

# Legal Liability for Medical Laboratory Errors at Hospitals

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**Abstract:** Medical laboratory service is an integral part of public health service. Medical specialist plays the role in the implementation of laboratory services as the person in charge or coordinator for examinations, testing, and laboratory personnel management as well as act as a daily controller to ensure quality medical laboratory services. Nonetheless, there is a possibility of medical errors to take place including providing lab results, diagnosis, and treatment done by a doctor. As a result, it is extremely important and needed as regards who can be held accountable for such medical lab errors in hospitals. The research design applied in this paper is legal research which focuses on examining legal norms in an applicable statutory regulation relevant to the subject matter. The research aims to analyze the authority and legal liability of the medical specialist in charge of labs in hospitals. The research found that the approval of a medical specialist as the person in charge of labs is carried out on a strong legal framework, and the clarity of the rules regarding the expected duties and obligations of the medical specialists significantly contributes to the improvement of the labs' services alongside medical and legal liability. Consequently, when an error occurs, the hospital is liable for all losses caused by negligence committed by personnel in hospitals, which is in line with the Indonesian Act on Hospital Law Article number 46. Considering that the legal relationship between doctors and patients in health services at hospitals is contractual, the patient is able to take a legal remedy to file a civil lawsuit to the local District Court for the liability for the loss caused by unlawful acts for the fact that hospitals do not provide quality, safe, and effective medical services that prioritize the patients' interests and safety

**Keyword:** Health Law, Medical Specialists, Medical Laboratory, Hospital

## I. INTRODUCTION

Medical lab services are inseparable from public health services. As one of the units providing healthcare, the laboratory is expected to provide comprehensive and accurate information on the lab aspects of the specimen tested. The public has the expectation that as diseases develop, the lab test result must improve as advanced as science and technology (Fachrul et al., 2022; Wiguna & Suhamdani, 2022).

Labs play a vital role in supporting medical services in hospitals, which are estimated to have around 60%-70% of the significant role in making diagnoses, follow-up treatment, monitoring, hospitalization, and patient discharge. However, the problem in terms of medical errors remains, both in presenting lab results, diagnosing, and treatment to patients. For this reason, special attention is required to address the authority liable for medical errors happening to patients along with its protection in hospitals (Enny & Nabila Sun, 2022; Magnette et al., 2016).

According to the study conducted in India by Brijesh Mukherjee and Saurav Patra (2013), pre-analytical errors affect the results of lab tests by 46%-68.2% of the total error. Such error is caused by inaccurate sample quality (47%), wrong patient identification (26.8%), no examination order from a doctor (14%), and the use of inappropriate test tubes (0.6%) (Saurav et al., 2013). This finding is also in line with Dureen Najat (2017) at the Iraqi Clinical Laboratory that reports the prevalence of the improper sample handled during the pre-analytical stage with the main reason that the error in samples undergoing hemolysis (9%), and identification errors in the sample (8%) as well as the frozen samples incidence is 6% (Najat, 2017).

Meanwhile, previous studies carried out in Indonesia by Aril Habiyoso (2021), it is found that the score obtained in the patient preparation examination stage was in the very good category (86.25%), the stage of identification was in the good category (60%), the stage of taking specimens was in the very good category (86.42%), the stage of specimen processing was also in the very good category (85%), the specimen storage stage and its delivery stage were in good category (71.25%) and (74.16%) respectively (Aril, 2021).

The medical lab is a high-risk business activity. Hence, the implementation of medical lab services requires an appointed person to be in charge of the labs to ensure it

operates well (Goswami et al., 2010). Such appointment in this case is regulated in the Regulation of the Minister of Health in 2010 Number 411 Article 14 regarding Clinical Laboratories. In addition, regarding the appointment is also listed in the Regulation of the Minister of Health of the Republic of Indonesia 2021 Number 14 Appendix Number 38 as regards the standard for business activities and products in the implementation of risk-based business licensing in the health sector. It is elaborated that the role of the medical specialist in providing labs service, appointed by the head of the medical labs, is the person in charge or coordinator of testing, examination, management, and daily technical personnel where duties and responsibilities are regulated in the provisions of Minister of Health 2010 Number 411 Article 16 paragraph 1.

