Volume 4/Issue 11/ November 2026 International Journal of Modern Science and Research Technology
ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

The Future of AI Healthcare Governance: Towards a Risk- Based Liability Framework

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I. INTRODUCTION

Artificial Intelligence (AI) is transforming healthcare delivery, but would you ever trust it more than your doctor? AI tools are being used for taking patient notes, doing predictive diagnosis and even robotic surgeries. They are shaping healthcare by making it more accessible and efficient. But they must be used with caution. Healthcare AI tools can show bias and raise concerns about data privacy and patient consent. The human touch is essential in health care,and AI tools are meant to assist, not replace, doctors.

To effectively integrate artificial intelligence into healthcare, we need a risk-based framework which clearly outlines categories of risk while deploying AI and allocation of liability, given the extremely sensitive nature of the healthcare industry. However, existing legal frameworks governing medical liability don't address this. This paper first examines the types of AI systems in healthcare and the legal problems associated with this deployment. It will also address the new way of looking at the standard of care, medical negligence and consent in healthcare. After examining the existing regulations, it will propose a risk-based framework for AI healthcare.

II. AI IN HEALTHCARE

2.1 Types of AI Systems in Healthcare

Artificial Intelligence systems in healthcare can be broadly classified into diagnostic tools, virtual assistants, robotic care systems, and robotic surgery platforms. These categories reflect both the functional diversity and the varying degrees of autonomy with which these AI systems operate. These categories will later form part of the proposed risk-based healthcare frame work,with AI systems classified into low, medium and high-level risk.

Diagnostic AI: The most sophisticated and popular form of AI in health care is diagnostic AI. These systems perform disease detection and prediction aided by machine learning and deep learning to process and analyse large volumes of data, including radiological images, genomic data, and electronic health records. As per the World Health Organisation (WHO), the application of AI in health care is rapidly evolving, with oncology imaging, dermatology ,pathology, and ophthalmology being the most promising. In certain scenarios, AI systems can perform diagnostic imaging, patient screening, and disease prognosis at a level comparable to that of human expert clinicians. Predictive analytics also help to identify cardiovascular diseases and diabetes earlier, thereby transforming the health care system from a reactive to a more preventive approach.[1]

Virtual assistants and AI-driven decision support systems: For patients, AI-enabled chatbots and digital health apps assist with symptom checking, medication adherence, and self-management of chronic conditions. For clinicians, these systems integrate patient information, identify high-risk patients, and assist in treatment decision-making. The WHO states that such systems may increase efficiency; however, there is a concern regarding "automation bias" ,where clinicians become too dependent on AI recommendations.[2]

Robotic care systems: Robotic care systems are being used more frequently in caregiving ,especially in elder care and rehabilitation. These systems are helping with routine monitoring, mobility assistance, and even companionship. AI-enabled wearables and remote monitoring are technologies that shift the focus of care from hospitals to the home, enabling continuous monitoring and just-in-time interventions. While this increases access to care, the issues of surveillance and data privacy are concerning.[3]Robotic surgery systems: This is an intermediate solution that combines human expertise with AI-controlled precision. Although the current systems remain largely controlled by surgeons, the addition of AI, real-time analytics and motion stabilisation enhances the precision and success of surgeries. There is an indication that robotic surgeries are more precise and efficient than their human counterparts, as the robotic arm has the ability to move in many more directions than the human arm. However, the traditional limits of duty and responsibility are becoming more and more blurred as these systems acquire greater autonomy.[4]

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All these AI systems demonstrate a paradigm shift whereby the human doctor-centric model is replaced by a data-driven model. The safe and effective implementation of AI in healthcare systems requires strong supervision, proper training, and ongoing assessment.[5]

2.2 Legal Problems

AI deployment in healthcare has several legal issues like data privacy, consent, the black box problem and bias and fairness. The implementation of these technologies can be life- threatening to people unless we seek solutions to these problems.

