UK Regulation of AI in Healthcare: A Comparative Study of UK and EU AI Governance in Healthcare Systems

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Introduction

Artificial intelligence (AI) is rapidly reshaping UK health policy as it becomes increasingly embedded in medical practice, aligning with the Government's long-term Plan for Change, which seeks to modernise the NHS through technological innovation (Cabinet Office, n.d.). Initiatives such as the NHS's 10-Year Health Plan and the New Commission's mission to accelerate AI adoption further position the UK as a leading global health-tech hub (Department for Health and Social Care, 2023). Leveraging emerging technologies promises improved clinical outcomes and economic growth; however, this rapid integration also risks outpacing the development of coherent safeguards (European Commission, 2024).

AI is advancing at an extraordinary speed and is now widely integrated into healthcare, where tasks that once required human intelligence can now be performed by AI systems (Uysal, 2025). By learning from large datasets, AI can transform medical records into precise diagnoses and optimizing diagnostic efficiency, by supporting abnormality detection, improving patient classification, and reducing error (Uysal, 2025). Moreover, AI improves patient flow, reduces waiting times, and automates administrative tasks, allowing clinicians to devote more time to patient care (Denniston et al., 2025).

These productivity gains are accompanied by reductions in inefficiencies, unnecessary services, and clinical errors (Royal Society, 2024). However, the rapid expansion of AI introduces significant regulatory challenges, raising ethical and legal concerns about liability, data privacy, accountability, transparency, and algorithmic bias (Royal Society, 2024). As General-Purpose AI Models (GPAI) become more sophisticated and evolve post-approval, the need for clear and adaptive governance intensifies (Medicines and Healthcare products Regulatory Agency, 2024a). Regulatory gaps will risk undermining public and clinical trust, thus, ensuring safe and trustworthy deployment will require multidisciplinary collaboration and robust regulatory frameworks for the UK to sustain its leadership in responsible AI adoption (Department for Health and Social Care, 2023).

Patients may refuse AI involvement due to fear, misinformation, or concerns that it could endanger their health, even when AI improves diagnosis or saves lives (Uddin, 2025). AI trials across the NHS—including large-scale collaborations with Microsoft UK and machine learning support for chemotherapy—demonstrate the UK's commitment to healthcare innovation (National Health Service England, n.d.). Additional national initiatives, such as AI Growth Labs and AI screening programmes, further illustrate this momentum (Department for Science, Innovation & Technology, 2024). There is

growing evidence of successful integration, with the UK and other countries making significant contributions and pioneering applications such as AI-powered clinical decision systems (Uddin, 2025).

The New Commission, in collaboration with the MHRA, is developing a new regulatory rulebook to address ethical and legal gaps that may hinder innovation. Their focus includes establishing accountability frameworks and regulatory models that balance innovation with patient safety and protection (Medicines and Healthcare products Regulatory Agency, 2024a). This paper compares key dimensions of the UK and EU regulatory approaches, identifies governance gaps, and proposes a framework to strengthen safety, equity, and trust in AI-assisted healthcare.

Understanding AI in Healthcare: Main Legal and Ethical Challenges

Research on AI in healthcare often prioritizes outcomes such as accuracy and efficiency while overlooking clinicians' critical insights into system limitations (Denniston et al., 2025). AI's ability to detect hidden patterns and deliver real-time insights enhances diagnostics, optimizes treatment pathways, and streamlines operations, where early detection improves survival, as demonstrated in medical imaging and oncology (Health Education England, n.d.-a). Applications also extend to personalized medicine, drug development, robotic surgery, and administrative automation (European Commission, 2024).

However, significant ethical, legal, and technical challenges persist. Barriers such as data privacy and security, algorithmic bias, transparency, and accountability hinder widespread adoption. Additionally, inadequate training and limited understanding among clinicians undermine both effective use and trust in these technologies (Uddin, 2025).

Transparency and explainability remain central ethical concerns, as many systems function as "black boxes" whose internal reasoning is difficult or impossible to interpret (Royal Society, 2024). Transparency is essential for informed consent and clinician oversight, ensuring patients understand the role and limitations of AI in their care (World Health Organization, 2021).

Accountability is likewise complex. While traditional responsibility rests with clinicians, AI complicates attribution when decisions involve both human and machine input (Royal Society, 2024). It remains highly debated whether a misdiagnosis involving AI would result in clinical negligence claims against clinicians or liability attributed to the system itself—and, if so, to what extent (Burton, 2025). Determining liability among developers, regulators, and clinicians is a critical challenge for legal and ethical governance (Royal Society, 2024).

Algorithmic fairness and data privacy present additional concerns. Accurate and reliable AI outputs depend on high-quality, standardized data; incompatibilities can undermine system accuracy and

introduce uncertainty into clinical decisions (Uysal, 2025). Biased training data, for example, can amplify systemic inequalities and disproportionately affect marginalized populations (Denniston et al., 2025). Promoting fairness and equity requires diverse, representative datasets and rigorous monitoring throughout development and deployment (Health Education England, n.d.-a). Addressing these issues—along with implementing comprehensive legal regulations for health data—is essential to maintaining stakeholder confidence and ensuring safe, equitable AI integration.

