Adapting to the Future: Redefining Duty of Care and Liability in Light of the Rise of Artificial Intelligence in Healthcare

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Abstract

This research examines the complex legal landscape surrounding duty of care, liability, and accountability in the context of Artificial Intelligence (AI) integration in healthcare. As AI systems become increasingly involved in medical practices and clinical decision-making, their unique characteristics, such as opaque "black box" decision-making and lack of human-like reasoning, pose significant challenges to existing legal frameworks. The study highlights the inadequacy of medical negligence laws in addressing AI-related incidents in healthcare and the potential of vicarious liability, product liability, the concept of the “reasonable computer”, and transparency regulations in addressing AI errors. The findings emphasise the importance of ongoing regulatory adaptation to ensure that legal frameworks evolve with advancements in AI technology, ultimately safeguarding the interests of patients and healthcare practitioners.

Keywords: Artificial intelligence, healthcare, liability, medical negligence, vicarious liability, product liability, transparency, algorithmic bias

1. Introduction

The integration of Artificial Intelligence (AI) into healthcare systems has catalysed a transformative era, one brimming with potential to revolutionise patient care and medical practices. AI technologies are being leveraged to automate clinical workflows, enhance diagnostic capabilities, and refine treatment decision-making processes through the analysis of medical data, including imaging scans, patient records, and genomic information. This approach empowers healthcare professionals to make more informed decisions and deliver tailored care to patients. However, the advent of AI in this domain brings forth new dynamics that prompt critical inquiries into the ethical and legal considerations surrounding whether clinicians can truly fulfil their duty of care

when relying on AI for diagnostic and treatment recommendations. The doctrine of duty of care, a cornerstone of medical practice, has traditionally hinged on human expertise, empathy, and accountability. Artificial Intelligence, in contrast, can be defined as the property of machines, computer programs, and systems to perform the intellectual and creative functions of a person, independently finding ways to solve problems, be able to draw conclusions, and make decisions.[1] As such, the emergence of AI systems challenges long-standing norms and raises questions about the ability of healthcare providers to uphold their legal obligations when AI plays an increasingly prominent role in clinical decision-making.

This article delves into the intricate interplay between AI and healthcare standards, scrutinising the implications for legal frameworks and accountability standards. The research conducts a critical examination of whether tort law is sufficiently equipped to handle the complexities and potential liabilities arising from the use of AI in healthcare or if new legal provisions are necessary to address the unique challenges posed by these emerging technologies.

The article begins by analysing the potential of medical negligence to determine accountability when harm is caused in situations where AI is used in healthcare. Highlighting potential challenges, the article turns to vicarious and product liability as two legal frameworks that could complement medical negligence in this context to hold those responsible to account for harm caused. The analysis demonstrates that traditional tort law is not equipped to handle the complexities arising from the use of AI in healthcare. Therefore, in a third step, the article considers adaptations of tort law as well as new regulations as possibilities to close the accountability gap.

2. Clinical Negligence and the Duty of Care of the Reasonable Practitioner

The foundational principles for determining clinical negligence – and with that accountability standards in healthcare settings – stem from the case of *Hunter v Hanely*.[2] It sets forth three essential criteria that must be proven: 1) That there is usual practise; 2) that the clinician did not adopt that practise; and 3) that the course the

[1] Jahanzaib Shabbir and Tarique Anwer, 'Artificial Intelligence and Its Role in near Future' (2015) 14(8) Journal of Latex 1.
[2] Hunter v Hanley (1955 SLT 213).

clinician adopted is one which no professional of ordinary skill would have taken if he had been acting with ordinary care.

The concept of duty of care originated from the landmark case *Donoghue v Stevenson*.[3] Lord Atkin's declaration in the case stated that everyone must exercise reasonable care to prevent acts or omissions likely to cause harm. It sets the stage for patients being owed a duty of care by clinicians in situations where harm is reasonably foreseeable, considering risks known to, or that ought to have been known by, the practitioner.[4] This means that healthcare professionals are under legal obligations to provide a certain standard of care to their patients, ensuring that they are not harmed by the healthcare provider's actions or inactions.[5] This includes practitioners' responsibility to provide patients with information about material risks associated with any treatment, thereby allowing them to give informed consent.[6]

The standard of care that healthcare practitioners have to provide is that of a reasonable professional, a competent practitioner in their field. This is known as the Bolam test.[7] According to this test, if a doctor's actions align with a responsible body of medical opinion, they are not negligent, even if other doctors might disagree.

