Commentary

The Time is Now: Making the case for a UK Registry of Deployment of Radiology AI applications

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Abstract

Artificial intelligence (AI)-based healthcare applications are rapidly evolving, and radiology is a target specialty for their implementation. In this paper, we put the case for a national deployment registry to track the spread of AI applications (AI-apps) into clinical use in radiology in the United Kingdom (UK). By gathering data on the specific locations, purposes and people associated with AI-app deployment, such a registry would provide greater transparency on their spread in the radiology field. In combination with other regulatory and audit mechanisms, it would provide radiologists and patients with greater confidence and trust in AI-apps. At the same time, co-ordination of this information would reduce costs for the National Health Service (NHS) by preventing duplication of piloting activities. This commentary discusses the need for a UK-wide registry for such applications, its benefits and risks, and critical success factors for its establishment. We conclude by noting that a critical window of opportunity has opened up for the development of a deployment registry, before the current pattern of localized clusters of activity turns into the widespread proliferation of AI-apps across clinical practice.

Introduction

Artificial Intelligence (AI)-based applications - AI-apps - are widely viewed as essential to modernising healthcare systems. Such apps have great potential to improve productivity and performance by supporting the analysis, interpretation, and categorisation of the enormous amounts of data generated for diagnosis and treatment[1,2]. Within the healthcare arena, radiology is seen as one of the most promising fields for the near-term deployment of clinical AI. The rapid development of image-based AI in the non-medical world offers ready applicability to the large volumes of stored imaging-based radiology data that are required to train AI-apps[3]. Should AI indeed fulfil its potential, then the resulting transformation of medical imaging and healthcare is expected to impact not only the work practices of radiologists[4] and outcomes for patients, but the whole field of radiology itself[5].

Despite their potential, experience to date suggests that integrating AI-apps into daily clinical practice will prove challenging[6,7]. Certainly, the adoption and implementation of radiology AI-apps in the UK to date is unevenly distributed, being more accessible to larger and more advanced hospitals. Major implementation challenges include the pressing need for appropriate governance structures and guidelines, unresolved ethical issues, and commercial sensitivity[8-11]. Furthermore, the working principles of the algorithms underpinning these apps may be so obscure as to create what is termed a 'black-box effect'[12]. These issues jeopardise radiologists' and patients' trust in AI-apps, especially as the implications for patient safety and outcomes remain uncertain[13]. In response, there are widespread calls for greater transparency around the use AI in healthcare[14]. But, while efforts are underway to increase the 'explainability' of the AI-apps themselves[15], at the healthcare system level such transparency is limited by a lack of information on what applications are deployed where, by whom, and with what purpose[16]. In this commentary, therefore, we argue for the need to build a UK-wide registry of deployed radiology AI-apps, discuss its benefits and risks, and consider critical success factors relevant to realising its development.

The need for a registry of deployed radiology AI-applications

As a first step towards outlining the development of a such a registry, we need to situate it within the current regulatory context. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) mandates that all medical devices are approved and registered with the agency prior to being lawfully marketed in the UK. This includes AI-apps as a medical device[17]. As with other medicines and devices, manufacturers are required to submit vigilance reports, including any incidents, as well as the plan for corrective action. In addition, patients or users can utilise the well-established yellow card system to report any unexpected findings or incidents related to using a medical device[18]. Further, as part of its response to the introduction of AI, the MHRA has taken an important step forward in its guidance document[19] by establishing a major work programme on 'Software and AI as a medical device change programme'. This is evaluating the changes that are needed to ensure that the regulatory

framework provides a high degree of protection for patients and public, and to ensure that the UK supports responsible innovation for medical device software.

A registry of AI-app deployment would be differentiated from the MHRA registration process, but would enhance safety in their implementation. The need for, and potential workings of such a registry, can be highlighted by a comparison with the drivers of existing UK-wide registries, which seek to monitor the deployment and performance of some non-AI related healthcare innovations. In the case of a deployment registry, the sites of deployment, rather than patient outcomes, would be recorded. Nonetheless, important comparisons can be made with patient-based registries. One such example is the renowned National Joint Registry (NJR) which is the largest orthopaedic registry in the world[20]. High quality and relevant data on the type of surgery, the implant used, and the patients receiving surgery are collected into the NJR via a secure electronic data entry system. The NJR was established in response to the high failure rate of a particular type of hip replacement: the 3M Capital Hip[21]. The initial absence of a registry prevented the timely tracing of 3M Capital Hip patients, causing significant complications for these patients and public concern. To avert incidents like these in the future, the introduction of the NJR enabled the monitoring of the cost-effectiveness, quality, and safety of joint replacement surgeries conducted in the UK[20].

