Regulatory challenges in ai-based diagnostics: legal implications of ai use in medical diagnostics

Yuris Tri Naili[1*], *Iis Setiawan* Mangkunegara[2], *Purwono*[2], *Muhammad Ahmad* Baballe[3]

[1] Faculty of Social Sciences, Universitas Harapan Bangsa, Indonesia
[2] Faculty of Science and Technology, Universitas Harapan Bangsa, Indonesia
[3] Department of Mechatronics Engineering, Nigerian Defence Academy, Nigeria.

Abstract. Artificial intelligence (AI) is being used more and more in medical diagnostics, with the potential to increase operational efficiency and diagnosis accuracy. But the use of AI also brings with it legal and regulatory ramifications, such as concerns about ethics, patient consent, and liability. The purpose of this study is to investigate how the legal system might be modified to clearly define obligations for healthcare professionals and technology innovators while defending patient rights. The approach was a thorough study of the literature that assessed the legal and regulatory implications of using AI in medical diagnosis. The research results indicated that algorithmic bias, data security, and the requirement for stringent rules to guarantee the ethical and safe application of AI are the primary obstacles. In order to guarantee equity and safety in medical practice, the study's conclusion highlights the significance of stringent regulation and openness in the application of AI. The creation of a more stringent evaluation system, independent audits of AI algorithms, and greater transparency in data collection and use are among the regulatory policy recommendations. To enhance algorithms, modify the legal framework to safeguard patient rights, and clearly define the obligations of technology creators, more study is necessary.

1 Introduction

The healthcare industry presently uses artificial intelligence (AI) extensively. AI is frequently employed in research, robotic surgery, and diagnosis due to the quick advancements in analysis techniques and the growing availability of health data [1]. Big data from multiple sources, including genetic information, electronic medical records, and medical pictures, can be processed by AI to provide more focused therapy and early illness detection. As AI becomes more widely used in many nations and medical facilities, its dependence in the healthcare industry grows [2]. Studies conducted by [3] demonstrate how AI has significantly altered diagnosis techniques, increasing hospital operational efficiency and accuracy. For

* Corresponding author : yurist@uhb.ac.id

instance, AI has been effectively applied to radiology image processing to accurately identify diseases like cancer [4]. Furthermore, by evaluating patient data, including genetic information, medical history, and lab results, AI helps personalized medicine by facilitating a more accurate and exact approach to therapy [5].

Despite all of AI's advantages, there are drawbacks, including concerns about patient consent, legal liability, and ethical standards. Aspects of data security and algorithm transparency must be taken into account when developing AI systems. In order for AI to be used in medical practice in a safe and responsible manner, these issues must be resolved [6]. Informed consent concerns and legal liability in the event of AI-induced diagnostic errors are just two of the major hazards that patients and medical staff may face if AI use is not properly regulated. The intricacy of AI technologies is sometimes not adequately covered by current legal frameworks, necessitating adjustments to guarantee their use is safe and equitable [7].

As AI's use in medical diagnostics develops, significant issues pertaining to the technology's use, ethics, and social impact surface.

1. Who has legal responsibility if AI diagnoses patients incorrectly ?
2. How can the involvement of AI in medical decision-making ensure patient consent ?
3. How can the regulatory obstacles to implementing AI in medical diagnostics be addressed ?

The objective of this study is to investigate and evaluate the legal ramifications of using artificial intelligence (AI) in medical diagnostics in various international jurisdictions. This study's primary goal is to determine how legal and regulatory frameworks might be modified to clearly define the legal obligations of medical professionals, healthcare providers, and technology developers. In order to guarantee the ethical, secure, and law-abiding application of AI in all jurisdictions, it also looks at the regulatory actions required to safeguard patients' rights to safety, privacy, and consent.

