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Reconstruction of Legal Liability Arrangements for Artificial Intelligence-Based Misdiagnosis in Health Services

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Abstract: The development of artificial intelligence technology in the healthcare sector offers high diagnostic efficiency, yet raises novel juridical issues when systems produce erroneous diagnoses that harm patients due to the inadequacy of conventional positive legal frameworks in regulating non-human entity liability. This study aims to analyze the substantive weaknesses of exclusive positive laws regarding liability for artificial intelligence-based diagnostic errors and to formulate a reconstructed legal regulation model that ensures justice and legal certainty for all stakeholders. A normative juridical approach is employed through library research examining primary, secondary, and tertiary legal materials, which are subsequently analyzed using qualitative juridical methods to identify norm vacuums and synthesize an ideal legal reconstruction model. The research findings indicate that current health law and consumer protection regulations still face substantive and procedural limitations, such as blurred fault boundaries among medical professionals, hospitals, and software developers, as well as significant evidentiary hurdles for patients resulting from a lack of algorithmic transparency within computing systems. The future reconstruction of legal regulations demands the establishment of specific regulatory instruments or statutory revisions that integrate principles of algorithmic accountability, operational oversight standardization, clear proportional liability distribution, and accessible patient rights recovery mechanisms to guarantee legal certainty and protective justice within the modern healthcare ecosystem.

Keywords: Artificial Intelligence, Diagnostic Error, Legal Liability

INTRODUCTION

The development of artificial intelligence technology has penetrated various strategic sectors of modern civilization, including the realm of health services that are directly related to the safety of human lives. Intelligent computing systems are now capable of processing large amounts of clinical data, recognizing complex radiological patterns, and formulating medical diagnosis recommendations at a speed that exceeds the conventional capabilities of human

medical personnel. The integration of machine learning algorithms in healthcare facilities promises high diagnostic efficiency, reduces the risk of human fatigue, and expands public access to accurate medical interpretation. This rapid progress has triggered a fundamental transformation from traditional healthcare models to a digital era that relies heavily on the automation of electronic data-based systems (Kusnandar, 2025).

The presence of smart technology in medical examination rooms has led to a radical shift in who is in control of the final clinical decisions on a patient. Doctors are no longer the only entities that conduct autonomous analysis of disease symptoms, but rather act as supervisors or validators of recommendations generated by diagnostic software systems. The reliance on *black box algorithms* whose internal reasoning processes is often intransparent or difficult to explain transparently creates complex new risk gaps. When systems provide incorrect analysis results, the boundaries of medical professional autonomy and the reliability of digital systems become blurred, creating real legal uncertainty for those involved in the healthcare ecosystem.

The current conventional legal liability system is still rooted in the principle of subjective error (*element of fault*) and professional negligence (*medical malpractice*) which is exclusively aimed at human legal subjects such as doctors and hospitals. The existing positive legal framework does not adequately regulate legal liability for non-human entities or software algorithm creators in the event of a fatal diagnosis failure. The uncertainty of the regulation includes the formulation of *strict product liability* for software developers, limitations on the legal liability of hospitals as providers of facilities, and legal protection for aggrieved patients. This void in material legal norms causes victims of artificial intelligence-based misdiagnoses to often find themselves at a dead end in demanding justice and restoration of their civil rights (Pratidina, 2025).

The absence of a firm and adaptive legal instrument to the characteristics of autonomous technologies creates structural vulnerabilities that endanger patient safety and create uncertainty for the health technology industry. Cases of misdiagnosis stemming from data bias training algorithms or computer system failures show that consumer protection regulations and national health laws are lagging far behind the pace of digital innovation. Medical personnel are in a dilemma between the demand to leverage technological innovations to improve the quality of service and the risk of legal fallout in the event of a system error that is beyond their technical control. Without clear regulatory reforms, the adoption of smart technologies in the healthcare sector has the potential to trigger protracted medical disputes without fair and proportionate legal resolution.

