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Legal Liability for Algorithmic Malpractice in Digital Medical Diagnosis

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Abstract: *The integration of artificial intelligence in digital medical diagnostics offers significant benefits but also introduces new risks, including algorithmic malpractice resulting from inaccurate or biased system outputs. This study examines the legal liability framework for algorithmic malpractice using a normative legal research method, analyzing statutory regulations, legal doctrines, and comparative international approaches. The findings indicate that liability remains predominantly placed on physicians, despite evidence that many algorithmic errors originate from design flaws, data bias, or technical failures outside clinical control. Hospitals and algorithm developers also contribute to systemic risks, highlighting the need for a multi-actor liability model. Regulatory reforms are required to establish algorithm audit obligations, risk assessments, human oversight mechanisms, transparency standards, and the adoption of shared or strict liability for developers. This study underscores the necessity of comprehensive regulation to ensure patient protection and legal certainty in the era of medical digitalization.*

Keywords: artificial intelligence, health law, legal liability, malpractice, medical algorithms

INTRODUCTION

Digital transformation in the healthcare sector has entered a crucial phase with the advent of artificial intelligence (AI) technology and algorithm-based diagnostic systems, which are now increasingly used in modern medical practice[1]. Hospitals and healthcare providers in developed countries are beginning to integrate algorithmic clinical decision support systems, with more than 65% of global healthcare institutions reporting the use of AI-based diagnostic systems in 2021[2]. In Indonesia, the acceleration of healthcare digitalization increased after the launch of the SATUSEHAT ecosystem, which encourages the use of electronic medical records and telemedicine services[3]. However, behind this progress, there is also an increased risk of *algorithmic malpractice*, which is a misdiagnosis that arises not solely from human negligence, but also from the inaccuracy of algorithmic systems.

[1] World Health Organization, *Global Report on Artificial Intelligence in Health* (Geneva: WHO Press, 2021), 44.

[2] Michael Anderson, "Algorithmic Clinical Decision Support Systems and Diagnostic Safety," BMJ Quality & Safety 31, no. 2 (2022): 151–160.

[3] Kementerian Kesehatan RI, Transformasi Digital Kesehatan: Laporan 2023 (Jakarta: Kemenkes RI, 2023), 28.

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The phenomenon of algorithmic malpractice is not merely a theoretical issue; a number of studies have revealed that automated diagnostic systems can produce false positives and false negatives that are dangerous to patient safety[4]. For example, algorithms for detecting breast cancer and tuberculosis have been found to be biased against certain genders and age groups when the training data is not representative[5]. When clinical decisions are heavily dependent on black box machine learning models, diagnostic errors become difficult to detect, verify, and account for. In such scenarios, patients may receive inappropriate treatment or experience delays in treatment, two conditions that legally constitute harm.

This technological development raises important questions about the structure of legal responsibility when diagnostic errors involving algorithms occur. In classical health law, malpractice is synonymous with a doctor's negligence in failing to meet professional standards. However, in digital diagnosis systems, the source of errors can originate from software code, data bias, model design errors, technical implementation in healthcare facilities, or improper use by medical personnel themselves.

This multi-actor complexity creates a potential liability gap, making it difficult for victims to obtain legal certainty. International jurisdictions are beginning to regulate this, but there is no global consensus yet.

The European Union, through the EU Artificial Intelligence Act, categorizes medical AI as a high-risk system and requires transparency and model audits[6]. The United States, through the FDA, regulates Software as a Medical Device (SaMD), but the aspect of legal responsibility still depends on the tort or contract regime of each state[7]. Meanwhile, Indonesia does not yet have specific regulations regarding legal responsibility for losses caused by algorithmic diagnostic errors. The 2023 Health Law, the 2022 Personal Data Protection Law, and telemedicine regulations only regulate general aspects of health services without addressing the issue of liability when automated technology makes mistakes.

In addition, the complexity is compounded by the fact that many medical algorithms are opaque, making it difficult to fulfill the principle of explainability, which is an important element of evidence in health law. The classic malpractice doctrine requires clear proof of a causal relationship between the wrongful act and the patient's harm. However, when clinical decisions are the result of doctor-algorithm interactions, identifying the source of the error becomes increasingly unclear. In this context, the absence of comprehensive regulations can weaken legal protection for patients while placing healthcare professionals in a vulnerable position because they bear the risk of misdiagnosis that actually originates from technology.