However, the law has evolved to provide more scrutiny. In the case of *Bolitho v City and Hackney Health Authority*,[8] the court stated that even if a doctor follows accepted medical practice, this practice must still be logical and defensible. In other words, courts can question whether the standard practice itself is reasonable. *Bolitho*[9] further determined that expert opinions must have a reasonable and logical basis to be admissible in court, allowing for scrutiny and questioning of illogical or inadequate views. The Bolitho amendment, therefore, exposes the vulnerability of the Bolam test defence if expert opinions or adherence to standard practise appear illogical, irrational, unsupported, or inadequate upon examination.

[3] Donoghue v Stevenson [1932] AC 562.
[4] Linda Sheahan and Scott Lamont, 'Understanding Ethical and Legal Obligations in a Pandemic: A Taxonomy of "Duty" for Health Practitioners' (2020) 17 Journal of Bioethical Inquiry 697.
[5] NJ McBride, 'Duties of Care--Do They Really Exist?' (2004) 24 Oxford Journal of Legal Studies 417.
[6] Rogers v Whitaker [1992] 175 CLR 479 at 490.
[7] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582.
[8] Bolitho v City and Hackney Health Authority [1997] 4 All ER 771.
[9] Ibid.

In addition to standard practice and expert opinion, the case of *Wilsher v Essex Area Health*[10] established that the duty of care could be discharged by seeking assistance from a senior knowledgeable colleague. The rise of the use of AI in healthcare poses the question whether it could be possible for a clinician to discharge their duty of care by referring to AI technology for assistance.

AI assistance might align with Lord Macmillan's observations in the case of *Glasgow Corporation v Muir*.[11] He stated that the reasonable professional test is an impersonal standard that presumes a balanced perspective without excessive apprehension or reckless overconfidence. He notes that while some individuals may be unduly timorous, others fail to foresee or nonchalantly disregard even the most obvious danger. The reasonable professional is thus presumed to be free from such extremes of over-apprehension and overconfidence.

Legal precedents such as the landmark case of *Montgomery v Lanarkshire Health Board*[12] underscore the crucial role of informed consent in the realm of medical care. The ruling dictates that, if there is a significant risk capable of influencing a reasonable patient's decision about their treatment options, it is the responsibility of the doctor to communicate that risk to the patient. As AI technologies become more integrated into medical practices, there arises the need for doctors to also apprise patients of any relevant risk or implications with the use of AI in their diagnosis or treatment. However, identifying this risk correctly may be challenging and affect the duty of care. The difficulty in identifying and communicating AI-related risks could compromise a healthcare provider’s ability to fulfil their duty of care, potentially leading to inadequate informed consent and exposing patients to unforeseen harms or legal liabilities. This indicates that, as the healthcare landscape undergoes evolution, there is a pressing need for considerations regarding duty of care and medical negligence standards to flexibly adapt to the dynamic interplay between AI technologies and traditional medical practices.

[10] Willsher v Essex Area Health Authority [1988] 1 AC 1074.
[11] Glasgow Corporation V Muir [1943] 2 AC 448.
[12] Montgomery v Lanarkshire Health Board [2015] UKSC 11.

3. AI in Healthcare: Opportunities and Obstacles

Originating from the 1950s when early attempts were made to enhance medical diagnoses through computer-aided programs,[13] AI has witnessed significant advancements in recent years, propelled by the significant growth in computing power and the availability of vast digital datasets. This evolution has led to an expanding interest in AI applications within medicine and health, particularly in clinical decision-making and disease diagnosis. Traditionally, health professionals have been at the forefront of guiding decision-making for patients in healthcare settings. Jeffrey De Fauw states the emergence and cautious implementation of AI systems in the healthcare sector represent a new and non-human element in the process of clinical decision-making.[14] According to Hamid, AI technologies have the capacity to process and analyse large volumes of medical data from various sources, enabling the detection of diseases and offering guidance for clinical decisions.[15] By leveraging medical big data, AI applications can uncover hidden patterns and insights, facilitating the development of innovative treatments and healthcare management strategies.

Although the prospect of AI in medicine is promising, further research is required to validate its efficacy and explore its diverse applications. As Gerke highlights, the key challenge surrounding AI integration involves determining liability when these complex systems contribute to patient harm.[16] A recent STAT investigation found Epic System's Artificial Intelligence algorithms are delivering inaccurate or irrelevant information to hospitals about the care of seriously ill patients.[17] This investigation shows the risk of AI. If an AI algorithm makes a wrong prediction that dissuades further testing, this can result in a delayed diagnosis and patient injury. Furthermore, with no current legal

