Legal Consideration in Implementing Artificial Intelligence when Dealing with Patients in Healthcare Services

Yuliana
Program Studi Pendidikan Dokter, Fakultas Kedokteran, Univesitas Udayana
E-mail Koresponden: yuliana@unud.ac.id

Abstrak
Kecerdasan buatan (AI) diterapkan dalam aktivitas besar kehidupan sehari-hari. Namun, selain sisi positif AI, masih banyak persoalan hukum tentang penerapan AI dalam praktik medis dan layanan kesehatan. Pertimbangan etis membutuhkan keterlibatan latar belakang hukum. Tulisan ini bertujuan untuk mendeskripsikan pertimbangan hukum dalam penerapan Artificial Intelligence (AI) ketika berhadapan dengan pasien di pelayanan kesehatan. Ini adalah ulasan literatur naratif. Literatur dicari dari Science Direct, Google Scholar, dan PubMed. Kriteria inklusi penelitian dan review. Kriteria eksklusi tidak tersedia di jurnal teks lengkap. Artikel dibaca dua kali untuk mengurangi kemungkinan bias. Terakhir, artikel terpilih dirangkum dan dinarasikan dalam sebuah ulasan. Kemungkinan jebakan dalam masalah hukum saat menggunakan Kecerdasan Buatan saat menangani pasien termasuk privasi pasien, berbagi data, prosedur pengujian yang ketat, dan proses yang mahal. Penyatuan dan harmonisasi rezim hukum harus diterapkan untuk pengaturan hukum. Prinsip non-diskriminatif diperlukan untuk memastikan tanggung jawab hukum. Masalah hukum tentang penerapan Kecerdasan Buatan (AI) dalam layanan kesehatan meliputi privasi pasien, berbagi data, dan prosedur pengujian. Tanggung jawab hukum harus dipastikan dengan prinsip non-diskriminatif.
Kata Kunci: kecerdasan buatan, masalah kesehatan, medis, pelayanan kesehatan

Abstract
Artificial intelligence (AI) is applied in large activities of daily life. However, besides the positive sides of AI, there are still many legal concerns about implementing AI in medical practice and healthcare services. Ethical consideration needs legal background involvement. This paper aims to describe the legal consideration in implementing Artificial Intelligence (AI) when dealing with patients in healthcare services. This is a narrative literature review. Literature was searched from Science Direct, Google Scholar, and PubMed. The inclusion criteria are research and review. The exclusion criteria are unavailable in full-text journals. The articles were read twice to reduce the possibility of bias. Finally, the selected articles were summarized and narrated in a review. Possible pitfalls in legal concerns when using Artificial Intelligence when dealing with patients include patient privacy, data sharing, rigorous testing procedure, and expensive process. Unification and harmonization of legal regimes have to be applied for legal regulation. Non-discriminative principles are required to ensure legal liability. Legal concerns about implementing Artificial Intelligence (AI) in healthcare

services include patient privacy, data sharing, and testing procedure. Legal liability should be ensured by non-discriminative principles.
Keywords: artificial intelligence, healthcare, legal concern, medical

A. INTRODUCTION

Artificial intelligence (AI) is applied in large activities of daily life. However, besides the positive sides of AI, there are still many legal concerns about implementing AI in medical practice and healthcare services. Ethical consideration needs legal background involvement. Possible pitfalls in legal concerns include patient privacy, data sharing, rigorous testing procedure, and expensive process. Unification and harmonization of legal regimes have to be applied for legal regulation. Non-discriminative principles are required to ensure legal liability.[1]
The special characteristic of AI is the ability to diagnose, predict, and study diseases. However, legal regulation in medical activities for AI implementation is still lacking. Therefore, a legal regime formation is needed to ensure a good digital society. The important aspects in the legal regime formation are the modes of AI's functioning, medical-legal relations, and the legal personality of AI.

