MHRA call for Evidence: National Commission into the Regulation of AI in Healthcare

Survey Questions

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

a) No change: The framework should be maintained as is.
b) Minor adjustments: The current framework works but requires small changes.
c) Significant reform: The current framework requires substantial changes.
d) Complete overhaul: The current framework should be replaced entirely.
e) Unsure

Q2.1: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: a) Safety & performance standards

- Strongly disagree
- Disagree
- Neither agree nor disagree
- **Agree**
- Strongly agree

Q2.2: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: b) Data privacy & data governance

- Strongly disagree
- Disagree
- Neither agree nor disagree
- **Agree**
- Strongly agree

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

- Strongly disagree
- Disagree

- **Neither agree nor disagree**
- Agree
- Strongly agree

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

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

Q2.5: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: e) Post-market surveillance

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

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

a) Too restrictive (stifles innovation)
b) Somewhat restrictive (creates some barriers)
c) About right (balances safety and innovation)
d) Somewhat loose (lacks necessary controls)
e) Too loose (risks patient safety)

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?

You may wish to consider some or all of the following in your response: (1) Gaps and other limitations of the existing regulatory framework, (2) Innovative and effective approaches to AI regulation used in other sectors, and other jurisdictions, (3) Ensuring public and patient safety whilst minimising the cost of complying with regulations (in terms of time and resource), (4)

The boundaries of regulation, including the ways AI can qualify as a 'medical device', and how such devices are classified according to risk.

The Royal College of Ophthalmologists believes that AI tools should be adopted in NHS settings via an iterative process, with services conducting regular audits, quality assurance and inclusive patient engagement to ensure safe, equitable and effective implementation. Data governance and privacy frameworks must cover the collection, storage and analysis of patient data, with clear guidelines on data usage and sharing between patients, practitioners, regulatory bodies and technology providers.

Consideration of requirements for regulatory approval should encompass levels of clinical risk, allowing lower-risk AI as a Medical Device (AIaMD) tools to reach NHS deployment faster. However, there is currently too sharp a regulatory jump between lower-risk (class i) and higher risk (class ii) devices. This incentivises manufacturers to design tools in ways that qualify for lower risk classification. Risk classification should accurately align with how AIaMD tools are used within clinical settings, to prioritise patient safety. NHS organisations should play a clearer role in identifying when manufacturers are not meeting these regulatory obligations.

Responsibility for recognising compliance issues should not lie with clinicians alone. Instead, standardised templates and reporting tools should be provided that have straightforward mechanisms for escalating concerns to MHRA.

The UK's regulatory framework should also enable greater use of trusted regulatory approvals from other countries, subject to appropriate quality assurance. Where AIaMD tools have already undergone robust assessment outside of the UK, there should be a mechanism for fast-tracking quality assurance in the UK so that they can be deployed within NHS settings sooner.

Comparative clinical studies would provide a better evidence base in support of an AIaMD tool's benefits, rather than assessing an AI-supported pathway in isolation. The studies would evaluate patient care when clinicians use an AIaMD tool in practice versus standard care without it. This would ensure consideration of patient outcomes, safety and efficiency in the assessment of clinical value. Such studies would provide accreditations to indicate where AIaMD tools work well and where they do not.

These studies can be supported by expanding the use of process mapping evaluation to analyse how AIaMD tools fit into existing NHS clinical pathways. This necessitates mapping each step of the patient journey before and after AI is introduced, to assess and understand its impact upon workflows and clinical decision-making and identify any arising risks or unintended consequences.

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

You may wish to consider some or all of the following in your response: (1) The challenges posed by novel and emerging types of AI, including foundation models and highly capable agentic AI, (2) AI systems which are capable of continuous learning and/or updating, (3) AI systems that are used for other purposes beyond the original intended use, (4) AI systems which are developed by a single institution for in-house use only, (5) Information sharing between healthcare provider organisations and manufacturers for the purposes of post-market surveillance.