The scientific literature shows that studies on legal liability for algorithmic malpractice are still fragmented. A study titled Liability in AI-Based Medical Decisions only discusses the responsibility of doctors without examining the role of algorithm developers in the formation of errors[8]. The study Accountability for Machine Learning in Clinical Settings emphasizes the technical aspects of model supervision but does not

[4] Ahmad, Sharique, and Saeeda Wasim. "Prevent medical errors through artificial intelligence: A review." *Saudi J Med Pharm Sci* 9, no. 7 (2023): 419-423.

[5] Vrudhula, Amey, Alan C. Kwan, David Ouyang, and Susan Cheng. "Machine learning and bias in medical imaging: opportunities and challenges." Circulation: Cardiovascular Imaging 17, no. 2 (2024): e015495..

[6] European Commission, *EU Artificial Intelligence Act Proposal* (Brussels: EU Commission, 2021).

[7] FDA, *Guidance for Software as a Medical Device* (Washington, DC: U.S. FDA, 2021).

[8] Lagioia, Francesca, and Giuseppe Contissa. "The strange case of Dr. Watson: liability implications of AI evidence-based decision support systems in health care." *Eur. J. Legal Stud.* 12 (2020): 245.

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provide a comprehensive legal accountability framework[9]. Meanwhile, "AI and Medical Negligence: Rethinking Professional Standards" discusses professional ethical standards but does not offer an operational legal model in the Indonesian context[10]. These three studies indicate a significant research gap.

This study aims to fill this gap by analyzing legal responsibility for algorithmic malpractice in the context of digital medical diagnosis in Indonesia, combining a positive legal approach, international comparisons, and modern medical ethical principles. The novelty of this research lies in the formulation of a multi-actor accountability framework that identifies the roles of doctors, hospitals, algorithm developers, and the state as regulators. The objective of this research is to formulate a legal liability model that is fair, adaptable to technology, and can provide optimal protection for patients in the digital medical era.

METHODOLOGY

This study uses a normative or doctrinal legal research method that focuses on examining primary, secondary, and tertiary legal materials to analyze the concept of legal responsibility in cases of algorithmic malpractice in digital medical diagnosis[11]. This approach is used because the main issues examined relate to legal norms, principles of responsibility, and harmony between technological developments and the health regulatory framework. In the context of algorithmic malpractice, the legal questions that arise require an analysis of the structure of responsibility, the position of the parties, and the legal obligations arising from the use of automated diagnosis systems. Therefore, doctrinal research is the most appropriate method to explain how the law should work in dealing with new issues arising from the development of artificial intelligence in medical services.

Data collection was carried out through an inventory of primary legal materials such as the 2023 Health Law, the 2022 Personal Data Protection Law, the Medical Practice Law, and technical regulations related to telemedicine services[12]. These legal materials were analyzed together with academic literature discussing liability, algorithmic accountability, and medical ethical standards as secondary legal materials. A conceptual approach was also used to understand concepts such as duty of care, negligence, strict liability, and the principle of prudence in the use of medical technology[13]. The analysis was conducted qualitatively by identifying the relevance of norms, consistency between regulations, and regulatory gaps that arise due to the absence of specific regulations on algorithmic malpractice.

In addition, this study uses a comparative law approach to compare regulations in the European Union, the United States, and certain Asian countries in regulating legal liability for algorithmic errors. This approach provides an overview of the liability models that have been implemented in other jurisdictions so that their suitability for the Indonesian legal system can be evaluated[14]. All analyses were conducted to formulate

[9] Zawati, Ma'N., and Michael Lang. "What's in the box?: uncertain accountability of machine learning applications in healthcare." *The American Journal of Bioethics* 20, no. 11 (2020): 37-40.

[10] Singh, Ajay Kumar. "Evolving Standards of Duty of Care: A Critical Analysis of Negligence in the Age of AI and Automation..

[11] Peter Mahmud Marzuki, *Penelitian Hukum* (Jakarta: Kencana, 2017), 35.

[12] Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan; Undang-Undang Nomor 27 Tahun 2022 tentang Perlindungan Data Pribadi; Undang-Undang Nomor 29 Tahun 2004 tentang Praktik Kedokteran.

[13] Bernard Arief Sidharta, *Refleksi tentang Struktur Ilmu Hukum* (Bandung: Mandar Maju, 2019), 112.

[14] European Commission, *EU Artificial Intelligence Act Proposal* (Brussels: EU Commission, 2021); FDA, *Guidance for Software as a Medical Device* (Washington, DC: U.S. FDA, 2021).