Formulating the AI legal regulation for healthcare is focused on medical-legal practices.[2] Innovations in AI need to be accompanied by legal responsibility to ensure the balance of legal concern.[3] However, a difficult situation happens when there is an error due to an "AI mistake." Who should take responsibility? Medical liability involves two parties, namely doctors and patients. Doctors usually hold responsibility for actions and decisions in the medical field. In the AI concept setting, AI takes responsibility for any error possibilities.[4]

Informed consent sometimes is not sufficient to handle the dispute in any AI error. Hospital systems might oversell the use of AI, while patients might overestimate the AI in healthcare. Therefore, legal concern is critical when implementing AI in healthcare services.[5]

Artificial intelligence (AI) is a computer program's capacity to execute tasks resembled human intelligence, i.e. learning and reasoning. Meanwhile, sensory understanding, adaptation, and interaction are also involved. Traditional computational algorithm is different with AI system because AI system can give output through training data (input) exposure. Therefore, AI might change

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[1] Vasiliy Andreevich Laptev, Inna Vladimirovna Ershova, and Feyzrakhmanova Daria Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)," *Laws* 11, no. 3 (2022): 1–18.
[2] Laptev, Ershova, and Rinatovna.
[3] Da Silva et al., "Legal Concerns in Health - Related Artificial Intelligence : A Scoping Review Protocol," *Systematic Reviews*, 2022, 1–8, https://doi.org/10.1186/s13643-022-01939-y.
[4] P Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human," *Clin Ter* 172, no. 6 (2021): 527–28, https://doi.org/10.7417/CT.2021.2372.
[5] I Glenn Cohen, "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient ?," *The Georgetown Law Journal* 108 (2020): 1425–69.

healthcare system by producing novel insights from the digital data created.[6] AI comprises of software and hardware. Software is associated with algorithms. Algorithms can be developed by an artificial neural network (ANN). ANN resembles a human brain. AI can correct minor algorithmic errors (training) and boost prediction model accuracy.[7]

Artificial intelligence (AI) is started to be used in healthcare services in some clinical settings.[8] The Food and Drug Administration (FDA) has approved the usage of artificial intelligence diagnostic system based on Machine Learning (ML).[9] However, there are many aspects to be considered. For example, legal and ethical issues. On the other side, AI cannot be done in full automation because it would be very difficult. The medico-legal issues must be considered when using AI due to automated decision-making by the machine. Therefore, the manufacturers of the AI instrument must demonstrate the accuracy and liability on populations before releasing the products to consumers.[10] AI should be used effectively to provide evidence- based management and decision-guide for the doctor in epidemiology, diagnosis, and personalized care. Otherwise, mistakes due to AI-based- decision could bring fatal consequences for the patients. Therefore, regulation is needed for ethical and medical protection.[11]

Diagnosis and treatment are complex processes. When those processes are delivered by AI machines, it would be complicated who would be in charge when there is a wrong diagnosis. AI technology cannot fully replace the role of a physician at the moment. However, approximately 61% of respondents accepted that AI would make the world better.[12]

With the development of AI, whole slide imaging (WSI) and scanning system are used to interpret the content of biopsy and cytological specimens at the diagnostic resolution. Pixel analysis and automated segmentation methods are used to yield diagnostic patterns and classifications. Image analysis is used to identify the sub-visual clues. Therefore, these advances in the WSI system are very helpful in identifying the potential diagnosis of new diseases and saving time as well[13]. On

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[6] Nithesh Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?," *Frontiers in Surgery* 9, no. March (2022): 1–6, https://doi.org/10.3389/fsurg.2022.862322.

[7] Naik et al.

[8] Ahmed Serag et al., "Translational AI and Deep Learning in Diagnostic Pathology," *Frontiers in Medicine* 6, no. October (2019): 1–15, https://doi.org/10.3389/fmed.2019.00185.

[9] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

[10] Serag et al., "Translational AI and Deep Learning in Diagnostic Pathology."

