Regulating the use of AI in healthcare: The Royal College of Radiologists' Position

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The Royal College of Radiologists

Contents

01 Executive Summary

Clinical radiologists and clinical oncologists are amongst the leading users of artificial intelligence (AI) in the NHS. Members of the Royal College of Radiologists (RCR) are developing and/or deploying cutting-edge AI tools to support clinical work, from tumour and normal structure contouring in radiotherapy planning to helping detect nodules in lung cancer screening.

While many of our members are embracing AI in their work, they also have concerns around the technology. A lack of trust in AI tool accuracy, unease around medical liability and a view that AI is not well regulated all contribute to poor confidence in AI. Introducing and monitoring AI tools also takes significant time and effort, which can add to clinical workload. Combined, these issues risk slowing down the safe and effective adoption of AI across the health service and could undermine the government's ambition for an AI-driven NHS.

These concerns are not unique to clinical radiologists or clinical oncologists. Indeed, in 2025 the government announced plans for a new Framework for AI Regulation and established the National Commission for AI Regulation in Healthcare, which has been tasked with addressing the issues outlined above. The RCR welcomes this approach, and we believe that effective regulation can improve patient safety, strengthen clinician confidence, and support innovation adoption.

To achieve this, we recommend focusing on three priority areas:

1. Establish a principle of data transparency and high levels of evidence which reflect the complexity of the task of the AI tool and/or the potential patient impact.
2. Develop a single, national post-deployment monitoring system for AI which provides clinicians with a simple means to flag errors or concerns and a fast-paced feedback loop.
3. Prioritise a national deliberation on medical liability in cases where AI has been used, involving all relevant parties, including industry, regulators, clinicians, Trusts/health boards, civil society and patients.

Addressing these priorities will help build trust in AI, reduce unnecessary burdens on clinicians, and provide clarity to patients and innovators. Getting this right now will not only support current AI use in radiology, oncology and the wider NHS, but also create a regulatory framework that remains effective as AI technologies continue to evolve.

02 Introduction

Artificial intelligence (AI) is already playing an important role in healthcare, from appointment scheduling and note writing, to informing clinical decision making and supporting radiotherapy planning. With the 10 Year Health Plan for England[i] committing the NHS to becoming the most AI-enabled health system in the world, the role of AI is expected to grow further.

Clinical radiologists and clinical oncologists are leading AI adoption in the National Health Service (NHS), with our 2024 census showing that 69% of radiology departments[ii] and 63% of cancer services[iii] are already using AI tools. A more recent snap survey found that 78% of our members supported AI use in their speciality. The public agrees, with Royal College of Radiologists (RCR)-commissioned public polling finding that 80% of respondents supported the use of AI in radiology in some capacity, as long as there is sufficient clinical oversight of AI use[iv].

The RCR provides training and guidance to our members to support safe AI use[v]. While many of our members are already making some use of the technology, we also know that there are reservations about it. 56% of radiology departments report no workload impact of using AI and 37% report an increased workload[ii]. Our members have limited trust in AI tool accuracy, are uneasy about medical liability, and are concerned that tools are not well regulated. Combined, these reservations can result in poor clinician confidence in AI which risks undermining ambitions for an AI-enabled NHS. If doctors are uncomfortable with how AI is being used, we cannot expect patients to be confident in its use either.

These challenges are recognised by government, reflected in the commitment for a new Framework for AI Regulation[vi] and the subsequent launch of the National Commission on the Regulation of AI in Healthcare in September 2025[vii]. The Royal College of Radiologists considers these as important opportunities to bolster clinical support for AI deployment and strengthening patient safety.

Regulation in a field where the technology is developing at pace can be challenging. In this document we outline key areas that we argue will ensure that any future regulatory model for AI is fit for purpose and addresses some of the key concerns our members have in this area.

Based on engagement with our members and sector experts, we identify three priority areas: evidence thresholds, post-deployment monitoring, and medical liability. Across the three priority areas, we make five ambitious but deliverable recommendations which we believe will enhance patient safety and strengthen clinician and public trust in AI. Combined, these will ultimately support the ambition for an AI-enabled NHS and delivery of the shift from analogue to digital.

03 Evidence

When seeking approval from the Medicines and Healthcare products Regulatory Agency (MHRA) for AI-driven medical devices[viii], manufacturers must provide evidence which demonstrates the safety and efficacy of their product. This evidence base not only supports regulator decision-making but also provides the basis for end-user confidence in AI use in clinical practice and helps to strengthen patient safety.