It is, therefore, necessary to improve the quality of medical lab services, including having objectives of the quality standards that ensure the accuracy of examination results, and increase the patients' and public trust in the quality of the lab testing assessment and testing. As the research has shown that all lab activities are subject to error in all phases of a diagnostic procedure (Magnet et al., 2016). There are three important stages in the lab examination process, namely the pre-analytical, analytical, and post-analytical stages. The pre-analytic covers patient preparation, sample identification, collection, storage, and delivery to the labs. The analytical part includes maintenance and calibration of tools, checking and monitoring accuracy. The post-analytic stage includes recording and reporting results (Enny & Nabila Sun, 2022). As many medical errors can happen such as in providing

### 1. The Authority of Medical Specialists in Charge of Labs in Hospitals

#### *a. The legal framework of medical laboratory actions by medical specialists in charge of labs in hospitals*

In terms of lab health services, there are 2 rules regulating the organizational structure of human resources or health workers assigned in the lab such as the Minister of Health Regulation 2010 Number 411 and *Permenkes* 2021 Number 14. The provisions of the Minister of Health 2010 Number 411 Article 14 argue that clinical labs must meet the following health manpower:

lab results, diagnosing, and performing treatment to patients, it is highly required to have someone be in charge and liable for the lab results for the errors committed in order to protect the patients. Along with the increase in the quantity and quality of health services, the health lab's role in health referrals becomes important, and so are other forms which should be developed and improved. An error found in the process of lab examination leads to the doctor's diagnostic error which later affects the doctor's therapy process and definitely has an impact on the patient's safety. Furthermore, clinicians also depend on the length of waiting time to immediately determine the diagnosis and treatment of patients. Hence, the legal facts need to be studied regarding the authority and responsibilities of the medical specialist as the person in charge of the labs in hospitals.

## II. METHOD AND THEORITICAL FRAMEWORK

The research methodology used is legal research (Marzuki, 2016). It examines legal norms in applicable laws and regulations concerning a profession's guidelines and ethical codes, particularly medical specialists in providing health services, such as medical labs in hospitals. The approach implemented is the statute and conceptual approaches (Marzuki, 2017). Meanwhile, the legal sources are primary, secondary, and tertiary sources. Data gained is collected and processed through a literature review and identification of laws and regulations related to the subject matter of the research.

## III. RESULT AND FINDINGS

- 1) The prime general clinical labs must have a technical person in charge at least a doctor with a training and health laboratory management certificate for at least 3 (three) months organized by professional and educational institutions collaborated with the Ministry of Health, as well as technical and administrative personnel of at least 2 (two) health analysts and 1 (one) administrative staff.
- 2) The mid-general clinical labs should have a technical person in charge at least a clinical pathology specialist, and 4 (four) health analysts, 1 (one) nurse, and 2 (two) administrative staff.
- 3) The main public clinical lab should have a technical person in charge, at least 1 clinical pathology

specialist, 6 (six) health analysts, 2 (two) people who have special microbiology training certificates, 1 nurse, and 3 (three) administrative staff.

- 4) A clinical microbiology laboratory must have a technical person in charge with at least 1 clinical microbiology specialist and at least 2 (two) health analysts who have received training certification in clinical microbiology, 1 nurse, and 1 administrative staff.
- 5) Clinical parasitology lab must have at least 1 clinical parasitology specialist, 2 (two) health analysts who have been certified for clinical parasitology training, 1 nurse, and 1 administrative staff.
- 6) The anatomical pathology lab should have at least one anatomical pathology specialist, at least 1 anatomical pathology technician/analyst/biology graduate, and 1 administrative staff.