MHRA should ensure that post-market surveillance (PMS) for AIaMD tools supports transparency beyond manufacturers.

Manufacturers provide AIaMD tools with regular updates to improve performance. Changes to the algorithm of AIaMD tools can affect their clinical performance. MHRA should be informed of significant updates to AIaMD tools and monitor them as part of PMS.

Manufacturers should take primary responsibility for aggregating PMS data and analysing national trends. This would strengthen regulatory confidence and reduce the burden on individual NHS providers.

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

a) Sufficient: Existing laws (e.g. medical negligence, Product Liability etc) can adequately handle AI-related disputes
b) Gaps exist: Existing laws work for most cases but leave uncertainty
c) Insufficient: Existing laws are unfit for AI
d) Unsure

Q7: How could manufacturers, healthcare provider organisations, healthcare professionals, and others best share responsibility for ensuring AI is used safely and responsibly?

You may wish to consider some or all of the following in your response: (1) The specific duties for each party, and (2) any duties which are shared.

Education and training must be given by healthcare provider organisations (HPOs) to equip healthcare professionals with the knowledge and skills to leverage AIaMD tools effectively and safely. This should include clarification of who is responsible for how AI is regulated in healthcare, as clinicians may not know.

To set the right conditions to encourage safe AI adoption across healthcare settings, MHRA should publish guidance that sets out clear allocations of liability across all manufacturers, healthcare commissioners and healthcare professionals involved in the design, manufacture, deployment and clinical use of an AIaMD tool.

It is important for HPOs to understand local performance and consider benchmarking clinician performance with and without use of AIaMD tools to safeguard against the risk of overreliance and automation bias.

Q8: In the event of an adverse patient outcome involving an AI tool, where should liability lie?

You may wish to first consider the following scenarios: (1) When the AI tool gives the correct answer, but is incorrectly overridden by the healthcare professional, (2) When the AI tool gives the incorrect answer and the healthcare professional follows it (i.e. they incorrectly choose to trust the AI).

Liability in AI-related patient harm should be distributed across manufacturers (design), healthcare organisations (implementation and oversight) and clinicians (clinical judgement). It should reflect who controlled the risk at each stage, and should not default to the clinician. Clinical accountability must be clearly defined by an intended use statement, distinguishing between user and manufacturer liabilities.

The clinician should retain responsibility for clinical judgement (unless the AIaMD tool has been authorised for fully-automated use, and the harm arises directly from automation), but they should not be held responsible for system-level failures.

Where liability rests with clinicians, it should be defensible provided they have used the AI tool within its regulated intended use, received appropriate training, practised in line with accepted clinical standards and responded appropriately to emerging safety signals. Clinician liability should only arise where there is evidence of negligence, such as persistent use despite repeated adverse outcomes.

For scenario 1, the clinician may be liable if they have disregarded a reliable test result, but not if the HPO did not provide adequate training on using the AIaMD, in which case, they become liable for harm. For scenario 2, liability should be shared between manufacturer, whose device is at fault, and clinician, who has not applied good clinical judgement.

Q9: Do you have any other evidence to contribute? (With the necessary permissions.)

Evidence demonstrating the benefit of AIaMD tools often compares their performance against an absence of established care pathways, particularly in low- and middle-income settings. In this scenario, AI-supported diagnosis or prognosis is likelier to outperform no care at all. While this evidence can be valuable, it is not directly transferable to the NHS context, where an AIaMD tool is typically introduced into mature, clinician-led care pathways.

There remains a paucity of robust clinical trials comparing AI-integrated care pathways with existing standard care in the NHS, including evaluation of patient outcomes, safety, workflow impact and equity. This evidence gap could be addressed through targeted National Institute for Health and Care Research (NIHR) commissioned research and the expansion of funded pilots. This would support MHRA to make informed, proportionate decisions about the adoption and oversight of AI-powered tools.

Q10: Upload any documents to be considered as part of this call for evidence.
(With the necessary permissions.)