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NAVIGATING LEGAL AND ETHICAL CHALLENGES IN AI-DRIVEN HEALTHCARE: ENSURING ACCOUNTABILITY, TRANSPARENCY, AND PATIENT PROTECTION

AUTHORED BY - JANVI ASHIKA G

ABSTRACT:

The integration of artificial intelligence (AI) into healthcare systems has the potential to revolutionize medical practices, improve patient outcomes, and enhance operational efficiency. However, the rapid adoption of AI technologies also raises significant legal and ethical concerns, particularly regarding accountability for misuse. This paper explores the legal frameworks surrounding AI in healthcare, with a focus on the challenges posed by algorithmic bias, data privacy, transparency, and the shifting nature of liability. Through an analysis of existing laws, regulatory gaps, and case studies of AI failures in healthcare, the paper examines how current legal structures address (or fail to address) the risks associated with AI misuse, such as misdiagnoses, breaches of patient confidentiality, and biased treatment recommendations. It also investigates potential legal reforms needed to ensure that healthcare providers, developers, and AI systems are held accountable for harms caused by malfunctioning or discriminatory algorithms. The paper argues for a multi-faceted approach to accountability, including the development of robust regulatory standards, greater transparency in AI decision-making processes, and clear guidelines for liability. In doing so, it aims to contribute to the ongoing conversation about balancing innovation with patient protection in the age of AI.

KEYWORDS: Artificial Intelligence, Accountability, Healthcare, Patient Protection, Human Rights.

1. INTRODUCTION:

Article 25 of the **Universal Declaration of Human Rights (UDHR)**[1] recognizes the right to a standard of living adequate for health and well-being, including access to medical care. Article 25 underlines the importance of accessible healthcare, framing it as a fundamental

[1] Universal Declaration of Human Rights (UDHR), Art. 25.

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human right. This aligns with global discussions on the right to health and access to essential medical services, which have been significantly influenced by international law, including frameworks such as the **International Covenant on Economic, Social and Cultural Rights (ICESCR)[2].**

Artificial intelligence (AI) has become a driving force in modern healthcare, offering unprecedented opportunities to improve patient outcomes, enhance operational efficiencies, and advance clinical decision-making. From diagnostic tools that analyse medical images with remarkable accuracy to AI-driven systems that recommend personalized treatment plans, the potential benefits are vast. AI technologies are reshaping the way healthcare providers approach patient care, enabling faster diagnoses, more precise treatments, and streamlined administrative processes.

However, alongside these advancements, there are significant risks associated with the integration of AI into healthcare systems. The same capabilities that promise to revolutionize healthcare also pose the potential for misuse, errors, and unintended consequences.[3] Misapplications of AI can lead to incorrect diagnoses, biased treatment recommendations, breaches of patient privacy, and other harmful outcomes. These risks raise important legal and ethical questions about accountability particularly in cases where AI-driven decisions may harm patients or lead to failures in care delivery.

This article will explore both the transformative potential of AI in healthcare and the perils that arise when these technologies are misused or inadequately regulated. By understanding these dual aspects, we can better assess the legal frameworks and mechanisms needed to ensure accountability in the age of AI, protecting both patients and providers while fostering innovation.

2. LEGAL FRAMEWORKS AND ACCOUNTABILITY IN HEALTHCARE IN THE AGE OF AI

The integration of Artificial Intelligence (AI) in healthcare has the potential to revolutionize diagnostics, treatment planning, patient management, and overall care efficiency. However, it

[2] International Covenant on Economic, Social and Cultural Rights (ICESCR), Art. 12.
[3] Qiao Jin, et al. Hidden Flaws Behind Expert-Level Accuracy of Multimodal GPT-4 Vision in Medicine. npj Digital Medicine, 2024, 10.1038/s41746-024-01185-7.

also raises significant legal and ethical concerns, especially in areas like accountability, patient safety, and malpractice. In India, the integration of Artificial Intelligence (AI) in healthcare is subject to a growing but evolving legal and regulatory landscape. The use of AI in healthcare presents a unique set of challenges, especially regarding accountability, patient safety, and legal liability. Let's explore the current legal frameworks and the role of medical malpractice law in the age of AI.