Regulation of the Minister of Health 2021 Number 14 states that every medical lab must have a policy that regulates Organizational Structure and Work Procedure elaborating all medical lab activities. The lab owner must then appoint a head of the medical lab responsible for all lab operations in terms of administrative and technical management. Furthermore, the medical lab must have an organizational chart/structure that covers the head of the medical lab who has the management skill and expertise in the lab field; the person in charge or a testing coordinator; human resources and general affairs coordinator; and lab technical staff. The other regulations of 2010 Number 411 and 2021 Number 14 both regulate the specialist as the person in charge of the lab examinations. With these laws on health service standards for medical labs, doctors performing medical practices in labs have strong legal guarantees for their rights.

b. The authority of the medical specialist in charge of the lab in hospitals

Based on the Regulations of the Minister of Health 2021 Number 14 regarding the organizational structure of human resources or health workers in labs, every medical lab must have a policy that regulates their Organizational Structure and Work Procedure that describes all activities of the medical labs. Therefore, it is obligatory to have persons in charge of the lab examination who is a

specialists and sub-specialist per the field of examination/testing/processing.

The Regulation of the Minister of Health 2010 Number 411 in the Provisions of Article 16 paragraph 1 comprises the description of the duties and responsibilities of the lab technical person in charge. The duties and responsibilities include:

1. Develop work plans and lab technical policies;
2. Determine work patterns and procedures;
3. Lead the implementation of lab technical activities;
4. Administer supervision, control, and evaluation of lab activities;
5. Plan, implement, and supervise quality assurance activities;
6. Provide an opinion on the results of lab examinations;
7. Provide consultation on the basis of lab examination results;
8. Provide input to lab management regarding the implementation of lab activities.

The authorization of the medical specialist as the person in charge of the lab is carried out based on a strong legal framework. It is with a strong level of legitimacy and is in line with legal objectives in which it creates a balance between justice, certainty, benefit, and order, in this case, the health sector. Such vivid and exact laws on the medical specialist's duties and obligations can contribute significantly to the services provided and accounted for both medically and legally.

## **2. Responsibilities of a Medical Specialist in Charge of Labs in Hospitals**

a. Potential risk due to errors in examining lab results

Patient safety becomes the most important thing when they are in the lab. Patient safety is a condition in which the patient is free from harm or injury that may cause illness, or injury in many forms such as physical, psychological, social; suffering, disability, death, and other harm which should not have happened. In addition to that, patient safety is also a system that makes patients safer through risk assessment, patient risk identification and management, incident report and analysis, the ability to

learn from incidents and follow-up, as well as the implementation of solutions to minimize risks and prevent injuries caused by mistakes due to action taken or not taken. In other words, all these standard operating procedures for lab services must be obeyed, there neither should be any sampling specimen errors, analytical errors, or errors in printing and submitting results.

These errors can occur in the diagnostic step such as errors or delays in diagnosing in which the examination is inappropriately done, applying the examining methods that are no longer used, or not acting on the examination result or treatment observation stage such as errors in treatment procedures, such as errors in treatment procedures, therapy implementation, drug use methods, and delays in responding to diagnostic and medical test results.

The main cause of misdiagnosis is generally not intentional factors, but difficulties in interpreting the various clinical manifestations and lab investigation performed. Misdiagnosis is sometimes hard to avoid by general practitioners and specialists or sub-specialists. As a matter of fact, even a doctor of expert level or a subspecialty doctor has experienced misdiagnosis (Salawati, 2020). This error taking place throughout the examining process in the lab is divided into two types of errors namely technical errors which frequently happens at the analytical stage (Aril, 2021); and non-technical errors which can happen in the pre-analytical and post-analytical stages. Errors in the pre-analytical stage, for example, are found in the sampling process such as patient preparation, identification, specimen collection, and storage, or specimen damage caused in the storage or delivery process. Furthermore, they can also happen in calculations and writing, which is considered part of the post-analytical errors in the form of inputting results. There are several case examples related to errors in lab test results that have been decided in the Supreme Court Decision Number 300/K/Pdt/2020 and Number 3571/K/Pdt?2015.