2.2.1 Data Privacy: According to statistics, 63 per cent of US adults mention the risks of

Data security as a significant factor in the implementation of AI in healthcare.6 Th[e] adoption of AI in healthcare raises significant concerns about the privacy of data, which, in the first place, is based on vast amounts of sensitive information about patients.
Medical records are often reused for non-clinical purposes, whether as research ,training algorithms, or commercial, and this is often done without the express knowledge or permission of the patient. Anonymised datasets are still vulnerable to re-identification. Moreover,the use of cloud services and third-party platforms increases the likelihood of a data breach. It has been found that doctors are not always clear on the regulatory boundaries of such data use, which can be traced to the wider gaps in the legal frameworks and accountability mechanisms.[7]

2.2.2 Consent: AI use in healthcare introduces a new layer of complexity to the concept of

Informed consent, in particular, about disclosure and data privacy, as discussed above .In the Indian context, the recent Digital Personal Data Protection Act (hereinafter DPDP Act)8· 2023 addresses obligations of data fiduciary while collecting data. Section 6 of the DPDP Act is the provision for consent. It states that data principal should give free, specific and informed consent with regard to their personal data.[9] It also provides for the right to withdrawal of consent at any time and the obligation of the data fiduciary to stop processing the data. Section5[10] talks about the notice requirement by the data fiduciary to the data principal for consent taken under section 6. The notice should disclose the purpose of processing personal data, the manner in which the data principal makes a complaint or exercises rights under section 6.[11] Even though this doesn't specifically target the healthcare sector, the data collected is personal data under the DPDP Act. These provisions could be utilised to support the proposed risk-based framework in this paper. The data collected and processed by AI healthcare devices should becompliant with this Act.

Studies have found that usually patients would prefer to be informed when AI is somehow involved in diagnosing them or treating them, but there is no standard for what information should be provided and to what extent it is sufficient. This uncertainty poses difficulties to healthcare providers, especially when AI plays a supportive or advisory role. Additionally, obtaining meaningful consent necessitates conveying the risks and limitations of AI, which can be challenging due to its intricate nature. Consequently, there is a risk that the consent process may become more about procedure than true understanding, thereby compromising patient autonomy.[12]

For example, how does one draw a clear line where consent begins and ends in an AI-embedded robotic surgery, which is operated by a surgeon, but the arm is robotic? Or what if a doctor signs off on a diagnosis given by an AI diagnostic machine, which later turns out to be false? In situations like these, where the role of doctor and AI is so intertwined, we need to rethink
and reframe how patient consent is taken.

2.2.3. Bias and Fairness: AI systems in healthcare bring forth significant concerns about bias and fairness, mainly because they depend on historical data that is often unrepresentative. Biases present in datasets, algorithms, and the broader healthcare framework can lead to unfair outcomes, such as incorrect diagnoses and unequal treatment across demographic groups. This is especially acute when AI systems are trained on data that does not sufficiently cover some groups of people, reducing the accuracy of at-risk groups and reinforcing existing health disparities. These biases are not only technical mistakes, but also point out bigger system issues that AIs can reproduce and worsen. Therefore, the application of biased AI systems poses a risk to undermining the principles of equity and equality within the healthcare industry.[13]

2.2.4. Liability: When something goes wrong, and a patient gives their consent, who is responsible for such an AI-healthcare intersection? The black box problem of AI systems is that it is hard to determine how an AI made a specific decision. The issue inside the system can't be pinpointed, making it impossible to repair and improve.

The introduction of AI into the clinical decision-making process makes the liability attribution extremely difficult because it is no longer the responsibility of a single person. Conventionally,clinicians have been subject to the negligence law, but with AI-assisted treatment decisions, the burden is distributed among clinicians, software developers, and healthcare organisations.Clinicians often face legal liability, even though they have limited control over the design and functioning of AI systems. This leads to the disconnect between

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

control and accountability,where developers are able to influence clinical decision-making situations but without direct liability. It might not be fair, just, or reasonable to make clinicians the sole bearers of liability,implying the necessity of shared or joint liability models that better reflect the collaborative process in AI-assisted healthcare.[14]

The AI-based healthcare applications have several legal dilemmas, as explained above. Even though there are different legal frameworks in place, like the European Union Artificial Intelligence Act[15] (hereinafter EU AI Act), to ensure safe AI and data usage. It does not have a particular framework governing and determining the levels of risk of AI use in healthcare.