2 Literature Review

2.1 Definition of Artificial Intelligence (AI)

Artificial Intelligence (AI) uses vast amounts of data, quick processing, and clever algorithms to automatically identify patterns or traits in the data. Systems that can learn from their experiences and adjust to novel stimuli can also be developed thanks to this technology. Machines may now perform tasks that would typically require human intelligence thanks to artificial intelligence [8]. Speech recognition, biometric identification, deep learning, and machine learning are a few of the main uses of AI [9]. AI has a big impact on many different fields. Automating repetitive operations like debugging and algorithm creation in software engineering boosts productivity and lowers production costs [10]. AI aids in drug discovery and disease early detection in biology and healthcare through the analysis of medical pictures [11]. AI has greatly enhanced teaching, learning, and administration in education by boosting productivity, encouraging student retention, and personalizing curricula [12]. The use of AI has many benefits, but there are drawbacks as well. Data security and privacy are one of the most significant obstacles. AI systems that use data extensively run the danger of misusing information and leaking personal data. Algorithmic bias presents further difficulties, as AI decisions may mirror the bias of the data used to train the system, thereby producing unfair outcomes [13]. Therefore, while AI offers many advantages, these challenges need to be addressed to ensure that the technology is used safely, ethically, and trustworthily in various sectors.

2.2 Definition of Medical Diagnostics

The process of determining a person's disease, problem, or health condition based on the symptoms and indicators found is known as medical diagnosis. Finding the best course of treatment for the patient depends on this diagnosis. The diagnosis process in modern medicine often consists of a number of tests, physical examinations, and patient interviews to obtain the data required to verify the existence of a medical problem. Decisions on the patient's medical condition's management and treatment are made at this point [14]. Physicians can now more accurately track the course of diseases and how well patients are responding to treatment thanks to modern diagnostic technology like genetic laboratory testing and imaging tools like MRIs, CT scans, and ultrasonography. In this situation, medical diagnostics provide more individualized and efficient treatment planning in addition to clinical decision-making [15]. Increased clinical efficiency and higher accuracy are made possible by the development of technology-based diagnostics; yet, issues with these contemporary technologies' affordability and accessibility persist, particularly in developing nations. Examples of how contemporary technology can produce more precise diagnostics include high-throughput sequencing (HTS), which is used to diagnose viral infections [16].

2.3 AI in Medical Diagnostics

Significant changes have been brought about in the healthcare industry by artificial intelligence (AI), particularly in the area of medical diagnostics. Medical imaging diagnostics is one of the AI applications that is expanding the fastest. Radiography images are analyzed using AI algorithms like machine learning and deep learning, which allow for the early detection of conditions including cancer, heart problems, and brain ailments. AI has been demonstrated to increase the precision of diagnoses, expedite decision-making, and lower operating expenses [17]. In addition, AI plays an important role in patient outcome prediction and more personalized treatment planning. Through big data processing, AI can analyze a patient's medical history and identify patterns that can assist doctors in planning more effective and efficient treatments [18]. AI is capable of processing large amounts of data in a short period of time, which helps doctors in speeding up the diagnosis and clinical decision-making process. This not only reduces the workload of doctors but also enables patients to receive faster and more timely treatment, especially in emergency situations [19].

2.4 Legal Aspects of AI Use in Medical Diagnostics

The study and use of artificial intelligence (AI) in medicine is expanding across a range of therapeutic settings. Even though AI has a lot of potential advantages, such lessening the strain for medical staff and increasing diagnosis accuracy, its use also brings up a number of ethical and legal concerns that have not yet been resolved [20]. The use of AI in medicine raises a number of significant ethical and legal concerns. The first is informed consent, which requires that patients be aware of the possible hazards and how their data will be handled. Second, in order for patients and medical professionals to comprehend the AI decision-making process, safety and transparency are essential. Algorithmic bias and fairness are other issues since AI has the potential to magnify preexisting biases in the data, which could result in unfair diagnoses. Additionally, data privacy is essential, particularly when it comes to safeguarding patient personal information. The safety and effectiveness of AI technology in medicine must be ensured through strict regulation, while legal liability in cases of misdiagnosis is a big challenge to determine, whether the responsibility lies with the AI developer or the healthcare provider [21]. Given these problems, more stringent guidelines and supervision are needed for clinical trials, product monitoring, and the creation of AI-

based medical software when using AI in medical diagnostics. Since new technology is developing so quickly, the legal system frequently falls behind. In order to guarantee that AI tools used in medical diagnostics fulfill recognized safety requirements and have undergone extensive testing prior to being employed in clinical settings, regulatory modifications are therefore desperately needed [22].

