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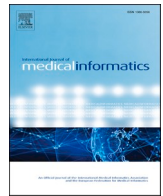
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Black box no more: A cross-sectional multi-disciplinary survey for exploring governance and guiding adoption of AI in medical imaging and radiotherapy in the UK

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ABSTRACT

Background: Medical Imaging and radiotherapy (MIRT) are at the forefront of artificial intelligence applications. The exponential increase of these applications has made governance frameworks necessary to uphold safe and effective clinical adoption. There is little information about how healthcare practitioners in MIRT in the UK use AI tools, their governance and associated challenges, opportunities and priorities for the future.

Methods: This cross-sectional survey was open from November to December 2022 to MIRT professionals who had knowledge or made use of AI tools, as an attempt to map out current policy and practice and to identify future needs. The survey was electronically distributed to the participants. Statistical analysis included descriptive statistics and inferential statistics on the SPSS statistical software. Content analysis was employed for the open-ended questions.

Results: Among the 245 responses, the following were emphasised as central to AI adoption: governance frameworks, practitioner training, leadership, and teamwork within the AI ecosystem. Prior training was strongly correlated with increased knowledge about AI tools and frameworks. However, knowledge of related frameworks remained low, with different professionals showing different affinity to certain frameworks related to their respective roles. Common challenges and opportunities of AI adoption were also highlighted, with recommendations for future practice.

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1. Introduction

1.1 Background

In healthcare, particularly in medical imaging and radiotherapy, the growth of new AI solutions is exponential [1,2]. Recent findings corroborate that AI will contribute to more efficient and effective clinical services for diagnosis and treatment, fewer disparities in the distribution of care, and enhanced precision medicine practices [3]. Both patients and healthcare staff will benefit from AI-based solutions that aim to improve clinical workflows, automate administrative tasks, optimise the accuracy of diagnosis and treatment, and improve patient outcomes [4].

In medical imaging and radiotherapy (MIRT), AI can assist in patient scheduling, protocol optimisation, radiation dose reduction, image quality improvement, streamlined image analysis, and advanced image post-processing [5,6]. For instance, the following examples of effective implementation of AI in MIRT can be given: a) The introduction of automatic lung nodule detection software to ease the workload of radiologists and reporting radiographers for chest x-rays and Computed Tomography (CT) chest scans, b) the integration of AI-enabled patient positioning for CT scanners to increase the reproducibility of patient positioning, c) the implementation of deep learning (DL) algorithms for the increase in signal-to-noise ratio in Magnetic Resonance Imaging (MRI) scans with reduced scan time, and d) the introduction of AI-based image segmentation for different anatomies (e.g., heart, brain) and pathologies (e.g., oncology, neurodegenerative diseases, autoimmune diseases) to facilitate early diagnosis, targeted treatment, and patient follow-up. This is timely, given that the global shortage in healthcare practitioners puts an extra strain on medical imaging departments, and AI could be recruited to offer support in the areas most in need.

Despite the increasing use of AI in the above fields, many requirements still exist for its safe and seamless integration into clinical practice. Rigorous governance frameworks need to be in place to enable safe adoption [7]. Practitioner education is also central for the optimal and safe use of new AI technologies, enabling practitioner acceptability [8–11]. Robust validation of AI models is essential before their deployment in practice [12,13]. Finally, clinical AI used in MIRT needs to be trustworthy, robust, and explainable [14].

1.2 Aim and objectives

This study aims to explore the current use of AI governance frameworks in MIRT, and to identify any opportunities, challenges, and unmet clinical and training needs for those professionals working with AI in the UK.

2. Methods

2.1 Study reporting

This study is cross-sectional, observational, aligned with the STROBE reporting guidelines [15] and in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [16].

2.2 Ethics

Ethics approval was obtained by City, University of London School of Health and Psychological Sciences Research Ethics Committee [ref: ETH2122-1015]. All participants had access to an information participant sheet, and informed consent was sought from them electronically [17]. Participation was anonymous, and no identifiable data was collected. No incentives were offered to participants.

2.3 Data collection instrument

An online questionnaire was built on Qualtrics (Qualtrics, Provo, UT), consisting of 28 closed and 5 open-ended questions, prompting a free text response. Answer options were randomised to prevent response bias [16].