Ultimately, to realize the full potential of AI in healthcare, stakeholders must address these intertwined ethical, legal, and technical challenges through robust policy, comprehensive training, and rigorous oversight.

UK Regulatory Landscape

Since Brexit, the UK has begun shaping its own AI regulatory framework, diverging from the EU's harmonised AI Act and instead emphasising pro-innovation policies (European Commission, 2024). However, rapid adoption of AI technologies necessitates the urgent development of robust regulatory systems to ensure patient safety and efficacy (Medicines and Healthcare products Regulatory Agency, 2024a).

Unlike traditional medical devices, General Purpose AI Models—such as large language models—evolve over time. This means that technologies initially considered safe may become unsafe following updates (Medicines and Healthcare products Regulatory Agency, 2024a). In the absence of a statute specifically regulating AI in healthcare, the UK has increasingly adopted a decentralized, independent regulatory strategy, incorporating international approaches from Canada and the United States (Department for Science, Innovation & Technology, 2024).

Currently, AI in healthcare is regulated under the Medical Devices Regulation 2002 and the Medicines and Medical Devices Act 2021 (Burton, 2025). A Private Members' Bill—the Artificial Intelligence (Regulation) Bill—is under scrutiny in the House of Lords and aims to replace the March 2023 AI White Paper (Burton, 2025). The Bill contains nine clauses, including the creation of an AI Authority, regulatory principles, new offences, and liability provisions for breaches (Burton, 2025). The AI White Paper has been widely criticized for relying on 'voluntary commitments to good practice' rather than establishing legally binding obligations to ensure compliance (Burton, 2025).

The UK's sector-specific framework is designed to be flexible and adaptable to technological advancements (Artificial Intelligence in Healthcare, n.d.). The National AI Strategy emphasises innovation while maintaining safety across sectors, including healthcare. AI as a Medical Device is

regulated under the UK Medical Devices Regulations, overseen by the MHRA, while NHS England's AI Lab supports the development of validation and transparency standards (Medicines and Healthcare products Regulatory Agency, 2024a).

AI Growth Labs—regulatory sandboxes that allow real-world testing under supervised relaxation of rules—are central to the UK's innovation-driven strategy (Department for Science, Innovation & Technology, 2024). Ongoing public consultation will determine whether these labs should be government-run or delegated to sector regulators like the MHRA, which has important implications for transparency and accountability (Medicines and Healthcare products Regulatory Agency, 2024a).

The MHRA's 2024 AI Airlock enables companies to test AI medical devices in controlled environments, including applications in cancer care and diagnostic safety (Medicines and Healthcare products Regulatory Agency, 2024a). While the UK's decentralised, pro-innovation approach encourages rapid technological experimentation, fragmented oversight risks inconsistencies in high-risk areas such as diagnostics (Artificial Intelligence in Healthcare, n.d.). Moreover, although independent regulation offers flexibility for UK firms, divergence from the EU imposes additional compliance burdens for those seeking access to the EU single market (European Commission, 2024).

Comparative analysis: EU vs UK

The EU employs a comprehensive, risk-based regulatory framework to create a safe, rights-respecting AI ecosystem (European Commission, 2024). The AI Act assigns AI systems to risk tiers, with healthcare AI classified as high-risk and subject to stringent requirements, including data governance, transparency, cybersecurity, and continuous post-market monitoring (European Commission, 2024). High-risk systems must maintain extensive documentation, undergo conformity assessments, and disclose their AI use to end users to enhance trust and accountability (European Commission, 2024).

In contrast, the UK applies sector-specific guidance, with the MHRA defining risk thresholds and regulatory expectations for healthcare AI (Medicines and Healthcare products Regulatory Agency, 2024a). Ethical guidelines vary by sector, and existing frameworks such as the Data Protection Act and ICO guidance shape transparency and security requirements (Information Commissioner's Office, n.d.). The Centre for Data Ethics and Innovation contribute to governance through evidence reviews and consultations (Department for Science, Innovation & Technology, 2024).

EU governance is centralised in the European Commission and the European Parliament, with Member States responsible for enforcement and market surveillance (European Commission, 2024). Civil society and industry stakeholders participate in consultations and pilot projects. The UK, by contrast,

adopts a decentralised approach anchored in the MHRA and supported by CDEI-led ethical guidance (Medicines and Healthcare products Regulatory Agency, 2024a).

While EU harmonisation enhances legal certainty and global standard-setting, strict compliance requirements may stifle innovation and disproportionately burden small firms (Financial Times, 2025). The UK's flexible model encourages rapid iteration but risks fragmented oversight and regulatory ambiguity for stakeholders navigating overlapping frameworks (Artificial Intelligence in Healthcare, n.d.). Ultimately, both systems struggle to reconcile rapid innovation with robust protections in high-stakes healthcare environments.