[13] Xia Yang and others, 'Concepts of Artificial Intelligence for Computer-Assisted Drug Discovery' (2019) 119(18) Chemical Reviews 10520.
[14] Jeffrey De Fauw and others, 'Clinically Applicable Deep Learning for Diagnosis and Referral in Retinal Disease' (2018) 24 Nature Medicine 1342.
[15] Sobia Hamid, 'The Opportunities and Risks of Artificial Intelligence in Medicine and Healthcare' (2016) <https://www.cuspe.org/wp-content/uploads/2016/09/Hamid_2016.pdf> accessed 11 September 2024.
[16] Sara Gerke, Timo Minssen, and Glenn Cohen, 'Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare' (2020) 1 Artificial Intelligence in Healthcare 295.
[17] Casey Ross, 'Epic's AI Algorithms, Shielded from Scrutiny by a Corporate Firewall, Are Delivering Inaccurate Information on Seriously Ill Patients' (*STAT*, 26 July 2021) <https://www.statnews.com/2021/07/26/epic-hospital-algorithms-sepsis-investigation/?utm_campaign=stat_plus_today&utm_medium=e6mail&_hsmi=143907479&_hsenc=p2ANqtz-8GWuvAgo9uiPOj583cPOE8plPk02eCtAY_lOjpX6L7lA_N7cU7kAqmVYe1ani> accessed 20 March 2024.

framework for harm by AI established, there is the question of who will bear responsibility, which is further complicated by the "black box" problem, where AI's complex decision-making processes remain opaque to users.

4. The Legal Implications of AI's "Black Box" Problem and Algorithmic Bias

As AI possesses the capability to learn and adapt its outputs through machine learning, this has the potential to lead to complex decision-making that appears opaque to non-expert users, conversationally referred to as a "black box".[18] Machine learning algorithms used in medicine are often opaque "black boxes" that predict and make recommendations that even their designers cannot fully explain. Bathaee explains that, while the input and output decisions are known, the exact steps the AI has taken to come to its conclusion cannot be retraced.[19] Most cutting-edge AI techniques such as deep learning utilise neutral networks that self-optimise at depths incomprehensible to humans. This results in AI systems that are capable of incredible achievements, yet unable to explain the logic behind their decisions.

The deficiency in explaining ability within AI systems presents profound legal implications in the realm of healthcare. In critical areas such as diagnosing illness, formulating treatment plans, and predicting patient outcomes, Nicholson Price highlights that the inability to comprehend or validate the reasoning behind AI decisions may hinder the assessment of issues related to clinician negligence or vendor product defects.[20] The lack of transparency and explicability surrounding how AI algorithms arrive at their outputs or recommendations poses a significant hurdle in determining whether the AI's actions or decisions can be considered reasonable or defensible within the context of accepted medical practices.[21] And while foreseeability is relatively straightforward in traditional medical negligence cases where physical injuries are the typical outcome, it becomes considerably more complex in AI-related

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[18] Siddhartha Mukherjee, 'A.I. Versus M.D.: What Happens when Diagnosis is Automated?' *The New Yorker* (27 March 2017) <https://www.newyorker.com/magazine/2017/04/03/ai-versus-md> accessed 11 September 2024.
[19] Yavar Bathaee, 'The Artificial Intelligence Black Box and the Failure of Intent and Causation' (2018) 31 Harvard Journal of Law & Technology 889.
[20] W Nicholson Price and I Glenn Cohen, 'Privacy in the Age of Medical Big Data' (2019) 25 Nature Medicine 37.
[21] Ryan Benjamin Abbott, 'The Reasonable Computer: Disrupting the Paradigm of Tort Liability' (2018) 86(1) George Washington Law Review.

scenarios. The intricate decision-making processes of AI systems make it challenging to predict or attribute specific outcomes to their recommendations. Consequently, healthcare providers may argue that they could not reasonably anticipate the consequences of following AI-generated treatment plans, thereby potentially absolving themselves of liability. When an AI diagnostic tool fails to identify an illness that a doctor could have recognised, the determination of liability hinges on whether the AI application was reasonably implemented, appropriately designed, and transparent enough for any shortcomings to be identified. Consequently, Lauritsen et al recognise transparency and explainability are a necessity for introducing AI into clinical practice.[22] As they note, clinicians must be able to understand the underlying reasoning of AI models so they can trust the predictions and be able to identify individual cases in which an AI model potentially gives incorrect predictions. The lack of transparency inherent in these AI "black boxes", however, directly challenges established medical duty of care standards and complicates questions surrounding liability.