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recommendations that can strengthen legal protection for patients and provide legal certainty for medical personnel and algorithm developers in the digital health service ecosystem.

RESULTS AND DISCUSSION

The Concept of Algorithmic Malpractice and the Challenges of Proof in the Legal System

Algorithmic malpractice is a new form of professional error in digital health services, namely errors arising from the use of algorithm-based diagnostic technology, whether it functions as a clinical decision support system or as a semi-automatic diagnostic tool[15]. From a legal perspective, malpractice essentially requires the fulfillment of the elements of negligence, professional standards, and a causal relationship between the action and the harm. However, when medical decisions are generated by complex algorithmic systems, the question of who is responsible becomes much more complex than in traditional medical malpractice[16]. This is due to the involvement of many parties, from software developers, healthcare facilities, data providers, to medical personnel, who collectively influence the diagnosis results.

In digital diagnosis systems, the source of error is no longer singular, but can arise from various points, such as models trained using biased data, programming errors, mismatches between algorithms and patient populations, or physician negligence in verifying automated recommendations[17]. This multi-actor complexity leads to the emergence of liability fragmentation, a condition in which each party only has partial responsibility, making it unclear who is most responsible for the loss. This differs from the doctrine of conventional medical malpractice, in which doctors are personally considered to have a full duty of care towards patients[18]. In the algorithmic context, reliance on automated systems can lead to a reduction in human control, creating new problems in proving negligence.

In addition, many medical algorithms are black box models, meaning that the decision-making methods within the model cannot be explained transparently. This problem has a direct impact on legal evidence, as malpractice law requires the ability to trace the chain of causation from an action to patient harm[19]. When algorithmic models cannot explain the basis for their decisions, doctors cannot show whether errors stem from human negligence or from system design. This causes difficulties in meeting commonly used standards of proof, such as the balance of probabilities in civil cases or beyond reasonable doubt in certain proceedings.

Another issue that arises is the concept of overreliance on automated systems. This phenomenon occurs when doctors rely on algorithms without performing adequate manual clinical assessments, because

[15] Michael Anderson, "Algorithmic Clinical Decision Support Systems and Diagnostic Safety," *BMJ Quality & Safety* 31, no. 2 (2022): 151–160.

[16] Lagioia, Francesca, and Giuseppe Contissa. "The strange case of Dr. Watson: liability implications of AI evidence-based decision support systems in health care." *Eur. J. Legal Stud.* 12 (2020): 245.

[17] Ahmad, Sharique, and Saeeda Wasim. "Prevent medical errors through artificial intelligence: A review." *Saudi J Med Pharm Sci* 9, no. 7 (2023): 419-423.

[18] Bernard Arief Sidharta, *Refleksi tentang Struktur Ilmu Hukum* (Bandung: Mandar Maju, 2019), 112.

[19] Vrudhula, Amey, Alan C. Kwan, David Ouyang, and Susan Cheng. "Machine learning and bias in medical imaging: opportunities and challenges." *Circulation: Cardiovascular Imaging* 17, no. 2 (2024): e015495..

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algorithms are considered to be more accurate or objective[20]. This reliance has the potential to lead to the neglect of medical professional standards, which have been based on independent clinical assessment. From a legal perspective, overreliance can be viewed as a form of medical negligence. However, if the algorithm systematically provides incorrect results, it is unfair to place the entire burden of responsibility on medical personnel. This situation creates the phenomenon of shared liability, but without a clear regulatory framework.

The next challenge lies in the fact that algorithms are dynamic (self-learning or adaptive algorithms) that can change over time based on new data. This type of model poses the risk that the accuracy of the algorithm may increase or decrease depending on the quality of the data received. This makes it difficult for regulators and law enforcement to determine whether the version of the algorithm used at the time of the loss is the same as the verified version.

This raises a big question in the context of product liability, namely whether software developers can be held responsible for changes in model behavior that are not entirely under their control. In the context of Indonesian law, the challenge is even greater because there are no specific norms governing the liability model for losses resulting from algorithmic malpractice.

The Medical Practice Law only regulates the obligations of doctors, while the Consumer Protection Law and the Health Law do not specifically regulate digital products as objects of legal liability[21]. The absence of these norms causes uncertainty regarding the role of algorithm developers, even though in many cases they are the parties with the most control over system design, model parameters, and training data quality. Without clear rules, patients may find it difficult to prove damages and seek appropriate compensation.