[11] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

[12] Serag et al., "Translational AI and Deep Learning in Diagnostic Pathology."

[13] Alexi Baidoshvili et al., "Evaluating the Benefits of Digital Pathology Implementation: Time Savings in Laboratory Logistics," *Histopathology* 73 (2022): 784–94; Sanjay Mukhopadhyay et al.,

the other side, the emergence of digital scanning can support the practice of pathologists and reduce workloads.[14]

Legal considerations in implementing AI are medical-legal practices and privacy matters.[15] Legal responsibility is needed to maintain the balance in legal concerns.[16] However, when there is an error due to "an AI mistake", the responsibility should be taken by AI itself.[17] Informed consent is critical to handle the dispute, although it is not enough for complicated cases.[18]

The research gap in this article is the lack of regulation in medical activities for AI implementation. The formation of a legal regime is not easy, because it must be done by some experts in medical, information technology, and law problems. Therefore, this paper aims to describe the prospect and legal consideration of implementing Artificial Intelligence (AI) when dealing with patients in healthcare services.

B. METHOD

This is a narrative literature review. Literature was searched from Science Direct, Google Scholar, and PubMed. The inclusion criteria are research and review. The exclusion criteria are unavailable in full-text journals. The articles were read twice to reduce the possibility of bias. Finally, the selected articles were summarized and narrated in a review.

C. RESULTS AND DISCUSSION

The History, Classification, and Characteristic of AI

The history of AI in medical systems had been developed over decades. At the beginning of the 1970s, MYCIN was introduced by Stanford University. It is an expert system that helps the doctor in identifying bacterial infections and suitable treatments. However, MYCIN was only implemented in an experimental setting. DXplain was developed by the University of Massachusetts in 1986. It was a support system for the decision and diagnoses list. Recently, AI is developed for structuring and analyzing data into clinical text, identifying diagnosis similarities,

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"Whole Slide Imaging Versus Microscopy for Primary Diagnosis in Surgical Pathology : A Multicenter Blinded Randomized Noninferiority Study of 1992 CAses (Pivotal Study)," *Article in The American Journal of Surgical Pathology* · 42 (2018): 39–42, https://doi.org/10.1097/PAS.0000000000000948.

[14] Stanley J. Robboy et al., "The Pathologist Workforce in the United States," *Arch Pathol Lab Med* 139 (2015): 1413–30, https://doi.org/10.5858/arpa.2014-0559-OA.

[15] Laptev, Ershova, and Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)."

[16] Silva et al., "Legal Concerns in Health - Related Artificial Intelligence : A Scoping Review Protocol."

[17] Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human."

[18] Cohen, "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient ?"

including medical thought. Therefore, AI is defined as a technology for managing information data.[19]

AI is divided into seven types, namely Limited Memory, Reactive Machines, Theory of Mind, Artificial Narrow Intelligence, Self-aware, Artificial Superintelligence, and Artificial General Intelligence.[20] Daily basis applications of AI are cardiac arrhythmias automatic detection in an electrocardiogram, electroencephalogram, echocardiography[21], and oncology.[22] Computer-aided drug design is developed to create medicine for COVID-19 infection. This action will minimize the time and cost.[23]

The positive sides of using AI are simplifying the detection method, also saving time, human labor, and salaries. There are ample diseases that can be detected by using AI. For example: in radiology, AI is important in detecting hemorrhage and coronary arterial diseases without contrast media, cardiomegaly, fibrosis, fracture, pneumonia, etc. In the future, the radiology test results will be detected and reviewed by the robotic radiologist before delivering to the attending human radiologist. This method can help the attending radiologist to triage urgent cases in a fast and easy way. However, meticulous maintenance is needed for the well-running system. It is also important to prevent any errors although the AI can do automation checks.[24]

The negative side of using AI is the possibility of error. Artifact detection is very difficult to be detected by using AI. The human radiologist is better at detecting artifacts than AI. AI can only do one task at one time. There is no special technology that can detect all pathologies in one radiology figure only because sometimes there is always a grey area in the diagnosis of medical cases. Binary languages for AI are zero (0) and one (1). AI can only detect based on databases. When there are slight differences between the databases, AI cannot detect any further and mistakes occur.[25] Deep learning and machine learning are two essential systems in operating AI. Although AI has many advantages, AI is difficult to be implemented in

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[19] Laptev, Ershova, and Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)."