The survey was developed by a multidisciplinary team of radiographers, radiologists, biomedical engineers, medical physicists, data scientists and a linguist with expertise in surveys. The team included professionals with different roles and responsibilities within the AI ecosystem, such as academics, researchers, clinical practitioners and digital health consultants. The content and formatting of the survey questions built on findings derived from the following sources: 1) a scoping review of the literature [14], 2) a focus group discussion with UK-based AI experts, 3) previously validated surveys ($n = 5$) on AI governance in other industries [18–22], 4) group discussion and dynamic editing by the team. After multiple iterations were explored, the final survey questions were based on consensus between the researchers. Piloting of the instrument [23] was performed by field experts ($n = 9$) to ensure face and content validity [24].

2.4 Participants

This study employed purposive sampling to ensure the most relevant respondents were included [25]. Participation criteria included a) being a UK-based qualified professional, b) working in MIRT, and c) having some theoretical and/or practical knowledge and expertise on AI-enabled software or hardware.

2.5 Data collection

All participants gained access to the survey via an anonymised link. The survey was open between November 7th to December 12th, 2022. It was distributed via email through the researchers' professional networks and shared in relevant professional groups on social media (Twitter, LinkedIn). The British Institute of Radiology, the Society and College of Radiographers, and the Institute of Physics and Engineering in Medicine supported the survey, all of which also helped with survey distribution and recruitment of participants.

2.6 Data analysis

Descriptive statistics was used to analyse the quantitative data of the survey. Where appropriate, cross-tabulations were employed alongside Pearson's chi-square test (χ^2) of independence to evaluate any relationships between important variables, such as professional background, years of prior experience with AI and prior AI training [26]. To measure the effect size of any statistically significant associations, Cramer's V coefficient was used; for Cramer's V larger than 0.25, the association was considered to be very strong, between 0.15 and 0.25 strong and between 0.10 and 0.15 moderate [27]. All statistical analyses were performed using the Statistical Package for the Social Sciences software, version 26 (Armonk, NY: IBM Corp.).

Open-ended questions were analysed using content analysis. Findings were organised in topic categories and themes [28]. This was achieved by iteratively coding and grouping the findings of this study. This analysis was performed by one researcher, double-checked by a senior researcher, and any discrepancies were resolved with team discussion.

3. Results

Out of 380 responses, 245 were deemed valid for analysis. Valid responses represented those who answered demographic questions and at least one of the governance-related questions of the survey. This approach was followed to ensure inclusion of all meaningful data.

3.1 Main demographics

A good range of geographical distribution was noted among the respondents (Fig. 1).

Over a third of the respondents (36.2 %) were 31–40 years old, followed by those between 41 and 50 (28 %), 51–60 (22.2 %), and 23–30 (8.2 %). Regarding gender, a moderate predominance of men was noted (53.7 %). Table 1 below summarises the workplace for survey respondents. University hospitals held the lion's share, compared to other work settings.

Respondents from a wide range of professional backgrounds were involved in this study (Fig. 2). Diagnostic, therapeutic radiographers and sonographers were all grouped under “radiographers”.

Regarding their predominant role, most of them (53.3 %) reported having a clinical practitioner role, followed by academics/researchers (14.8 %), educators (8.3 %), vendor representatives (7.0 %), clinical applications specialists (4.5 %), consultants on digital health/medical informatics (4.1 %), and professional/regulatory body officers (2.7 %). A further 5.3 % of the respondents reported having other types of roles, including managerial or newly developed roles, such as AI leads or digital transformation leads.

Those with 0–10 years of experience accounted for over a third of the respondents (37 %), followed by those with 11–20 years (34.5 %) and those with over 20 years of experience (28.5 %).

3.2 AI training and education

Almost half of the respondents (47.6 %) reported not receiving any AI training in the past, compared to 46.3 % who had. Of the latter, a quarter (25.9 %) said they had received self-guided training. Over a third (34.2 %) of that training was online, with onsite/on-campus training (21.8 %), knowledge gained from textbooks (15 %), hybrid forms of training (14 %), and training via online applications (8.3 %) as other options.

