



Patients and the public

The MHRA established the independent [National Commission into the Regulation of AI in Healthcare](#) in September, bringing together global AI leaders, clinicians and regulators to advise on how the regulatory framework should evolve to be **Safe, Fast and Trusted**.

Patients and the public have been central to this work. Through extensive [research and engagement](#) including public surveys, the Call for Evidence, deep-dive discussions with the Health Foundation, workshops with National Voices, direct engagement through the Ask Me Anything webinar and MHRA's Patient and Public Committee, patients and the public were clear about the changes needed to support the safe and effective use of AI in healthcare.

The Commission's report [Recommendations for a future regulatory framework](#), published in September 2026, responds directly to these priorities. The Government has now accepted the recommendations and will take a coordinated, cross-government approach to implementation.

What this means for you: protecting your safety, strengthening your voice

- 1 Better care, with people still at its heart**
AI should support healthcare professionals and improve care, while keeping your individual needs at the centre of decisions.
- 2 Safety checks that continue after AI is introduced**
Stronger monitoring to identify and act on changes in safety or performance once AI is being used.
- 3 AI that works for everyone**
Greater focus on whether AI works safely and effectively for different people, not simply whether it performs well on average.
- 4 Clearer information and a stronger voice**
Better information about how AI is used in healthcare and more opportunities to influence how it is regulated.
- 5 Clearer responsibility and support if something goes wrong**
Greater clarity about who is responsible for your care and clearer routes to raise concerns and access redress.



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full report**



What this means for you

Better care, with people still at its heart

AI is already being used in healthcare to help detect disease, support treatment and reduce administration. Used well, it could help people get earlier diagnoses, more personalised care and better outcomes.

The Commission heard that patients value empathy, trust and personal interaction, and want AI to support healthcare professionals rather than replace them. Its recommendations reflect this.

For example, an AI tool might highlight something unusual on a scan or help draft notes, but trained healthcare professionals would remain responsible for decisions about care, taking into account a patient's symptoms, medical history, circumstances and preferences.

The recommendations also recognise the need for healthcare staff to be properly trained, with clear guidance, oversight and safeguards for organisations using AI.

Ultimately, the National Commission's work is about ensuring that patients can benefit from advances in AI while maintaining the safety, trust and human judgement that are at the heart of good healthcare.

The aim is for new technology to deliver real benefits for patients and supports healthcare professionals to provide the best possible care.

What this could mean for you: earlier access to beneficial technologies where appropriate, while keeping your individual needs at the centre of decisions about your care.

“ From the outset of the discussion, participants were clear that the use of AI in their care was only acceptable on the condition that an appropriately qualified human would check the results and have the final say.

The Health Foundation
[The public's views on the regulation of AI in health care](#), page 26

“ Healthcare professionals remain responsible for exercising clinical judgement when using AI tools. AI should support, not replace, professional decision-making.

Think Tank
[Call for Evidence findings report](#), page 14

Safety checks that continue after AI is introduced

Checks before an AI product is made available are important. But AI can change when software is updated and may perform differently in different hospitals, services or patient groups. This means safety cannot rely on a single check before a product starts to be used.

Instead, authorisations, safety checks and oversight will need to become more agile, proportionate and continuous.

The regulatory framework will need to enable device manufacturers to work closely with the MHRA. This will make it easier for anyone who sees safety issues or experiences poor outcomes from AI-enabled care to report their concerns.

The National Commission makes several recommendations, proposing:

- **earlier access** to promising new treatments and medical technologies, while appropriate safeguards are in place to protect patients
- **more opportunities** for patients to share their experiences and feedback directly with both the regulator and the company that makes the product
- **stronger monitoring** of products once they are in use, including requiring manufacturers to tell the MHRA quickly if they identify any unexpected changes in performance, so action can be taken before patients are affected

What this could mean for you: greater confidence that AI continues to be checked after it is introduced, so changes in safety or performance can be identified and acted on.

“ *Post-market surveillance for AI health technologies must be significantly strengthened to address the unique, evolving risks of novel AI, far beyond the current manufacturer-led, largely reactive approach.*

Patient / Public Respondent,
[Call for Evidence findings report](#), page 17

“ *Post-market surveillance for AI as a Medical Device should include continuous evaluation of real-world performance, including root-cause analysis of errors, false negatives and near-misses, to identify trends and emerging risks.*

Public Body
[Call for Evidence findings report](#), page 12

AI that works for everyone

AI performance and outcomes can depend on the information used to develop and test it, the population it is used with, and the setting in which it is introduced.