In addition, proving cases of algorithmic malpractice requires a high level of technical expertise, making it difficult for courts to understand technological evidence such as machine learning model architecture, training datasets, and error rates. In international practice, several countries have begun to implement explainability standards as a requirement for algorithm accountability. However, these standards do not yet exist in Indonesian health regulations, making it difficult to effectively apply the doctrine of legal responsibility. This difficulty in proving liability has the potential to place patients in an unequal position vis-à-vis large institutions such as hospitals or medical technology companies.[22]

Overall, the concept of algorithmic malpractice poses a major challenge to the legal system because the source of errors can be dispersed, technical evidence is difficult to understand, and there is no clear framework of accountability. Therefore, it is necessary to rethink the legal liability model that can accommodate the realities of modern medical technology and ensure adequate legal protection for patients.

Legal Liability Framework: Doctors, Hospitals, and Algorithm Developers

Determining legal liability in cases of algorithmic malpractice requires careful analysis because the structure of digital diagnostic services involves interactions between doctors, healthcare institutions, and

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system developers. In classical health law doctrine, doctors have a duty to act in accordance with professional standards and due care (*duty of care*)[23]. However, technological developments mean that medical decisions are no longer entirely under the control of individual doctors. Algorithm-based diagnostic systems now provide clinical recommendations that are often considered automatically valid, blurring the line between human and machine judgment. Nevertheless, Indonesian law still places doctors as the main party responsible for patient safety, as stipulated in the Medical Practice Law, which emphasizes the obligation of doctors to provide services in accordance with professional standards[24]. In this context, if a doctor accepts an algorithmic recommendation without adequate clinical verification, they may be deemed to have neglected their professional obligations.

However, placing full responsibility on doctors is no longer adequate because some errors in algorithm-based services do not originate from medical actions, but rather from the design, testing, or updating of software. Algorithm developers control the quality of data, model configuration, and system validation that determine the level of diagnostic accuracy[25]. When algorithmic errors occur due to data bias or model mismatch, developers should also be held responsible under a product liability scheme. In European jurisdictions, the concept of producer liability allows for the prosecution of technology developers when errors stem from digital product defects.[26]

This is relevant because algorithms, as technological products, can contain design flaws or instruction flaws that lead to diagnostic errors. Hospitals, as healthcare providers, also have legal responsibilities because they act as users, implementers, and supervisors of medical technology. Hospitals are responsible for ensuring that the diagnostic devices used meet safety standards, undergo adequate testing, and are used in accordance with standard operating procedures.

The doctrine of hospital liability recognizes that healthcare institutions can be held liable if losses arise from negligence in selecting technology, lack of training, or the implementation of systems that are not yet ready for use.[27] In the context of medical algorithms, a hospital's unpreparedness to conduct audits or risk assessments of AI systems can be considered a form of administrative negligence.

The legal liability framework becomes even more complex when AI-based clinical systems operate automatically and generate decisions that doctors rely on. In this situation, the concept of *share liability* may arise, which is the division of responsibility between doctors, hospitals, and algorithm developers. However, digital diagnostic systems cannot work independently of their context of use; their success and failure are the result of human-technology interaction. In legal doctrine, there is a theory of enterprise liability which emphasizes that all parties in the production and service chain can share responsibility for the risks created.[28] This approach is relevant in cases of algorithmic malpractice because the risk does not arise from one party alone.

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[23] Bernard Arief Sidharta, *Refleksi tentang Struktur Ilmu Hukum* (Bandung: Mandar Maju, 2019), 112.

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In addition, there is also the concept of strict liability which can be applied to medical software developers if the error stems from a digital product defect even though there is no element of negligence. This concept is commonly used in cases of defective products, especially in countries with more advanced AI regulations such as the European Union. In the draft AI Liability Directive, there are provisions regarding the reversal of the burden of proof for victims when algorithms are not transparent, making them difficult to analyze.[29] This regulatory update shows that modern legal systems are beginning to recognize the unique nature of AI technology, which makes it difficult to prove and places a greater burden of responsibility on developers.

In the Indonesian context, the application of the concept of strict liability in digital medical technology has not been explicitly regulated. However, the Consumer Protection Law provides a legal basis for suing businesses for products that are defective or harmful to consumers, including software if it is classified as a product.[30] If algorithms are used as part of telemedicine services or digital health devices, their developers may fall into the category of businesses and therefore be held liable. However, this interpretation still needs to be confirmed through derivative regulations or jurisprudence, as there have been no cases of algorithmic malpractice tested in Indonesian courts to date.

