The Royal College of Radiologists

Global approaches to AI in radiology: international literacy and vigilance for the future

Report of a high-level roundtable discussion of global thoughtleaders in healthcare AI at the RCR-NHS Global AI Conference 2025

July 2025

Summary

- Artificial intelligence (AI) will soon become embedded across all of healthcare.
- AI has the potential for both great benefit and, if used inappropriately, significant harm.
- Moreover, the rapid evolution of AI tools and their capabilities means the potential benefits and harms are also always potentially changing.
- Therefore, clinicians and healthcare systems across the globe need to focus their attention and efforts on AI vigilance[1].
- Similarly, individual clinicians and healthcare systems around the globe can and should learn from one another and collaborate internationally.

Background and context

On Tuesday 4 February 2025, the RCR convened a group of international clinical AI experts from worldwide radiological societies during the inaugural RCR Global AI Conference. The aim of this session was to share insights and information from a range of jurisdictions about AI deployments in radiology and healthcare more broadly, and to scope out the potential for international cooperation and collaboration.

This document summarises the discussion held by the participants and highlights the major topics that were considered. Discussions were held under the Chatham House rule. A list of attendees can be found in the appendix.

International variation in barriers to AI deployment

- AI deployment projects face similar challenges in most jurisdictions. However, the overall barriers to deployment can be higher or lower in different countries, owing to legislation and regulation. For example, barriers to deployment are relatively high in the UK, whereas they are relatively low in South Korea[2].
- The balance between deployment barriers and post-deployment surveillance should be inversely proportional. **Barriers to deployment can and should be lower where there is better post-deployment surveillance** of AI tools' performance.
- The European Union's AI Act, on top of its Medical Device Regulation, makes it clear that post-market monitoring for AI tools is a legal requirement[3]. The obligation is upon the providers of these tools to conduct the monitoring and act upon its results where necessary. Deployers of AI tools are also obligated in various ways, including to log their use of the tool, report on its performance, and inform of any serious incidents. In the Act, 'deployer' refers both to healthcare organisations and the individual healthcare professionals they employ[4].
- In many nations, regulatory bodies and their processes were established decades ago, prior to the advent of healthcare AI. This means that current regulatory frameworks governing AI are often based on previous approaches, such as those taken for pharmaceuticals.

- The challenge will be in **scaling at sufficient pace** any AI-specific framework that is put in place, given the pace of change of AI tools' capabilities and availability. The Food and Drug Administration in the USA has recently indicated it would like to see greater clinician ownership of the shaping of AI healthcare regulation and the delivery of its requirements[5].

AI vigilance

- What is currently missing in most, if not all, countries is an **AI equivalent of pharmacovigilance**. This would be the process by which the performance of AI products are monitored and evaluated after they have been approved for routine use, with the aim of identifying adverse effects not previously reported, and monitoring those already known.
- During the discussion, the term "**AI vigilance**" was proposed to describe a combination of processes concerned with the awareness and surveillance of AI products to ensure they are performing in the way it is believed they ought and to ensure the outcomes of their use are congruous with predicted models within a pre-specified population and use case scenario.
- Any AI vigilance framework **should not merely duplicate the processes of pharmaceutical trials** and pharmacovigilance. This is for several reasons. Pharmaceutical trials are expensive and time-consuming; given the pace at which healthcare AI is moving and given the financial situation of many start-up companies developing these tools, it is unrealistic to expect a similar situation to develop for AI at this stage.
- Moreover, once a drug is prescribed, the medical practitioner has little control over its effect on the patient or trial participant. By contrast, with AI tools, the clinician can directly intervene and interact with the AI's treatment recommendations. It may be more useful to **think of an AI tool as an "additional clinician" that requires supervision** and direction, rather than an exogenous pharmaceutical agent.