Another example is the Breast and Cosmetic Implant Registry (BCIR), which captures data on breast implant surgeries conducted in England, Scotland, and Northern Ireland[22]. Similar to joint replacements, breast implants were introduced to the market without a supporting deployment registry. However, safety and regulatory issues emerged, such as the unsafe Poly Implant Prostheses silicone breast implants, which had to be withdrawn from the market due to a high risk of rupturing and complications in patients[23,24]. To better monitor the safety of breast and cosmetic implants and allow for the tracing of patients fitted with implants, the BCIR collects data on patient, implant, surgery, and after-care details.

The case for a new AI-app registry is reinforced by more recent experience directly targeting such apps in healthcare. The Kent Surrey Sussex Academic Health Science Network was commissioned by Health Education England to map AI-apps ready for the UK healthcare market to understand their impact on the workforce and patient care[25]. The produced AI roadmap only includes publicly available data and findings were not validated, but the efforts show the clear need for information on deployment of such apps. For radiology specifically, the Scottish Radiology Transformation Programme, with support from NHS Scotland, developed a Scotland-wide registry to foster a consistent and efficient approach to the adoption of such applications[26]. The registry holds data on those responsible for the applications' deployment, manufacturer and regulatory details, the applications' intended purpose, and the location and date of implementation. Rather than collecting identifiable patient data, such as in the NJR and BCIR, this registry focuses on deployment information only. This helps to avoid the duplication of piloting activity, and enhances opportunities for learning across the radiology community. This pioneering work provides an excellent exemplar for the development of a UK-wide registry.

Current status in radiology AI-app deployment

Apart from the aforementioned Scottish registry of AI-app deployment and the AI roadmap, the extent of deployment of each radiology AI-app into clinical systems in the UK is not tracked and the authors are not aware of any national registries of radiology AI-app deployment. However, there is considerable interest in radiology AI-app deployment and several surveys have been undertaken, or indeed are currently circulating, to investigate various aspects of AI-app usage in radiology. These surveys explore ethical considerations, attitudes to use, expectations and hurdles encountered (Table 1)[11,27-36]. An on-line overview of CE-marked or FDA approved tools was published as a resource which is designed to be of interest to those wishing to identify a radiology AI-app for use in their

department[36]. The authors found that only 18% of these had evidence of efficacy of level 3 (demonstrating added value to the diagnosis) or higher.

The American College of Radiology (ACR) undertook a large survey[27] of their members which found that 30% of radiologists are currently using AI-apps in their practice. They are most commonly used in breast, thoracic and neurological imaging, and primarily for assisting with image interpretation. These findings were consistent with a recent European Society of Radiology (ESR) survey[31], where 40% of members responding had experience with AI-apps, up from 20% from their 2018 survey[30]

The ACR survey also found that many of the US FDA approved algorithms were not being used in clinical practice. In fact, 10% of radiologists using AI-apps in clinical practice are using algorithms they had developed locally, which, in aggregate, is a higher use rate than any of the commercially developed algorithms (9%). They also found that large practices are more likely to be using AI-apps than smaller practices. Overall, the survey authors felt the penetrance of AI in clinical practice was limited by concerns about inconsistent results, productivity, and a lack of trust in the safety and efficacy of AI-apps.

Table 1: Summary of literature review on surveys of AI in radiology**.**

Author/year of publication	Participants, design, and number of respondents	Topics covered	Results summary
Collado-Mesa[37]	• Radiology • US - local	• Demographic information	• 29% of respondents using AI in practice (N.B. predominantly

J Am Coll Radiol (2018)	• Email with online survey • Jul-Aug 2017 • 69 respondents (66% of invitees)	• Familiarity with AI medical literature • Current use of AI (N.B. including voice recognition tools, rather than specifically radiology AI apps) • Predicted impact of AI on jobs	voice recognition rather than radiology AI apps) • 67% willing to help train/develop AI • 80% think AI will dramatically affect job of radiologists in the future
European Society of Radiology[30] Insights Imaging (2019)	• Radiology • EU • Email to members with online survey • Nov-Dec 2018 • 675 respondents (2.8% of invitees)	• Demographic information • User feelings/forecasts about AI in radiology in the next 5-10 years • Involvement in AI system development	• 20% of respondents using AI in practice • Expect AI to impact on job opportunities, reporting workload and job profile of radiologists, though variation in what these impacts would be • 30% are planning to use AI in the future
Ooi[38] Singapore Medical Journal (2021)	• Radiology • Singapore - national • Email with online survey	• Demographic information • Predicted impact of AI • Perceptions of career prospects	• 17% of respondents involved in AI research • 89% feel AI will drastically change practice