The opacity of AI systems also raises broader concerns about fairness and equality in healthcare delivery. A pivotal concern in the integration of AI systems in healthcare lies in the frequent manifestation of algorithmic bias where these systems mirror prejudiced data inputs or biased practices from their developers. Bias in AI systems presents a significant challenge to healthcare providers' duty of care, potentially leading to discriminatory treatment and breaches of legal and ethical obligations. If biased AI denies treatment opportunities or exacerbates impacts for protected groups, developers could face prosecution under equality laws.[23] This bias can directly conflict with healthcare providers' duty to act in patients' best interests and provide equal, non-discriminatory care. An illustration of the potential harm induced by such bias is exemplified by an AI-driven pulse oximeter, which, by overestimating blood oxygen levels in individuals with darker skin, led to the undertreatment of hypoxia.[24] This

[22] Simon Meyer Lauritsen and others, 'Explainable Artificial Intelligence Model to Predict Acute Critical Illness from Electronic Health Records' (2020) 11 Nature Communications 3852.
[23]Ivana Bartoletti and Raphaële Xenidis, 'Study on the Impact of Artificial Intelligence Systems, their Potential for Promoting Equality, Including Gender Equality, and the Risks they may Cause in Relation to Non-Discrimination' (2023) <https://rm.coe.int/study-on-the-impact-of-artificial-intelligence-systems-their-potential/1680ac99e3> accessed 20 March 2024.
[24] Andrew Gregory and Alex Hern, 'AI Poses Existential Threat and Risk to Health of Millions, Experts Warn' *The Guardian* (10 May 2023) <https://www.theguardian.com/technology/2023/may/10/ai-poses-existential-threat-and-risk-to-health-of-millions-experts-warn> accessed 11 September 2024.

scenario illustrates how AI bias can result in substandard care for certain patient groups, potentially breaching the healthcare provider's duty to deliver appropriate and equitable treatment. Another example was presented in a study by Jabbour. The study explored the impact of integrating AI models, alongside image-based AI model explanations, on clinicians' diagnostic accuracy and unveiled intriguing insights. When clinicians were presented with patient clinical vignettes accompanied by standard AI model predictions and explanations, a significant 4.4% boost in diagnostic accuracy was observed compared to baseline performance. However, the introduction of systematically biased AI model predictions resulted in an 11.3% decline in diagnostic accuracy, and notably, the inclusion of model explanations failed to mitigate these detrimental effects.[25] This illuminates the complex trade-offs between explaining ability and performance in medical AI systems, underscoring the need for rigorous safeguards before clinical integration. In essence, AI bias not only risks compromising patient care but also places healthcare providers in a precarious position where they may unknowingly breach their duty of care. Addressing this issue requires rigorous testing and validation of AI systems, ongoing monitoring for bias, and maintaining human oversight to ensure that the use of AI aligns with healthcare providers' legal and ethical obligations to their patients. Healthcare leaders must proactively assess AI for embedding unfairness before deployment and continually audit for discrimination, in case reliance on flawed automation exacerbates biases.

In addition to diagnostics and treatment, the opacity and potential bias of AI systems can also impact healthcare providers' ability to fulfil their duty of informed consent. The European Union Agency for Fundamental Rights stated that, if clinicians cannot comprehend biased AI's reasoning, this obstructs their ability to probe recommendations, communicate transparently with patients around decisions, or intervene in possible algorithmic discrimination.[26] This lack of transparency and explainability directly challenges healthcare providers' duty to provide patients with clear, comprehensible information about their treatment options and associated risks. Implementing biased AI in care decisions without adequate transparency or validation

[25] Sarah Jabbour and others, 'Measuring the Impact of AI in the Diagnosis of Hospitalized Patients: A Randomized Clinical Vignette Survey Study' (2023) 330 JAMA 2275.
[26] The European Union Agency for Fundamental Rights, 'Bias in Algorithms: Artificial Intelligence and Discrimination' (2022) <https://fra.europa.eu/sites/default/files/fra_uploads/fra-2022-bias-in-algorithms_en.pdf> accessed 11 September 2024.

steps may breach the fundamental duty of healthcare providers to act objectively in the best interests of their patients. It undermines the trust relationship between healthcare providers and patients, potentially leading to ethical violations and legal liabilities.[27]

5. Vicarious Liability and Product Liability

These ethical and legal challenges surrounding AI's "black box" nature and algorithmic bias inevitably lead to a critical question: When AI systems are involved in medical decision-making, who bears the responsibility when things go wrong? The discussion above highlighted that the integration of AI systems in healthcare poses significant challenges to the existing legal frameworks governing medical negligence. Could liability be attributed to employers and manufacturers through vicarious and product liability?

Vicarious liability, also known as the doctrine of respondent superior, holds employers liable for the negligent acts of their employees.[28] The main purpose of applying vicarious liability to AI systems is to balance acknowledging AI's independent activity while ensuring a legally recognised entity remains responsible for its acts. By treating AI as an agent, liability is effectively channelled to the legally recognised principal exercising control over the AI, such as the developer, deployer, or end-user, aligning with established principal-agent legal principles. This could be used in the context of AI errors as healthcare organisations that employ or deploy AI systems may be held vicariously liable for errors or harm caused by these systems in the same way as they are currently liable for the negligence of their clinicians.