Preserving AI tools' intended use

- It is also important to consider how to **avoid AI being used outside the scope** of its use-case scenario. In all cases, prevention of poor outcomes is better than responding to them after they occur.
- A given AI technology may, in and of itself, be a good tool with an intended use and intended user. However, **using AI outside of its intended context is what carries risk**.
- An obvious example of this would be the use of an AI tool to replace a clinician altogether in unsociable hours, e.g. overnight. Though the tool would be appropriately used during the daytime, when under clinician supervision, unsupervised activity would be inappropriate unless the tool were specifically designed and tested for this purpose.
- Another example would be the use of an AI algorithm trained for interpreting adult chest X-rays on the X-rays of children. If the product is not correctly labelled for "adult use only", then it may be used in the reporting of child X-rays, thereby risking incorrect outcomes.
- Existing regulations can result in partial or narrow approvals. For instance, the FDA has cleared an AI solution that identifies large vessel occlusions from CT-Angiography scans – but only to

triage stroke patients, not to detect strokes[6]. Currently, neither the USA nor the EU have cleared AI solutions to diagnose strokes from CTA scans.

- These scenarios raise the question of **who should be responsible** for the correct use of an AI tool in a clinical setting? It is clear that **responsibility needs to be distributed** across different individuals and groups.
- For their part, governments must require that **manufacturers clearly identify the use case scenarios** of their AI products, and define the populations on which the AI algorithms have been trained or are suitable for use.
- For example, in Germany, it may soon be federal law that AI be used in lung cancer screening, following the announcement of the country's first national programme[7] [8]. There is little agreement about which AI tools should be used, however. German colleagues are hoping to be able to provide tools for evaluating multiple tools via quality assurance of their outputs, in order to facilitate these decisions.

The importance of AI literacy

- One barrier to AI deployment is a **lack of education in AI fundamentals** and the use of AI in healthcare. AI education is also an important aspect of AI vigilance and the post-market surveillance of AI tools, to generate 'AI literacy'.
- Education of healthcare professionals in AI must consider both the **general principles** of AI as well as the **specific skills and knowledge** required for AI's use within specific use case scenarios or medical specialties.
- There are various ways in which AI products could be understood as healthcare tools. By analogy, AI could be akin to a stethoscope – something that all doctors would understand how to use at medical school before beginning ward-based work. If this were the case, then AI training would form a part of undergraduate medical curricula.
- Alternatively, AI could be akin to a scalpel – a tool all doctors have training in, but which is primarily wielded by specialist doctors with additional training, who can wield it to great effect. In this scenario, AI education would fall into postgraduate medical training, but prior to specialisation.
- Thirdly, AI could be akin to a machine, such as a diagnostic scanner, which everyone has an awareness of, but the use of which to acquire and interpret medical images requires skilled personnel (radiographers and radiologists). In this scenario, AI education would take place during specialty training.
- None of these three scenarios is likely to come to pass exclusively. Indeed, it is **likely that all doctors will require some grounding in the fundamentals of AI, whilst specific specialties receive further training** in specific AI use cases.
- Eventually, **AI training is likely to become a core part of fundamental medical education**. However, until the first cohort of doctors trained under such a regime become sufficiently senior, there will be a need to educate the current under-trained workforce in AI vigilance and regulation.

Education and upskilling: who needs to train who?

- Responsibility for AI literacy sits across various organisations. Colleges and professional bodies are well placed to enable local practitioners to safely discharge care. **Clinicians need to become confident in using their clinical judgment in the use of AI, for which they require support**.
- For example, within radiology, the professional body in each nation has a role to play, via training and education, to enable radiologists to understand and use AI tools, in the same way that they use other radiological software or equipment.
- In Sweden, the Swedish Society of Radiology have created short, two-page learning materials for radiologists on the use of AI tools in clinical practice. Successful completion of these materials represents certification of the ability to successfully use AI tools.
- Radiology is a highly digital specialty. The **radiologist of the future will know the capabilities of the AI tools** they are using to make frontline clinical decisions, whilst working with technologists and IT specialists. Just as a radiologist needs to understand the fundamentals of MRI physics, so too will they need to understand the basics of data science. Indeed, this will arguably become a requirement of all clinicians.

Policymakers and the public

- It is important also to consider the **AI literacy of the general public and of lawmakers**. This is true of all nations and jurisdictions, though some may be further along than others.
- It is perhaps unrealistic to expect that elected lawmakers and policymakers within government departments will be informed in the intricacies of the use of AI in specific healthcare contexts, and how patient pathways may be affected by its adoption. RSNA in the USA have drafted model legislation for US lawmakers with this consideration in mind; radiological societies around the globe may wish to conduct similar exercises.
- This points to the **importance of clinician involvement in the development of governments' and healthcare systems' strategies and plans** for AI adoption. Clinician involvement will be key to making AI deployments both safe and effective for patients.
- **Clarity for the public** would also help their understanding and acceptance of how AI is being used in their healthcare. Public acceptance of AI may be enhanced if they understand that the right regulatory frameworks and safety nets are in place, along with an educated, vigilant clinician in the loop.