Where AI tools do not require MHRA approval, the NHS expects International Organization for Standardization (ISO) standards[ix] to be met and NHS Digital Technology Assessment Criteria[x] (or the equivalents in Scotland, Wales and Northern Ireland) inform procurement decisions.

To build clinician confidence, the new Framework for AI Regulation must clearly set out what evidence is required for different AI use cases. Priorities include training data transparency, maintaining robust and proportionate levels of evidence in all use cases, and a regulator-led review of significant model updates.

Data transparency

Clinical radiologists and clinical oncologists must be confident that the AI tools they are using will work for their local populations. However, there are currently understandable concerns about data and algorithm bias that can result in adverse events in some demographic groups. News stories about sub-optimal AI tool performance, such as "downplaying women's health issues"[xi] or being "less accurate" for individuals with darker skin tones[xii] can contribute to clinician concern that AI tools will fail to work in their local context and could increase the risk of poor patient outcomes.

Many AI tools would require fine-tuning using local population data which will help allay some concerns about data and algorithm bias. However, a principle of data transparency and support for data release processes at the national regulator and trust/health board/clinician level will boost clinician confidence and ultimately help ensure that AI tools are doing their intended job. Patients and the public will also be reassured to know that the AI tools supporting their care have been trained on appropriate data sets.

Companies seeking MHRA approval and/or NHS procurement of their AI tools must be expected to provide detailed information of the data on which their model has been trained and how it has been trained.

The data used to train an AI tool should be representative of the intended patient cohort. High quality labelling is expected, and the data sample size should be large enough to 1) support robust statistical evaluation, 2) prevent overfitting and 3) produce generalisable results.

Although training datasets cannot generally be made public, we suggest that the MHRA should be able to summarise their confidence in data quality and labelling in its Public Assessment Reports for AI medical devices. Vendors should also provide trusts/health boards and clinicians using their AI models with model cards which summarise training data composition and limitations.

Complexity and impact-based evidence requirements

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AI use cases in healthcare vary widely. This means that the same approach to evidence levels required for different use cases in the regulatory approval and procurement process will not always be appropriate.

Clinicians and their patients rightly expect AI tools to meet robust safety and effectiveness standards. However, research suggests that some of these technologies are not always meeting the required safety standards[xiii] and this understandably causes concern and undermines clinician and public trust in them.

The MHRA must maintain their expectation for high levels of evidence that are proportionate to the complexity of the task the AI model is expected to perform and/or the potential impact of its output on patient care. This approach should be adopted by the NHS in cases where direct approval from a regulator is not required.

This approach is not novel. Rather, it builds on existing approaches to medical device classification where different evidence levels are needed for different devices. In the context of 'AI as a medical device' use cases, the current classification model should be reviewed and updated. The broad regulatory principle should be that the more autonomous the task and/or the more significant the potential impact on patient care and outcomes, the higher the level of evidence that should be required.

While current evidence increasingly supports assistive AI use in radiology and oncology, we recognise that capabilities are advancing. Although not currently permissible or well-evidenced, autonomous/agentic AI could, in time, play a greater role in supporting diagnosis and workflow and the UK has a number of large clinical trials exploring these applications.

Any clinical implementation of AI in healthcare must be scientifically evidenced as safe and accurate, consistently adding clinical value across diverse real-world settings, with the impact on training and workflow effectively considered and addressed before implementation. Regulators and the health service should expect the same, and the regulatory principle described above will facilitate a regulatory system that works for AI use cases both now and in the future.

Reviewing AI tool upgrades

Our members are concerned about unannounced or poorly explained AI system updates, which can change outputs and undermine previously presented evidence and trust.

MHRA and NHS commissioners should expect AI tool vendors to inform them of significant changes in their models and conduct a review of them prior to re-deployment. The National Commission for AI Regulation is an ideal forum to establish how this process could be implemented in a proportionate way. AI tool vendors must also inform the clinicians using their products about any updates to their models.

Regulators and the NHS should also review the process surrounding what happens when an AI tool shifts from not requiring regulatory approval to needing it. For example, many ambient scribing products which transcribe a patient-clinician interaction and process sensitive patient data do not currently require MHRA approval. However, in some cases these products have evolved to provide more sophisticated functionality, such as using Generative AI for summarisation, and therefore require MHRA approval.

Such changes highlight the need for clear and well-understood definitions of AI in different

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use cases. These changes can put trusts/health boards at risk of legal challenge, along with the clinicians working for them, if they find themselves using AI tools that are not compliant with regulation. For clinicians, this can erode confidence and willingness to use AI tools that may offer significant benefit to their work.

