

Professional Standards Authority response to the National Commission into the Regulation of AI in Healthcare: Call for Evidence

1. About us

- 1.1. The Professional Standards Authority for Health and Social Care (PSA) is the UK's oversight body for the regulation of people working in health and social care. Our statutory remit, independence and expertise underpin our commitment to the safety of patients and service-users, and to the protection of the public.
- 1.2. There are 10 organisations that regulate health professionals in the UK and social workers in England by law. We audit their performance and review their decisions on practitioners' fitness to practise. We also accredit and set standards for organisations holding registers of health and care practitioners not regulated by law.
- 1.3. We collaborate with all of these organisations to improve standards. We share good practice, knowledge and our right-touch regulation expertise. We also conduct and promote research on regulation. We monitor policy developments in the UK and internationally, providing guidance to governments and stakeholders. Through our UK and international consultancy, we share our expertise and broaden our regulatory insights.
- 1.4. Our core values of integrity, transparency, respect, fairness, and teamwork, guide our work. We are accountable to the UK Parliament. More information about our activities and approach is available at www.professionalstandards.org.uk

2. Responses to questions

Q1: Which of the following best describes your view about the need to change the UK's framework for regulating AI in healthcare?

- Significant reform: The current framework requires substantial changes.

Q2.1: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Safety and Performance Standards:

- Disagree

Q2.2: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Data Privacy and Data Governance:

- Neither agree nor disagree

Q2.3: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Transparency:

- Disagree

Q2.4: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Requirements for clinical evidence:

- Neither agree nor disagree

Q2.5: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Post Market Surveillance:

- Neither agree nor disagree

Q3: How would you rate the current framework's impact on innovation?

- Somewhat loose [lacks necessary controls]

Q4: How might the UK's framework for regulation of AI in healthcare be improved to ensure the NHS has fast access to safe and effective AI health technology?

- 2.1. The Commission will play an important role in accelerating the safe and effective use of medical devices that use AI, advising on a regulatory framework that supports innovation and safeguards patient safety. This work, providing clarity on AI tools and addressing regulatory uncertainty, will be vital in enabling patients and professionals to benefit from these technologies. Professional regulation will need to align with product and device regulation.
- 2.2. The PSA oversees professional regulation in UK health and social care. Professional regulation needs to be included in discussions on regulating AI in healthcare, including proposals for medical devices that use AI.
- 2.3. It is essential for healthcare professionals, regulators, patients and the public to have clarity and confidence around expectations for professionals and making this an explicit part of how AI in healthcare is regulated. Professional regulation and registration can provide a framework for accountability and trust in the use of AI across health and care.
- 2.4. As AI becomes increasingly embedded in healthcare, the regulatory framework must clearly define which AI tools qualify as medical devices under MHRA oversight. It must also ensure risks from wider uses of AI not captured by existing classifications are assessed and mitigated. Professional regulators, alongside employers, will be expected to play a significant role guiding professionals toward the safe use of AI technologies.

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- 2.5. Regulation of AI must explicitly address the risk of exacerbating existing health inequalities and ensure AI does not adversely impact particular groups, including those with protected characteristics. The Commission should strengthen its focus on work to reduce health inequalities.
 - 2.6. The landscape of liability is complex, involving healthcare professionals, institutions, the developers of AI systems, and providers of indemnity insurance. Professional liability should be clearly defined, proportionate, and framed within broader accountability and assurance. Regulators should be able to set out boundaries of responsibility. Clear articulation of professional accountability, who is responsible or liable, for what, and at which point, would increase professional confidence and support faster, safer adoption of AI in healthcare.
 - 2.7. Education, training and capability building are essential enablers. AI's integration in health has increased the need for up-to-date guidance from professional regulators on deploying AI safely. Regulatory expectations should ensure healthcare professionals receive continual training to understand the strengths, limitations, and risks of AI relevant to their practice. This should include the impact AI has on professional practice and patient outcomes.
 - 2.8. AI technologies are highly adaptable and continuously evolving, raising questions around continuous assurance and recertification.
 - 2.9. Recent reports from the NHS AI Lab and Health Education England on **healthcare workers' understanding and confidence in AI**. However, they offer little specific guidance for the health professionals who will use AI in patient care. Further work should help bridge the gap between regulating medical devices that use AI, AI's potential, professional and public confidence, and ensuring staff feel empowered to use AI effectively and safely, while maintaining patient safety.

Q5: How should the regulatory framework manage post-market surveillance for AI health technologies?