To manage this risk, the National Commission recommended that the MHRA provides guidance for manufacturers on how to demonstrate that their device is safe and provides fair outcomes for different people. This will include people of different ages, sexes, ethnicities and locations, with particular attention given to underserved groups.

This guidance will also set out steps that manufacturers can take to ensure their device works for everyone throughout its lifetime. This could include monitoring the outcomes that their device produces for specific groups of people.

The National Commission also recommended clearer expectations for how people should safely use health apps and wearable technologies accessed at home.

What this could mean for you: stronger consideration of whether AI works safely and effectively for everyone, not simply whether it performs well on average.

“ *The UK does not need a complete overhaul of AI regulation in healthcare, but it does need to be much clearer about equity and real-world impact.*

Charity
[Call for Evidence findings report](#), page 11

“ *Crucially, participants also believed that the existing standard of care must not be made worse for any group – this was a red line.*

The Health Foundation
[The public's views on the regulation of AI in health care](#), page 30

Clearer information about AI and a stronger voice in how it is used

Public trust in the healthcare system must be earned. A critical part is making sure that you, as patients and the public, know when AI is playing a meaningful role in your care and what that means for you.

The National Commission recommended a proportionate approach to communicating this to patients. This means more people being aware of how AI is being used in health in

general, as well as more detailed communication from healthcare professionals when AI is used in higher-risk or sensitive cases. This approach to transparency means people can expect to be informed of how AI affects their care and can opt out where this is possible or appropriate.

The National Commission also recommended more ways for patients and the public to influence how AI use in healthcare is regulated, including a Patient Engagement Advisory Committee, workshops and deliberative events.

The Commission recommends regular surveys to help track people's experience, understanding and trust in AI over time. Patients should have access information about adverse incidents related to a specific software of AI-enabled medical device to inform their understanding of risks.

What this could mean for you: clearer information about how AI is being used and when safety problems emerge, and more opportunities to influence the rules and decisions that shape AI-enabled healthcare at a high-level.

“ *Participants wanted to be told – in plain language – when AI is used and what role it plays.*

The Health Foundation
[The public's views on the regulation of AI in health care, page 40](#)

“ *Ongoing, meaningful engagement with the public is therefore critical and should be seen as an essential part of any regulatory regime designed to maintain public trust.*

The Health Foundation
[The public's views on the regulation of AI in health care, page 45](#)

Clearer responsibility and support if something goes wrong

Various different people and bodies, from device manufacturers to hospitals and healthcare professionals, may affect the care you receive. This can make it difficult to understand who is responsible if things go wrong. The National Commission recommended the clarity on the responsibilities of those involved in delivering care, to establish who is to blame if harm occurs, and to improve access to redress if it is below standard.

The National Commission also recommended that health organisations work with patients to define what high-quality care looks like in an AI-enabled health system and making sure that you can provide feedback and report any concerns.

What this could mean for you: greater clarity about who is responsible for your care and clearer routes to raise concerns and access redress if harm occurs.

“ *Patients advocate for a shared responsibility approach in liability for when things go wrong when using AI. They feel that liability should not rest with just one person, but should reflect the roles of regulators, manufacturers, healthcare organisations and healthcare professionals.*

Charity
[Call for Evidence findings report](#), page 13

“ *Require incident reporting, redress routes, and compensation mechanisms that are easy to use.*

National Voices
[Good regulation for AI in healthcare](#), page 18

Keeping people at the heart of AI-enabled healthcare

AI should help improve your care without losing the human connection that matters to you.

The National Commission’s recommendations, which the Government is taking forward, aim to make AI safer and fairer, help you understand when it is used, and make it easier to speak up if something goes wrong.

Patients and the public helped shape this work through the Call for Evidence, public discussions with the Health Foundation, an open Ask Me Anything webinar with leadership, the MHRA’s Patient and Public Community, and workshops with National Voices. The workshops included people with lived experience and members of groups including Carers UK, Learning Disability England and the Association for Young People’s Health.

The message heard was clear: patients and the public want stronger safety checks, fair treatment and clear information about when AI is used in their care. They want healthcare professionals involved in decisions and confidence that any concerns they raise will be heard and acted on.

“ *This is about creating a future healthcare system that is increasingly tech-enabled but always people-centred.*

Professor Alastair Denniston, Chair
Professor Henrietta Hughes, Deputy Chair



National Commission into the Regulation of AI in Healthcare
[Recommendations for a future regulatory framework](#), page 5

The Commission's overall vision