3 Methodology

This study found and assessed scholarly material about the difficulties and legal ramifications of applying AI in medical diagnostics using the Systematic material Review (SLR) method. Major scientific databases like ScienceDirect, Google Scholar, SpringerLink, and IEEExplore were used to search for relevant material. Keywords like "AI in medical diagnostics," "regulation of AI in healthcare," and "legal implications of AI use in diagnostics" were used. To ensure that they were pertinent to the most recent advancements in this sector, the articles included were written in English and published within the last five years.

Criteria for inclusion and exclusion were established to guarantee that the chosen literature was pertinent to the study's main topic. The criteria were the year of publication to include the most recent advancements, the use of AI in medical diagnostics, and relevance to regulatory and legal concerns. Based on their contribution to the conversation around AI regulation, ethics, and legal accountability in the medical context, pertinent papers were chosen.

The impact of the changes brought about by the application of AI in medical diagnostics was assessed, and the related legal and regulatory issues were described, using qualitative analysis. A qualitative method was used because it offers a more profound comprehension of intricate phenomena and permits a thorough investigation of the ways in which AI impacts patient safety, algorithmic bias, and legal culpability. A comprehensive examination of the legal ramifications and regulatory obstacles of implementing AI in medical diagnostics was supported by the use of case studies and document analysis.

4 Results and Discussion

4.1 Application of AI in Medical Diagnostics

AI in medical diagnostics refers to the use of artificial intelligence algorithms to analyze medical data, such as images, clinical, and genetic data, in order to generate diagnoses and treatment recommendations accurately and quickly. By utilizing machine learning, AI is able to process large amounts of data more efficiently and consistently compared to human analysis, providing the necessary speed and accuracy in the medical field [23]. Today, AI is used in a variety of diagnostic fields. In radiology, for example, this technology helps detect cancer through image analysis such as mammography and tomography, providing support in finding tumors at an early stage that may be difficult for human radiologists to detect [24]. In digital pathology, AI analyzes histopathology images for automatic detection of cancer and evaluation of biomarkers, which supports more accurate treatment, such as identification of HER2 and PD-L1 biomarkers for targeted therapy [25]. In addition, AI also plays a role in predictive analysis, such as projecting patient response to therapy, for example, in predicting tumor response to chemotherapy in breast cancer [26]. Recent advances in AI include the application of deep learning algorithms, which improve the accuracy of diagnosis, such as in the early detection of brain tumors through MRI imaging using convolutional neural networks (CNNs) [27]. AI technology is also developing in radiogenomics, which links

radiological features with genomic expression for more precise diagnosis and treatment [28]. One example of the application of AI in medical diagnostics is the use of AI in skin cancer diagnostics, which can be observed in Fig. 1.

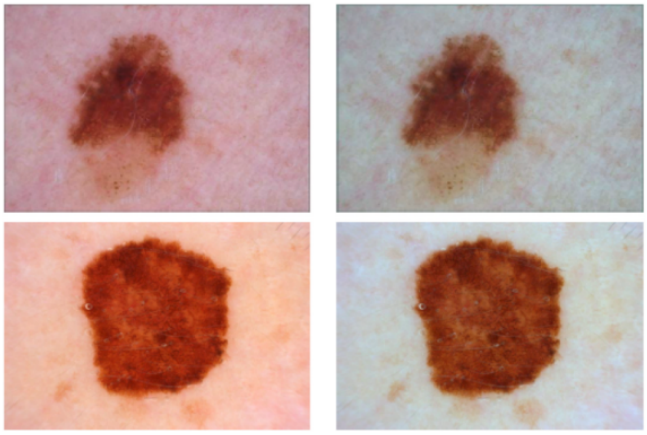

Fig. 1 Skin Cancer Diagnostic Process Using Deep Learning.

