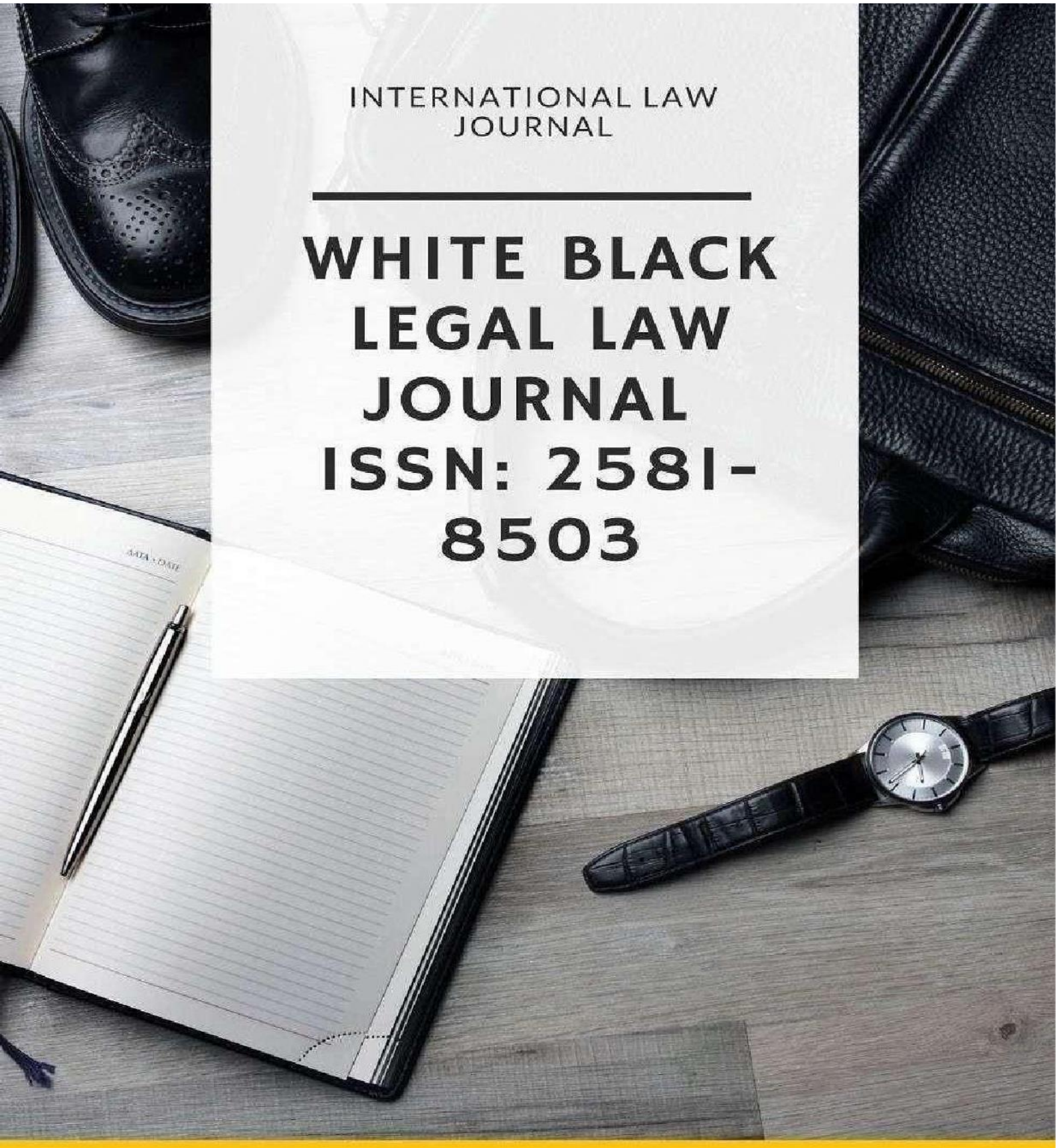

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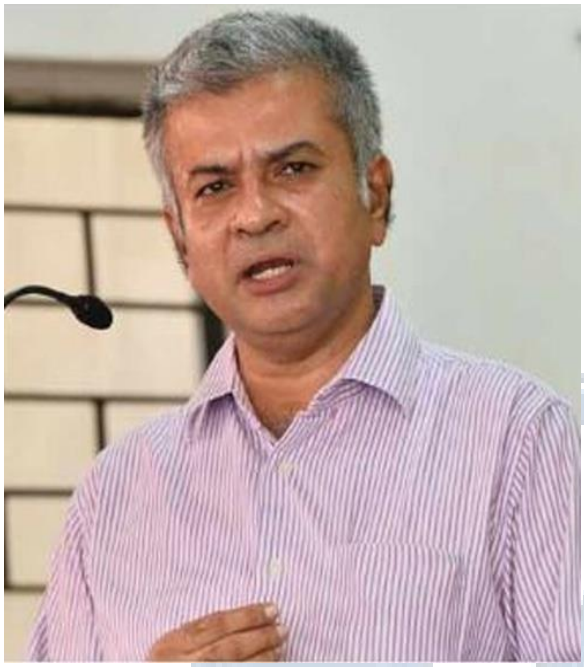

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Subhrajit did his LL.M. in Sports Law, from Nottingham Trent University of United Kingdoms, with international scholarship provided by university; he has also completed another LL.M. in Energy Law from University of Petroleum and Energy Studies, India. He did his B.B.A.LL.B. (Hons.) focussing on International Trade Law.

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THE LAW, THE BODY, AND THE ALGORITHM: A BIOETHICAL LENS ON AI IN HEALTHCARE

AUTHORED BY - SONALI DEBBARMA
Research Scholar, Faculty of Law,
ICFAI University, Tripura Kamalghat, Mohanpur, West Tripura

ABSTRACT

Artificial Intelligence (AI) is quickly changing the healthcare sector through better diagnosis, treatment planning, and clinical decision-making. Nevertheless, AI penetration into the medical practice is associated with important bioethical and legal issues that have to be considered to guarantee the patient safety, autonomy, and accountability. The analysis in this article is founded on the ethical challenges of AI systems, including algorithmic bias, lack of transparency, risk of data privacy, and the possibility of losing human control over the system, in the context of healthcare delivery. It also evaluates the new legal protections aiming to control AI-based decisions, basing on the principles of informed consent, transparency, fairness and liability. With the growing use of predictive algorithms and automated tools in health institutions, it is important to discuss the necessity of well-developed legal frameworks that can help reduce the risks and safeguard vulnerable groups. The paper states that the application of AI should be ethically applied with a mix of robust data-protection legislation, precise accountability frameworks, constant systems of monitoring, and the compliance with human-centric values. Through the analysis of bioethics and law interplay, this paper has demonstrated that there is a need to challenge the governance systems in place that tend to be more innovative and less responsible. Finally, it highlights the fact that patient welfare should be the main driving force because AI is still transforming the face of modern healthcare and decision-making.