2.1. CURRENT LAWS AND REGULATIONS GOVERNING AI IN HEALTHCARE

The use of AI in healthcare is governed by a variety of legal frameworks and regulations. These regulations are evolving as the technology matures, and the specifics vary by country, but the following broad areas are commonly regulated:

2.1.1. Medical Device Regulations (FDA, EMA, CDSCO, etc.)

In many jurisdictions, AI applications in healthcare are classified as medical devices when they are used for diagnostic, therapeutic, or monitoring purposes. Regulatory bodies like the U.S. **Food and Drug Administration (FDA)[4],** the **European Medicines Agency (EMA)[5],** and other national health authorities assess AI systems before they can be deployed in clinical settings. In India, the **Central Drugs Standard Control Organization (CDSCO)[6],** under the **Drugs and Cosmetics Act, 1940[7],** regulates the approval of medical devices, including AI-based technologies.

i. **FDA (U.S.):** The FDA classifies AI-driven software as a **software as a medical device (SaMD)[8]**. The FDA evaluates these products for safety and efficacy, similar to other medical devices. Recently, it has streamlined its approval process to account for AI's dynamic learning and adaptation capabilities. For example, AI systems that learn and evolve post-deployment may be subject to ongoing oversight and monitoring through mechanisms like post-market surveillance.

[4] Food and Drug Administration (FDA), available at: https://www.fda.gov/
[5] European Medicines Agency (EMA), available at: https://www.ema.europa.eu/en/homepage
[6] Central Drugs Standard Control Organization (CDSCO), available at: https://cdsco.gov.in/opencms/opencms/en/Home/
[7] Act No. 23 of 1940.
[8] Artificial Intelligence and Machine Learning in Software as a Medical Device, Food and Drug Administration; 2024 https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

ii. **EMA (Europe):** The European Union regulates AI under the **Medical Device Regulation (MDR)**[9] and **In-vitro Diagnostic Medical Device Regulation (IVDR)**[10]**.** AI software that provides medical decisions or clinical guidance is regulated as a medical device, and manufacturers are required to undergo clinical evaluations and provide ongoing post-market surveillance. Also, The EU just enacted the **EU AI Act**[11], the first complete legislative framework for AI in history.

iii. **CDSCO (India):** The **AI/ML-based Software as a Medical Device (SaMD)**[12] is regulated by the CDSCO in India. AI-based software that diagnoses, monitors, or helps in clinical decision-making is considered a medical device and needs approval before being used. The regulatory requirements involve testing for safety and efficacy, clinical trials, and post-market surveillance. The Ministry of Health and Family Welfare (MoHFW) issued guidelines (AI Medical Device Guideline) in 2021 for regulating AI/ML-based Software as a Medical Device (SaMD), outlining a risk-based classification for AI products. This classification takes into account the intended purpose and the potential risk to patients. For example, diagnostic tools that analyze medical imaging or perform predictive analytics are classified as high-risk devices.

2.2. Gaps in Regulatory Oversight:

While these existing frameworks offer essential regulatory oversight for AI in healthcare, there are notable gaps that leave significant risks unaddressed.

- **Lack of Standardized AI Evaluation**: AI technologies in healthcare are evolving rapidly, but regulatory bodies have struggled to keep up with the speed of innovation. The FDA and EMA's existing frameworks often do not account for the adaptive learning capabilities[13] of AI systems. For instance, AI algorithms that evolve over time through machine learning might require continuous monitoring and approval[14],

[9] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, 2017.
[10] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, 2017.
[11] Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act), 2024.
[12] Regulation of Software as Medical Device (SaMD) in India, Freyr, (Aug. 9, 2022), https://www.freyrsolutions.com/blog/regulation-of-software-as-medical-device-samd-in-india
[13] Tumaini Kabudi, et al. AI-enabled adaptive learning systems: A systematic mapping of the literature, Computers and Education: Artificial Intelligence, Volume 2, 100017, (2021), https://doi.org/10.1016/j.caeai.2021.100017.
[14] V. Sounderajah, et al. Developing specific reporting guidelines for diagnostic accuracy studies assessing AI interventions: The STARD-AI Steering Group. *Nat Med* **26**, 807–808 (2020). https://doi.org/10.1038/s41591-020-0941-1

something traditional medical devices do not need. Current regulations often fail to address the post-market surveillance of AI systems after their approval, allowing for potential safety concerns to remain undetected.