Conclusion

Across the globe, healthcare systems and healthcare professionals are starting to consider how they can adopt and adapt to the use of AI in their clinical practice. Approaches vary by national legislation, regulation, and processes of healthcare delivery.

However, all healthcare professionals, regardless of location, will have to make similar considerations and tackle similar issues. Clinicians everywhere need to be upskilled in the skills of AI vigilance and AI literacy, with professional bodies playing a key role. Medical training curricula need to adapt to the rising tide of new AI technology by preparing the doctors of tomorrow to be adept at assessing, implementing and utilising AI. Governments and regulators must ensure frameworks are in place to facilitate safe and effective AI deployment; these frameworks must be fit for purpose and easy to use. Clinical voices must have a place at the table to inform policy development and promote public trust.

Healthcare systems and professional bodies should take every opportunity to learn from their counterparts in other nations. Collaboration and cooperation would be invaluable in terms of identifying opportunities and ameliorating risks posed by AI in healthcare.

Appendix: list of attendees

- Professor Owen Arthurs – Roundtable chair, and Chair of RCR-NHS Global AI Conference
- Doctor Stephen Harden – Vice President for Clinical Radiology, RCR
- Dr Dana Smetherman – Chief Executive, American College of Radiology (ACR)
- Prof Christoph Wald – Chair, Department of Radiology, Lahey Hospital
- Dr Martin Völker – Deputy Managing Director and Head of Science, Young Talent and Quality, Deutsche Röntgengesellschaft
- Prof Matthias May – Senior Attending Physician, University Hospital Erlangen
- Dr Sophia Zackrisson – Professor of Radiology, Lund University
- Dr Joakim Crafoord – Senior Consultant Radiologist, Karolinska University Hospital and CMO, Telemedicine Clinic
- Dr Seung Eun Jung – President, Korean Society of Radiology (KSR) KSR
- Prof Seong Ho Park – Department of Radiology, University of Ulsan College of Medicine and Editor-in-Chief, Korean Journal of Radiology
- Kicky van Leeuwen, PhD – AIFI Project Lead, Clinical and Governance, The Dutch Society of Radiology (NVvR) and Co-Founder and Managing Partner, Romion Health

[1] Tongia, R (28 May 2024) "Why regulating AI can be surprisingly straightforward, when teamed with eternal vigilance". Available at: https://www.weforum.org/stories/2024/05/why-regulating-ai-can-be-surprisingly-straightforward-providing-you-have-eternal-vigilance/ (Accessed April 2025).

[2] South Korea's National Assembly recently passed its 'AI Basic Act' which would create a framework for AI regulation. Healthcare AI would be classified under this Act's regulations as 'high-impact', requiring greater safety assessments. However, the Act will not come into effect until January 2026 at the earliest. See: https://www.trade.gov/market-intelligence/south-korea-artificial-intelligence-ai-basic-act

[3] See Chapter IX, Article 72 of the Act: https://artificialintelligenceact.eu/article/72/

[4] https://www.sciencedirect.com/science/article/pii/S0168851024001623#tbl0001

[5] See here for the FDA's approach to AI regulation in medical devices: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation

[6] https://www.aidoc.com/learn/blog/stroke-ai/

[7] See this statement from the Deutsche Röntgengesellschaft: https://www.drg.de/de-DE/10953/lungenkrebsfrueherkennung/. The programme follows on from on the HANSE study, which used AI tools as a second reader of low-dose CT scans. This may be replicated on the national level once the Federal Joint Committee issues its guidance. See: https://www.thieme-connect.de/products/ejournals/html/10.1055/a-2178-2846

[8] Hahn, Horst K. et al. (February 2025) "Requirements for Quality Assurance of AI Models for Early Detection of Lung Cancer". Available at: https://arxiv.org/abs/2502.17639

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