Safety includes minimizing the risk of infection, harmful side effects, and other potential hazards in health services. Trust in the hospital is measured by the presence of well-being felt by patients while being in the hospital, for instance, feeling safe and protected. For patients, this trust

can general hospital loyalty and influence them in choosing where to seek treatment (Padma et al.m 2010).

b. Criminal, civil, and administrative liability for the occurrence of risk of errors in the lab test results

The legal relationship between doctors, hospitals, and patients often seems complicated, particularly when it is connected to the doctor's position in the hospital. However, looking deeper into this, such tripartite relationships can generate three patterns of legal relations such as 1) legal relationship between doctors and hospitals; 2) legal relationship between doctors and patients, and 3) legal relationship between hospitals and patients (Zamroni, 2022).

Hermie Hadiati Koeswadji asserts that the legal relationship between a doctor and a hospital is an employment relationship (*dienstverband*), meaning that doctors work in hospitals to carry out their professional duties. There is also medical staff who are specialist doctors who are not part of hospital workers (*werknemers*) as their legal relationship is based on a contract to treat or to patient admission to get treatment (*toelatings contract*). Therefore, the legal position of doctors in their legal relationship with hospitals can be classified into 2 types including doctors as employees and doctors as independent contractors (Zamroni, 2022).

There are two types of legal positions of doctors as employees such as doctors as private employees and doctors as government employees. Doctors as private employees consist of permanent and contract doctors, while doctors as government employees consist of civil servant doctors (PNS), Indonesian National Armed Forces doctors (TNI), Indonesian National Police doctors (POLRI), and government employee doctors with work agreements (PPPK). Privately-owned doctors usually work in private and public hospitals managed by non-profit legal entities. In the Provisions of the Hospital Law Article 20, government employee doctors normally work in public hospitals owned by the central government, local government, TNI, and POLRI. This does not rule out the possibility for government employee doctors to practice in private hospitals and vice versa, just as stipulated in the Provisions of the Medical Practice Law Article 37

paragraph (2), that doctors are permitted to practice in three different places.

Legal position of doctors both as employees and as independent contractors does not necessarily abolish hospital liability for losses due to unlawful acts committed by a doctor working in the hospital. It is worth considering that the relationship between doctors and hospitals is based on the legal relationship between business actors and workers. According to R. Soetojo Prawirohamidjojo and Marthalena Pohan, the employer is liable for the unlawful acts of his workers who carry out the work. In fact, they cannot even be forgiven (*disculperen*) even if they cannot prevent the actions of their workers (Kamagi, 2018). This is in line with the Provisions of the Civil Code Article 1367 which states liability for fault with the reverse burden of proof and risk refers to the liability caused by the actions of other people who are under their responsibility. Furthermore, hospital liability can also be based on the doctrine of vicarious liability, where this doctrine is based on a pattern of legal relations between the employers and subordinates that generate representative liability (Drs. H. Adami Chazawi, 2007).

Almas Shaikh asserts that the legal relationship between a doctor and a patient has three dimensions. The first is the contractual dimension in which doctors and patients must comply with the principles of contract law. The second dimension is called consensual relationship where the doctor is required to obtain consent from the patient before taking medical action. The last one is related to the quality of medical services where doctors should provide these services as instructed in the operational service standards.

Legal relationship in terms of contractual dimension has been emphasized in the Medical Practice Law Article 39 which is based on an agreement between the doctor and the patient. In a practical sense, agreements are generally made verbally which results in doctors and patients not having written evidence that can confirm their legal relationship. This very case lead to conflict, which cannot be separated from the demands and efforts made by the parties who feel aggrieved. As explained in the Provisions of the Hospital Law Article 46 that the hospital is legally liable for all losses incurred due to errors committed by health workers at the hospital. The liability of a hospital in the implementation of its health

services can be seen from the aspects of administrative law, civil law, and criminal law.