The urgency of legal reform of the accountability system requires a philosophical, juridical, and sociological reconstruction so that the law is able to respond to the times without sacrificing the principle of human rights protection for health. The ideal legal construction must be able to distribute the burden of responsibility fairly between artificial intelligence software manufacturers, health facility management, and medical personnel who use these instruments. The conventional normative approach needs to be reviewed through the establishment of new legal norms that integrate the principles of algorithmic accountability, system transparency, and professional risk insurance mechanisms specific to the digital age. This rearrangement of the legal framework is an absolute prerequisite to ensure legal certainty, social benefits, and justice for all legal subjects in the modern healthcare ecosystem.

The purpose of this research is to analyze and evaluate the positive legal weaknesses that apply to accountability for misdiagnosis of artificial intelligence systems, as well as to formulate a comprehensive and ideal legal regulation reconstruction model to ensure legal protection for patients and certainty of responsibility for stakeholders in the health care sector.

METHODS

This study uses the normative juridical method as the main approach to examine the legal issues raised. The normative juridical method is a literature law research conducted by examining secondary and primary legal materials, which focuses on legal norms, legal principles, laws and regulations, and applicable legal doctrines (Askin & Masidin, 2023). The application of this method to the title of the research on the reconstruction of legal liability arrangements for artificial intelligence-based misdiagnosis is carried out by examining various positive legal instruments such as laws and regulations in the health sector, civil law, and consumer protection provisions. The analysis is directed to find inconsistencies, gaps in norms, and weaknesses in regulations that regulate legal accountability between medical personnel, hospitals, and artificial intelligence system developers.

Literature study is the main data collection technique that collects various legal literature, written documents, and legal materials relevant to the topic of discussion. Primary legal materials include national laws and regulations directly related to medical practices, health, electronic transactions, and consumer protection. Secondary legal materials consist of legal textbooks, scientific journals, results of previous research, articles, and literature of legal experts on artificial intelligence and civil and criminal liability. Tertiary legal materials are in the form of legal dictionaries, encyclopedias, and various supporting information sources that provide explanations of technical and juridical terms.

The data analysis technique applied is juridical qualitative analysis, which describes and systematizes the data obtained in a logical, systematic, and structured manner without using statistical calculations. All the collected legal materials are analyzed in depth to identify substantive weaknesses of existing regulations that have not accommodated the characteristics of artificial intelligence-based autonomous technology. The results of the legal interpretation are then synthesized to formulate the concept of reconstruction of the ideal legal arrangement, fairness, and provide legal certainty for patients, medical personnel, and technology developers in the future.

RESULTS AND DISCUSSION

Weaknesses of Positive Legal Arrangements related to Legal Accountability for Misdiagnosis Generated by *Artificial Intelligence* Systems in Health Services

The use of artificial intelligence (AI) in healthcare presents legal problems, especially when the system produces inaccurate diagnoses and results in losses for patients. AI systems can help medical personnel analyze symptoms, read examination results, and determine possible diseases based on available data. However, the use of this technology still faces the risk of errors due to limited data, inaccuracies in algorithms, and inconsistent recommendations for patient conditions. The World *Health Organization* (WHO) emphasizes that the application of AI in the health sector requires human supervision, transparency, and accountability mechanisms to protect patients from the negative impacts of technology use. This problem shows the need to adjust legal arrangements to be able to accommodate the characteristics of AI as a technology that also influences medical decision-making (Ardiyanti et al., 2024).

Indonesia's positive legal regulation has not specifically regulated all aspects of liability for misdiagnosis generated by AI. Indonesia already has a number of regulations that can be used to solve this problem, including Law Number 17 of 2023 concerning Health and its implementing regulations, as well as provisions on civil liability and relevant consumer protection. However, the application of these general provisions to AI-based misdiagnoses still raises problems, especially when patient losses arise due to the interaction between medical personnel decisions, system weaknesses, and hospital policies. The absence of regulations that specifically explain the characteristics of AI errors can make it difficult to determine the legal basis and who is responsible for patient losses.

The division of responsibility between doctors, hospitals, and AI system developers also does not have fully clear boundaries. Doctors can be held accountable if they use AI recommendations without conducting adequate clinical assessments, while hospitals can be held liable if losses are related to negligence in procurement, selection, supervision, or application of technology that is not in accordance with service standards. Software developers also have the potential to be liable if errors stem from design defects, programming errors, inadequate training data, or failure to provide information about system limitations. Problems arise when misdiagnosis is the result of a combination of these factors, making it difficult to determine the relationship between the actions of each party and the losses suffered by patients. This situation shows the need for stricter limits on liability so that there is no unilateral transfer of responsibility (Choiriyati, 2026).