3.3 Regulation

A significant proportion of respondents (42.1 %) felt unsure when asked if the organisations they worked at used AI governance frameworks (Fig. 3).

Radiographers were more likely to use such frameworks (43.9 %)

Table 1

Workplace of respondents.

University Hospital	41.7 %
District General Hospital	16.2 %
University or other type of Higher Education Institution (HEI)	12.0 %
Medical Imaging and Radiotherapy Company	7.3 %
Another type of clinical setting	7.0 %
Private Hospital	6.3 %
AI-start up	3.6 %
Other type of setting	3.6 %
Private Clinic	2.3 %

compared to medical physicists (28.8 %) and radiologists (9.1 %). A significant association was found between professional background and use of frameworks (p -value = 0.049, V = 0.214).

Most of the respondents (57.5 %) said that they were aware of the guidance issued by the Medicines and Healthcare Regulatory Agency (MHRA) regarding the need for CE-marking and UKCA-marking on all AI medical devices for use in the UK [29]. Half of those who were aware of this guidance were medical physicists, followed by radiographers (28.5 %) and radiologists (6.3 %).

Of those unaware of the MHRA guidance, the majority (69 %) had not received any training, and there was a statistically significant association between training and MHRA knowledge (p -value = 0.007, V = 0.215).

Most of the respondents (73.1 %) were not aware of the 82304–1 standards issued by the International Organization for Standardization (ISO) for deployment of AI software in clinical practice [30]. Respondents with no previous AI-related training were generally not aware of these standards (53.9 %), compared to those who had received training (42.5 %), with a significant relationship between training and ISO awareness (p -value < 0.001, V = 0.257).

With regard to informed consent, a large proportion (41.5 %) reported having specific protocols. Furthermore, a 53.4 % confirmed that their organisation used a locally devised protocol for data security.

3.4 AI adoption considerations

Table 2 summarises the involvement of respondents in the different stages of an AI model lifecycle.

Over a third of respondents reported (38.4 %) that AI being

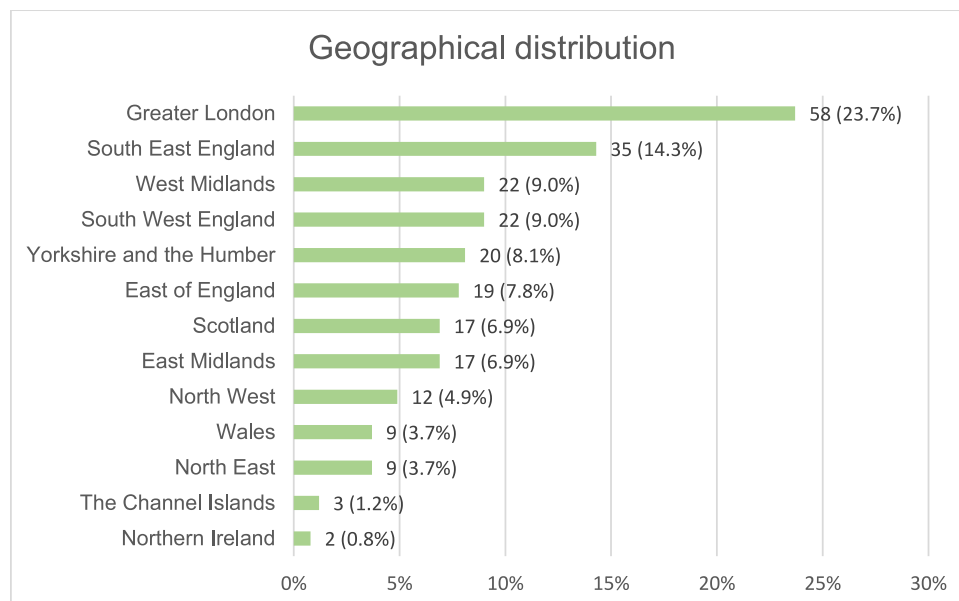


Fig. 1. Geographical distribution of the respondents.