III. STANDARD OF CARE & MEDICAL NEGLIGENCE

The introduction of artificial intelligence into healthcare practice has already started to undermine the basis of medical negligence. The existing legal regimes, based on human judgment and individual accountability, are becoming increasingly tense when there is a shared accountability between clinicians and algorithmic systems. This part discusses how AI makes the quality of care, burden of proof, and liability attribution more problematic in the current negligence law.

3.1 Traditional Medical Negligence

The law on medical negligence has traditionally been based on the Bolam test[16], according to which a doctor is not negligent when his or her actions are consistent with a responsible body of medical opinion (Bolam v Friern Hospital Management Committee [1957] 2 All ER 118). The doctrine was also developed further in Bolitho v City and Hackney Health Authority [1998] AC 232, where the court held that such professional opinions had to pass the logical test as well.

A combination of these requirements presupposes that clinical decisions are taken by individual professionals based on their own judgment. Consequently, the paradigm is essentially physician-focused, resting on personal experience and responsibility, which is not consistent with the changing nature of healthcare.

3.2. AI and change in the standard of care:

AI-driven CDSS[17] alter the structure of clinical decision-making by combining algorithmic logic with medical opinion. These systems are not just useful; they affect clinical outcomes by making suggestions that clinical practitioners can rely on, unlike traditional tools. The result of this is that there is a grey zone between the independent professional judgment and decisions driven by technology, which puts the underlying principles of the medical negligence law in question.[18]

The current legal norms, especially the Bolam and Bolitho tests, do not fit well into this change, as it is assumed that the clinical choices are based on human reasoning that can be explained and questioned. Conversely, AI systems are black boxes, and it is hard to determine whether the use of such systems is justifiable or whether a clinician has made a different decision. This leaves the assessment of professional conduct and a decision on whether the standard of care has been met in doubt. Additionally, although doctors are theoretically in charge of decision- making, in practice, they might rely on AI output, particularly in cases where AI systems are viewed as more accurate or evidence-based. This creates a conflict between autonomy and the technological reliance of doctors and questions the ability of doctors to significantly ignore algorithmic recommendations. Lastly, AI makes the issues of accountability and causation complex since courts might not be able to know whether the harm is caused by the trust placed in AI by the clinician or the malfunctioning of the system itself. [19]

IV. EXISTING REGULATORY AND GOVERNANCE FRAMEWORKS

4.1 The EU AI Act The EU AI Act[20] is the first comprehensive, binding legislation worldwide on AI, covering its development and use throughout its life cycle. It classifies AI systems, depending on the risk level, into four categories: unacceptable, high, limited and minimal. It also subjects the use of AI in diagnostic imaging, clinical decision support and surgical robotics to mandatory conformity assessment, transparency requirements, and post-market monitoring, placing them in the high-risk category in Annex III.[21]

Despite its importance, the Act has three aspects relevant to healthcare. It is a market regulation measure that regulates pre-deployment safety, but expressly relies on civil liability rules of Member States and the proposed AI Liability Directive, as of yet unadopted as of this writing in 2025.[22] Second, its level of granularity for risk classification is not enough for clinical use. The same classification of "high risk" for all diagnostic AI carries with it the assumption that everything that the AI flags for a clinician to review is the same risk profile and degree of human oversight, as well as accountability. Third, the Act does not cover the assessment of the standard of care of a clinician in an environment where AI is being used, nor does it discuss the distribution of liability between the institution, AI developers and clinicians. These are not incidental "gaps", they are missing parts of the system that leave the most significant legal issues in the field of healthcare AI completely unaddressed.