- 2.10. An effective post-market surveillance framework for AI health technologies should build on existing mechanisms, while addressing the specific risks associated with medical devices that use AI and the use of AI by healthcare professionals.
- 2.11. The MHRA's **Yellow Card scheme** provides a foundation for monitoring adverse incidents and malfunctions of medical devices currently on the market, including safety concerns involving software and AI, or AI as a medical device. For medical devices that use AI, post-market surveillance would benefit from greater granularity in surveillance and reporting. In particular it should further distinguish, where possible, between issues arising from product performance and those linked to user interaction, including but not limited to inappropriate use, insufficient training, or misunderstanding outputs. Such distinction is essential to support proportionate regulatory action across device regulation and professional regulation.
- 2.12. Consideration should be given for how professional regulation can be effectively and proportionately integrated into post-market surveillance arrangements. Integrating professional regulation into post-market surveillance for medical devices that use AI bridges the gap between manufacturer data and real-world clinical use. This could include collaboration between the MHRA, professional regulators, employers,

health professionals, developers, and indemnifiers.

- 2.13. Transparency around AI use should be actively promoted. Many AI models, particularly deep learning systems where the internal workings are undisclosed and only the inputs and outputs are known, lack explainability, making it difficult to determine how decisions are made. Detailed technical explanations may not be necessary, but adequate explainability is needed. Fostering trust through transparency helps assure professionals and patients that AI is used responsibly, pre-empting concerns and strengthening public confidence in health care. Patients should be consistently informed when AI is involved in their care, and healthcare professionals must implement AI tools with confidence, underpinned by robust training and clear operational guidelines.
- 2.14. For an effective post-market surveillance framework for AI health technologies, healthcare professionals need to feel safe to report AI errors or issues. Professionals need assurances their practice will not be unreasonably questioned as a result of raising issues. No fault reporting is essential, assuming professionals have worked within their competence and ethical and professional standards (set by the regulator), and that AI tools are used for their intended use. Additionally, where there has been responsible and safe use of AI, the focus needs to be on identifying learning when something goes wrong, not individual blame.
- 2.15. Ongoing monitoring should recognise AI will evolve and that the rapid development of AI tools in healthcare is set to continue. Post-market surveillance should be continuous and agile, rather than episodic. There should be clear responsibilities on developers and providers to share updates and on healthcare organisations and professionals, and regulators to monitor real world performance.
- 2.16. A robust post-market surveillance framework for AI health technologies should combine technical oversight with consideration of professional standards and accountability. This integrated approach would help ensure patient safety and reinforce public and practitioner confidence in the safe adoption of AI.

Q6: Which statement best reflects your view on the current legal framework for establishing liability in healthcare AI tools?

- Insufficient: existing laws are unfit for AI

Q7: How could manufacturers of AI health technologies, healthcare provider organisations, healthcare professionals, and other parties best share responsibility for ensuring AI is used safely and responsibly?

- 2.17. Right-touch regulation is the approach the PSA applies in its work: <https://www.professionalstandards.org.uk/improving-regulation/right-touch-regulation>. Right-touch regulation explains that for regulation to be effective and contribute to the wider goals of the system within which it operates, and the objectives of government, a collaborative approach should be taken wherever possible and beneficial. This is a commitment to draw on the roles and responsibilities of different parts of the system to deliver the best regulatory response, including through collaborative approaches where they would be most effective.

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- 2.18. The PSA collaborates extensively by overseeing UK regulators, accrediting registers, and working with governments, healthcare bodies, and patients to improve safety and quality in health and social care and ensure effective public protection. Greater clarity and consistency are needed around expectations for healthcare professionals when using AI. To begin to address this, a conversation needs to be had between multiple bodies who will be concerned with this issue. This should consist of stakeholders representing a broad range of expertise and disciplines to ensure comprehensive oversight.
 - 2.19. Last year the PSA established a Regulatory Data and AI Group to coordinate work across regulators and Accredited Registers. The Group meets regularly to share best practice, identify risks, and discuss barriers and enablers for the use of AI by regulators and how to work together to regulate its use.
 - 2.20. The PSA is working with Professor Jonathan Ives and Dr Helen of the University of Bristol Medical School to run a one-day workshop focused on the question of ethical AI use by health and care professionals, and informing approaches to regulation. The overall objective is to develop recommendations from participants, including regulators and patient representatives, about professional ethical guidance for regulating for AI use by health and care professionals.
 - 2.21. The PSA is in a unique position, overseeing regulators and registers, to help coordinate across the whole healthcare sector. The PSA is committed to working with other partners, including the MHRA, registrants and accredited registers, to support the delivery of the benefits that can come from adopting medical devices that use AI, while maintaining patient safety.

Q8: In the event of an adverse patient outcome where an adverse patient outcome involved an AI tool, where do you think liability should lie?