[20] Zeynettin Akkus et al., "Artificial Intelligence (AI) -Empowered Echocardiography Interpretation : A State-of-the-Art Review," *Journal of Clinical Medicine*, no. Ml (2021): 1–16.

[21] Wojciech Marlicz, George Koulaouzidis, and Anastasios Koulaouzidis, "Artificial Intelligence in Gastroenterology — Walking into the Room of Little Miracles," *Journal of Clinical Medicine* 9 (2020): 7–10.

[22] Ryuji Hamamoto et al., "Application of Artificial Intelligence Technology in Oncology : Towards the Establishment Of," *Cancers* 12 (2020): 1–33.

[23] Arun Bahadur Gurung et al., "An Updated Review of Computer-Aided Drug Design and Its Application to COVID-19," *BioMed Research International*, 2021, 1–18.

[24] Morgan P. McBee et al., "Deep Learning in Radiology," *Academic Radiology* 25, no. 11 (2018): 1472–80, https://doi.org/10.1016/j.acra.2018.02.018.

[25] McBee et al.

psychiatry cases. Psychiatric patients need more anamnesis and consultation which cannot be fulfilled by AI.[26]

The quick development of AI in medical practice has led to the problem of legal regulation. Legal regulation is very important because it is related to drug development, disease diagnosis, and treatment. Protection of data privacy is very essential in the legal aspect.[27]

AI has great potential for development in many countries, including Indonesia. However, the application needs meticulous design of the legislation in medical practice. The Indonesian Penal Code and Law No. 36 of 2009 on Health Law are used for supporting the advanced technology used in medicine.[28]

In the Italian legal landscape, Law n. 24/2017, it is stated the obligation of all healthcare personnel in preventing risks while giving any medical procedures. However, when difficult cases arise in emergencies (obstetrical field/psychiatric cases/other situations in which physicians do not have adequate protection/any unclear symptoms), there will be cultural changes in jurisprudence.[29]

The "Civil Law Rules on Robotics", was published by the European Parliament's Committee on Legal Affairs in 2017. The rules include appropriate guiding principles for autonomous vehicles, education and employment, and liability. When there is any damage from AI or robot action, the responsibility would be equally concerned and questioned among their own. Therefore, insurance is mandatory in the legal framework although AI machinery or robotics are used.[30] Errors could derive from human behavior that uses the technologies. Therefore, the Committee of Legal Affairs of the European Parliament stated that AI systems have no legal personality or human conscience. The technology's task is to serve humanity. AI could not be given any legal personality because there are just the same as previous technology but in an advanced and sophisticated form. People

[26] Daniel A Hashimoto et al., "Artificial Intelligence in Surgery: Promises and Perils," *Annals of Surgery* 268, no. 1 (2018): 70–76, https://doi.org/10.1097/SLA.0000000000002693.

[27] Laptev, Ershova, and Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)."

[28] Hary Abdul Hakim, Chrisna Bagus Edhita Praja, and Hardianto Djanggih, "The Urgency on Designing the Legislation for the Use of Artificial Intelligence in Indonesian Medical Practice," *Jurnal Penelitian Hukum De Jure* 21, no. 4 (2021): 541–50.

[29] Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human"; A Luca and T Marsella, "Letter The Italian Supreme Court Joint Sections Set Forth the Inter- Pretative Underpinnings of the ' Gelli-Bianco ' Law : Varying Degrees of Guilt Aimed at Limiting Medical Liability , Article 2236 c . c . Makes a Comeback," *Clin Ter* 172, no. 5 (2021): 425–26, https://doi.org/10.7417/CT.2021.2352.