Recommendations

1. **AI vendors must be expected to provide transparent information of the data on which their model has been trained when seeking regulatory approval from the MHRA.** A summary of MHRA confidence in the training data should be included in Public Assessment Reports for AI medical devices and vendors should provide trusts/health boards and clinicians with model cards which summarise training data composition and limitations.

2. **The MHRA must maintain their expectation for high levels of evidence** that are proportionate to the complexity of the task the AI model is expected to perform and/or the potential impact of its output on patient care.

3. **The MHRA should conduct a review of AI tools whenever significant changes to their models have been made.**

04 Post-deployment monitoring

Performance of AI tools can change over time. Changes in local population and patient demographics, changes to imaging equipment, and software updates are just some of the reasons why AI tool performance may change. Performance monitoring is essential for ensuring that AI tools are doing their intended job effectively.

While manufacturers are legally required to conduct post-market surveillance of their AI medical devices, local services also conduct post-deployment monitoring, which is essential for bolstering patient safety and detecting and escalating performance issues quickly. There is extensive guidance and support available for AI tool manufacturers on post-market surveillance. The same is not true, however, for local radiology departments and oncology services conducting vital post-deployment monitoring.

A national post-deployment monitoring system

While the number of AI tools used in radiology departments and cancer centres varies from site to site, the overall number is growing rapidly. Many of these technologies have the potential to enhance efficiency and patient care, but their real-world performance must be monitored.

With each new tool introduced into a service, a new system for post-deployment monitoring is required. This places a growing and significant burden on already busy clinicians, adding to the pressures they are under.

As the number of AI tools being used in the NHS proliferates, a new approach to post-deployment monitoring is required that enhances patient safety and mitigates against the significant potential increase in demand on clinicians' time.

A single, national digital post-deployment monitoring system for AI tools being deployed in the NHS should be developed. This system should provide clinicians with a simple means to flag errors or concerns and a fast-paced feedback loop that alerts local departments to any identified problems in their locality, as well as nationally, quickly.

This single, national system would help to reduce the post-deployment monitoring burden placed on clinicians. It could also offer a useful post-market surveillance tool for smaller innovator companies who may struggle with the potential cost of robust post-market surveillance themselves. This approach would, in addition, allay the concerns that some health professionals will have of vendors 'marking their own homework', and importantly enable quick notification of any issues at a national scale.

We recognise that a large national, digital infrastructure project of this nature is challenging and will take time to develop and deliver. It will require a simple way for clinicians to flag concerns about AI tool errors and, where relevant, it will also need to be able to pull performance data directly from local areas. It will need to bring cross-sector stakeholders together from the start, to strengthen its chances of success. The system would require piloting in a variety of different sites, using a variety of different AI use cases, tracked over

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time to ensure lasting accuracy. We suggest that this single, national system should focus on AI medical devices, rather than wider AI-driven digital health technologies being used in the health service.

Recommendations

4. **A single, national digital post-deployment monitoring system for AI tools being deployed in the NHS should be developed. This system should provide clinicians with a simple means to flag errors or concerns and a fast-paced feedback loop** that alerts local departments to any identified problems in their locality, as well as nationally, quickly.

05 Medical liability

The medical liability implications of AI use in the NHS are regularly cited by our members as a major concern. There is limited case law in the context of healthcare AI tools failing to perform as expected, resulting in an understandable nervousness from clinicians.

A national deliberation on AI-related medical liability

Some of our members have told us that a degree of responsibility should and will always lie with the clinician, regardless of the extent of an AI tool's involvement in decision making. However, what this might look like in practice is unclear and a range of joint-liability and vendor-liability models have been proposed[xiv]. This includes joint manufacturer and trust/health board liability, joint manufacturer and government liability, and sole liability sitting with the manufacturer in cases where AI tools are used autonomously.

A national deliberation on liabilities surrounding AI tools in the NHS should be prioritised. This deliberation should involve all relevant parties, including industry, regulators, Trusts/health boards, clinicians, patients and civil society. The National Commission for AI Regulation should lead this national deliberation, with the support of government.

The national deliberation should examine what appropriate liability models should look like for different use cases both now and in the future – i.e. if fully-autonomous AI tools are used in the NHS. The deliberation should also consider liability in cases where not using an AI tool is considered medical malpractice. It would be prudent to look at approaches beyond the UK and explore how they could be adapted to a national context.

Recommendations

5. **A national deliberation on liabilities surrounding AI tools in the NHS should be prioritised. This deliberation should involve all relevant parties, including industry, regulators, Trusts/health boards, clinicians, patients and civil society.**

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