KEYWORDS: Artificial Intelligence (AI), Bioethics, Healthcare Law, Clinical Decision-Making, Legal Safeguards.

1. INTRODUCTION

Artificial intelligence is fundamentally reshaping the landscape of healthcare, challenging established boundaries between the law, the human body, and the algorithmic systems now mediating medical decisions. As digital technologies and machine learning become increasingly integral to diagnostics, treatment, research, and healthcare management, bioethical questions have come to the forefront, addressing autonomy, justice, transparency, and accountability[1][2][3][4][5].

The future AI promises can help increase clinical accuracy and efficiency and make the most out of the enormous amount of health data. Nevertheless, new risks of bias, data misuse and decreased human oversight are associated with this promise, necessitating the development of legal systems and medical ethics frameworks that respond to the changes. In this introduction, I explore how law, body, and algorithm are triadically connected and suggest that bioethical approach is required to regulate the implementation of AI in healthcare in a manner that would uphold the human dignity, rights of patients, and fair access to transformative advantages of digital medicine[6].

2. Conceptual Background / Theoretical Framework

2.1 Core Concepts of Artificial Intelligence in Healthcare

Artificial Intelligence (AI) in healthcare can be defined as the use of sophisticated computing methods that can allow machines to handle the tasks that are supposed to be done by humans. Such tasks involve diagnosis, analysis of medical imaging, treatment planning, predictive modelling, and monitoring the health of patients. The AI systems are used to analyze large volumes of clinical and biological data to find patterns, create insights, and aid decision-making.