- **Absence of Clear Liability Frameworks**: Another significant gap in AI regulation is the lack of clear guidelines on liability when AI systems cause harm or errors in healthcare. Regulatory oversight should address how liability is distributed in cases of AI-related malpractice or errors.
- **Algorithmic Transparency and Explainability**: Many AI systems in healthcare operate as "black boxes"[15], meaning the decision-making process is often not transparent to users or patients. Regulatory frameworks have not sufficiently addressed the need for transparency and explainability in AI decision-making processes.
- **Bias and Discrimination in AI**: AI systems in healthcare, if not properly regulated, can inadvertently perpetuate or even exacerbate biases in treatment, diagnosis, or care. Algorithmic bias can lead to discriminatory practices, affecting marginalized groups based on gender, race, age, or socioeconomic status.[16] Regulatory bodies have not yet fully developed methodologies for evaluating and mitigating bias in AI healthcare systems, leaving significant gaps in oversight.
- **Global Discrepancies in Regulation**: AI regulation in healthcare varies significantly across jurisdictions. For example, while the EU has a more robust data privacy framework through GDPR[17], other regions may lack sufficient AI-specific healthcare regulations, leading to cross-border regulatory challenges. This inconsistency complicates the development and deployment of AI systems globally, especially for multinational healthcare organizations or developers.

3. CHALLENGES IN DETERMINING LIABILITY

Determining "liability" and "accountability" in the context of "AI errors" in healthcare is a highly complex issue that raises fundamental questions about the roles and responsibilities of the key stakeholders involved: AI developers, healthcare providers, and manufacturers. As AI technologies become increasingly integrated into healthcare systems, these challenges are

[15] A. Marey, et al. Explainability, transparency and black box challenges of AI in radiology: impact on patient care in cardiovascular radiology. Egypt J Radiol Nucl Med **55**, 183 (2024). https://doi.org/10.1186/s43055-024-01356-2
[16] Xavier Ferrer, et al. Bias and Discrimination in AI: A Cross-Disciplinary Perspective. IEEE Technology and Society Magazine. 40. 72-80, (2021). 10.1109/MTS.2021.3056293
[17] General Data Protection Regulation, L119, p. 1–88, 4 May 2016.

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amplified by issues of autonomy, decision-making, and human oversight. **UNESCO's Recommendation on the Ethics of AI**[18] focuses on ensuring that AI development aligns with human rights, fairness, and transparency. It emphasizes the need for AI systems to be responsible and accountable for their actions.

3.1. Dissecting Issues of Liability and Accountability

3.1.1. Role of AI Developers

AI developers are responsible for creating the underlying algorithms, training data, and models that power healthcare AI systems. However, determining their liability when an AI system makes an error is a nuanced issue. Potential issues related to AI developer liability:

Algorithmic Errors: If the AI algorithm makes an incorrect diagnosis or treatment recommendation due to errors in its programming or design, the developers could be held responsible. This could include issues like insufficient training data, biased datasets, or flawed model architecture.[19] For example, if an AI system used for diagnostic imaging incorrectly identifies a tumour due to incomplete training data or algorithmic bias, the developers of the system may be held liable for negligence in developing the algorithm.[20]

Training Data: AI systems learn from data, and the quality of this data is essential for the performance of the system. If the training data is flawed, developers may be held accountable for failing to use accurate or diverse data, resulting in poor AI predictions. For example, an AI diagnostic tool trained predominantly on data from one demographic group (e.g., white patients) may fail to accurately detect conditions in patients from other groups (e.g., Black or Asian patients), leading to misdiagnoses.[21]

Product Liability: Developers could also face liability under product liability laws if the AI system is considered a defective product. If an AI system causes harm due to a defect in its design or functionality, developers could be held responsible for the defect, particularly if the system does not perform as intended or as promised. In India, **the Consumer Protection Act,**

[18] UNESCO's first-ever global standard on AI ethics – the 'Recommendation on the Ethics of Artificial Intelligence', adopted in 2021, is applicable to all 194 member states of UNESCO. 16 May 2023, Last update:26 September 2024.

[19] Grote, Thomas, and Geoff Keeling. "On Algorithmic Fairness in Medical Practice." Cambridge Quarterly of Healthcare Ethics, vol. 31, no. 1, pp. 83-94, (2022), https://doi.org/10.1017/S0963180121000839.

[20] Bernstein MH, et al. Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography. Eur Radiol. (Nov 2023); 33(11):8263-8269. doi: 10.1007/s00330-023-09747-1.