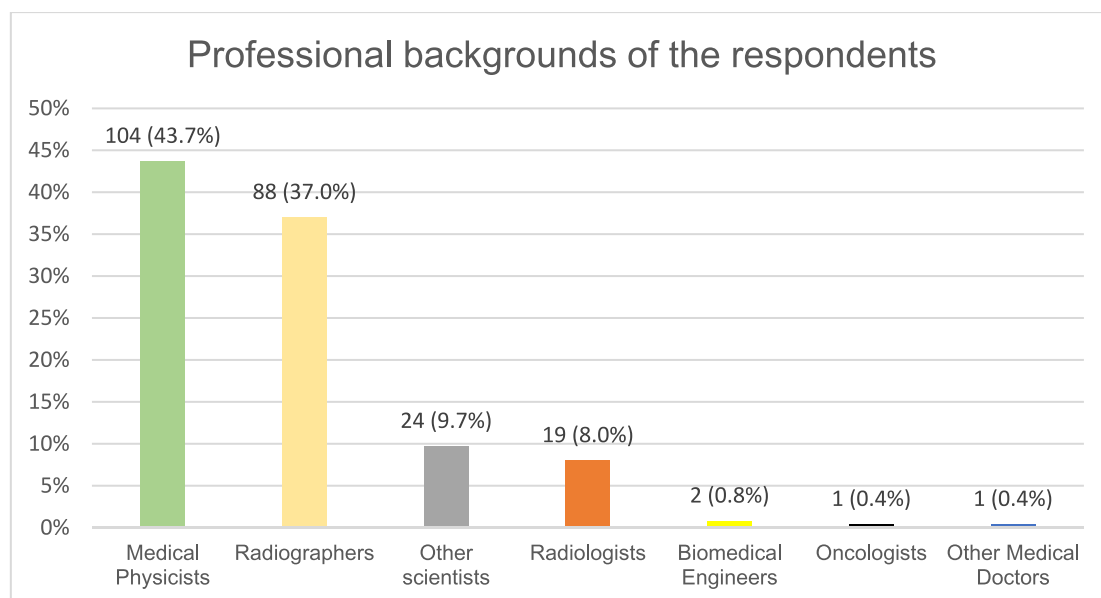


Fig. 2. Professional backgrounds of the respondents.

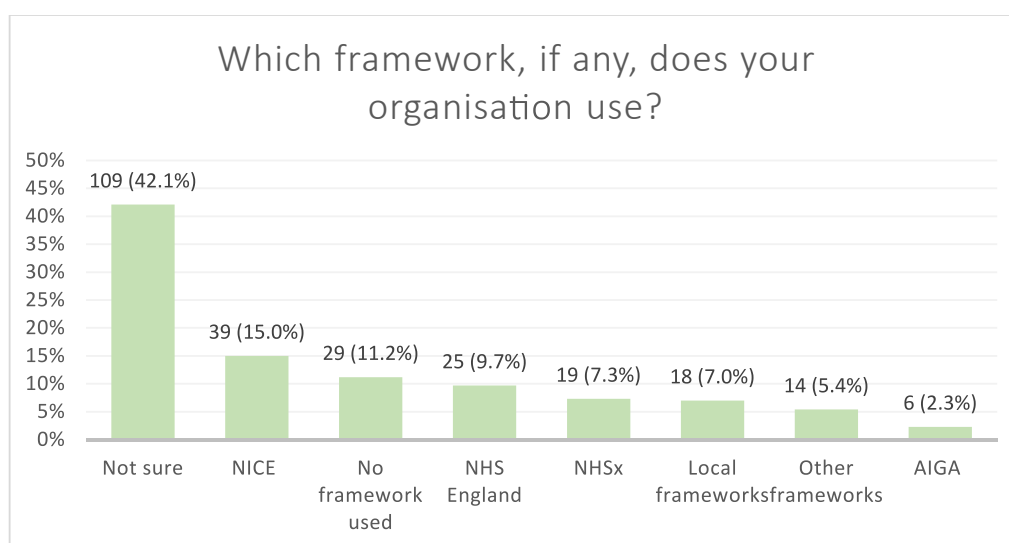


Fig. 3. Governance frameworks used (NICE = National Institute for Healthcare Excellence, NHS = National Health Service, AIGA = Artificial Intelligence Governance and Auditing, NHSx = digital transformation service of the NHS).