There are a number of important elements to healthcare AI. Machine Learning (ML) enables algorithms to benefit over time as medical data like lab reports, imaging findings, and electronic

[1] HI TRUST, https://hitrustalliance.net/blog/the-ethics-of-ai-in-healthcare (last visited on Nov. 16, 2025)
[2] ICMR, https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare (last visited on Nov. 16, 2025)
[3] Farhud DD, Zokaei S. *Ethical Issues of Artificial Intelligence in Medicine and Healthcare*. IRAN J PUBLIC HEALTH. 2021
[4] CDC, https://www.cdc.gov/pcd/issues/2024/24_0245.htm (last visited on Nov, 16, 2025)
[5] Frontiersin, https://www.frontiersin.org/journals/surgery/articles/10.3389/fsurg.2022.862322/full
[6] *Ibid*.

health records are learned and therefore become more accurate. Deep Learning (DL), a branch of ML, is analysed by a neural network, which is particularly useful in radiology, pathology, and genomics. Natural Language Processing (NLP) allows AI systems to make sense of clinical notes, patient histories, and medical literature that allow professionals to extract information that is relevant and fast.

Clinical decision support is another essential concept, as AI devices can guide doctors by giving evidence-based recommendations using evidence-based patterns. Predictive analytics also promotes healthcare by predicting the risk of diseases, the success of treatment and patient degradation. There is also automation in healthcare, like robotic surgery, automated monitoring, and computerized triage systems, which lessens the workload and increases accuracy.

Combined, these fundamental ideas depict AI as a supportive, informative technology that is intended to improve the efficiency, precision, and quality of the care of patients.

2.2 Bioethics and Its Relevance to AI

Bioethics provides a foundational framework for evaluating the ethical challenges introduced by artificial intelligence in healthcare, helping to ensure that innovation aligns with fundamental moral principles and safeguards human dignity. Its relevance to AI is rooted in the systematic approach bioethics offers for navigating complexities in clinical decision-making, data use, patient autonomy, and medical justice[7][8][9][10].

2.2.1 Central Principles

Bioethics has been generally oriented in four principles, namely, autonomy, beneficence, non-maleficence, and justice. The following principles apply to AI in the healthcare directly:

- **Autonomy:** AI should not negatively impact the right of patients to make informed choices regarding their care but should promote them, which necessitates the explanation of the algorithmic processes and their transparency[11].

[7] *Ibid*.
[8] XENOSTACK, https://www.xenonstack.com/blog/ethics-and-governance-of-ai-in-healthcare (last visited on Nov. 16, 20250
[9] HARVARD, https://www.ethics.harvard.edu/blog/post-9-how-bioethics-can-inform-ethical-ai-governance (last visited on Nov. 16, 2025)
[10] WHO, https://www.who.int/news/item/16-05-2023-who-calls-for-safe-and-ethical-ai-for-health (last visited on Nov. 16, 2025)
[11] *Ibid*.

- **Beneficence and Non-maleficence:** Algorithms are to be created and implemented in a way that the maximum patient good and the minimum patient harm are achieved, where safety, reliability, and evidence-based outcomes are of high priority[12].
- **Justice:** AI in healthcare must be equitable, focus on the problem of bias, and provide fair access, without a systematic discrimination of marginalized groups[13].

2.2.2 Operational Relevance

Bioethics will provide healthcare providers, technologists, and policymakers with a moral compass to create AI responsibly, develop it, and use it. It educates such processes as informed consent concerning clinical algorithms, health data privacy management, and human oversight and accountability approaches. Bioethical frameworks assist in resolutions of ethical dilemmas which occur in high stakes contexts like end-of-life choices, resource management and dealing with biased or incomplete information[14151617].]

Healthcare systems that base AI governance on bioethical principles can better protect patient rights, develop public trust, and stimulate innovation that is not just technologically sound but also ethically robust[18].

2.3 Ethical Principles Applied to AI Decision-Making

Ethical guidelines serve as a crucial framework for incorporating artificial intelligence into healthcare decision-making, ensuring that automation supports rather than detracts from essential values like patient welfare, fairness, and trust[192021].