Fig. 1 is a example of how AI-based algorithms can be used to detect and classify various skin lesions based on specific visual patterns. AI, especially those based on deep learning, are trained using thousands of similar images to recognize the features of both benign and malignant lesions. By using AI in skin lesion diagnostics, experts can reduce diagnostic errors and improve clinical efficiency. AI can be an invaluable tool in helping doctors make faster and more informed decisions, especially in areas that lack dermatology specialists or other medical resources [29].

While AI offers various benefits in medical diagnostics, there are still some challenges that need to be overcome. One of them is algorithmic bias. If the data used to train AI models does not cover a diverse population, AI may produce biased results, which may lead to misdiagnosis or discrimination against certain groups. In addition, challenges related to data privacy also arise, as AI requires access to sensitive medical data, so strict regulations on data protection are necessary [30].

4.2 Regulation of AI in Medical Diagnostics

The regulation of artificial intelligence (AI) in medical diagnostics is now a key focus to ensure the safety, transparency and reliability of the technology. Each jurisdiction presents a legal framework that covers data protection, cybersecurity, and ethics, to address the challenges in the application of AI in healthcare. In Europe, the regulation of AI in the medical field is governed by two main regulations, namely the Medical Devices Regulation (MDR) 2017/745 and the In-vitro Diagnostic Medical Devices Regulation (IVDR) 2017/746. The MDR applies to AI devices used for medical purposes, including diagnosis. While the IVDR is more specific to devices used in genetic testing or in-vitro diagnosis [31]. Meanwhile, in the United States, primary oversight is conducted by the Food and Drug Administration (FDA) using a risk-based approach to assess AI-based devices, focusing on total product lifecycle surveillance to ensure patient safety [32].

In Europe, the MDR and In-Vitro Diagnostic Regulation (IVDR) provide a strict regulatory framework to ensure medical AI devices meet safety and performance standard. The MDR demands that AI-based medical devices must undergo certification by a designated

body, which monitors their performance both before and after they are marketed [33]. Meanwhile, in the United States, the FDA adopts a risk-based approach to evaluate AI medical devices, using approval pathways such as 510(k), PMA, and De Novo. Most FDA-approved medical AI devices go through the 510(k) pathway, which is a faster approval pathway for low-risk devices [34]. Besides the FDA and MDR, other national regulatory bodies also play an important role, such as in India, where the Central Drugs Standard Control Organization (CDSCO) regulates AI devices through local medical device regulations. Each country has a different approach, but the main focus remains on patient safety and effectiveness of AI-based medical devices [35].

4.3 Liability in AI-based Diagnostics

Liability for errors generated by AI-based diagnostics is still a matter of debate. In general, if a medical professional uses an AI tool beyond the limits of regulatory approval or misuses it, they could be subject to penalties or liability. However, in other cases, the liability could fall on the creator and the company that developed the tool. The interpretation of the law in this regard varies depending on various factors, so this situation remains a gray area with no clear resolution [36]. A joint liability approach or common enterprise theory could be a solution, where doctors, developers and hospitals are considered as one entity in the division of liability. This approach provides encouragement for all parties to ensure that AI devices are used carefully and in accordance with applicable safety standards [37].