Proving the elements of error, negligence, and causal relationships becomes a problem when a misdiagnosis involves an AI system. In conventional medical services, the assessment of alleged negligence can be carried out through an examination of medical personnel's actions, professional standards, service standards, and patient conditions. The use of AI adds technical problems because the recommendations produced can be influenced by algorithms, input data, training processes, and system updates. Patients who suffer losses do not necessarily have sufficient knowledge or access to prove that the error came from doctors, hospitals, or software developers. These difficulties are even greater when information about how the system works is not available to the patient or the party conducting the legal examination. As a result, the proof process has the potential to require cross-field experts, increase the cost of dispute resolution, and extend the time it takes for patients to obtain compensation.

The limited transparency of AI systems also affects legal certainty for patients and medical personnel. A number of AI technologies use models whose decision-making process is difficult to understand directly by users, including medical personnel who use their recommendations. This situation can make it difficult to trace the reasons why the system provides certain diagnoses, the data that affects the recommendations, and the factors that cause the system to fail to recognize the patient's disease. If the technical information is only controlled by the developer, the patient may experience obstacles to obtaining an explanation about the cause of the loss he or she experienced. This issue is also related to the fulfillment of patients' rights to health service information and access to the complaint mechanism. Legal regulations need to clarify the obligations of technology providers and health service facilities related to decision documentation, system audits, access to relevant technical information, and the provision of explanations in the event of misdiagnosis (Eldkak et al., 2024).

Monitoring the safety and accuracy of AI systems throughout their lifetime also requires clearer settings. The accuracy of diagnosis depends not only on the quality of the technology when it is first applied, but also on the suitability of the data, changes in patient characteristics, software updates, and the condition of healthcare facilities. A system that shows good performance in one group of patients does not necessarily provide the same level of accuracy in another group. Inconsistencies in training data have the potential to cause bias so that the diagnosis becomes less accurate for certain groups of patients. If evaluation after implementation is not carried out adequately, system errors can continue to recur without being detected. This condition indicates the need for more targeted provisions regarding safety and accuracy testing, human supervision, periodic audits, incident reporting, and discontinuation of the use of systems that are proven to be harmful to patients.

The protection and restoration of the rights of patients harmed by AI-based misdiagnoses has also not fully addressed the problems arising from the use of the technology. Patients can experience delays in treatment, worsening health conditions, additional treatment costs, disability, and even death due to improper diagnosis. Although applicable legal provisions can be the basis for filing a claim, their application to damages involving many

parties has the potential to cause differences in interpretation regarding who is obliged to provide compensation. Problems also arise when the developer is abroad, the hospital uses third-party AI services, or the technical evidence is under the control of a technology provider. These conditions can hinder patients' access to effective dispute resolution. Legal updates are needed to clarify the complaint mechanism, access to evidence, proportionate distribution of the burden of proof, and recovery of patient losses. A more targeted arrangement is expected to provide certainty regarding the responsibilities of doctors, hospitals, and developers without ignoring patients' rights to safe and quality health services (Fotheringham & Smith, 2024).

Juridical Implications of Legal Uncertainty on the Limitation of Errors and Negligence of Medical Personnel, Hospitals, and *Artificial Intelligence* Software Developers on the Protection of the Rights of Injured Patients

Legal uncertainty regarding the limits of errors and negligence between medical personnel, hospitals, and artificial intelligence software (*AI*) developers has juridical implications for the fulfillment and protection of the rights of patients who suffer losses due to misdiagnosis. This problem arises when the AI system produces inappropriate medical recommendations, while the determination of the responsible party does not yet have clear limits. Law Number 17 of 2023 concerning Health has regulated the rights and obligations of medical personnel, health workers, and patients, but the use of AI presents new problems regarding the division of responsibility between those who provide health services and those who provide technology. This uncertainty can create uncertainty for patients when demanding responsibility for the losses they experience. The *World Health Organization* (WHO) also emphasizes the need for accountability mechanisms that allow individuals to recover when harmed by algorithm-based decisions (Jioe et al., 2025).