[30] Victoria Dipla, "Bioethica AI and the Healthcare Sector: Industry, Legal and Ethical Issues," *Bioethica* 7, no. 1 (2021): 34–45.

served by AI should have the same protection as people served by humans (physicians).[31]

Article 22 of the General Data Protection Regulation (GDPR) against fully automated processing by machine only. Humans must be the final decision-maker. The highest level of authority should be human. Physicians are the last decision maker. Physicians should have direct consent from the patients (either in written or electronic form). This form states that medical data will be processed automatically. The health data controller should ensure three safety precautions such as the possibility of human intervention, opinion from the subject, and decision dispute.[32]

AI has a role in improving patient outcomes by offering better health care. AI can reduce costs due to automation. Although there are many good prospects for AI implementation in the future, caution in legal aspects must proceed. Relevant stakeholders such as AI developers, clinicians, regulators, policymakers, and patients have to address the challenges, maintenance, and limitations of using AI for healthcare practices. Legal considerations are human rights, privacy, and equity.[33]

AI is expected to enhance drug discovery based on the robotic models. The progression of the diseases, pharmacokinetics, efficacy, and safety of the drug discovery are determined.[34] Some prospects in using AI for healthcare are the detection of severe sepsis in children, coronary heart disease, rheumatic heart disease, and cerebrovascular disease. The basic requirements for using AI in healthcare are predictions by using machine learning, data mining, and electronic healthcare record (EHR) automated monitoring.[35] Molecular profiling is another advanced method for tumor risk stratification. This kind of machine learning is helpful in treatment selection as well.[36]

Patient Privacy and Data Sharing in the Testing Procedure

Electronic medical records can be used to display data such as body weight, diet, glucose level, and activities. Pre-operation automatic data analysis and clinical

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[31] Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human."

[32] Dipla, "Bioethica AI and the Healthcare Sector: Industry, Legal and Ethical Issues."

[33] Michael Matheny, Sonoo Thadaney Israni, and Mahnoor Ahmed, "Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril," in *National Academy of Medicine*, 2019.

[34] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

[35] Sidney Le et al., "Pediatric Severe Sepsis Prediction Using Machine Learning," *Frontiers in Pediatrics* 7, no. October (2019): 1–8, https://doi.org/10.3389/fped.2019.00413; R Alizadehsani et al., "A Database for Using Machine Learning and Data Mining Techniques for Coronary Artery Disease Diagnosis," *Scientific Data* 6, no. 227 (2019): 1–13, https://doi.org/10.1038/s41597-019-0206-3.

[36] Chao Wu et al., "Using Machine Learning to Identify True Somatic Variants from Next-Generation Sequencing," *Molecular Diagnostics and Genetics* 66, no. 1 (2020): 239–46, https://doi.org/10.1373/clinchem.2019.308213.

data will give a specific risk factor for the patient. This kind of data is very critical for the pre-operation plan. It is also a valuable complication predictor for intraoperative management. Real-time analysis and pre-operative data are useful in helping the clinical decision-making process. Meanwhile, post-operative data can be integrated with hospital data. Video data analysis is also done to assess any complications or errors during the operation.[37] Robotic surgery is implemented to reduce human error nowadays.[38]

Multimodal data usage can be used to strengthen the clinician's decision-making. Therefore, the combination of AI implementation and the clinician's expertise is important to draw a precise treatment. The decision cannot be taken only from the machine learning data because sometimes there will be an error from the machine.[39]

In the case of AI in the oncology testing procedure, intelligent oncology is used. There is an integration of oncology, pathology, molecular biology, radiology, and computer sciences. The aims are to increase precision in screening, early diagnosis, and precise treatment. The AI methods are deep learning, natural language processing, computer vision, and robotic automation.[40]