Table 2

Are you routinely involved in any of the following stages of an AI model's lifecycle in your current practice?

No, I am not involved in any stage of an AI model's lifecycle	20.4 %
Yes, in AI model clinical validation, evaluation and adoption	18 %
Yes, in training and education for other staff for AI models and adoption	12.3 %
Yes, in AI model training, testing or technical validation	10.4 %
Yes, in AI model audit, quality assurance and monitoring	8.3 %
Yes, in AI model procurement	8 %
Yes, in AI model conceptualisation and design	6.9 %
Other	4.5 %
Yes, in AI model marketing	3.5 %
Yes, in AI model ethics and integrity (equity, transparency, explainability)	3.5 %
Yes, in AI model co-production using patient and public involvement	3 %
I am not sure	1.2 %

embedded in MIRT software/hardware would make them more likely to buy a product, compared to those who said no (23.1 %) or were unsure (23.1 %). Finally, a further 15.4 % of the respondents highlighted that this process depended on the AI product's purpose, use, and specifics.

Respondents were asked if their organisation used validation and evaluation frameworks to explore the local clinical effectiveness of AI models. Over a third of them (35.8 %) reported using locally developed frameworks. Many of them (29.5 %) felt unsure about this, whilst 2.5 % reported using an already established framework, such as a specific framework issued by the Royal College of Radiologists for pulmonary nodule detection [31], a framework by the National Consortium of Intelligent Medical Imaging [32], and engagement with the UK's multi-agency advisory service framework [33].

Regarding the clinical validation of AI models, 33.3 % of the respondents reported that their organisation required vendors to provide evidence that clinical validation had been performed before procurement. However, the majority (42.3 %) were unsure of validation

requirements before procurement in their local context. Professional backgrounds were statistically associated with the responses on clinical validation (p -value < 0.001 , $V = 0.278$).

Many survey participants (41.8 %) said that their organisations assessed the AI model's usability and interoperability before procurement but a further 39.8 % were unsure about such processes in their organisation.

Many respondents (45.4 %) said that their organisations examined the expected costs and scalability of costs before procurement. Many (46 %) were unsure whether their organisation considered evidence of cost savings/budget impact when making reimbursement decisions. Organisations generally considered such evidence (35.3 %) compared to those that did not (6.6 %). Of those being unsure, almost half were radiographers (46.3 %), followed by medical physicists (39.1 %), and a significant association was noted (p -value = 0.001, $V = 0.268$).

Most of the respondents (55.1 %) were unsure whether their organisations had any operational policies for using AI. A further 17.6 % answered that such policies did not exist within their organisation, and only 13.6 % responded positively.

Respondents were also asked where they thought AI could generate the most cost savings in MIRT. The most potent cost-saving, AI-enabled workflow aspect in MIRT was, according to different professions a) reduced turnaround times for radiographers (23 %), b) reduced errors for radiologists (25.7 %), c) more efficient use of resources for physicists (25.9 %) (Fig. 4).

Only 32.4 % of the respondents confirmed that their organisations performed ongoing monitoring to assess the AI models' effectiveness and safety over time. Nearly half of them (44.5 %) reported being unsure about such assessments taking place.

3.5 Priorities for successful AI adoption

Respondents were also asked to choose the top five priorities for successful AI adoption in MIRT (Table 3).

The following graph (Fig. 5) demonstrates the distribution of these top 5 priorities according to the dominant professional groups in the sample size. While both physicists and radiographers seemed to prioritise AI standards (27.9 %) and governance frameworks (24.1 %), respectively, radiologists felt the focus should be towards better leadership for a successful AI adoption (28.1 %).

Respondents were also asked about challenges around AI adoption,

Table 3

Top priorities for a successful AI adoption by MIRT professionals in the UK.