The responsibility of hospitals also needs to be strengthened, as healthcare institutions play an important role as providers of services that use this technology. Hospitals have an administrative obligation to ensure that algorithmic devices meet safety standards through due diligence, technology audits, and risk monitoring. Hospital negligence in ensuring system quality can result in the application of hospital administrative liability, especially if errors arise from the use of unverified devices. Under Indonesian law, the principle of vicarious liability may apply if hospitals are deemed responsible for the actions of medical personnel under their authority.

Overall, the legal liability framework for algorithmic malpractice requires a multi-actor approach that combines the professional responsibility of doctors, the administrative responsibility of hospitals, and the product responsibility of algorithm developers. The complexity of this structure highlights the need for more specific regulations so that legal certainty can be achieved and patient protection remains a top priority in the era of digital medical diagnosis.

The Direction of Regulatory Reform and Legal Accountability Models for Algorithmic Malpractice

The development of algorithm-based health technology requires the legal system to adapt to new protection needs arising from the automation of clinical decisions. Algorithmic malpractice, as a form of misdiagnosis resulting from digital systems, shows that the existing regulatory framework is not yet able to provide adequate legal certainty for patients and health workers.[31] Therefore, regulatory reform is urgently needed so that national jurisdictions can respond to the complex challenges arising from the use of algorithms in medical services. This reform must take into account the dynamic and non-transparent nature of AI technology, which involves many actors in the entire medical decision-making process.[32]

[29] European Commission, *AI Liability Directive Draft* (Brussels: EU, 2022).
[30] Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen.
[31] Ahmad, Sharique, and Saeeda Wasim. "Prevent medical errors through artificial intelligence: A review." *Saudi J Med Pharm Sci* 9, no. 7 (2023): 419-423..
[32] Bernard Arief Sidharta, *Refleksi tentang Struktur Ilmu Hukum* (Bandung: Mandar Maju, 2019), 95.

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In international discourse, various regulatory models are being developed to anticipate the risks of "high-risk" technologies, including medical diagnostic algorithms. The European Union, through the EU Artificial Intelligence Act, classifies medical algorithms as high-risk AI systems, requiring developers to implement pre-market surveillance, sustainability audits, and post-market monitoring mechanisms as part of the legal requirements.[33] In addition, the AI Liability Directive formulates a reversal of the burden of proof for victims of losses caused by algorithms, on the grounds that the black box nature makes it impossible for patients to prove technical errors that are beyond their control.[34] This approach is considered progressive because it recognizes the technical reality that proving damage caused by AI cannot be equated with proving damage caused by traditional medical devices.

Meanwhile, the United States places greater emphasis on a technical standards-based approach through the Food and Drug Administration (FDA) by issuing the *Software as a Medical Device* (SaMD) guidelines. These guidelines regulate risk evaluation mechanisms, clinical validation, and adaptive algorithm updates.[35] However, the legal liability system still relies on the tort law regime, so victims still bear the burden of proof to demonstrate negligence or defective product. This differs from the European Union's policy direction, which places greater emphasis on victim protection through reversal of the burden of proof. These differences in approach provide important insights into the regulatory model options that can be adapted by Indonesia, especially in the context of a legal system that emphasizes patient protection as part of the right to health.

In the Indonesian context, regulatory reform must take into account the characteristics of the civil law-based national legal system and the existing health law structure. The 2023 Health Law, the Medical Practice Law, and the Personal Data Protection Law are the initial frameworks that can be used as a basis for regulating the use of medical algorithms.[36] However, these norms do not yet contain specific clauses regarding legal liability in the event of AI-based misdiagnosis. Therefore, it is necessary to strengthen the norms through government regulations or ministerial regulations that specifically regulate the standards for the use of medical algorithms, audit obligations, and mechanisms for reporting algorithmic incidents.

One mechanism that can be implemented is the obligation to conduct an algorithmic impact assessment (AIA), which is a comprehensive risk assessment of algorithms before they are used in medical services. AIA can include an evaluation of data bias, model accuracy, error rate, and potential impact on vulnerable groups. Countries such as Canada have adopted this model in assessing automated systems in the public sector, which can be a reference for Indonesia.[37] The application of AIA in the health sector will help ensure that digital diagnosis systems have undergone adequate testing before being used on patients.