Data privacy sharing is very sensitive based on the personal health condition. On a law sue case, illegal access and disclosure to any personal information could infringe the Personal Privacy Act. Even though the privacy right is regulated under the constitution since the 1980's, sometimes the implementation is not satisfied. For example, there is a case of law suit for US$2,400 due to humiliation of releasing false HIV-related information about a patient. However, the rights to privacy are along with the rights to life and death.[41]

Data privacy is very important. However, due to electronic based health records system, it is difficult to prevent the spread of information. AI in electronic health records is critical for clinical care improvement. When AI is created with enough data, it can enhance the clinical practices. Data leakage due to cyber security weakness can be a severe threat for the AI users.[42]

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[37] Cohen, "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient ?"
[38] Abdulwahab F Alahmari, "Artificial Intelligence in Radiology," *International Journal of Radiology* 6, no. 1 (2019): 231–33, https://doi.org/10.17554/j.issn.2313-3406.2019.06.73.
[39] Hashimoto et al., "Artificial Intelligence in Surgery: Promises and Perils."
[40] Bo Lin et al., "Center Intelligent Oncology: The Convergence of Artificial Intelligence and Oncology," *Journal of the National Cancer* 3 (2023): 83–91, https://doi.org/10.1016/j.jncc.2022.11.004.
[41] Falah Al Ghozali, Try Hardyanthi, and Sarah Fadhilah, "The Implementation of the Patient's Privacy Regulations in The People's Republic of China," *Indonesian Comparative Law Review* 2, no. 2 (2019): 6–10.
[42] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

Unification and Information Fusion

Unification means the combination of data of similar patients from different hospitals to create a database. Although the data are heterogenous, the approach showed the superior result.[43] AI solutions could be imprecision and incorrect when there are changes in the setting and context. AI might have a drastic decrease in intelligence because it has limit. Therefore, the clinician as the human decision-maker has to be aware of the system limitation when using AI for similar patients.[44] Information fusion is integration of multiple information sources. The aims of information fusion are getting more effective, precise, and reliable data. Therefore, information fusion is very helpful in decision-making process.[45]

Information fusion means the bridge of the gaps between research and application. This is a transformation role to make the application as a trustworthy artificial intelligence. As an integrative tool, information fusion comprises of complex network, causal model, and verification.[46]

Information fusion is critical for explanation process. There should be a traceability concept from the process of data collection, output, and audience profile. This is essential for consumers of the artificial intelligence from various backgrounds and expertise.[47] Other benefits of information fusion are reducing data ambiguation, enhancing knowledge extraction, storage, and data mining. [48]

Harmonization of Legal Regimes

Legal problems are related to the quick development of AI systems in medical practice. Therefore, legal regulation should be prepared. Some critical issues such as the protection of data and any errors should be well addressed.[49] Each country has its legal regulation for AI systems. In Indonesia, The Indonesian Penal Code and Law No. 36 of 2009 on Health Law support technology used in medicine.[50] In Italia, Law n. 24/2017 regulates the obligation of all healthcare personnel in preventing risks while giving any medical procedures. When

[43] Lin et al., "Center Intelligent Oncology: The Convergence of Artificial Intelligence and Oncology."
[44] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"
[45] Xieling Chen et al., "Information Fusion and Artificial Intelligence for Smart Healthcare: A Bibliometric Study," *Information Processing and Management* 60, no. 1 (2023): 1–40, https://doi.org/10.1016/j.ipm.2022.103113.
[46] Andreas Holzinger et al., "Information Fusion as an Integrative Cross-Cutting Enabler to Achieve Robust, Explainable, and Trustworthy Medical Artificial Intelligence," *Information Fusion* 79 (2022): 263–78.
[47] Holzinger et al.
[48] Jingren Zhou, Xin Hong, and Peiquan Jin, "Information Fusion for Multi-Source Material Data: Progress and Challenges," *Applied Sciences* 9 (2019): 1–18.
[49] Laptev, Ershova, and Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)."
[50] Hakim, Praja, and Djanggih, "The Urgency on Designing the Legislation for the Use of Artificial Intelligence in Indonesian Medical Practice."