Guidance/standards on AI validation and evaluation	12 %
A robust, unified AI governance framework	11.4 %
Training on AI basic principles and key concepts	9 %
Leadership to manage AI adoption	8.5 %
Research to create the evidence base for AI governance	8 %
More financial support/better reimbursement frameworks to enable AI adoption	7.7 %
Transparency when it comes to regulation for the clinical use of AI	7.3 %
Teamwork among the different healthcare practitioners in medical imaging	7 %
AI champions to scale up and support the adoption locally	6.3 %
Transparency around AI procurement	6.2 %
Radiographers/radiologists or other healthcare professionals to manage the workload AI adoption creates	5.9 %
Patient, public and practitioner involvement in the early phases of designing AI tools	5.6 %
Autonomy related to implementation for healthcare practitioners	3.4 %
Other	1.7 %

and what potential opportunities AI brings. The emerging themes and categories derived from content analysis of the responses in the open-ended questions are summarised in Tables 4 and 5.

The area in which respondents felt they mostly needed support was having clear guidance and AI frameworks, followed by appropriate training to understand and effectively use AI technologies.

4. Discussion

This work is the first to explore the current use of AI governance frameworks in MIRT in the UK. It has also identified opportunities, challenges and unmet clinical and training needs for professionals working with AI in the UK.

4.1 Opportunities

There are opportunities for more patient involvement as well as leadership. While the respondents overall highlighted standards and governance as critical priorities for adoption, radiographers were the ones who overwhelmingly pushed for more patient, public and practitioner involvement in designing AI tools. However, disappointingly, this did not reach the top of the list. Similarly, radiologists emphasised the

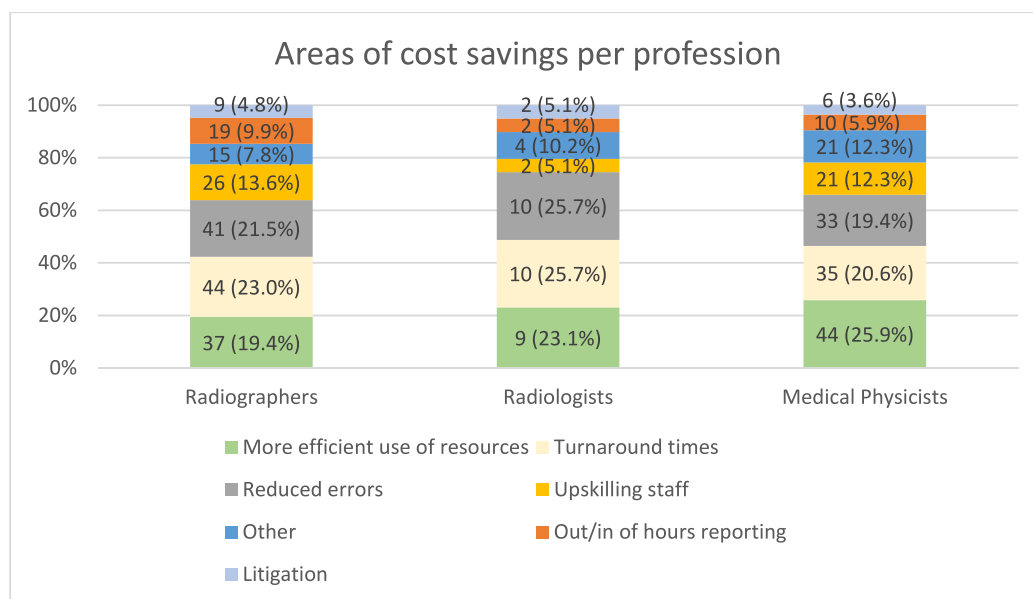


Fig. 4. Expected cost savings with the use of AI, as reported by different professional groups in MIRT.