In addition to AIA, a human oversight mechanism is needed that places doctors as the final decision makers and ensures that algorithms do not replace professional clinical judgment. This principle is in line with the European Commission's recommendation that high-risk AI systems must always be under human supervision.[38] Indonesian regulations need to include this clause so that the burden of professional

[33] European Commission, *EU Artificial Intelligence Act Proposal* (Brussels: EU Commission, 2021).
[34] European Commission, *AI Liability Directive Draft* (Brussels: EU, 2022).
[35] FDA, *Guidance for Software as a Medical Device* (Washington, DC: U.S. FDA, 2021).
[36] Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan; Undang-Undang Nomor 27 Tahun 2022 tentang Perlindungan Data Pribadi.
[37] Government of Canada, *Directive on Automated Decision-Making* (Ottawa: Government of Canada, 2022).
[38] European Commission, *EU Artificial Intelligence Act Proposal* (Brussels: EU Commission, 2021).

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responsibility remains with doctors, but without placing doctors as the party responsible for all damages that actually originate from digital systems.

In terms of the legal liability model, Indonesia needs to consider applying a *shared liability* model that divides responsibility between developers, hospitals, and medical personnel. This model is relevant because the risk of misdiagnosis in algorithmic systems is a form of collective risk that arises from the layered interaction between technology and humans.

This approach has been applied in several health-tech cases in the UK, where hospitals and system developers share responsibility depending on the source of the error. Thus, patients can obtain fairer compensation without having to prove in detail who is most at fault. The application of a strict liability model for algorithm developers also needs to be considered, especially if digital diagnosis systems are classified as high-risk products.

In the context of consumer protection law, these systems can be viewed as products that must meet certain safety standards. If losses occur due to algorithmic defects, developers can be held liable without having to prove negligence[39]. This mechanism is important to overcome the difficulty of proof and provide incentives for developers to implement stricter safety standards.

Regulatory reform must also include strengthening algorithm transparency. Digital medical diagnosis systems must have a minimum level of explainability so that medical personnel and courts can assess whether algorithm recommendations are ethically and legally justifiable. Without transparency, patients' rights to know the basis for medical decisions may be violated, and legal proof becomes nearly impossible. Therefore, standards of openness, technical documentation, and independent audits must be a mandatory part of national regulations.

Overall, the direction of regulatory reform in Indonesia requires a holistic approach that covers technical, ethical, and legal aspects. Appropriate regulations will provide legal certainty, improve the quality of digital health services, and ensure that the use of algorithmic technology remains within the corridor of patient protection and the principle of justice.

CONCLUSIONS

The development of algorithm-based medical diagnosis technology has brought fundamental changes to healthcare practices, but it has also given rise to a new form of risk in the form of algorithmic malpractice, which is not yet fully accommodated within the Indonesian legal framework[1]. The complexity of digital diagnosis systems, which involve doctors, hospitals, and algorithm developers, poses a major challenge in determining the source of errors, cause-and-effect relationships, and the structure of legal liability. Analysis of the discussion shows that the traditional liability model, which focuses solely on physician negligence, is no longer adequate, as some errors may stem from data bias, system design flaws, or algorithm incompatibility with specific clinical populations[2]. Thus, a liability approach is needed that captures the collaborative nature of humans and technology in the medical diagnosis process.

The current Indonesian regulatory framework does not yet include specific norms regarding the use and supervision of algorithms in digital medical services. This has led to a regulatory gap that has the potential

[39] Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen.

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to harm patients while creating uncertainty for medical personnel and technology developers. Regulatory reform must be directed at establishing algorithm audit obligations, risk assessments, and minimum transparency standards so that algorithmic recommendations can be held legally accountable[3]. In addition, the principle of human oversight must be maintained to ensure that medical personnel continue to play a crucial role in verifying the diagnostic results of digital systems. In terms of accountability, the shared liability and strict liability models need to be considered to provide a balance between patient protection and fairness for parties involved in the AI-based healthcare ecosystem.

As a recommendation, new regulatory instruments are needed, in the form of government regulations or ministerial regulations, that specifically regulate standards for the use of medical algorithms, mechanisms for reporting algorithmic incidents, and the division of responsibilities between doctors, hospitals, and software developers. Strengthening the capacity of regulators to understand the technical aspects of algorithmic systems is also an urgent need, given that proving cases of algorithmic malpractice requires a deep understanding of AI technology structures. With a more comprehensive legal framework, Indonesia can ensure that the development of health technology remains within the corridor of patient protection, legal certainty, and the principle of accountability.

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