However, the complexity arises when AI systems are developed and deployed by third-party vendors or technology companies.[29] For example, in the case of IBM Watson for Oncology,[30] the question of vicarious liability hinged on the relationship

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[27] Qian Yang, Aaron Steinfeld, and John Zimmerman, 'Unremarkable AI: Fitting Intelligent Decision Support into Critical, Clinical Decision-Making Processes' [2019] Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems.
[28] Nicholas J McBride and Roderick Bagshaw, *Tort Law* (6th edn, Pearson 2018) 829.
[29] George Maliha and others, 'Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation' (2021) 99(3) The Milbank Quarterly 629.
[30] Angela Chen, 'IBM's Watson Gave Unsafe Recommendations for Treating Cancer' (*The Verge*, 26 July 2018) <https://www.theverge.com/2018/7/26/17619382/ibms-watson-cancer-ai-healthcare-science> accessed 11 September 2024.

between the healthcare provider and the AI system. Establishing vicarious liability in this scenario required demonstrating that IBM Watson was acting within the scope of its intended use and that the healthcare provider exercised reasonable care in its implementation, which is evidence that the system did not act within its scope as it provided wrong recommendations and treatment for cancer patients. As discussed above, while healthcare providers may rely on AI-generated recommendations as part of their decision-making process, the opacity of AI systems challenges traditional notions of agency and accountability. If a healthcare provider follows inaccurate AI recommendations that result in patient harm, allocating vicarious liability becomes less clear, as the system operates independently of direct human control.[31]

In addition to vicarious liability, product liability might be used to attribute liability for AI-related harm in healthcare. Product liability is where the manufacturer can be held liable for defective design, manufacturing, or inadequate warnings related to their products. The European Union's (EU) Product Liability Directive[32] serves as a cornerstone for holding manufacturers accountable for defective products. This framework emphasises that producers or suppliers bear the responsibility for ensuring that their products are safe and fit for their intended purpose. Similarly, under the UK Consumer Protection Act 1987,[33] the burden of liability for defective products falls squarely on the shoulders of the producer or supplier.

In the context of AI-driven healthcare technologies, this would mean that companies developing and supplying AI systems are legally obligated to ensure that their products meet safety standards and perform as expected. Importantly, the definition of product liability encompasses not only physical defects but also failures to provide adequate warnings or instructions about the reasonable use of the product. Thus, manufacturers must provide clear and comprehensive guidance to users to mitigate the risk of harm. For example, if IBM was implemented in hospitals and IBM failed to adequately warn healthcare providers about the limitations or risks associated with using the system, it could strengthen the argument for product defectiveness.

[31] European Commission, 'Liability for Artificial Intelligence' (2019) <https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/JURI/DV/2020/01-09/AI-report_EN.pdf> accessed 11 September 2024.
[32] Council Directive for Product [1985] OJ L 210/29–33.
[33] Consumer Protection Act 1987.

However, the application of product liability principles to AI systems is complex. It requires demonstrating specific defects or failures in the AI technology as well as proof that the harm caused by a product was reasonably foreseeable to the manufacturer. This may be challenging given the opacity, complexity, and unpredictability of AI decision-making processes.[34] Furthermore, the rapid development of scientific and technical knowledge provides a challenge to the foreseeability of harm. Consequently, Article 7(e) of the EU's Product Liability Directive[35] provides an exemption for producers if the state of scientific and technical knowledge at the time of product circulation was insufficient to foresee the existence of a defect. Applied to AI in healthcare, this provision suggests that producers of AI systems may not be held liable for unforeseeable errors or defects resulting from limitations in scientific understanding or technological capabilities at the time of development. However, this exemption should be balanced against Article 1 which states that producers are liable for damage caused by defects in their products.[36] In the case of AI in healthcare, this means that producers could still be held accountable for the harm caused by AI errors or defects, even if they were unforeseeable at the time of development.

However, the established legal doctrine known as the learned intermediary doctrine presents a barrier to direct lawsuits against medical device manufacturers.[37] This doctrine traditionally holds that plaintiffs cannot directly sue manufacturers of medical devices, instead requiring them to seek recourse through the healthcare professionals who prescribe or administer the device.