Hospital liability in the context of administrative law and its implication on the legal relationship of the patients is closely related to policies or provisions that are a requirement for the administration of health services that must be fulfilled to provide quality health services, especially for employing health workers in hospitals. In the case the hospital does not fulfill these administrative obligations or requirements, then based on Hospital Law Article 46, hospitals can be subject to administrative sanctions in the form of verbal and written warnings, no extension of operational license, and/or fines and license revocation.

Hospital liability in the context of criminal law must fulfill 3 elements including 1) the perpetrator must have the ability to be liable or accountable for, meaning that they have a stable mental state; 2) there is a family principle between the perpetrator and the victim which can be intentional or negligent; 3) excuses for eliminating errors/mistakes and reasons for forgiveness do not apply. Provisions regarding malpractice in order to provide legal protection for the victims are regulated in Hospital Act Article 32 letter q and Article 46. The provisions of Article 32 letter q talks about patient's rights where every patient has the right to sue and/or sue the hospital if the hospital is suspected of providing services that are not in accordance with standards both civilly and criminally. Meanwhile, the provisions of Article 46 state that the hospital is liable in case of the health workers' negligence that causes harm to the public or patients. These provisions are meant to guarantee compensation that must be obtained by the victims as a result of the actions of doctors who commit malpractice as well as a control for the hospital to carry out with full caution (Fitriano et al., 2016; Koto & Asmadi, 2021).

Doctors' legally binding provisions in performing his profession is a responsibility that must be met based on the element of deliberate action or negligence of himself. One of them is criminal liability for doctors regulated in the Criminal Code i.e. Article 90, Article 359, Article 360 paragraphs (1) and (2) and Article 361. Article 360, for instance, states that:



1. Whoever due to negligence causes a person to be severely injured shall be punished with imprisonment for a maximum of one year;
2. Whoever due to negligence causes a person to be injured in such a way that the person becomes temporarily sick or unable to perform his duty or work shall be punished with imprisonment for a maximum of 9 months or punished with confinement for maximum 6 months or a maximum fine of four thousand five hundred rupiahs if applied in the case mentioned above.

An act can be considered criminal malpractice if it fulfills the formulation of a criminal offense, in which the act must be a disgraceful act and committed out of ill intent that is careless or negligent. Adam Chazawi argues that malpractice is a doctor or a person under his orders intentionally commits both active and passive actions in medical practice on his patients at all levels that violate professional, procedural, and medical standards and principles or by violating the law (without authority). As it is without informed consent and outside informed consent, without SIP or without STR, it is not in accordance with the patient's medical needs which causes (causal verband) harm to the patient's body, physical and mental health, and or life that lead to the liability for the doctor (Drs. H. Adami Chazawi, 2007).

Errors made by health workers can happen in the field of criminal law. There are several actions that are included in criminal acts regulated in the Criminal Code (hereinafter referred to as the Criminal Code), such as Article 263 regarding falsification of documents, Article 267 concerning forged doctor's certificates, Article 299 about abortion, Article 304 regarding letting people in misery, Article 322 concerning revealing confidentiality, Article 344 about acts of euthanasia, Articles 347, 348, 349, 350 regarding crimes against life, Article 351, 352, 353, 354, 355 about persecution, Article 359 and Article 360 concerning causing death or injury due to negligence.

Hospital liability in the context of civil law is based on the provisions of the Health Law Article 58 that asserts:

1. Everyone has the right to claim compensation against a person, health worker, and/or health provider who causes harm due to errors or negligence in the health services they receive.

2. Claims for compensation as referred to in paragraph (1) do not apply to health workers who take actions to save lives or prevent someone from becoming disabled in an emergency.