[21] Obermeyer, Ziad, et al. "Dissecting racial bias in an algorithm used to manage the health of populations." Science (American Association for the Advancement of Science), vol. 366, no. 6464, pp. 447–453, (2019), https://www.science.org/doi/10.1126/science.aax2342

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2019[22] provides a framework for product liability, and AI tools, if considered "products", might fall under this law, making developers and manufacturers liable for harm caused by defective products.

3.1.2. Role of Healthcare Providers (Doctors, Hospitals)

Healthcare providers, including doctors, nurses, and hospitals, have traditionally been the main parties held responsible for patient care. However, with the introduction of AI tools, the question arises as to whether their liability extends to errors caused by the AI systems they use. Potential issues related to healthcare provider liability:

Failure to Validate AI Recommendations: Healthcare providers are still expected to use professional judgment in diagnosing and treating patients, even when using AI-based tools.[23] If a healthcare provider blindly follows an AI recommendation without critically assessing its appropriateness for the patient, they may be held liable for negligence.

Duty of Care: In cases where AI assists in diagnostics, healthcare providers have a duty to ensure that the AI system is functioning correctly, is appropriate for the case at hand, and is validated for its accuracy. A failure to check or question the output of AI tools might lead to legal exposure for the healthcare provider. For example, if a doctor relies on an AI system for diagnosing a rare condition but fails to verify the AI's output, and the misdiagnosis results in harm, the doctor could be deemed negligent in failing to exercise due diligence.[24]

Shared Responsibility: In collaborative settings, such as hospitals or healthcare organizations, AI tools may be used across multiple levels of care. In these cases, liability could be spread across various individuals or entities, depending on the structure of the organization and the AI's specific role in the treatment.

3.1.3. Role of Manufacturers (Hardware and AI System Vendors)

The manufacturers of AI-powered medical devices or systems play a key role in ensuring that the hardware and software meet safety standards and are designed to function correctly. In cases of AI error, the question is whether manufacturers are liable for faulty products or insufficient safety measures. Potential issues related to manufacturer liability:

Defective Products: If an AI medical device malfunctions due to a hardware failure or a bug

[22] Act No. 35 of 2019

[23] Ahsan MM, et al. Machine-learning-based disease diagnosis: a comprehensive review. Healthcare. 10(3):541, (2022), https://doi.org/10.3390/healthcare10030541.

[24] Myszczynska MA, et al. Applications of machine learning to diagnosis and treatment of neuro degenerative Diseases, Nat Reviews Neurol, 16(8):440–56, (2020), https://doi.org/10.1038/s41582-020-0377-8.

in the software, the manufacturer may be held liable under product liability laws. This could apply to the hardware, such as medical imaging devices with AI capabilities, or to the AI software itself.[25] For example, if a medical imaging AI system consistently misidentifies conditions due to faulty image processing or software bugs, [26]the manufacturer may be held liable for producing a defective product.

Failure to Warn: Manufacturers of AI tools might also face liability if they fail to properly warn healthcare providers and patients about the limitations and risks associated with their systems. This could include inadequate labeling or failure to provide proper training for users. For example, if a hospital uses an AI system to predict patient outcomes, and the manufacturer does not adequately disclose the system's limitations, the manufacturer may be held responsible for harm caused by relying on inaccurate results.

Post-Market Surveillance: Manufacturers have an ongoing obligation to monitor the performance of their AI systems after they are deployed in clinical settings. If the manufacturer fails to conduct proper post-market surveillance, or if they ignore warnings about potential risks or defects, they could be liable for harm caused by the system.[27]

4. ALGORITHMIC BIAS AND DISCRIMINATION: LEGAL IMPLICATIONS

Algorithmic bias in AI refers to the systematic favouritism or prejudice that occurs when an AI system's decisions, predictions, or outputs disproportionately benefit or disadvantage certain groups based on factors such as race, gender, age, or socio-economic status. AI systems that perpetuate bias or discrimination may violate the core principles of the **Universal Declaration of Human Rights**, particularly **Article 1,** [28]the right to equality before the law. In healthcare, the consequences of AI bias can be particularly serious, leading to discriminatory practices in diagnosis, treatment, and overall patient care. This raises significant legal and ethical challenges in terms of accountability, patient safety, and fairness. AI systems are trained on large datasets to recognize patterns and make decisions, but if these datasets are incomplete or unbalanced, the AI may develop biased decision-making, leading to biased treatment recommendations, misdiagnoses, or unequal care in healthcare.