- 2.22. While AI has potential to improve medical practice, errors will certainly occur, sometimes resulting in adverse patient outcomes. Without clarity, health professionals may be reluctant to use AI tools and patients may have no clear path for recourse if something goes wrong. Regulation, and related legislation, should be developed as a priority to outline the rights and expectations of those working with AI in healthcare, making explicit where liability for the safe deployment and use of AI primarily sits across different scenarios.
- 2.23. The landscape of liability for AI related injury and adverse patient outcomes where an AI tool was involved is complex, involving healthcare professionals and institutions, the developers of AI systems, and indemnifiers. The determination of liability in the event of an adverse patient outcome would depend on specific laws, regulations, facts of the incident and the specific circumstances of the case.
- 2.24. AI health technologies remain new which means explicit legal consideration is relatively scarce, with few examples of the legal ramifications of the use of AI tools in healthcare available and a corresponding absence of case law in this area. It is noted that in its meeting on 20 November 2025, the Commission agreed a lack of clarity around defining AI liability was a significant blocker to its adoption in healthcare. A joint project between the UK's Law Commissions to establish a clear legal framework would help provide the clarity needed.

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- 2.25. Liability issues are of particular interest to the PSA. Those working in health and social care are aware of their ethical and legal responsibilities, but need greater clarity and assurance of what will happen to them if avoidable harm occurs, which may be linked to their use of AI technologies. Additionally, questions about legal liability need to be framed within those of broader accountability and assurance.
- 2.26. AI could be considered as fundamentally different from other health technologies in that it can have decision-making or decision-supporting abilities, and capacity for self-learning. Clarity about the extent to which it should bear on decisions is needed. Additionally, the opacity of AI decision-making raises concerns over transparency, accountability, and explainability.
- 2.27. Healthcare liability regarding AI tools is a developing area. Regulatory frameworks and legislation need to keep pace with rapid advancement of AI disruption.
- 2.28. There is academic research examining ethical and legal considerations in healthcare AI, including preventing harms and questions of liability in the event of adverse patient outcome where an AI tool is involved. Dr Helen Smith has published a paper examining the risk of gross negligence manslaughter and corporate manslaughter charges when clinicians use AI system's outputs in their practice. The paper identifies elements of these offences in the context of the law of England and Wales and explores how they could be applied in a potential scenario where a patient's death has followed AI systems use by a clinician: **Artificial Intelligence for Clinical Decision-Making: Gross Negligence Manslaughter and Corporate Manslaughter**

Q9: Do you have any other evidence to contribute? You can submit written evidence in the comment box.

- 2.29. Professor Jonathan Ives and Dr Helen Smith are researching the ethics and law of AI in healthcare, with interests in creating professional ethical guidelines for clinicians using AI, addressing legal responsibility for AI-related harm, and exploring solutions like shared responsibility models to protect doctors. They recently published a paper detailing a pilot study gathering data on what healthcare practitioners need in professional ethical guidance: **Developing professional ethical guidance for healthcare AI use (PEG-AI): an attitudinal survey pilot**
- 2.30. Professor Jonathan Ives, Professor John Downer and Dr Helen Smith have published a paper exploring the increased use of AI in healthcare and medical settings, and the lack of professional guidance around it. The paper acknowledges the potential of AI to help improve medical care and alleviate the burden on healthcare workers, but argues there is no precedent for when AI or AI influenced professionals make a mistake, it recommends regulation should be developed as a priority to outline rights and expectations of those working closely with it: **Clinicians and AI use: where is the professional guidance?**
- 2.31. Kit Fotheringham and Dr Helen Smith have published a paper on legal liability and responsibility for patient harm where AI is used in healthcare. In it they note that due to the structure of negligence liability in England and Wales, it is likely clinicians would be held solely negligent for patient harms arising from software defects, even though AI shares the decision-making space with clinicians. They recommend law reform to consider the use of risk pooling, alongside detailed professional guidance for the use of AI in healthcare spaces: **Accidental injustice: Healthcare AI legal**

responsibility must be prospectively planned prior to its adoption

- 2.32. The Shared Care AI Role Evaluation project examined the impact of AI decision-support tools on clinicians, bringing together researchers with expertise in safety, medicine, AI, human-computer interaction, ethics and law. The outcomes of the research informed a White Paper that warns the greatest threat to AI uptake in healthcare comes from frontline clinicians seeing the technology as burdensome, unfit for purpose or are wary about it impacting their decision-making, patients and licences. A key concern in the paper is that clinicians risk absorbing all legal responsibility for AI-influenced decisions, even when the AI system may be flawed: **Avoiding the AI ‘Off-Switch’: Make AI Work for Clinicians, to Deliver for Patients**