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

4.2 WHO Guidance

The six principles of AI governance in health from the WHO framework of 2021 are: Promote wellbeing, Protect autonomy, Ensure transparency, Promote accountability, Ensure equity, and Promote sustainable AI. These principles give a normative basis, and the responsibility of translating them into laws and regulations is given to the national and regional authorities by the WHO itself. The framework is unable to address issues of civil liability, to adjust the standard of care doctrine and to define the distribution of responsibility if patients are harmed as a result of AI-supported health care. It's not a legal solution, it's an ethical one. [23]

4.3 Existing Gap

The combined analysis of the EU AI Act and WHO guidance reveals a structural gap in the existing governance of healthcare AI. First, there is a regulatory gap, i.e. no binding instrument classifies AI healthcare tools according to their specific clinical risk, degree of autonomy, and potential for irreversible patient harm to guide deployment decisions in clinical settings.Second, there is a liability gap wherein no instrument specifies how responsibility for AI-related harm should be distributed among developers, healthcare institutions, and individual clinicians. Third, the foundational concept of standard of care in medical negligence law has not been formally adapted to the changing dynamics of AI-based decision-making in healthcare.

The risk-based framework proposed in this paper will likely address the lacunae identified above. It does not intend to replace the current regulatory tools, but rather to complement them.The proposed framework has taken inspiration from the EU AI Act, which gives risk-based AI tiers. At the same time, it intends to fill the gaps left by the Act, to give meaning to the ethical principles set out in the WHO, and to create a clear framework for the courts, clinicians and developers, to understand their respective duties and liabilities.

V. THE PROPOSED RISK-BASED FRAMEWORK FOR AI IN HEALTHCARE

5.1 Rationale for the Framework

There are three premises for the framework. First, in the healthcare sector, the category of risk that is appropriate for an AI-powered scheduling tool is completely different from that for an AI-powered diagnostic system. Secondly, it is not only the design choices and deployment decisions that interact, but also clinical judgment, resulting in the harm occurring in a process that is rarely the responsibility of a single player. Third, patient autonomy is a right, as is recognised by law, and AI systems that conceal the fundamentals of clinical decisions are a challenge to patient autonomy. These premises are supported by Scherer's argument that the present tort law assumes a human agent with actions that can be evaluated against a reasonable care standard, which is not applicable where the AI system is the "direct cause" of the injury.[24]

5.2 Tier One: Low-Risk AI

The first tier relates to AI tools that are used for administrative or informational purposes, but not directly for clinical decision-making. These include tools for transcription, appointment scheduling, medication reminders, and patient communication chatbots. These systems process sensitive information and connect with patients, but do not generate any clinical information that influences or limits the diagnosis or treatment of patients. The classification criteria are:

- Autonomous clinical output – none
- Direct patient safety consequence – none unless there is an intervening human decision
- Human review of all output – prior to clinical action being taken

Under the ordinary employer liability principle, the healthcare institution is considered the deploying party and thus liable as Tier One. Tier Two is given to the healthcare institution as the data processor under the liability on this side. Developer liability only attaches when the developer has a system defect, apart from misuse or inappropriate deployment, which causes damage. Patients should be informed that their data is being processed by an AI software, and relevant data regulation frameworks should be followed to handle such data.

5.3 Tier Two: Medium-Risk AI

The second level focuses on AI that provides input to clinical decision-making, but does not replace it. These include Clinical Decision Support Systems (CDSS), diagnostic imaging AI that alerts clinicians to abnormalities, and remote monitoring platforms that alert clinicians.

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

The classification criteria include:

- An AI output is sent to a clinician who still has the final say.
- The AI system provides at least partial interpretability, i.e., it can indicate which aspects of the input data led to its recommendation, even when full interpretability is not achievable. The final criterion is a direct response to the black-box issue mentionedabove, meaning that partial explainability is a requirement.