[25] Channa R, et al. Autonomous artificial intelligence in diabetic retinopathy: from algorithm to clinical application, J Diabetes Sci Technol, (2021), https://journals.sagepub.com/doi/10.1177/1932296820909900
[26] Fenton JJ, et al. Influence of computer-aided detection on performance of screening mammography. N Engl J Med. 356(14):1399-1409, (2007).
[27] Karnika Singh &Praveen Selvam, Medical device risk management, Trends in Development of Medical Devices, Academic Press, Pages 65-76, (2020), https://doi.org/10.1016/B978-0-12-820960-8.00005-8
[28] Universal Declaration of Human Rights, art. 1

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Examples:

- **Racial Bias**: AI systems used for diagnostic purposes might be less accurate for minority groups if the data used to train the models is predominantly from one racial group. For instance, an AI system designed to predict the risk of heart disease might underdiagnose Black patients if the model was primarily trained on data from white patients.[29]
- **Gender Bias:** A diagnostic AI tool could misinterpret symptoms of heart disease in women, who may experience symptoms differently than men, leading to delayed or incorrect treatment.[30]
- **Socioeconomic Bias:** If data reflects socioeconomic disparities, AI systems might prioritize care for wealthier individuals, leaving lower-income patients with fewer resources or less optimal treatment plans.[31]

4.1. Impact on Patient Care

AI algorithms used in radiology, pathology, and medical imaging can be affected by biases if they are trained on images that predominantly represent certain groups of people. For instance, if an algorithm is trained mostly on data from a specific demographic (e.g., white patients), it may struggle to accurately diagnose conditions in patients outside of that demographic, leading to worse outcomes for underrepresented groups. For example, an AI system used for skin cancer detection may fail to correctly identify melanoma in patients with darker skin tones because it was trained mostly on images of lighter-skinned individuals.[32]

Even though AI has the potential to make healthcare more accessible, the unequal development and deployment of AI tools could deepen existing healthcare disparities. Rural areas or underprivileged communities might have less access to AI-powered diagnostic tools, or the algorithms used in those regions might not be appropriately calibrated to reflect local

[29] Parikh RB, Teeple S, Navathe AS. Addressing Bias in Artificial Intelligence in Health Care. JAMA.322(24):2377–2378 (2019) https://jamanetwork.com/journals/jama/article-abstract/2756196
[30] D. Cirillo, et al. Sex and gender differences and biases in artificial intelligence for biomedicine and healthcare. npj Digit. Med. **3**, 81 (2020). https://doi.org/10.1038/s41746-020-0288-5
[31] Juhn YJ, et al. Assessing socioeconomic bias in machine learning algorithms in health care: a case study of the HOUSES index. J Am Med Inform Assoc.29(7):1142-1151, (Jun 14, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9196683/
[32] Esteva A, et al. Dermatologist-level classification of skin cancer with deep neural networks. Nature. 542(7639):115–8, (2017). https://doi.org/10.1038/nature21056.

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population needs. If patients believe that AI systems are unfair or biased, they may lose trust in healthcare providers who rely on these technologies, which can result in poorer health outcomes, lower patient satisfaction, and hesitancy to engage with the healthcare system.

4.2. Legal Consequences of Discriminatory Outcomes in AI-Driven Healthcare

AI bias in healthcare not only threatens patient well-being but also exposes healthcare providers and developers to significant legal risks. The consequences of AI-driven discrimination can be profound, with various legal frameworks addressing these issues.

4.2.1. Violations of Anti-Discrimination Laws:

In many countries, there are specific anti-discrimination laws that prohibit unequal treatment based on race, gender, ethnicity, and other protected characteristics. In India, laws such as the **Constitution of India (Article 15)**[33] and the **Rights of Persons with Disabilities Act, 2016**[34] mandate non-discriminatory practices, and failure to comply with these principles can expose healthcare providers to legal action.

Consumer Protection Act, 2019 (India)[35]**:** AI tools in healthcare that are discriminatory may also face legal scrutiny under the Consumer Protection Act. If a healthcare provider uses an AI system that leads to discriminatory outcomes, patients could seek legal recourse for unfair trade practices, including the failure to provide equal treatment.

Equal Protection Clauses (U.S. and other jurisdictions): In the U.S., the **Civil Rights Act**[36] and **Affordable Care Act**[37] have provisions that prohibit discrimination in healthcare based on race, colour, national origin, sex, age, or disability. If AI systems result in unequal care or outcomes, healthcare providers could face lawsuits or regulatory actions.