The juridical implications that arise are related to the inhibition of the fulfillment of the patient's right to obtain legal protection and compensation. Patients who experience misdiagnosis can suffer losses in the form of delayed treatment, deteriorating health conditions, additional treatment costs, disability, and death. Uncertainty about the responsible party can cause patients to face a lengthy legal process to determine whether the loss comes from the negligence of medical personnel, failure of hospital supervision, or defects in AI software. In fact, the provisions of Article 1365 and Article 1366 of the Civil Code can be the basis for claiming compensation if the elements of unlawful acts or negligence are met. Problems arise when patients have difficulty proving the actions of certain parties as the cause of loss. This situation has the potential to reduce the effectiveness of legal protection because patients' rights recognized by laws and regulations cannot necessarily be realized optimally through the dispute resolution process.

The uncertainty of the liability limit also has implications for determining the legal subjects who are obliged to account for misdiagnosis. Medical personnel are in principle still obliged to use professional competence and conduct clinical assessments before determining a diagnosis or medical procedure, even if they receive assistance from the AI system. Hospitals have an obligation to provide health services according to standards, including ensuring the feasibility of the technology used and supervising its implementation. Software developers can be held liable if it is proven that there are product defects, development errors, or violations of legal obligations that cause patient losses. Article 193 of Law Number 17 of 2023 concerning Health also regulates the responsibility of hospitals for losses caused by the negligence of hospital health human resources. However, this provision does not necessarily solve the issue of the liability of AI developers or all losses that arise from technological failures. Without strict limits, there is a risk of throwing responsibility between the parties involved so that patients find it difficult to obtain certainty about who must provide recovery (Nadayanti & Nur, 2026).

The issue of proof becomes the next juridical implication because patients often do not have access to the technical information needed to identify the source of error. AI systems can generate recommendations based on algorithms, training data, input data, and processing mechanisms that are not fully understandable by the user. If the developer masters the technical documentation, while the hospital only has service records and medical personnel only know the recommendations displayed, the process of tracing the cause of the error becomes more complicated. Patients must prove the existence of errors or omissions, losses incurred, and causal relationships according to the basis of the lawsuit used. Inequality of access to such evidence can weaken the position of patients when dealing with hospitals or technology companies that have greater resources and technical capabilities. WHO highlights the issue of AI legal accountability in the healthcare sector, including determining the responsibilities of healthcare providers, technology developers, and hospitals that choose AI systems. This situation shows the need for a proof mechanism that is able to take into account the characteristics of technology without eliminating legal certainty for the parties.

Legal uncertainty also affects the fulfillment of patients' rights to information, openness, and consent to medical procedures. Patients have the right to an explanation of the health services they receive, including relevant information about the use of technology to assist in the diagnosis process. When medical personnel use AI recommendations without explaining the role of the technology, its limitations, or the risks associated with its use, patients may have difficulty understanding the basis of medical decision-making. The problem becomes even more serious when misdiagnosis occurs due to over-reliance on system recommendations without adequate clinical examination. Unclear obligations to disclose the use of AI can also lead to different interpretations regarding the limits of the information that must be provided to patients. WHO places human autonomy, transparency, safety, and accountability as the main principles of the use of AI in the health sector. This principle supports the need for regulation that ensures patients obtain adequate information and still places medical personnel as parties who carry out professional considerations in health services (Pham, 2025).

Another implication is related to the effectiveness of complaint mechanisms and medical dispute resolution. Unclear division of responsibility can prompt patients to file claims against multiple parties at once without certainty about the basis of their respective liability. This has the potential to increase the cost of litigation, prolong the dispute resolution process, and cause differences in interpretation in the application of the law. Problems can also arise if the software developer is domiciled abroad, the AI system is provided through a third-party service, or the technical evidence is not directly accessible to the patient. As a result, the remedy mechanism that is formally available may not be easily accessible to the aggrieved party. Effective legal protection requires clear complaint procedures, access to relevant evidence, examination by independent experts, and compensation mechanisms appropriate to the form and level of loss. These efforts need to be supported by a clear division of authority between health service supervisory agencies and authorities handling security and technology compliance aspects.