Tier Two is a shared liability. If a clinician performs an action recommended by the AI that causes harm, the responsibility must be shared between the clinician (for not using proper independent judgment) and the developer (for failing to validate or be transparent). This model supports that responsibility in an AI-assisted environment is truly distributed and that models that do not account for this will systematically misallocate responsibility. Courts should distribute liability on a "contributory basis" similar to the concepts of contributory negligence and not require the clinician alone to be held liable.

If a Tier Two AI is deployed, there must be a clear disclosure of such usage and a clear explanation of the role of the AI and its limitations, as well as its known error rates. The disclosure requirement following Montgomery v Lanarkshire Health Board is based on patient autonomy, where the doctor is expected to disclose the risks, reasonable alternatives and whatever a reasonable patient would want to know.[25] For care using artificial intelligence, disclosure must not only be made of the use of AI but also the role that AI played in the care, the reliability of the AI and whether there is an alternative without AI.

5.4 Tier Three: High-Risk AI

AI systems with high autonomy in clinical relevance are included in the third tier, which includes fully autonomous diagnostic AI. AI-integrated robotic surgery platforms with real-time intraoperative decision-making, and AI systems for treatment planning with limited clinician input.

The classification criteria are:

- The system generates outputs which directly affect or significantly limit the clinical actions that could be taken without independent override.
- A failure of the system could cause irreversible consequences such as death orpermanent disability.

Primary responsibility for Tier Three is with developers and healthcare institutions. Clinician liability is limited to cases where the clinician was furnished with sufficient information and had ample opportunity to disregard the AI and did not do so for inadequate reasons. This allocation is based on the principle that if the AI system is complicated, opaque, and commercial, the primary legal risk should be on the clinician, who has minimal ability to access the inner workings of the system. It also tackles the ‘moral crumple zone' problem that Elish highlighted[26], where the legal system passes on responsibility for the harm to the human individual closest to the harm, which means that those in control of the technology are shielded from its effects.

Tier Three systems should be held to high standards of liability for foreseeable harm from system failure, just as the revised EU Product Liability Directive (2024/2853)[27] proposes for software and AI systems, which, for the first time, brings product liability into this realm. Before deployment, there is an obligation to carry out the bias audit in all demographic sub-populations of the intended population. There is an obligation to test in adverse scenarios, or test at the edge of the problem of failure and an obligation to conduct audit tests independently from the third party to review explainability mechanisms. Consent requirements are equally rigorous: patients need to be told how autonomous the AI is, what is known about its failures and errors, and whether there are any ways to access the system without the use of AI, as well as who the developer is and who will be held legally responsible.

5.5 Reconceptualising the Standard of Care

Formally reconceptualising the standard of care is required by the framework. The Bolam Test is inadequate to evaluate clinical practice that is significantly influenced by an AI system whose reasoning is not understandable, and whose outputs cannot be subjected to cross-examination. As Xiong and Chow[28] have pointed out, a Bolitho gloss, one that demands that professional opinion be capable of being logically challenged, is especially inappropriate for decisions made with the help of AI, because the very element that is required for dispute (the basis of the AI's opinion) is missing.

Instead, the framework suggests a dual approach of care that will be followed in all three tiers.The first limb is: Did the AI system operate within the bounds of its validated parameters? This is a technical question that needs expert evidence to determine system design

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

and performance benchmarks. The second limb was to determine if the clinician's response to the AI outputs was consistent with a reasonably competent clinician who was working in an AI-integratedenvironment. It also tests whether they used independent judgment and were sensitive to the possibility of automation bias. This system provides a degree of accountability to the clinician,encourages the development of accurate and transparent AI tools, and provides courts with principles to distribute liability in the "multi-actor" contexts that AI-enabled healthcare brings.