sophisticated cases arise in which physicians do not have adequate protection/any unclear symptoms), there will be changes in jurisprudence.[51]

When any mistakes happen in implementing AI (including robotic surgery or actions), the responsibility should be taken by humans and the AI developer. Errors could come from human behavior that uses AI. AI has no legal personality. Therefore, AI cannot take the responsibility for any mistakes. Patients should have the same protection when they are dealing with doctors and AI. Thus insurance is very important in AI implementation.[52]

Bias could come from selection bias and facial recognition. Facial recognition bias happens when recognizing the darker-skinned patients, especially women. Other source of bias is the underpresented patient groups in the algorithms.[53]

Technologists are not responsible for their conduct in AI system; instead, ethical standards of practice are used. The argument over whether technologists should be held liable if AI is used in a healthcare setting and negatively impacts patients can be summed up by this comparison. If a clinician decides to use that data, they will not be able to properly defend their decisions if they cannot account for the output of the AI they are using. The potential safety repercussions of deploying unverified or unvalidated AI in clinical settings are raised by this lack of accountability. Some examples illustrate how each stakeholder is impacted by opacity.[54]

AI will be utilized in healthcare more and more, thus it must be morally responsible. By employing proper algorithms based on unbiased real-time data, data bias might be prevented. It is necessary to conduct regular audits of the algorithm, including how it has been implemented in a system, and to form diverse and inclusive programming groups. Despite the fact that AI might not be able to fully replace clinical judgment, it can nonetheless aid physicians in making wiser decisions. In situations when medical expertise is lacking and resources are scarce, AI is used to undertake screening and evaluation. Unlike human judgment, all AI decisions—even the shortest ones—are systematic due to algorithms involvement. Therefore, even if actions don't result in legal consequences, they always result in accountability—not from the machine itself, but from the people who created it and use it. While there are ethical dilemmas associated with the use of AI, the action of not adopting AI may also be immoral and unscientific.[55]

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[51] Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human"; Luca and Marsella, "Letter The Italian Supreme Court Joint Sections Set Forth the Inter-Pretative Underpinnings of the ' Gelli-Bianco ' Law : Varying Degrees of Guilt Aimed at Limiting Medical Liability , Article 2236 c . c . Makes a Comeback."

[52] Dipla, "Bioethica AI and the Healthcare Sector: Industry, Legal and Ethical Issues"; Tozzo et al., "The Difficult Role of Artificial Intelligence in Medical Liability: To Err Is Not Only Human."

[53] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

[54] Naik et al.

[55] Naik et al.

Furthermore, Article 22 of the General Data Protection Regulation (GDPR) is against fully automated AI as the final decision maker. Doctors have to be the final decision maker. Oral and written informed consent must be obtained from the patients. There are three safety precautions for any medical case, such as intervention, opinion from the subject, and decision dispute.[56]

Informed consent is needed when patients use AI for clinical practice, especially regarding data privacy, safety, transparency, and possibility of biases. The increase of AI usage in high-risk medical situations requires an accountable AI design and management. Transparency in AI means the comprehensibility and accessibility. Therefore, patients, AI developers, physicians, nurses, or other health staff have important roles in implementing AI in the clinical settings.[57]

Human and social biases can be widely incorporated and used by AI algorithms. The underlying data behind the algorithm itself should be reliable and accountable. Models can be developed using either data that includes human decisions or data that shows the second-order impacts of historical or societal injustices. To our knowledge, there are no standards or criteria for reporting and comparing these models; nevertheless, future work should include this to help physicians and researchers.[58]