Based diagnostics is usually regulated through medical malpractice claims. If something goes wrong, the liability may fall on the doctor, the AI developer, or the hospital, depending on the case. Doctors who follow AI recommendations according to the standard of care are usually safer from malpractice claims. However, if they follow AI advice that is not in line with the standard, the risk of legal liability is higher [38]. In the European Union, the Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) require AI device developers to ensure that their products meet safety standards before clinical use. Developers have a huge responsibility to ensure that AI devices are safe and effective through a rigorous certification process before they are marketed. However, the physician using the AI remains responsible for its proper use. If something goes wrong, the liability can be shared between the developer and the user of the device [39]. Meanwhile, in Canada, the law is sufficient to handle the liability related to AI in medical diagnosis. Liability can be shared between the doctor using the AI and the developer of the technology. Developers are responsible for ensuring that their AI devices are safe and compliant with applicable regulations, while doctors must ensure that the devices are used safely and do not harm patients [40].

One of the case studies described by [41] describes the application of AI-based algorithms for cervical cancer detection, it was found that initially reports regarding AI accuracy were very promising. However, once applied in the clinic, the results were not as accurate as expected. Challenges arise in terms of how AI handles ambiguous cervical images, which trigger misdiagnosis. In this case, legal responsibility for the misdiagnosis was split between the AI software developer who failed to properly validate the algorithm, and the healthcare provider who used the technology without performing additional validation. This case highlights the importance of more thorough testing of AI before it is applied in a clinical setting.

4.4 Legal and Ethical Challenges in Informed Consent for AI-Based Diagnostics

A patient's decision regarding their treatment is a right known as autonomy. Informed consent is not just signing a document, but encompasses the entire process where the patient is given

an explanation of their illness, diagnostic options, as well as details of the intervention methods to be performed. As informed consent is a patient's right and the basis of trust in the doctor-patient relationship, it is important that it is delivered in a language that is easy to understand, fully comprehended by the patient, and properly documented [42]. However, the complexity of AI in medical diagnostics often poses challenges in obtaining truly informed consent. Often, patients do not have an adequate understanding of how AI systems work or the risks that may be associated with their use. Several studies have shown that patients do not always receive sufficient information or do not fully understand the impact of AI use in medical decision-making, especially in systems that lack transparency [42]. Other challenges include limited time to provide in-depth explanations of AI as well as technical terms that are difficult for patients without a medical background to understand [44]. While explaining the complexities of AI technology can be a challenge in this process, legal standards regarding consent for the use of artificial intelligence (AI) in healthcare still demand that doctors must provide clear and comprehensive information regarding risks, benefits, and treatment alternatives. This is important so that patients can make informed decisions and maintain their autonomy [45].

4.5 AI Regulatory Approval of AI-based Diagnostic Devices

The approval process of AI/ML-based diagnostic devices in the United States and Europe has important differences. In the US, the Food and Drug Administration (FDA) manages approval through three pathways : pre-market approval for high-risk devices, a de-novo pathway for low-to-moderate risk devices, and a 510(k) pathway for devices deemed equivalent to existing ones. Meanwhile, in Europe, approval is done by Notified Bodies that evaluate medical devices, but there is no specific pathway for AI/ML-based devices. As a result, some devices may be approved faster in Europe than in the US due to less rigorous evaluation [46]. Here are challenges in the approval process of AI devices under FDA regulation, such as data overfitting issues, algorithmic bias, and limited testing in clinical environments. Overfitting occurs when an AI device shows excellent performance on training data, but is unable to maintain those results in the real world. Meanwhile, algorithmic bias can result in less accurate diagnoses in certain population groups. In addition, many devices are tested only in limited locations, thus not reflecting wider clinical diversity. The complexity of FDA regulation also hinders innovation, as the approval process requires very extensive testing [47]. Such complex regulatory processes may hinder the development of AI tools, especially since AI has the unique ability to continuously evolve and learn from new data. So to address this issue, approaches such as Total Product Lifecycle (TPLC) have been proposed to reduce the regulatory burden while maintaining high quality standards for patient safety. This approach allows AI developers to innovate faster, while still ensuring that the devices meet stringent safety and performance requirements [48].