VI. CONCLUSION

The legal landscape must adapt to how AI is changing clinical decision-making. The Bolamand Bolitho tests are based on explicable individual judgment, but do not assess actions in settings where algorithmic systems produce opaque, statistically-based outputs. While the EU AI Act focuses on pre-deployment safety but doesn't cover post-harm liability. The WHO framework does not impose legal requirements. This leaves the current scenario with no accountability, no liability, and no protection for the patient.To tackle this, the proposed framework classifies AI in the healthcare industry into three levels based on the clinical independence, explainability, and patient safety of the tools. It assigns liability as per individual control over the AI system and its results. The framework is not meant to be an end in itself. However, with the rapid advancement of AI, a regulatory framework must be continually updated to keep pace with the evolving capabilities and autonomy of AI systems. It is, however, a necessary foundation, legally grounded and specific to the health care sector, which fills the spaces left by the existing instruments.

ACKNOWLEDGEMENT

I would like to extend my deepest appreciation to everyone who has assisted and guided me during the entire process of writing this research paper. Firstly, I would like to offer my sincere gratitude to my faculty mentor, Mr Nikhil Naren, for his constant guidance, feedback, and encouragement during my ideation, research and writing. I would also like to thank O.P. Jindal Global University and Jindal Global Law School for providing me with all the required facilities for this research work.I am thankful to my parents for their unwavering encouragement and support. Finally, my sincere thanks are due to my dear friends, Kuhoo Bhavya Sahay and Yashvendra Pandey, for their encouragement and advice, which helped me to improve my outlook.

REFERENCES

Footnotes

[1]. 1 World Health Organisation, Ethics & Governance of Artificial Intelligence for Health (2021), 6
[2]. https://www.who.int/publications/i/item/9789240029200.
[3]. 2 Ibid 9.
[4]. 3 Gareth Francis, '6 Ways that Robotics are Transforming Healthcare' (World Economic Forum, 12 June
[5]. 2025) https://www.weforum.org/stories/2025/06/robots-medical-industry-healthcare/ accessed 7 May 2026.
[6]. 4 Jack Ng Kok Wah, 'The Rise of Robotics and AI-Assisted Surgery in Modern Healthcare' (2025) 19 Journal of
[7]. Robotic Surgery 311, https://pmc.ncbi.nlm.nih.gov/articles/PMC12181090/.
[8]. 5 Id.
[9]. 6 The Hidden Legal Risks in Healthcare AI Implementation: What Medical Practice CEOs Need to Know,
[10]. Michael Best (Aug 12, 2025), https://www.michaelbest.com/insights/the-hidden-legal-risks-in-healthcare-ai-
[11]. implementation-what-medical-practice-ceo-102kzcy/.
[12]. 7 Neel Yadav, Data Privacy in Healthcare: In the Era of Artificial Intelligence, 14 Indian Dermatology Online J.
[13]. 788 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10718098/.
[14]. 8 Digital Personal Data Protection Act 2023.
[15]. 9 Ibid, S. 6.
[16]. 10 Ibid, S. 5.
[17]. 11 Ibid.
[18]. 12 Hye Jin Park, Patient perspectives on informed consent for medical AI: A web-based experiment, (2024), 1-2
[19]. https://pmc.ncbi.nlm.nih.gov/articles/PMC11064747/.
[20]. 13 Tuan Pham, Ethical and legal considerations in healthcare AI: innovation and policy for safe and fair use, 12
[21]. Royal Society Open Science 241873 (2025), 4-5, https://doi.org/10.1098/rsos.241873.
[22]. 14 Id.
[23]. 15 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 (EU AI Act).
[24]. 16 A. Samanta & J. Samanta, Legal Standard of Care: A Shift from the Traditional Bolam Test, Clinical Med. 443
[25]. (2003), https://pmc.ncbi.nlm.nih.gov/articles/PMC4953641/.
[26]. 17 Malek Elhadded and Sara Hamam, 'AI-Driven Clinical Support Systems: An Ongoing Pursuit of Potential'
[27]. (2024) 16(4) Cureus, https://pubmed.ncbi.nlm.nih.gov/38711724/.