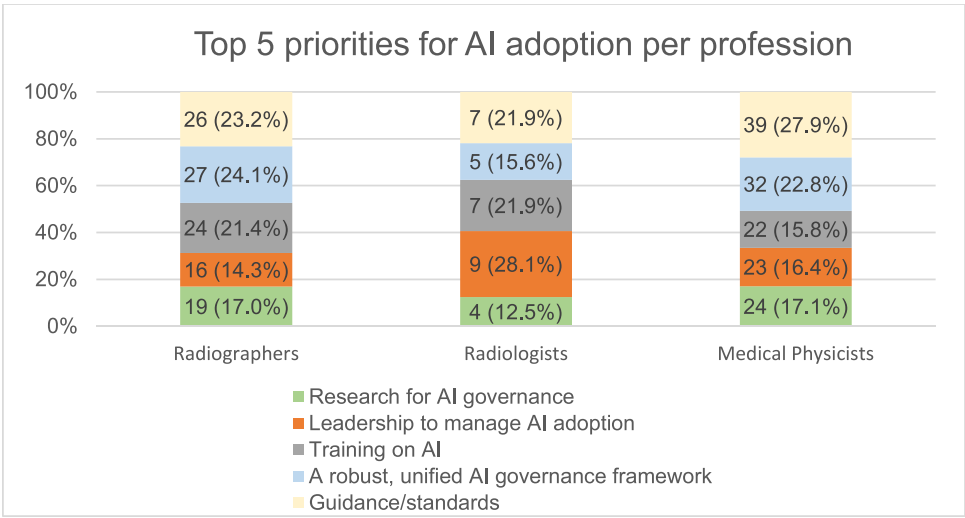


Fig. 5. The top 5 priorities for AI adoption as reported by different professional groups in MIRT.

Table 4
Challenges around AI adoption.

Themes	Categories
Lack of knowledge	<ul style="list-style-type: none">• Staff competences• Fundamental principles of AI• Knowledge on governance• Appropriate training
Financial issues	<ul style="list-style-type: none">• Skills on validation/monitoring• Lack of funding• Need for cost/benefit analysis• Cost for staff training• Cost of AI solutions
Data issues	<ul style="list-style-type: none">• Poor data quality• Data privacy concerns• Bias arising from data• Data sharing policies• Lack of central data banks
Resistance to change	<ul style="list-style-type: none">• Users hesitant to adopt new technologies• Skepticism about AI• Practitioners not convinced about benefits of AI• Reliance on AI advocates within organisations
Validation/evaluation	<ul style="list-style-type: none">• A good level of validation required• Staff resources needed to assist with validation• Need for central validation• Need for clinical evaluation• Lack of standards for clinical evaluation
Explainability	<ul style="list-style-type: none">• Need to enhance transparency• No more 'black box' solutions• Need for staff to understand all processes• Details often not provided by suppliers

need for robust leadership to drive the AI agenda forward.

4.2 Challenges

The results highlight a consistent lack of knowledge and uncertainty regarding different aspects of AI implementation and governance in medical imaging and radiotherapy in the UK, even within professionals that work with AI. AI tools remain essentially a black box for their end users. This is comparable to other studies in Europe and the USA in a similar context [34,35]. It was interesting and reassuring to see the affinity of different professions with different regulations and standards, closely tied to their everyday roles in clinical practice.

4.3 Unmet clinical and training needs

While we did not generally observe strong correlations between

Table 5
Potential opportunities brought on by AI.

Themes	Categories
Time savings	<ul style="list-style-type: none">• Reduced scan times• Reduced turnaround times for reporting• Faster image processing• Quick diagnosis• Faster treatment planning• Saving staff time• Reduced cancer waiting times• Less time needed for QA
Reporting	<ul style="list-style-type: none">• Reduced cognitive load when reporting• Standardised reporting• Responsible use during reporting• Faster reporting• AI to act as a 2nd reader
Diagnostic accuracy	<ul style="list-style-type: none">• More accurate diagnosis• Recognition of disease early onset• Outperformance of humans in certain tasks
Image processing	<ul style="list-style-type: none">• Reduced errors• Automated contouring• Image analysis• Image measurements• Image reconstruction• Advanced segmentation
Patient care	<ul style="list-style-type: none">• Improved patient care• Better patient experience• Enhanced patient safety• Better person-centred care decisions

knowledge of AI governance/regulation and years of experience, there was an overwhelmingly strong correlation between prior training and knowledge of AI. Similarly, where respondents answered negatively or with uncertainty about their knowledge of specific governance and regulation questions, these answers were strongly correlated with lack of relevant training. There is, therefore, some evidence that to overcome the uncertainties around AI, more customised and content/context-appropriate AI education should be available. Higher education institutions that offer vendor-neutral, pedagogically sound educational provisions on AI have a lot of work to do to meet this demand [8,10,13], which, for the time being, is covered by ad-hoc, mainly industry-driven webinars.