4.6 The Impact of Algorithmic Bias on Medical Diagnosis

Bias refers to a condition in which an algorithm unintentionally relies on specific attributes in data pertaining to a particular demographic group [49]. Algorithmic bias can cause ethical concerns and is one of the biggest challenges in the generalization of current AI models [50]. Bias can be influenced by a number of factors, including clinical experience, environmental conditions, and cognitive processes. If bias is not addressed, it can result in missed or delayed diagnoses, inappropriate treatment plans, as well as negative impacts on patient health [51]. For example, if an algorithm fails to detect medical conditions in minority groups due to bias in its training data, technology developers and healthcare providers may face legal liability [52].

A case study conducted by [53], describes an AI algorithm used to detect aortic stenosis (AS) through electrocardiogram (ECG). The study found spectrum bias, where the algorithm was trained on a dataset that differed in spectrum from the actual target population, which led to performance degradation when applied to the real population. Algorithms that initially showed good sensitivity and specificity in testing, experienced significant performance degradation when applied to patients with more diverse characteristics. This shows that restricting the dataset to overly positive or negative labels leads to overestimation of the algorithm's capabilities, and when applied to a wider population, the algorithm's performance degrades. This is a clear example of how algorithmic bias can affect the accuracy of diagnosis and risks producing serious errors in medical decisions. Another study conducted by [54] showed inequities in misdiagnosis rates between racial groups, with black patients often receiving less accurate diagnoses compared to white patients. Laws in the United States, such as the Civil Rights Act, require that AI systems be developed and used fairly without triggering discrimination. To address this bias, the concept of algorithmic fairness is applied to ensure AI predictions are fair to all groups. However, challenges arise as correcting bias towards one group may decrease accuracy for another, leading to legal debates on how to define fairness and prevent AI from exacerbating inequalities in healthcare.

4.7 Legal Policy Recommendations for the Use of Medical Diagnostic AI

To improve the legal framework for the use of medical diagnostic AI, a more comprehensive approach that includes transparency, auditability, and independence in evaluation is needed. Many AI algorithms are based on large datasets that do not cover the diversity of the population, leading to systemic bias in diagnosis. Stricter regulations should include full transparency in the data collection and training process, as well as testing involving a wider population to ensure fair and reliable results across different clinical contexts [55]. In addition, [56] suggested the implementation of a more rigorous evaluation framework to improve fairness in the use of AI. This framework includes separation between diagnostic tasks and algorithms, and involves independent assessment by a third party to reduce potential conflicts of interest. The aim of this measure is to ensure that algorithms achieve a high standard of performance before being used in the clinic, and to ensure safety and fairness for all patients. Another suggestion by [57] explains that independent audits of AI systems can be integrated into governance principles to ensure that algorithms comply with safety standards and applicable jurisdictions. These audits include prospective risk evaluation, operational track records, and system compliance with legal requirements. These measures will help reduce the risk of misdiagnosis caused by algorithmic bias or failure and ensure that the AI performs according to expected clinical standards. In their research, [58] emphasized the importance of reporting guidelines that are specific to AI-based diagnostic studies. For example, STARD-AI is designed to improve the quality of reporting in AI diagnostic accuracy studies by setting specific standards that address unique methodological challenges, such as the use of external datasets and bias in underrepresented population subgroups. Continued research is also needed to improve algorithms and adjust the legal system to protect patient rights and establish clear responsibilities for technology developers and healthcare providers.

5 Conclusion

AI has brought significant changes to the healthcare sector, as it can improve diagnosis accuracy and operational efficiency. AI is able to analyze large amounts of medical data and provide recommendations that assist medical personnel in decision-making. However, the use of AI also faces complex regulatory challenges, including issues of legal liability in case

of misdiagnosis, patient consent, and personal data protection. In addition, continuous research is essential to update and improve AI algorithms to keep them relevant and accurate in the face of technological developments and medical complexity. Addressing regulatory challenges in the use of AI for medical diagnostics is essential to ensure safety and fairness in its application. A stricter legal framework is needed to ensure transparency, fairness, safety, and support for ongoing research so that AI can continue to provide optimal benefits in the medical field.

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