	• Dec 2018 • 125 respondents (25% of invitees)		• 67% keen to be involved in an AI project
Waymel[39] Diagnostic and interventional imaging (2019)	• Radiology • French - local • Email with online survey • Jan 2019 • 270 respondents (43.8% of invitees)	• Demographic information • Level of AI knowledge • Expectations for use of AI in practice • Predicted impact of AI	• 7% of respondents using AI in practice • 24% are planning to use AI in the future • 79% feel AI will have a positive impact on their practice • Main perceived advantages are lowering imaging-related medical errors (81%) and lowering interpretation time (74%)
Coppola[29] Radiol Med (2021)	• Radiology • Italy - national • Email to members with online survey • April 2019	• Demographic information • Level of AI knowledge • Attitude towards AI	• No data on use in practice • 77% were favourable to the adoption of AI • Main perceived advantages included

	• 1032 respondents (9.5% of invitees)	• Expectations of potential benefits and disadvantages	lower diagnostic error rate (73%) and optimising workload (68%) • Main concern is negative impact on professional reputation of radiologists (60%)
Huisman[32,33] Eur Radiol (2021)	• Radiology • International • Survey distribution by radiology societies, websites and social media • Apr-Jul 2019 • 1041 respondents (estimated 3.9% of society invitees)	• Demographic information • Fear of replacement, knowledge, and attitude • Expectations, hurdles to implementation, and education	• No data on use in practice • Higher levels of knowledge of AI are inversely associated with fear of AI • 85% willing to use AI in the clinical setting • Expected roles of AI are as a second reader and work-flow optimisation • Ethical, legal issues and a lack of knowledge were most common barriers mentioned

Scheetz[35] Scientific Reports (2021)	• Ophthalmology, dermatology, radiology & radiation oncology • Australia & New Zealand – national • Jun-Aug 2019 • 632 respondents (9.4% of invitees)	• Demographic information • Perceived impact of AI on the profession • Expectations of potential benefits and disadvantages • Preparedness for the introduction of AI in clinical practice	• 31% of respondents were in radiology, of those 5% have used AI in practice • Ophthalmologists most likely of specialties included to use AI in practice (16%) • Most common perceived advantage was improved patient access to disease screening • Most common perceived disadvantage was divestment of data to technology companies • 14% felt adequately prepared for introduction of AI into clinical practice
Allen[27]	• Radiology • US - national	• Demographic information	• 30% of respondents using AI in practice

J Am Coll Radiol (2021)	• Email to members with online survey • Apr-May 2020 • 1427 respondents (7% of invitees)	• How they were using AI as part of clinical work • Evaluate AI models in their practice	• Large practices more likely to use AI than smaller ones • Most common use was for enhancing interpretation • Of those not using AI, 20% plan to in the next 5 years
MacCormick[11] Clinical Radiology (2021)	• Radiology • UK- regional • Email with online survey • Date unknown • 88 respondents (58.6% of invitees)	• Whether and how often they used radiology mobile AI • What devices they used to access the AI • Awareness of and practices around assessment of reliability	• 55% of respondents used radiology mobile AI and 35% used this daily • Respondents mentioned a total of 33 phone apps which they predominantly used on their phones (53%) • 33% of respondents assessed the AI for reliability
Rainey[34] Front Digit Health (2021)	• Radiography • UK - national	• Demographic information	• 1% of respondents using AI in practice • 80% respondents were in diagnostic

	• Survey promoted on social media • Feb-Apr 2021 • 411 respondents (1.3% of workforce)	• Perceived knowledge, skills, and confidence in AI in radiography	radiography, 20% in radiotherapy • 79% of diagnostic and 52% radiotherapy felt they understood AI in general • 57% of diagnostic and 49% radiotherapy felt not adequately trained to implement AI clinically
Banerjee[28] BMC Med Ed (2021)	• Postgraduate doctors • UK – regional • Email with online survey • Oct-Dec 2021 • 210 respondents	• Demographic information • Current use of AI and exposure to AI • Perceived impact on AI on training and education • Expectations of potential benefits and disadvantages	• 2.4% of respondents were in radiology • 16% of respondents using AI in practice • 61% felt AI would reduce their workload • 59% felt AI will improve education and training • Radiology respondents had more AI positive perceptions than other specialties