In addition to the lack of AI knowledge or expertise, even when some expertise is established, it is not always being used; about 1 out of 5 participants in our study confirmed they were not involved in any part of the AI tool's lifecycle, relevant to their practice.

Rigorous, comprehensive AI governance frameworks are essential to

assist MIRT professionals in the optimal evaluation and validation of any AI-enabled solutions before they are integrated into clinical practice [14]. Governance frameworks such as the one by the National Institute for Health and Care Excellence [36], or the NHSx [37] should be assessed and contextualised by MIRT departments, to adjust to their local practices and needs. AI governance is a field that is actively growing; recently the BS 30440 validation framework for the use of AI in healthcare was published by the British Standards Institute after a long period of public consultation [38,39], hoping to provide clear guidance on validating and monitoring AI tools used in healthcare. The added value of all these frameworks will be tested in clinical implementation by the end users.

4.4. Future work

The findings of this study could inform future research projects, but also policy and educational initiatives. It is clear that enriching the AI curricula with AI governance and regulation perspectives is necessary for understanding and facilitating AI implementation by clinical practitioners. This work comes very timely as AI governance in the UK and Europe becomes formalized in the form of the UK AI Bill and the EU AI Act, both of which are expected to be finalised within 2024. Future research could replicate this work within a larger sample size of the wider AI ecosystem and assess knowledge, benefits, and challenges of AI implementation as the technology and policy mature over time.

5. Limitations

While every effort was made to invite and include a diverse sample of participants, the small sample size of this study cannot be considered representative of the broader UK AI ecosystem. Therefore, the results should be treated as solid indications, but should not be overinterpreted. Furthermore, the scope of the work was limited to the UK, to ensure homogeneity when it comes to regulation and governance for AI implementation.

The results of this survey cannot be used to differentiate current practice between medical imaging and radiotherapy departments, because there was not enough statistical power to support this for subgroups. Nevertheless, they enable correlations with the generic professional backgrounds of participants, such as radiologists, radiographers, medical physicists etc.

There is inevitably selection bias in the population showing interest in responding to a survey on AI. This was because the majority of the respondents came from university hospitals, where there is expertise, culture, funding, and networks to ensure implementation happens. However, the reality is that in district general hospitals there are fewer opportunities for knowledge of and interaction with AI tools. The respondents of this survey are more likely to be those interested in, and potentially more knowledgeable about AI.

The differences between AI versus machine learning, deep learning, health informatics or other algorithmically driven tools can be subtle, and we cannot be sure that respondents did not conflate these when they were answering the questions.

6. Conclusion

There is still a lot to be done when it comes to AI governance and AI education, to ensure a safe and effective clinical adoption in medical imaging and radiotherapy in the UK. The AI ecosystem shows varied levels of knowledge and confidence in AI governance aspects, many of which strongly correlate with professional background and prior training of this study's participants. Robust AI governance frameworks and customised AI training to address each profession's needs, strengths and knowledge gaps are needed to facilitate seamless and successful AI adoption.

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CRedit authorship contribution statement

Nikolaos Stogiannos: Formal analysis, Writing – original draft, Writing – review & editing. **Lia Litosseliti:** Project administration, Writing – original draft, Writing – review & editing. **Tracy O'Regan:** Project administration, Writing – original draft, Writing – review & editing. **Erica Scurr:** Project administration, Writing – original draft, Writing – review & editing. **Anna Barnes:** Project administration, Writing – original draft, Writing – review & editing. **Amrita Kumar:** Project administration, Writing – original draft, Writing – review & editing. **Rizwan Malik:** Project administration, Writing – original draft, Writing – review & editing. **Michael Pogose:** Project administration, Writing – original draft, Writing – review & editing. **Hugh Harvey:** Project administration, Writing – original draft, Writing – review & editing. **Mark F. McEntee:** Conceptualization, Funding acquisition, Writing – original draft. **Christina Malamateniou:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing – original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Summary table.

What was already known

AI innovation in medical imaging and radiotherapy is a fast-growing field
AI implementation and adoption is impeded by different challenges
What this study added to our knowledge
Knowledge gaps of MIRT professionals in relation to AI governance in the UK are highlighted
Challenges, opportunities, and areas of support required for faster AI implementation of MIRT professionals in the UK are discussed

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