Legal uncertainty regarding the limits of errors and negligence between medical personnel, hospitals, and AI software developers can result in reduced legal certainty, inhibition of proof, difficulty in determining the responsible party, and not optimal restoration of patient rights. These conditions show that the recognition of patients' rights through laws and regulations needs to be accompanied by an accountability mechanism that can be effectively applied when AI technology is used to assist medical diagnoses. Updates to legal regulations need to clarify the standards of due diligence of medical personnel, the obligation of hospitals to select and supervise technology, and the responsibility of developers for the security, reliability, and limitations of software. These regulations also need to ensure

information disclosure, patient access to evidence, and compensation mechanisms based on the level of error and proven cause-and-effect relationships. Clarity on the boundaries of responsibility is expected to prevent unilateral transfer of responsibility while ensuring that the use of AI does not reduce patients' rights to safety, information, legal protection, and recovery of losses due to misdiagnosis (Pratami & Dzulfiqar, 2024).

Reconstruction Model for Legal Accountability for Artificial Intelligence-Based Diagnosis Errors in the Future that Is Fair and Provides Legal Certainty for All Parties in the Health Service Ecosystem

The reconstruction model of legal accountability for diagnostic errors based on artificial intelligence (*AI*) in the future needs to be directed at the establishment of a legal system that is able to provide justice for patients, legal certainty for medical personnel and hospitals, and clear limits of responsibility for software developers. The current regulations need to be developed in order to be able to answer the problems that arise due to the involvement of AI technology in the medical decision-making process. Law Number 17 of 2023 concerning Health can be one of the foundations for drafting these regulations, but it needs to be equipped with provisions that specifically regulate the use of AI as a diagnosis support (Puspita & Ikhsan, 2026). This need is in line with the recommendations of the *World Health Organization* (WHO) which emphasizes patient safety, human rights protection, transparency, and accountability of all parties involved in the development and use of AI in the health sector. Legal reconstruction needs to place patient protection as the main principle without ignoring the legal interests of other parties who carry out their obligations professionally.

The establishment of special regulations regarding legal accountability for AI-based misdiagnoses is a form of reconstruction that needs to be considered. These regulations can be drafted through amendments to existing laws and regulations or the establishment of implementing regulations that specifically regulate the use of AI in health services. The regulatory material needs to include the definition of AI-based misdiagnoses, technology risk classification, system use requirements, supervisory obligations, and dispute resolution mechanisms if patients suffer losses. These provisions also need to explain the relationship between the professional responsibilities of medical personnel, the institutional responsibilities of hospitals, and the responsibilities of software developers. The Ministry of Health in 2026 has highlighted the need for strong governance and adaptive rules for the use of AI in the health sector, including the issue of responsible parties if the diagnosis recommendations generated by the system turn out to be wrong. The policy direction can be the basis for encouraging the formation of more measurable rules that are able to keep up with technological developments.

The division of responsibility between medical personnel, hospitals, and software developers needs to be formulated based on the legal obligations and sources of each party's fault. Medical personnel may be held liable if they are found to have committed professional negligence, such as accepting AI recommendations without adequate clinical examinations or ignoring patient conditions that conflict with system recommendations. Hospitals may be liable if losses arise from failure to meet institutional obligations, such as using systems that do not meet safety requirements, neglecting technology evaluations, or failing to provide adequate training for medical personnel. Software developers may be held liable if there are design defects, programming errors, inaccuracies that could have been prevented, or violations of the obligation to provide information about system limitations. Such division of responsibility must be accompanied by provisions on joint liability if multiple parties are found to have contributed to the same loss. This model can prevent unilateral transfer of responsibility while ensuring that the determination of the responsible party is based on relevant evidence and legal obligations (Rahmalillah, 2026).