Unlike conventional medical devices, however, AI systems often operate autonomously, making decisions without direct human intervention. As a result, the traditional intermediary role of healthcare professionals may be diminished or even removed in certain AI-driven contexts. In this context, manufacturers and developers of AI systems may face increased responsibility to provide clear and comprehensive warnings and disclosures directly to end-users within healthcare, particularly for AI

[34] McBride and Bagshaw (n28) 362; Anastasiya Kiseleva, Dimitris Kotzinos, and Paul De Hert, 'Transparency of AI in Healthcare as a Multilayered System of Accountabilities: Between Legal Requirements and Technical Limitations' (2022) 5 Frontiers in Artificial Intelligence.
[35] Council Directive for Products (n 32).
[36] Ibid.
[37] Scott J Schweikart, 'Who will be Liable for Medical Malpractice in the Future? How the use of Artificial Intelligence in Medicine will Shape Medical Tort Law' (2021) 22 Minnesota Journal of Law, Science & Technology 1.

systems that operate with a high degree of autonomy or make critical decisions without human intervention.

6. Closing the Accountability Gap

The analysis of AI applications through the lenses of negligence, vicarious liability, and product liability principles reveals the potential erosion of traditional legal doctrines and therefore the need for adapting and evolving current legal paradigms. Ultimately, the increased use of AI in healthcare requires a multifaceted approach to reconciling its transformative potential with the imperative of preserving patient safety and upholding foundational legal principles.

As the above discussion demonstrates, AI systems become part of the overall duty of care owed by healthcare providers to patients. Therefore, healthcare providers owe a duty of care to patients to ensure AI tools that are relied upon meet safety and performance standards before use. From Jones's research it is evident that healthcare providers must exercise reasonable care and skill expected at their level of expertise when determining whether and how much to rely on AI guidance.[38] The Bolam/Bolitho framework that expects doctors to follow responsible, logically valid medical opinion can also apply to judging appropriate dependence on AI assistance. Smith suggests that the Bolam standard could be adapted to assess a duty of care based on the reasonable reliance on AI.[39] Courts may also build on the Caparo criteria[40] and analyse factors like foreseeable harm, the proximity of relationship, and the fairness of imposing a duty to determine if and how liability frameworks should adapt to account for this new AI context. Furthermore, AI-related liability disputes will require new precedent setting case law to balance the interests of different parties and establish proportional accountability, appropriately allocating responsibility across clinicians, institutions, and AI systems.[41]

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[38] Caroline Jones, James Thornton, and Jeremy C Wyatt, 'Artificial Intelligence and Clinical Decision Support: Clinicians' Perspectives on Trust, Trustworthiness, and Liability' (2023) 31(4) Medical Law Review 501.
[39] Helen Smith and Kit Fotheringham, 'Artificial Intelligence in Clinical Decision-Making: Rethinking Liability' (2020) 20 Medical Law International 131.
[40] Caparo Industries v Dickman and Others [1990] 2 AC 605.
[41] Haytham Siala and Yichuan Wang, 'SHIFTing Artificial Intelligence to Be Responsible in Healthcare: A Systematic Review' (2022) 296 Social Science & Medicine 114782.

Courts could also apply the legal doctrine of res ipsa loquitur, which is Latin for 'the thing speaks for itself',[42] to AI error cases. This doctrine holds that the mere occurrence of an accident implies negligence, without the need to delve into the specific details of how the negligence occurred. In healthcare, res ipsa loquitur in cases involving apparent errors attributable to AI systems could stem from the significant control exerted by developers and operators over these systems. Just as in manufacturing processes where employees oversee production, healthcare professionals and developers oversee the design, implementation, and operation of AI in medical settings.[43] In the context of AI errors, the application of res ipsa loquitur could potentially avoid the challenges posed by the "black box" theory and the opacity of AI decision-making processes. Under this approach, if an AI system causes harm or produces an undesirable outcome, the system or its designers could be held liable, without the need to understand the specific reasoning behind the AI's decision. By applying strict liability to AI error cases, it could incentivise developers and organisations to prioritise safety and risk mitigation in the design and deployment of AI systems. However, the application of res ipsa loquitur to AI error cases could affect innovation, as organisations may become hesitant to develop and deploy AI technologies due to concerns over potential liability. Additionally, there are concerns that this approach could lead to overcompensation or disproportionate liability in cases where the harm caused by an AI system was unforeseeable or unavoidable.