AI is evolving from a "nice-to-have" to an indispensable component of contemporary digital systems. It is imperative to make sure that decisions are made ethically and without unfair biases as we begin to rely more and more on AI for decision-making. We see a need for accountable, transparent, and responsible AI systems. Artificial intelligence (AI) algorithms are increasingly used to enhance patient paths and surgical outcomes, outperforming humans in several domains. In the artificial intelligence era in healthcare, it is likely to be limited, coexist with current systems, or replace them. Not utilizing AI might be considered unethical and unscientific.[59]

Although a structure and methodology are required for the approval of AI systems, the ultimate responsibility for their use rests with the practitioners and hospitals who will be using them. AI-powered medical equipment will make it easier for people to make decisions about how to carry out treatments and procedures, not to completely replace them. There is a shortage of literature in this area, so the highest bodies of policy makers must create a thorough framework. Artificial Intelligence System (AIS) should be validated before launching. Testing, measurement, and evaluation of the reliability are important procedure before implementing any AIS.[60]

When a clinician chooses to use an artificial intelligence system (AIS), verification and validation may enable them to fairly account for their actions. As was already mentioned, unaccountable behavior is prohibited under clinical

[56] Dipla, "Bioethica AI and the Healthcare Sector: Industry, Legal and Ethical Issues."
[57] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"
[58] Naik et al.
[59] Naik et al.
[60] Naik et al.

standards of professional conduct. However, it has been argued that doctors can also be opaque and that AIS is not the only thing that can be opaque. If AIS is not held accountable, it won't be allowed to accept jobs requiring care for people. It should be made clear by managers of AIS users that doctors cannot avoid responsibility by blaming the AIS. Without the help of a doctor or another human, autonomous machine learning will give immediate prognostic and control statements. The developer's desire for an autonomous machine learning stage must be made known because it clearly affects the assumption of responsibility and accountability. The question should be whether they could comprehend and understand those risks, rather than whether they were aware of the dangers and bad decision-making.[61]

Non-Discriminative Principles

The prospects of implementing AI in healthcare services are improving the quality of healthcare, detecting diseases earlier, and suggesting better treatment in a shorter time. Precise data can be better accomplished by using machine learning. It saves money and time. AI can do administrative tasks, for example, registration, data entering, and appointment scheduling. Legal concerns about implementing Artificial Intelligence (AI) in healthcare services include patient privacy, data sharing, and testing procedure. AI could not be given any legal personality because there AI is just an advanced and sophisticated form of technology. When there is an error in the AI implementation, the responsibility has to be taken by the attending physician and AI developers, because AI has no legal personality. Oral and written informed consent is very critical for patient and physician protection.[62] Non discriminative principle is also applied for sensitive case such as HIV/AIDS patients and relatives.[63] In the legal and ethical issues in the Artificial Intellegence implementation, human judgement has a critical role to minimize the bias and discrimination.[64]

D. CONCLUSION

Legal concerns about implementing Artificial Intelligence (AI) in healthcare services include patient privacy, data sharing, and testing procedure. Legal liability should be ensured by non-discriminative principles. AI could not be given any legal personality because there are just the same as previous technology but in an advanced and sophisticated form. People served by AI should have the same protection as people served by humans (physicians). The unification principle

[61] Naik et al.
[62] Laptev, Ershova, and Rinatovna, "Medical Applications of Artificial Intelligence (Legal Aspects and Future Prospects)."
[63] Ghozali, Hardyanthi, and Fadhilah, "The Implementation of the Patient's Privacy Regulations in The People's Republic of China."
[64] Naik et al., "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility ?"

in AI means the combination of data of similar patients from different hospitals to create a database. A combination of complex networks, counterfactuals, and graph causal models, also verification steps in ethical and legal aspects are used to increase precision and minimize errors.

Further research should be targeted on the possible cases of any error in using AI in healthcare system and the legal solution for the problems. Specific legal regime is needed to manage special healthcare cases of error in AI. Therefore, this needs collaboration of many researchers from legal, health, and information technology expertise.

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