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

[28]. 18 Lauren Xiong & Timothy Chow, Cloud on the Horizon: Why Medical Negligence Needs to Take a New
[29]. Approach to AI-Driven Medical Decisions, Oxford U. Undergraduate L.J.
[30]. (2025), https://www.law.ox.ac.uk/sites/default/files/inline-
[31]. files/11.%20Cloud%20on%20the%20Horizon_%20Why%20Medical%20Negligence%20Needs%20to%20Take
[32]. %20a%20New%20Approach%20to%20AI-Driven%20Medical%20Decisions%20-
[33]. %20Lauren%20Xiong%20%26%20Timothy%20Chow.pdf.
[34]. 19 Id.
[35]. 20 EU AI Act.
[36]. 21 EU AI Act, Annex III, para 5.
[37]. 22 Philipp Hacker, 'The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for
[38]. the Future' (2023) 51 Computer Law & Security Review 105871, 1-2
[39]. https://www.sciencedirect.com/science/article/pii/S026736492300081X .
[40]. 23 Ibid [1].
[41]. 24 Matthew Scherer, 'Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and
[42]. Strategies' (2016) 29 Harvard Journal of Law and Technology 353,
[43]. https://jolt.law.harvard.edu/articles/pdf/v29/29HarvJLTech353.pdf .
[44]. 25 Montgomery v Lanarkshire Health Board [2015] UKSC 11, [87].
[45]. 26 Madeleine Clare Elish, 'Moral Crumple Zones: Cautionary Tales in Human-Robot Interaction' (2019) 5
[46]. Engaging Science, Technology and Society 40,
[47]. https://www.researchgate.net/publication/351054898_Moral_Crumple_Zones_Cautionary_Tales_in_Human-
[48]. Robot_Interaction, accessed 8th May 2026.
[49]. 27 Regulation (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for
[50]. defective products.
[51]. 28 Xiong and Chow (n 13).

ANNOTATED BIBLIOGRAPHY

Cases

1. Bolam v Friern Hospital Management Committee [1957] 2 All ER 118This is the landmark case laying down the "Bolam Test" for medical negligence. This is used to establish the existing standard of negligence in the medical sector and what needs to be changed with the integration of AI in healthcare.
2. Bolitho v City and Hackney Health Authority [1998] AC 232This is the landmark which evolved the Bolitho test, wherein a doctor's medical opinion should have logical reasoning. This is used in the same relevance as the Bolam Case.
3. Montgomery v Lanarkshire Health Board [2015] UKSC 11This case is fundamental to medical consent and is used to emphasise that patients should have complete information before giving consent to AI-based healthcare devices.

Legislation

1. Digital Personal Data Protection Act 2023The DPDP Act is the principal data protection regulation in India. It is used to describe consentwhile processing healthcare data.
2. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June2024 laying down harmonised rules on artificial intelligence (Artificial IntelligenceAct)The EU AI Act serves as an essential regulation as it proposes a risk-based framework for AI
3. deployment. The paper also proposes a risk-based framework, but it's specific to healthcare and has drawn inspiration from the model of the AI Act.
4. Regulation (EU) 2024/2853 of the European Parliament and of the Council of 23October 2024 on liability for defective products
5. The EU Product Liability Act makes the manufacturer liable for defective products, and nowit also includes AI software. It is the suggested framework for the allocation of liability to manufacturers of AI Healthcare systems.