Regulations regarding standards of human prudence and supervision also need to be strengthened so that the use of AI does not eliminate the professional role of medical personnel. AI systems should function as a decision-making tool, while the determination of medical diagnoses and actions still takes into account clinical examinations, individual patient conditions, and professional and service standards. Such oversight obligations need to be adjusted to the type of technology, risk level, and purpose of use, so that not every system error is automatically charged to the doctor who uses it. Medical personnel also need to receive training on the capabilities, limitations, risk of bias, and possible errors in AI recommendations. Hospitals are obliged to establish operational procedures that govern the use of the system, verification of recommendations, recording of decisions, and reporting of incidents. The WHO Recommendations on AI governance for health emphasize that humans must remain in control of medical decisions and that the technology used must meet the requirements of safety, accuracy, and effectiveness according to the purpose of its application. This principle can be translated into legal standards that provide protection to patients as well as certainty for medical personnel.

Legal reconstruction needs to include a fair and enforceable evidentiary mechanism against the characteristics of AI technology. Patients often do not have the technical capabilities or access to the documentation necessary to identify the source of misdiagnosis. Future regulations may establish obligations to keep records of system usage, history of AI recommendations, software versions, relevant input data, and documentation of medical personnel actions after receiving recommendations. This information should be verifiable by authorities and used as evidence as long as it complies with legal requirements, personal data protection, and medical confidentiality. Regulations may also authorize independent experts to evaluate the causes of errors and determine each party's contribution to patient losses. Where technical evidence is under the control of a hospital or developer, the evidence disclosure mechanism needs to ensure that patients do not lose the opportunity to obtain justice simply because of limited access. The distribution of the burden of proof can be formulated proportionally according to the mastery of the evidence and the obligations of each party, without removing the need to prove the element of liability based on the legal basis used (Rosyid & Alamsyah, 2026).

The protection of patients' rights needs to be strengthened through a clear, accessible, and undue burden mechanism for patients. Future regulations may regulate complaint procedures, independent examinations, out-of-court dispute resolution, and court lawsuits if a settlement is not reached. Patients need to obtain adequate explanations about the use of AI in the diagnosis process, relevant risks, and steps that can be taken if allegations of wrongdoing arise. Compensation mechanisms can also be developed based on the form of loss, the degree of error, the causal relationship, and the involvement of each party. For cases involving multiple parties, the rules need to provide a mechanism for determining responsibility and redress that prevents patients from getting caught up in internal disputes between hospitals, medical personnel, and developers. The implementation of these mechanisms must still take into account the right of the parties to defend themselves and obtain a fair trial. WHO recommends the availability of accountability and recovery mechanisms for individuals who are adversely affected by algorithm-based decisions, so that these principles can be used as one of the cornerstones for the formation of a patient protection system (Setiyanta, 2025).

The reconstruction model of legal accountability for AI-based misdiagnosis in the future needs to integrate certainty of norms, division of responsibility, technological supervision, proof, and restoration of patients' rights into a single interrelated legal framework. This framework can be realized through special regulations or changes to existing regulations, accompanied by technical standards and implementation guidelines that can be updated according to technological developments. Supervision of AI systems need to be carried out

from the stage of development, testing, approval of use, implementation in health facilities, to evaluation after the system is used. The government also needs to involve medical personnel, hospitals, technology developers, legal experts, and patient representatives when drafting provisions so that the interests of each party can be considered proportionately. The success of legal reconstruction is not only measured by the availability of written rules, but also by the ability of these rules to provide access to justice, prevent the recurrence of mistakes, and ensure recovery for aggrieved patients. A fair legal framework must ensure that the development of AI technology supports the improvement of the quality of health services without compromising the protection of patients' rights or imposing inappropriate responsibilities on medical personnel, hospitals, and software developers (Turangan et al., 2025).

CONCLUSION

The positive legal system in Indonesia still faces a lack of norms and substantial limitations in accommodating the characteristics of artificial intelligence technology, especially related to the complexity of cause-and-effect relationships and the division of liability boundaries between medical personnel, hospitals, and software developers in the event of misdiagnosis. This legal uncertainty has a direct impact on weakening the victim's position in proving and hindering the fulfillment of the civil rights of patients who are medically and materially harmed.

The recommended suggestion is the need to reform regulations through the establishment of special legal instruments or revisions of health-related laws that expressly formulate the principles of algorithm accountability, standardization of system operational supervision, and proportional responsibility sharing that integrates the principle of strict product liability for technology manufacturers to ensure legal certainty and protection of justice for all parties in the modern health service ecosystem.

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