In addition to holding clinicians, employers, and manufacturers to account, the autonomous nature of AI systems raises the question whether they themselves could be held responsible for their actions.[44] They exercise non-human agency but lack personhood and consciousness in their decision-making, operate based on algorithms and data inputs, and lack moral agency or subjective reasoning.[45] Considering these challenges, Abbott has proposed the concept of "reasonable computer" as a potential solution.[46] This framework suggests evaluating AI actions against what a rational AI

[42] LexisNexis PI & Clinical Negligence expert, 'Res Ipsa Loquitur Definition' (2024) <https://www.lexisnexis.co.uk/legal/glossary/res-ipsa-loquitur-#:~:text=What%20does%20Res%20Ipsa%20Loquitur> accessed 11 September 2024.
[43] Grant v Australian Knitting Mills [1935] 54 CLR 49; Fletcher v Toppers Drinks Pty Ltd [1981] 2 NSWLR 911; Suthern v Unilever Australia Ltd [2007] ACTSC 81.
[44] Rafael Dean Brown, 'Property Ownership and the Legal Personhood of Artificial Intelligence' (2020) 30 Information & Communications Technology Law 208.
[45] Bathaee (n 19).
[46] Abbott (n21).

system would do in similar circumstances. However, how can we define what constitutes reasonable behaviour for an AI system when its decision-making processes are driven by complex algorithms and vast datasets that may diverge significantly from human expectations and reasoning? Moreover, AI systems are designed to learn and adapt, often surpassing human capabilities in certain domains. This evolutionary nature of AI technology poses a significant challenge to the notion of a reasonable computer. Nevertheless, the implications of this concept extend beyond assessing AI systems. In practice, it could also affect how we evaluate human decisions made in conjunction with AI tools. The notion of reasonableness in the context of negligence law is deeply rooted in human psychology, ethics, and societal norms.[47] In practise, this would mean that, instead of judging a defendant's actions against what a reasonable person would have done, the defendant would be judged against what a computer would have done.[48] For example, imagine a scenario where a healthcare professional is faced with a medical issue where swift action is crucial, and they have access to an AI-powered diagnostic tool. If a competent clinician would reasonably make similar diagnostic and treatment decisions given the circumstances, they might not be held accountable for any adverse outcomes. However, if we adopt a reasonable computer standard, the evaluation changes. If the AI system could have provided a more accurate diagnosis or effective treatment plan, the clinician might face liability for not adhering to the AI's superior judgment.

In addition to adapting current legal paradigms, the UK could adopt regulations like the EU AI Act, which introduces centralised transparency obligations for all general-purpose AI models. This approach recognises the inherent opacity of AI algorithms and seeks to mitigate it by requiring AI systems to provide explanations for their actions and decisions,[49] and high-risk AI systems to undergo conformity assessments and be accompanied by detailed documentation.[50] This offers standardised and rigorous transparency measures across the EU member states, which could provide clarity and

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[47] Benjamin C Zipursky, 'Reasonableness in and out of Negligence Law' (2015) 163 University of Pennsylvania Law Review 2131.
[48] Abbott (n21).
[49] Giacomo Lusardi, 'FinTech: Who Is Responsible if AI Makes Mistakes when Suggesting Investments?' (*IPT Italy*, 11 June 2019) <https://blogs.dlapiper.com/iptitaly/2019/06/fintech-who-is-responsible-if-ai-makes-mistakes-when-suggesting-investments/> accessed 29 March 2024.
[50] Debbie Heywood, 'To Legislate, or Not to Legislate on AI? The UK Government Thinks it has the Answer' (5 March 2024) <https://www.taylorwessing.com/en/insights-and-events/insights/2024/02/radar-to-legislate-or-not-to-legislate-on-ai--the-uk-government-thinks-it-has-the-answer#:~:text=As%20the%20EU%27s%20AI%20Act> accessed 2 April 2024.

assurance for healthcare practitioners and patients alike. Proponents of the EU's approach argue that, by shedding light on the reasoning behind AI outputs, users and regulators can better understand and evaluate AI behaviour. This transparency could potentially alleviate some of the difficulties in assessing reasonableness and assigning liability in AI error cases. The transparency obligations introduced by the EU AI Act could potentially help in preserving and clarifying duty of care roles in situations where AI systems are involved, thereby mitigating the impact of AI on the traditional duty of care principles. The transparency requirements outlined in the EU AI Act could help address this issue by providing greater clarity and insight into the decision-making processes of AI systems.[51] By mandating that AI systems provide clear explanations and documentation on their characteristics, capabilities, and limitations, stakeholders involved in the development, deployment, and use of these systems would have a better understanding of the AI's role and potential impact.

In the UK, the AI White Paper and subsequent response to consultations emphasises transparency through principles such as appropriate transparency (providing clear, understandable, and relevant information about an AI system's capabilities, limitations, and decision-making processes) and explainability.[52] This approach places responsibility on relevant regulators to ensure that AI systems used in healthcare adhere to these principles, thereby fostering a culture of accountability and governance within the sector. However, this sector-focused approach might result in varying implementation of these principles, potentially leading to variations in transparency standards and practices across the healthcare landscape.