Journal Articles

1. Elhadded M and Hamam S, 'AI-Driven Clinical Support Systems: An Ongoing Pursuit of Potential' (2024) 16(4) Cureuse The article discusses Clinical Decision Support Systems (CCDS) and the integration of AI in CDSS. It's used to elaborate on how AI-based CCDS functions in today's world.
2. Elish MC, 'Moral Crumple Zones: Cautionary Tales in Human-Robot Interaction' (2019) 5 Engaging Science, Technology and Society 40 The concept of moral crumple zones is used in this paper to address why the doctors should not bear the sole responsibility in case of an AI malfunction. Responsibility should be dividedamong all stakeholders

ISSN :2584-2706 DOI: https://doi.org/10.67317/IJMSRT26NOV055

3. Hacker P, 'The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future' (2023) 51 Computer Law & SecurityReview 105871 This paper analyses and critiques the AI Liability Directive and Product Liability Directive. It supports the claim that current frameworks aren't adequate to tackle AI in healthcare.
4. Ng Kok Wah J, 'The Rise of Robotics and AI-Assisted Surgery in Modern Healthcare'(2025) 19 Journal of Robotic Surgery 311
5. The article talks about AI Robots used for surgery and used to define the same as a category ofAI deployment in healthcare.
6. Park HJ, 'Patient Perspectives on Informed Consent for Medical AI: A Web-Based Experiment' (2024) Park's paper talks about his survey in South Korea to know how patients perceive consent in medical AI. It is used to advance the argument that medical AI should have high patient autonomy and proper disclosures.
7. Pham T, 'Ethical and Legal Considerations in Healthcare AI: Innovation and Policy for Safe and Fair Use' (2025) 12 Royal Society Open Science 241873 This policy paper talks about the ethical ways to deploy Healthcare AI and addresses issues of bias, fairness and transparency. It is relied upon to explain the issue of bias and fairness.
8. Samanta A and Samanta J, 'Legal Standard of Care: A Shift from the Traditional Bolam Test' (2003) Clinical Medicine443 The article explains the transition from Bolem to Bolitho Test by the U.K. courts and how it shapes the legal standard of care. It's usedto define both of these tests in this paper.
9. Scherer M, 'Regulating Artificial Intelligence Systems: Risks, Challenges,Competencies, and Strategies' (2016) 29 Harvard Journal of Law and Technology 353 Scherer's article examines the present challenges to tort law with the advancement of AI systems. Thisisusedas the base of liability allocation to AI systems in the proposes risk basedframework.
10. Xiong L and Chow T, 'Cloud on the Horizon: Why Medical Negligence Needs to Take
11. a New Approach to AI-Driven Medical Decisions' Oxford University Undergraduate
12. Law Journal (2025)
13. Xiaong and Chow emphasise the new approach towards the medical negligence principle after
14. AI integration. It is used to support the need for a new standard of care and what it should look
15. like.
16. Yadav N, 'Data Privacy in Healthcare: In the Era of Artificial Intelligence' (2023)
17. 14 Indian Dermatology Online Journal 788
18. The source highlights data privacy concerns in AI Healthcare, like patient data and its uses. It
19. is used to support the argument that AI deployment has serious data concerns which need to be
20. addressed.

Reports

1. 17. World Health Organization, Ethics and Governance of Artificial Intelligence for
2. Health (WHO 2021)
3. The WHO Guidance is referred to define the types of AI systems in Part 2.1 of this paper. The
4. definitions of diagnostic AI and virtual assistants have been taken from Part III of the guidance.
5. The Guidance is also referred to as a whole in Part 4.2 to identify the lacunae in existing
6. frameworks.

Online Sources

1. 18. Francis G, '6 Ways that Robotics are Transforming Healthcare' (World Economic Forum, 12 June 2025) https://www.weforum.org/stories/2025/06/robots-medical-industry-healthcare/ accessed 7 May 2026This talks about AI robotics helping to deliver elder care and rehabilitation. It's used to explain the concept of robotic care systems.
2. 19. Michael Best, 'The Hidden Legal Risks in Healthcare AI Implementation: WhatMedical Practice CEOs Need to Know' (12 August2025)https://www.michaelbest.com/insights/the-hidden-legal-risks-in-healthcare-ai-implementation-what-medical-practice-ceo-102kzcy/ accessed 7 May 2026This source explains the legal risks and challenges of implementing AI in healthcare. It's used to support a statistics in the paper.