European Society of Radiology[31] Insights Imaging (2022)	• Radiology • EU • Email to members with online survey • Jan-Mar 2022 • 690 respondents (2.5% of invitees)	• Demographic information • Experience with AI-based algorithms • Technical integration, confidence in diagnostic performance, quality control mechanisms • Impact on workload • Intentions to use AI in the future	• 40% of respondents using AI in practice • Most used in diagnostic interpretation, image post-processing, and prioritisation of workflow • 76% considered the results of algorithms to be generally reliable • Minority (23%) experienced significant reduction in workload
MONAI Deploy Working Group[40] Unpublished	• Radiology, medical physics, radiography • International • Social media with online survey • Mar 2022-current	• Demographic information • Priorities for clinic AI • Current use of AI • Challenges in AI deployment • Quantifying imaging studies processed by AI	• Unpublished

The AI roadmap shows that in 2021 a total of 14 AI-apps were implemented in an NHS site, but limited information on the deployment process is provided by the roadmap[25]. The Scottish registry of AI-app

deployment has currently identified 18 radiology AI-apps, which have been deployed or are in the process of deployment on the basis of research (n=7) or clinical validation (n=11). No radiology AI-apps have been identified that are being used in routine clinical practice. Although the Scottish initiative is encouraging, it may be that the scale of creating a UK-wide registry of radiology AI-app deployment is a challenge. Nonetheless, the range of surveys demonstrate significant variation in radiologists' attitudes, expectations and knowledge of AI-apps. However, there is limited evidence on the scale of deployment of AI-apps, as well as their impact on patient outcomes and radiologists' workloads. The benefits of such a registry should therefore be considered.

Opportunities and challenges

A registry for clinically deployed radiology AI-apps would provide many opportunities, but also comes with challenges. The balance of opportunities and challenges is summarised in Table 2 below. In relation to the opportunities, post-marketing surveillance would be enhanced by allowing independent bodies to collect and analyse multi-site information concerning the experiences of technical deployment and usage as well as any suspected safety concerns that could be linked to the deployment or clinical use of a radiology AI-app. This would be a valuable addition to the MHRA's voluntary yellow-card reporting system, not least because this system is not uniformly used by all patients or app-users. Indeed, an app-related problem encountered at one site may not be recognised at that site as being potentially a wider problem. The registry could also serve as a basis for audits, helping bodies such as the Clinical Radiology Audit and Quality Improvement Committee of the Royal College of Radiologists (RCR) to identify when and where an audit is needed and to coordinate the audit. For example, if large numbers of a particular AI-app have been deployed, the audit committee may wish to prioritise a national audit of the performance of this app. In the longer term, well-developed independent post-marketing surveillance and auditing contributes to the quality and safety of radiology AI-apps, thereby assisting in the monitoring of patient safety.

Opportunities for research and evaluation could also flow from an AI-app deployment registry since this would reduce duplication and repetition in studies of radiology AI-apps, supporting more efficient allocation of the NHS's scarce resources. Multi-site research studies would also be easier to coordinate by using the information held in the registry. The potential of the registry to support research would increase as the registry matures and holds more data on the deployment and adoption of AI-apps in radiology.

One less tangible but nonetheless valuable opportunity of a deployment registry would derive from connecting the individuals involved in similar AI projects[41]. Building such links facilitates the emergence of communities of practice and the sharing of tacit knowledge and best practice which may prove invaluable to the successful adoption of radiology AI-apps[42]. In addition, the spread of the most valued apps might be boosted by the registry by enabling greater awareness and knowledge of their use in the radiology community[43].

All the aforementioned opportunities contribute to increased transparency around the deployment of radiology AI-apps, which in turn can contribute to public and practitioner trust in the quality and safety of the applications[14]. This transparency is dependent on the availability and accessibility of the data held in the registry. Public availability of data, though risking frictions around commercial sensitivity and confidentiality, would undoubtedly enhance transparency. To fulfil this potential, however, it is key that the registry remains up-to-date, complete and accessible. This may be particularly challenging to achieve if inclusion of deployed apps on the registry is voluntary.

In identifying the challenges of developing a registry that is fit for purpose, we were conscious of the additional burdens of collecting, curating and storing data that might be placed on different stakeholder groups. One concern, for example, would be to prevent over-regulation of AI deployment. There is a risk that keeping the registry up-to-date is seen as an onerous undertaking due to

administrative time and costs, particularly in the early stages of setting up the registry when the benefits may not be instantly available. If mandatory, the administration of adding each site to the registry could take too much time from stakeholders in an already pressured healthcare system such as the NHS and this could potentially hamper the implementation of AI-apps altogether[44]. Conversely, if inclusion on the registry is voluntary, the information would be incomplete, thereby decreasing, though not negating, its reliability and value as a representation of current practice[24,44].

Table 2. Opportunities and challenges of a registry for deployed radiology AI-apps.