In addition to adopting regulations like the EU has to mandate transparency for AI algorithms used in medical settings, regulations could establish mechanisms for ongoing monitoring and evaluation of AI systems to identify and address potential risks or defects as they arise. By adopting regulations that consider the complexities of AI in healthcare, policymakers can promote the responsible development and use of AI technology while safeguarding patient welfare. This approach would help address

[51] European Commission, 'AI Act' (29 September 2022) <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai> accessed 11 September 2024.
[52] Department for Science, Innovation & Technology, 'Implementing the UK's AI Regulatory Principles: Initial Guidance for Regulators' (2024) https://assets.publishing.service.gov.uk/media/65c0b6bd63a23d0013c821a0/implementing_the_uk_ai_regulatory_principles_guidance_for_regulators.pdf accessed 11 September 2024.

concerns related to the “black box” nature of AI systems and ensure that AI-driven medical interventions adhere to the highest standards of safety and efficacy. The importance of such regulatory mechanisms is underscored by recent research highlighting the potential pitfalls of AI in medical applications. Research from the University of Cambridge and Simon Fraser University[53] devised a series of tests for medical image reconstruction algorithms based on AI and deep learning. This revealed a wide collection of artifacts and significant errors in the resultant images. For any AI algorithm to be dependable, it requires both accuracy and stability. This research shows that critical details like tumours may be lost or erroneously added, obscuring important information and introducing unwanted objects into the image. This can be most concerning especially for radiologists if they misconstrued an image as actual medical issues rather than mere technical glitches. Healthcare professionals may still have a duty of care to exercise reasonable judgment in relying on AI systems, much like they do with other medical technologies and guidelines. However, as AI systems become more autonomous, the duty of care may shift more towards the developer and manufacturers of these systems to ensure their safety, reliability, and appropriate use. Healthcare organisations may have a duty of care in properly vetting, implementing, and overseeing the use of AI systems within their facilities, like their responsibilities for other medical equipment and technologies. AI developers and manufacturers may bear an increased duty of care in ensuring the safety, transparency, and ethical development of their systems, as well as providing adequate training, warnings, and support to end-users.

However, rather than enacting new AI-specific legislation, the UK framework tasks existing regulators with interpreting and applying five core principles within their respective domains using current laws and regulations The principles are: safety, security, and robustness; appropriate transparency and explainability; fairness; accountability and governance; and contestability and redress.[54] Key UK regulators like the Competition and Markets Authority and Information Commissioner's Office will publish strategic plans by 30 April 2024, detailing how they will operationalise the AI

[53] University of Cambridge, ‘AI Techniques in Medical Imaging may lead to Incorrect Diagnoses’ (12 May 2020) <https://www.cam.ac.uk/research/news/ai-techniques-in-medical-imaging-may-lead-to-incorrect-diagnoses> accessed 11 September 2024.
[54] Department for Science, Innovation & Technology, ‘AI Regulation: A Pro-Innovation Approach’ (29 March 2023) <https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach> accessed 11 September 2024.

principles.[55] The UK Government believes enshrining fixed rules would be premature given the rapidly evolving AI landscape.

7. **Conclusion**

In conclusion, the integration of AI in healthcare presents both unprecedented opportunities and complex challenges to existing legal and ethical frameworks. This research has highlighted the pressing need for adaptive legal approaches to address the unique issues posed by AI in medical settings, particularly regarding duty of care, liability, and accountability. The analysis of regulatory approaches and proposed legal adaptations underscores the inadequacy of current tort liability frameworks in fully addressing AI-related incidents in healthcare. As AI systems continue to evolve and play an increasingly significant role in medical decision-making, it is imperative that legal and regulatory frameworks evolve alongside. The adaptation of medical negligence, vicarious and product liability laws, the concept of a "reasonable computer", and the adoption of transparency regulations offer promising avenues for addressing AI errors, but further refinement and testing are necessary.

Moving forward, a balanced approach that fosters innovation while safeguarding patient safety and rights will be crucial. As we navigate this complex landscape, the ultimate goal must remain clear: to harness the potential of AI to improve patient outcomes while maintaining the highest standards of care and accountability in healthcare delivery.

[55] Michelle Donelan and Kemi Badenoch, ‘Letter from DSIT and DBT Secretaries of State to the Competition and Markets Authority’ (15 February 2024) <https://www.gov.uk/government/publications/request-for-regulators-to-publish-an-update-on-their-strategic-approach-to-ai-secretary-of-state-letters/letter-from-dsit-and-dbt-secretaries-of-state-to-the-competition-and-markets-authority-html> accessed 21 March 2024.

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