Based on Article 58 above, it is understood that the legal protection of patients' rights in health services is to protect their rights through civil lawsuits to demand compensation. Hospital liability can bind to the hospital's actions as an organization (policy and management), and so does the actions of the workers in it (Drs. H. Adami Chazawi, 2007; Koto & Asmadi, 2021). Roy K. Lisko argues that hospital liability for medical malpractice is based on two main theories including the superior vicarious liability of respondeat theory and the corporate negligence theory (Zamroni, 2022). The first theory is based on the agency principles that make the employer liable for the mistakes done by their workers, while the latter places the hospital in a position of being directly accountable to patients according to their obligations. In other words, hospital liability for losses suffered by patients can be divided into two types which are liability due to hospital negligence as a corporation (corporate negligence) and liability for errors committed by the health workers in the hospital (vicarious liability of respondeat superior). Basically, hospital liability is not distinct from personal liability. It is stated in the provisions of the Civil Code Article 1243 for liability for default and Article 1356 on liability for unlawful acts. The legal remedy that can be made by the patient is to file a civil suit to the local District Court on liability for the loss due to unlawful acts committed by the hospital that does not provide good, safe, quality, and effective medical services that do not prioritize the safety and interest of the patients.

c. Legal protection for the occurrence of errors in lab test results

The quality of health services is a measurement tool used to assess the fulfillment of patients' needs and expectations in hospitals (Hastuti et al., 2017). This received service will be compared to the patient's expectations which are called patient satisfaction. Both health service quality and patient satisfaction are inseparable as they are interconnected and influence each

other. Patient satisfaction depends on the quality of the services provided at the hospital. Quality service will instill a sense of trust in the patients for the service provided, which can establish a strong relationship between the patient and the hospital (Wirmando; Melani Astari, Asti; Yuliatun, 2021). If this quality is neglected, as a consequence, it will affect the number of patients due to the absence of trust and turn to other medical institutions that are considered to meet their expectations (Setyawati, 2018).

Quality service greatly influences patient satisfaction as they believe that it is the factor in choosing a good and trustworthy hospital and thus requires hospitals to be more thorough and careful in providing their health services. If the quality presented meets or exceeds the expectations, then the services are considered to be of high quality. Patients will get satisfied if the services they receive are in accordance with what they expect, which includes product quality, price, work performance, emotional capacity, location, atmosphere, and health facilities available at the hospital.

Granting authority to medical specialists as the person in charge and coordinator to provide lab services in the hospital is one of the efforts to improve the quality of health services to patients in the aspect of establishing the patients' own diagnosis, which in particular has a strong legal basis. Having a clear legal basis for such a role will give equal legal protection for both patients and the medical profession that aims to avoid a lack of public trust in the medical profession, particularly in Indonesia.

#### IV. CONCLUSION

The authorization of a medical specialist as the person in charge of labs is carried out on a strong legal framework. It is accompanied by a strong level of legitimacy and correlated to the objectives of law which are to create a balance between justice, certainty, benefit, and order, in this case, the health sector. Such vivid description of the duties and obligations of medical specialists is expected to bring a significant contribution to the health service provided and can be accountable medically and legally will automatically lead to a just and certain medical practice.

In regards to the occurrence of errors in lab test results, the provisions of Hospital Law Article 46 reiterate

that the hospital is liable for all losses caused by the negligence committed by health workers at the hospital. Patients can take several legal efforts to get legal protection covering civil legal and criminal remedies and administrative sanctions efforts. Considering this legal relationship between doctors and patients referred to as contractual, the role of the Civil Code becomes a reference or guideline in such liability in case of loss experienced by patients. The legal remedy can be made by the patient through filing a civil suit to the local district court on the case of liability for losses due to unlawful acts considering the hospitals do not provide good, safe, qualified, and effective medical services by prioritizing the patients' interest and safety.

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