	Opportunities	**Challenges**
Surveillance and audit	• Post-market surveillance can be conducted by an independent body • Possibility to audit by the RCR audit committee • Possibility to monitor patient safety	• Over-regulation of AI deployment
Efficiency and cost-effectiveness	• Improved use of resources • Shared learning from deployments • Greater awareness of AI-apps	• Administrative costs
Research	• Possibility for (multi-site) research	• Incomplete data if the registry is voluntary

Trust	• Increased transparency and trust	• Confidentiality of data

Critical success factors

As the development of a national registry is resource intensive and complex, it will inevitably require the construction of a detailed business case. Although this task is beyond the scope of this commentary, we will discuss a few critical success factors relevant to such a business case. A first such factor is the engagement of stakeholders, such as manufacturers, purchasers, radiologists, and patients[16]. Registries such as the BCIR teach us that stakeholders can provide invaluable clinical input, advice on the content of the registry, the way the registry can contribute to governance, and the presentation of outputs coming from the registry[22]. For the radiology AI-apps registry, this suggests that there is a valuable role to be played by professional networks such as the Royal College of Radiologists (RCR) in reaching out to, and engaging, its members, as the end-users of these AI-based innovations. Industry would also need to be fully engaged as essential stakeholders and the registry would need to work in tandem with the MHRA.

All stakeholders would need to make critical decisions on key issues in the design and scope of the registry, such as its key purpose, the domain it focuses on and the type of radiology AI-apps that will be included in the registry. Designing the registry appropriately in terms of scope and data collection is crucial to ensuring that it is usable and adds value over and above the time and resources required to build and maintain it. This is especially the case since any subsequent changes to the initial design may be costly to implement. A pilot is likely to be an important first step, and the Scottish registry could be used as an initial template.

Regarding purpose, while the registry may have multiple purposes, it is important to establish its primary purpose, be this patient safety, resource efficiency, or learning capture as well as targeting

the primary audience, such as professionals, healthcare providers, industry or regulators. The overarching purpose will inform not only what data are collected in the registry, but also how this data will be used and by whom.

Another important scoping decision relates to the choice of domain, including, as follows: the research domain (where AI-apps are subjected to initial research and not used in clinical practice), the clinical evaluation domain (where an AI-apps are subjected to an evaluation of their performance when used as intended; usually part of pre-market surveillance), or the clinical use domain (where AI-apps are implemented in clinical practice and its use evaluated continuously; usually part of post-market surveillance).

Regarding the scope of the registry, the decision on the type of radiology AI-apps for inclusion is also crucial. Although AI-apps come in many shapes and forms, we can roughly distinguish between software-based applications (e.g. medical image analysis) and hardware-based AI, such as medical devices augmented with AI[45]. The aims of these two types of AI-apps potentially overlap (e.g. to increase early diagnosis of disease and improve decision-making processes in healthcare), but when it comes to building a registry, the different types of applications would pose significantly different challenges in terms of scale, data collection and maintenance. Hardware-based AI, for example, proliferates much more widely in healthcare and is more difficult to monitor as it is embedded within devices rather than identified as a discrete entity. This form of AI would therefore likely not be the focus of a deployment registry.

A final consideration is how to demonstrate the value of a registry. Periodic evaluation of the functionality and use of the registry is crucial to making sure the registry is up-to-date and continuously meets the need of stakeholders and users.

Once stakeholders agree on the design and scope of the registry, resources will need to be mobilized to realize it. These include ICT-support to digitalise and embed the registry in a secure platform and financial support, especially to maintain the registry long-term. Finally, clear ownership and leadership are important as it clarifies who is responsible for the maintenance and monitoring of the registry. Once the registry is ready to go live, the RCR can play an invaluable role in creating awareness of the registry amongst its membership and in approaching those members who are working with AI in radiology themselves or know of colleagues in their networks who do so.

Conclusion

Since radiology AI-apps are evolving and spreading rapidly, there is a need for a UK-wide registry to track the deployment of these applications. As we have shown, smaller-scale initiatives as well as national registries for non-AI medical innovations can provide useful models. In conclusion, however, it is also important to stress the urgency of the case for a deployment registry. A critical window of opportunity currently exists whereby the design and scope of such a registry could be trialled and tested with limited resources around currently localized clusters of activity. One important lesson from examples such as the NJR and BCIR highlighted above is that early development of a registry is key to patient safety outcomes. Stakeholders can and should play a key role in decisions on the purpose, design, and scope of the registry to ensure its functionality and usability. Such a registry could then provide the robust platform required when AI-apps become much more widely spread across clinical practice; the point at which tracking their deployment becomes both immensely more challenging and immensely more important to patients and the NHS in general.

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