Towards a Safe and Effective Framework

Artificial intelligence has developed at an unprecedented pace and has experienced rapid growth in the healthcare sector in recent years. When effectively integrated into healthcare practices, it holds tremendous potential to enhance healthcare delivery (Uddin, 2025).

Trust is an essential condition for the successful deployment of AI-powered systems in healthcare. As AI increasingly operates in high-risk and life-critical environments, stakeholders across the AI lifecycle require confidence in its use. This trust can only arise with robust regulatory oversight and the embedding of clear ethical and legal principles throughout the lifecycle. While existing international standards, such as ISO 21448, aim to foster trustworthy AI, they lack actionable guidance and practical implementation—especially in a dynamic and interdisciplinary sector like healthcare (Alelyani, 2025).

However, as AI increasingly operates in high-risk, life-critical environments such as healthcare, stakeholders across the AI lifecycle require confidence in its use. Trust, therefore, becomes an essential condition for the successful deployment of AI-powered systems in healthcare (Alelyani, 2025). This trust can only arise with robust regulatory oversight and the embedding of clear ethical and legal principles throughout the lifecycle. While existing international standards, such as ISO 21448, aim to foster trustworthy AI, they lack actionable guidance and practical implementation—especially in a dynamic and interdisciplinary sector like healthcare (Alelyani, 2025).

In the absence of a unified framework comparable to the EU, the UK relies on sector-specific guidance and soft law instruments, creating uncertainty for stakeholders about what is legally binding versus best-practice recommendations (Al-Mamaari, 2025). For instance, the ICO establishes guidelines for data protection and automated decision-making, encouraging organizations to implement meaningful "information disclosure" (Al-Mamaari, 2025). Issues such as transparency, accountability, and data

protection must be treated as legal obligations rather than voluntary standards. Healthcare AI should be regulated rigorously and transparently across its entire lifecycle.

Frameworks should mandate AI systems to provide meaningful information about their underlying logic and ensure that outputs are interpretable by both professionals and patients. It is essential that stakeholders understand the processes underlying AI-generated decisions (Carroll et al., 2025). Under the GDPR, patients subjected to automated decision-making have a right to an explanation and to meaningful information about the logic underlying the AI's decision-making process (Ploug et al., 2025). Patients should also have the right to know which data were used and how they contributed to AI-powered decision outcomes.

However, successful deployment of AI in healthcare requires more than regulatory oversight; it also includes meaningful integration into clinical workflows and sustained clinical engagement. Hospitals must redesign existing practices to incorporate AI tools effectively into clinical settings, making investment in AI literacy essential. Clinical involvement in AI implementation requires clinicians to be educated about novel technologies and the broader legal and regulatory implications of using AI in practice (Carroll, 2025). Additionally, hospitals should conduct local evaluations to ensure these technologies perform well in specific clinical contexts. The UK's efforts in creating regulatory sandboxes represent a step in this direction (Carroll, 2025). Human input and clinical engagement are crucial to understanding what the AI is approved to do, assessing its outputs, and interpreting its recommendations. As AI systems are often "black boxes," clinicians must be able to explain why an AI made a specific recommendation to avoid inappropriate reliance on such systems.

Liability is another significant challenge. The UK does not explicitly provide specific regulations for liability regarding errors caused by AI systems, focusing instead on those who use the technology. Determining responsibility for clinical errors involving AI is increasingly challenging, and in the absence of a clear regulatory framework, doctors may become 'liability sinks,' absorbing responsibility even when AI is the primary contributor (Lawton et al., 2024; Lawton et al., 2025). A shared responsibility model may help address this challenge, as supported by the (FUTURE)-AI guidelines (Carroll, 2025). From the patient's perspective, implementing strict liability could alleviate the burden of proving fault or negligence, especially given the opacity of these technologies (Carroll, 2025).

Given the nature of AI, which continues to learn and adapt after deployment, it is essential to ensure robust post-market surveillance for its use in healthcare. AI deployment is a dynamic process that requires continuous monitoring, reassessment, and updating of evidence to ensure safety, effectiveness, and public trust are maintained (Carroll, 2025).

Ultimately, early interdisciplinary collaboration and stakeholder engagement are essential to developing both a robust framework and the effective integration of AI into clinical practice. Involving stakeholders—including patients, clinicians, developers, and society—through focus groups can help ensure AI solutions are pragmatic and acceptable (Carroll, 2025).

Conclusion

In conclusion, it is essential that clinicians understand the processes underpinning AI applications in healthcare, given their increasing prevalence and potential to address the growing challenges faced by the UK's healthcare system. Regulating and addressing the challenges posed by AI in healthcare will require iterative, ongoing assessment to ensure that regulation keeps pace with rapid technological change and innovation.

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