2.3.1 Core Principles in Practice

- **Autonomy:** AI systems should honour and facilitate patient autonomy by offering clear and understandable explanations for algorithmic suggestions. Patients must have the right to be involved in decisions, provide informed consent, and maintain ultimate

[12] *Ibid*.
[13] *Ibid*.
[14] KMC, https://www.kosinmedj.org/journal/view.php?number=1305 (last visited on Nov. 2025)
[15] https://pmc.ncbi.nlm.nih.gov/articles/PMC11906199/ (last visited on Nov. 2025)
[16] ICMR, https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare (last visited on Nov. 16, 2025)
[17] *Ibid*.
[18] *Ibid*.
[19] ROYAL SOCIETY PUBLISHING, https://royalsocietypublishing.org/doi/10.1098/rsos.241873 (last visited on Nov. 16, 2025)
[20] https://www.glenwoodsystems.com/post/ai-and-ethics-and-safety (last visited on Nov. 16, 2025)
[21] *Ibid*.

control over their care, with AI serving as a support rather than a replacement[22][23].

- **Beneficence and Non-maleficence:** Algorithms need to be crafted to enhance patient benefits (beneficence) while reducing harm (non-maleficence). This involves thorough evidence, vigilance for unintended effects, and prioritizing safety and clinical efficacy at every phase of AI implementation[24].
- **Justice**: The development and application of AI must be guided by fairness and equity. This involves efforts to remove bias in training data and results, ensuring equitable access to AI-driven healthcare, and monitoring for discriminatory or unjust effects across various groups[25].
- **Accountability and Transparency:** AI-related decisions must be open to audit and traceability. Healthcare professionals and organizations should be able to explain, justify, and, if necessary, contest algorithmic results. Transparent AI design enhances scrutiny, builds user trust, and supports legal and ethical accountability systems[26].
- **Privacy and Data Protection:** Strong privacy safeguards for health data are vital, necessitating strict data governance, informed consent for data usage, and security measures to prevent misuse or unauthorized disclosure[27].

2.3.2 Practical Application

AI systems should be centered around humans, governed by continuous human oversight, and aligned with societal good, public trust, and patient interests. Integrating these ethical principles into clinical practice, technology development, and policy ensures that AI not only fosters innovation but also maintains the moral integrity fundamental to medicine[28].

2.4 Legal and Regulatory Background

Introduction of Artificial Intelligence into the healthcare field needs a defined system of laws in place so that the technological advancement does not undermine the patient rights, medical ethics, or the safety of the clinical place. The legal safeguards can be viewed as protection systems that control the development, deployment, and utilization of AI systems in a medical setting. These measures consider major issues, including accountability, data protection,

[22] BCPHR, https://bcphr.org/79-article-fritz/ (last visited on Nov. 16, 2025)
[23] *Ibid*.
[24] *Ibid*.
[25] *Ibid*.
[26] *Ibid*.
[27] *Ibid*.
[28] *Ibid*.

patient autonomy, and system transparency.

One key legal principle is the privacy and confidentiality of data, which regulates the manner of collecting, storing, computing, and transferring sensitive health information by the AI systems. Given that AI models are very dependent on large datasets, stringent regulations should be put in place to ensure that they are not abused, used by unauthorized personnel, or violate patient trust.

The other fundamental aspect is the concept of liability and accountability, which is concerned with establishing who is responsible when the AI-assisted diagnosis or treatment produces undesirable results. With AI erasing the historic boundaries between doctor, developer and institution, there is a necessity of legal norms to explain who is responsible to mistakes, omissions or algorithmic bias.

Also, regulation can be crucial in making sure that AI tools are used in accordance with the existing safety measures, ethics, and clinical practices.

To prevent dangerous or untrustworthy technologies from entering the healthcare ecosystem, regulatory agencies assess algorithmic transparency, risk, data integrity, and actual performance. A combination of these legal provisions fosters a controlled system in which innovation can thrive but patient well-being, dignity, and informed decision-making are protected.

2.5 Theoretical Basis for Ethical AI Governance

Theoretical frameworks for ethical AI governance integrate classic ethical theories with contemporary governance models to ensure responsible, accountable, and socially beneficial deployment of artificial intelligence, especially in high-stakes areas like healthcare.

2.5.1 Foundational Ethical Theories

- **Utilitarianism:** AI governance seeks to maximize overall benefits while minimizing harm, guiding the evaluation of risks, patient outcomes, and societal impacts when deploying healthcare algorithms[29].

[29] *Ibid*.

- **Deontology:** Rules-based ethics emphasize adherence to duties, rights, and obligations such as patient autonomy, informed consent, and privacy regardless of outcomes, driving requirements for transparency, data protection, and adherence to medical standards[30].
- **Virtue Ethics:** Focuses on moral character and the embedding of human values like empathy, fairness, and integrity in both the development and oversight of AI systems.