4.2.2. Negligence and Malpractice Claims:

Healthcare providers might be found negligent if they fail to monitor and intervene when AI systems provide discriminatory or biased outputs. If a healthcare provider relies on an AI system that leads to harm due to bias (such as overlooking a diagnosis for a specific demographic group), they could be held liable for medical malpractice or negligence under

[33] India Const. art. 15.
[34] Act No. 49 of 2016
[35] Act No. 35 of 2019
[36] Civil Rights Act of 1964; 7/2/1964; Enrolled Acts and Resolutions of Congress, 1789 - 2011; General Records of the United States Government, Record Group 11; National Archives Building, Washington, DC.
[37] 124 Stat. 119.

laws that mandate providing a reasonable standard of care. In India and many other jurisdictions, healthcare providers have a duty of care to ensure that AI tools are effective, accurate, and free from bias.[38] A failure to properly vet AI tools for discriminatory outcomes could lead to lawsuits if patients are harmed.

4.2.3. Violation of Data Protection and Privacy Laws:

In countries like India, AI tools often use sensitive health data, and biased outcomes can raise concerns related to data privacy and fairness. If AI systems disproportionately affect certain groups due to biased data or algorithms, it may constitute a violation of data protection regulations like the **Personal Data Protection Bill**[39] in India, or the **General Data Protection Regulation (GDPR)**[40] in the **EU.** Regulatory bodies such as **India's Central Drugs Standard Control Organization (CDSCO),** and the **U.S. Food and Drug Administration (FDA),** can take actions against AI tools that lead to discriminatory outcomes. Regulators can mandate companies to withdraw products from the market, issue fines, or require manufacturers to make improvements to prevent discrimination.

5. CASE STUDIES

The IBM Watson for Oncology Controversy (2018),[41] where the IBM Watson for Oncology was introduced as a tool to assist doctors in making cancer treatment decisions by analyzing data from clinical trials and patient records. However, the system faced significant criticism for recommending unsafe and incorrect treatments. This case raised questions about the responsibility of healthcare providers when relying on AI tools for critical medical decisions. Legal challenges focused on whether Watson's creators or the healthcare providers were liable for the harm caused by incorrect treatment recommendations. This case highlights the issue of accountability in AI-driven decision-making, where patients or their families may pursue malpractice claims against healthcare providers using AI tools.

In the **Google Health AI Misdiagnosis Lawsuit (2020),**[42] Google Health's AI system for

[38] Williams, Betsy Anne, et al. "How Algorithms Discriminate Based on Data They Lack: Challenges, Solutions, and Policy Implications." Journal of Information Policy (University Park, Pa.), vol. 8, pp. 78-115, (2018), https://doi.org/10.5325/jinfopoli.8.2018.0078.
[39] Personal Data Protection Bill, 2023, Government of India.
[40] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.
[41] S. Bhattacharya, "IBM Watson for Oncology and the AI revolution in healthcare: A critical review." Journal of Cancer Policy, 24, 100191, (2020). https://doi.org/10.1016/j.jcpo.2020.100191
[42] Sweeney, L. "Google Health's AI and the 2020 Misdiagnosis Lawsuit: Implications for Healthcare and Data Privacy." Journal of Health Law and Policy, 32(2), 215-233. https://doi.org/10.1016/j.jhlp.2020.05.003

analyzing medical images showed promise in diagnosing breast cancer. However, a study revealed that the AI made errors in certain contexts, leading to false negatives and incorrect diagnoses. The lawsuit that followed highlighted the potential for AI systems to misdiagnose and how patients might hold AI developers or healthcare providers accountable for errors that lead to harm. The case echoes concern about the limits of AI technology in healthcare and who bears the burden of liability when AI systems fail to perform as expected.

The Rise of Diagnostic Errors Due to AI in Radiology[43], in the field of radiology, AI is being increasingly used to interpret medical images like CT scans, MRIs, and X-rays. However, some patients have reported misdiagnoses, including missed cancer diagnoses, due to AI's inability to correctly interpret images. Legal proceedings in these cases focus on the allocation of liability, especially when an AI misdiagnosis leads to delayed treatments or wrongful death. Questions arise about whether the radiologists, AI developers, or healthcare institutions are responsible. Such cases are likely to set precedents on how the courts view the role of AI in medical malpractice suits, particularly in determining whether AI acts as a substitute or tool for human decision-makers.

