causing serious injury, or death, and there is a directive from the Health Department or the Ministry, follow-up actions are conducted using RCA. However, if the incident is classified as a near miss, follow-up actions may be carried out through discussion forums, MIRCA, Failure Mode and Effects Analysis (FMEA), clinical audits, or other forms of investigation..

Table 2. Differences in Patient Safety Incident Reporting Regulations in Hospitals in Indonesia and Malaysia.

No.	Indonesia	Malaysia
1	Indonesia adopts a presidential system of government.	Malaysia adopts a parliamentary system of government.
2	Indonesia is led by a president.	Malaysia is led by a constitutional monarch (king).
3	Indonesia has ministers who assist the president in carrying out governmental duties and who have the authority to issue regulations directly.	Malaysia has ministers who assist the king in carrying out governmental duties, with regulatory authority exercised through a Director-General.
4	Regulations on patient safety incident reporting in hospitals are formulated and directly signed by the Minister of Health.	Regulations on patient safety incident reporting in hospitals are proposed and signed through the Director-General of Health.
5	Guidelines for patient safety incident reporting are explicitly stipulated in Health Regulation No. 11 of 2017 concerning Patient Safety.	Guidelines for patient safety incident reporting are contained in a publication entitled *"Guidelines for the Implementation of the Incident Reporting and Learning System 2.0 in Hospitals of the Ministry of Health, 2017."*
6	There are five types of patient safety incidents: Adverse Events, No-Harm Incidents, Near Misses, Potential Harm Conditions, and Sentinel Events resulting in death, all of which are mandatory to report.	There are two types of patient safety incidents: actual incidents (events that occur and reach the patient) and near-miss incidents (events that do not reach the patient).
7	Incident management applies an initial grading system using green, blue, yellow, and red categories. Green and blue cases require investigation, while yellow and red cases require a Root Cause Analysis (RCA).	Incident management does not apply a grading system; incidents may be directly investigated using MIRCA or RCA, and in cases of uncertainty, the RCA method may be applied immediately.
8	From a regulatory perspective, there are specific procedures for managing incidents with widespread impact.	From a regulatory perspective, there are no specific procedures for managing incidents with widespread impact.

IV. CONCLUSIONS

Based on the comprehensive analysis presented in this study concerning the regulation of patient safety incident reporting in Indonesia and Malaysia, it can be concluded that there are both fundamental similarities and differences between the two countries. The similarities lie in the existence of patient safety incident reporting guidelines in hospitals that are derived from legal provisions, as well as in the shared objective of reporting, namely to prevent the recurrence of similar incidents in the future. In addition, in both countries, the leadership of healthcare facilities, particularly hospitals, plays an active role and is involved in the implementation of patient safety incident reporting. Conversely, differences in regulatory arrangements are evident in the systems of government adopted, the mechanisms by which the Ministries of Health issue regulations, as well as the guidelines or principles applied in incident reporting. Further distinctions can be observed in the classification of incident types, the mechanisms for handling incidents at the hospital level, and the procedures for managing incidents that have widespread impacts on the community. Based on these conclusions, it is recommended that the government conduct a judicial review of Minister of Health Regulation Number 11 of 2017 concerning Patient Safety, particularly with regard to the regulation of patient safety incident reporting. This review is intended to simplify reporting mechanisms so that they are more easily understood and implemented by all relevant stakeholders. Furthermore, hospitals are expected to consistently and continuously fulfill their obligation to report patient safety incidents as part of ongoing efforts to improve service quality and ensure the protection of patient safety.

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