2.5.2 AI Governance Frameworks and Principles

Several international and national bodies have articulated pillars for ethical AI governance, such as:

- **Transparency and Explainability:** All AI-based decisions in healthcare should be understandable and open to scrutiny by both professionals and patients, supporting autonomy and trust[31].
- **Accountability:** Clear assignment of responsibility for AI decisions, with mechanisms for audit, redress, and continuous oversight[32].
- **Fairness and Non-discrimination**: Ensures AI does not perpetuate bias or inequality, reinforcing justice and equity as central goals[33].
- **Privacy and Data Protection**: Emphasizes responsible data stewardship, confidentiality, and compliance with regulatory standards for sensitive health information[34].
- **Safety and Robustness:** AI systems must perform reliably and safely, with robust risk mitigation and harm prevention measures in place[35].

2.5.3 Collaborative and Multi-stakeholder Models

AI governance theory acknowledges the need for collaborative frameworks involving individuals, organizations, regulators, and society at large. Self-regulatory guidelines, public policy, and legal instruments work in tandem to operationalize ethical principles and make them enforceable across diverse settings[36].

[30] *Ibid*.
[31] DUALITY, https://dualitytech.com/blog/ai-governance-framework/ (last visited Nov. 16, 2025)
[32] *Ibid*.
[33] *Ibid*.
[34] *Ibid*.
[35] *Ibid*.
[36] ACADEMIC, https://academic.oup.com/ppmg/advance-article-abstract/doi/10.1093/ppmgov/gvaf013/8186962?redirectedFrom=fulltext (last visited on Nov. 16, 2025)

By grounding ethics in robust theories and evolving, pluralistic governance models, AI in healthcare can be guided toward outcomes that are not only innovative and effective but also just, safe, and deeply respectful of human rights and societal values[37].

3. Analysis / Discussion

3.1 Current Scenario / Context

Artificial Intelligence is increasingly being woven into healthcare systems, aiding in areas like diagnostics, predictive analytics, robotic surgery, patient monitoring, and administrative decision-making. As hospitals and policymakers advocate for digital health, AI-powered tools are being utilized for quicker decision-making, greater accuracy, and better patient outcomes. However, the swift growth of AI has surpassed current legal and ethical frameworks. While regulators recognize AI's transformative potential, there is an ongoing discussion on how to implement safeguards without hindering technological progress. Currently, healthcare institutions rely on a combination of internal protocols, government guidelines, and emerging sector-specific regulations to guide AI adoption[38].

3.2 Key Issues / Challenges

The implementation of AI in healthcare presents several ethical, legal, and technical challenges:

- **Algorithmic Bias and Discrimination** – AI systems trained on limited or biased data may lead to skewed clinical decisions, disproportionately impacting vulnerable populations.
- **Opacity and Lack of Transparency** – Many AI models function as "black boxes," making it challenging to comprehend the basis of algorithmic recommendations or errors.
- **Accountability Gaps** – Traditional legal frameworks do not clearly define who is responsible for harm caused by AI-assisted healthcare decisions: doctors, hospitals, developers, or device manufacturers.
- **Data Privacy and Security Risks** – AI systems require extensive datasets containing sensitive health information, heightening the risk of breaches, unauthorized use, or commercial exploitation.

[37] UNESCO, https://www.unesco.org/en/artificial-intelligence/recommendation-ethics (last visited on Nov. 16, 2025)
[38] *Ibid*.

- **Informed Consent Challenges** – Patients may be unaware of AI tools' involvement in diagnosis or treatment, limiting their ability to make informed decisions.
- **Ethical Tensions** – AI may create scenarios where human judgment is overshadowed by machine outputs, raising concerns about autonomy, dignity, and human oversight.

3.3 Legal or Policy Analysis

Several legal and policy mechanisms address or attempt to regulate AI use in healthcare:

- **Statutory Frameworks**

  Existing health privacy and data protection laws govern the handling of medical information used by AI systems. These laws emphasize confidentiality, informed consent, and lawful data processing. Additionally, medical device regulations increasingly consider AI-driven tools under risk-based classifications.
- **Rules and Guidelines**

  Government bodies and health authorities have issued guidelines on safe AI deployment, focusing on transparency, risk assessment, ethical compliance, and patient protection. These rules recommend internal audits, algorithmic testing, and human oversight mechanisms.
- **Judicial Principles**

  Courts emphasize standards such as duty of care, negligence liability, and product safety when evaluating disputes involving AI technologies. Though case law on AI is still developing, judicial reasoning tends to prioritize patient welfare and professional responsibility.
- **Institutional Mechanisms**

  Hospitals and healthcare institutions now establish AI ethics committees, data protection units, review boards, and technical oversight bodies to ensure compliance with ethical and legal standards. These mechanisms monitor system performance, address grievances, and maintain accountability.