In AI-Powered Predictive Models for Patient Outcome[44], AI systems are being developed to predict patient outcomes, such as readmission risks or future health complications. However, there have been instances where predictions were not accurate, leading to missed opportunities for early interventions. If a predictive model fails and results in harm (e.g., a preventable death), patients or families might seek legal redress against healthcare providers or AI developers. The question here is whether the AI system should have been thoroughly vetted before being used in clinical practice. This scenario raises issues related to medical negligence, informed consent, and whether AI systems need to undergo the same level of regulatory scrutiny as other medical devices.

In **Autonomous Robotic Surgery and Surgical Malpractice[45]**, the Robotic surgery, powered by AI, has been gaining popularity for its precision and minimal invasiveness. However, cases

[43] Le, M. H., & Nguyen, T. "AI in Radiology: Implications for Diagnostic Accuracy and Errors." Journal of Medical Imaging and Radiation Sciences, 51(4), 468-474, (2020). https://doi.org/10.1016/j.jmir.2020.02.002
[44] Rajkomar, A., et al. "Scalable and accurate deep learning for electronic health records." npj Digital Medicine, 1, 18, (2018). https://doi.org/10.1038/s41746-018-0029-1
[45] Mazzone, P., et al. "Legal and Ethical Implications of Autonomous Robotic Surgery." Journal of Medical Robotics and Computer Assisted Surgery, 15(2), 115-124, (2019). https://doi.org/10.1002/rob.21815

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have emerged where robotic systems malfunctioned or failed to follow surgeon commands, resulting in patient harm. These cases often revolve around determining who is liable when an autonomous system fails whether the surgeon who used the technology is at fault, the manufacturer of the AI system, or the hospital. Such cases are critical in setting precedents regarding the limits of AI autonomy in surgical procedures and the need for adequate human oversight.

These case studies provide valuable lessons in the intersection of AI, healthcare, and law, and will likely continue to shape how courts handle malpractice claims involving AI in the medical field.

6. CONCLUSION & WAY FORWARD

As AI technologies continue to reshape healthcare, ensuring accountability becomes critical to balancing innovation and patient protection. A multi-faceted approach to accountability involves the development of robust regulatory standards, enhancing transparency in AI decision-making processes, and establishing clear guidelines for liability. This approach aims to address the ethical, legal, and operational challenges posed by AI systems in healthcare, ensuring that these innovations benefit patients while minimizing potential harm. Governments and regulatory bodies must develop comprehensive standards for the use of AI in healthcare. These standards should focus on safety, effectiveness, and ethical considerations while allowing for innovation. This includes guidelines for data privacy, algorithm validation, and risk management. While some aspects of healthcare AI are regulated through existing frameworks (like FDA guidelines for medical devices), new AI-specific regulations are necessary to address the unique challenges posed by machine learning and autonomous systems.

AI systems in healthcare must be transparent in their decision-making. This means that the algorithms should be interpretable by healthcare providers and patients, ensuring that both can understand how decisions are made. The AI developers and healthcare providers should communicate openly with the public and medical professionals about how AI is used, its benefits, and its limitations. Informed consent and patient education are essential to maintaining trust in AI-powered healthcare solutions.

When AI systems cause harm or lead to errors in healthcare, liability must be clearly defined.

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This includes determining who is responsible: the AI developer, the healthcare provider, or a combination of both. Clear legal frameworks should address issues such as medical malpractice involving AI tools, establishing who is accountable in case of misdiagnosis, treatment errors, or data breaches. New insurance models may be needed to cover the risks associated with AI in healthcare. These models would ensure that patients can receive compensation for harm caused by AI, and they would provide financial protection for healthcare providers and developers against legal claims. Accountability mechanisms are essential to ensuring that AI systems are not only effective and efficient but also responsible and transparent in their decision-making. The increasing integration of AI in healthcare demands a legal infrastructure that can evolve to address emerging challenges while keeping pace with the rapid advancement of technology.

The balance between innovation and accountability will also require global cooperation. AI in healthcare is a global phenomenon, and legal frameworks should promote international harmonization of standards to avoid conflicts and ensure consistency in the application of regulations across borders. The ongoing development of global ethical standards, along with cross-border data protection agreements and continuous monitoring of AI systems, will be vital in creating a safe and equitable healthcare environment worldwide.