4. RECOMMENDATIONS

1. **Create a thorough legal framework for artificial intelligence in healthcare.**

   There is a need for domain-specific law that establishes explicit standards for AI deployment, validation, liability, and patient. A special piece of legislation pertaining to AI deployment, validation, liability, and patient rights is required. Developers,

hospitals, and regulatory bodies should all be required to comply with this framework.

2. **Algorithmic Mandate Explainability and Transparency**

   Medical professionals must be able to comprehend the decision-making processes of AI systems employed in clinical contexts. To promote accountability, regulatory bodies ought to mandate transparency disclosures, risk justifications, and algorithmic logic documentation.

3. **Enhance data protection and privacy safeguards.**

   Healthcare organizations should use robust encryption, anonymization, and rigorous data access protocols. Regulatory enforcement must ensure that patient data used for AI training is obtained legally, treated ethically, and protected from unlawful use or commercial exploitation.

4. **Develop clear liability and accountability standards.**

   Laws should define liability in circumstances when AI-assisted judgments cause harm. A shared or tiered liability model could be used, allocating responsibility to developers, medical practitioners, and institutions based on their role in the decision-making process.

5. **Implement ethical AI audits and continuous monitoring.**

   Regular ethical and technical audits should be required before and after implementing AI tools in healthcare. Monitoring should consider bias, accuracy, patient risk, and ethical compliance to ensure that systems remain safe and dependable over time.

6. **Promote Human Oversight in Decision-Making**

   Qualified healthcare professionals should supervise the use of AI systems. Policies should require human experts to make ultimate clinical judgments, maintaining patient autonomy and avoiding overreliance on automated technology.

7. **Improve healthcare professionals' training.**

   Medical practitioners should obtain specific training in AI technology, ethical considerations, data security, and risk assessment. This capacity-building will promote responsible use and reduce the misuse or misinterpretation of AI outcomes.

8. **Create institutional AI ethics committees.**

   Prior to using AI technologies, hospitals should organize internal committees to review them. These groups can oversee ethical compliance, patient consent difficulties, and resolving processes for AI-related challenges.

9. **Ensure patient-centered policies and informed consent.**

   Patients must be notified when AI systems are used in diagnosis or treatment. Clear

standards should need unambiguous, understandable consent that describes the risks, benefits, and AI's participation in medical decisions.

10. **Encourage Global and National Collaboration.**

    Collaboration among government agencies, international health organizations, technologists, and bioethicists can help to unify standards, share best practices, and address cross-border difficulties associated with AI in healthcare.

5. CONCLUSION

The use of artificial intelligence into healthcare represents one of the most major technical shifts of the contemporary period, with prospects to increase diagnostic accuracy, clinical decision-making, and overall healthcare delivery. However, this revolutionary potential raises difficult ethical and legal issues that cannot be overlooked. Issues including data privacy, algorithmic bias, accountability gaps, and reduced human control underline the critical need for strong safeguards.

This analysis reveals that existing legal frameworks are not adequately ready to manage the particular hazards posed by AI-driven medical systems. Although numerous norms and institutional processes exist to monitor AI use, they are scattered and reactive. As a result, if AI tools are not properly regulated, patient rights, ethical values, and trust in healthcare may be jeopardized.

To guarantee that AI promotes rather than threatens ethical medical practice, a comprehensive and forward-thinking regulatory strategy is required. Clear liability rules, strong data protection standards, transparent algorithms, and required human monitoring can all help to assure patient safety and respect key bioethical objectives. Finally, appropriate governance, ongoing monitoring, and interdisciplinary collaboration will determine whether AI is a technology that improves healthcare justice or introduces new vulnerabilities.

AI's future in healthcare must be built on ethics, accountability, and respect for human dignity—only then will its benefits be fully realized while protecting both patients and the integrity of the medical profession.