AI Implementation in Pediatric Radiology for Patient Safety:

A Multi-Society Statement From <blinded>

Abstract

Artificial Intelligence (AI) has potential to revolutionize radiology, yet current solutions and guidelines are predominantly focused on adult populations, often overlooking the specific requirements of children. This is important because children differ significantly from adults in terms of physiology, developmental stages, and clinical needs, necessitating tailored approaches for the safe and effective integration of AI tools. This multi-society position statement systematically addresses four critical pillars of AI adoption: (1) regulation and purchasing, (2) implementation and integration, (3) interpretation and post-market surveillance, and (4) education. We propose pediatric-specific safety ratings, inclusion of datasets from diverse pediatric populations, quantifiable transparency metrics and explainability of models to mitigate biases and ensure AI systems are appropriate for use in children.

Risk assessment, dataset diversity, transparency and cybersecurity are important steps in regulation and purchasing. For successful implementation, a phased strategy is recommended, involving early pilot testing, stakeholder engagement, and comprehensive post-market surveillance with continuous monitoring of defined performance benchmarks. Clear protocols for managing discrepancies and adverse incident reporting are essential to maintain trust and safety. Moreover, we emphasize the need for foundational AI literacy courses for all healthcare professionals which include pediatric safety considerations, alongside specialized training for those directly involved in pediatric imaging. Public and patient engagement is crucial to foster understanding and acceptance of AI in pediatric radiology. Ultimately, we advocate for a child-centered framework for AI integration, ensuring that the distinct needs of children are prioritized and that their safety, accuracy, and overall well-being are safeguarded.

Keywords:

Artificial Intelligence, Children, Radiology, Safety, Implementation

Introduction:

As artificial intelligence (AI) continues to reshape the landscape of healthcare, pediatric radiology faces specific requirements that demand special attention. Unlike adult patients, children have distinct anatomical, developmental, and physiological considerations that necessitate tailored approaches for safe and effective AI implementation [1, 2]. Despite the rapid evolution of AI tools, most of the research, development, and application of these technologies has focused on adult populations [3]. The consequences of using AI models primarily trained and validated on adult data can result in misdiagnoses, ethical dilemmas, and biases that disproportionately affect children.

This multi-society statement has drawn international experts across a variety of pediatric imaging societies including the pediatric subcommittee of <blinded>, <blinded>, <blinded>, <blinded>, <blinded>, <blinded> and <blinded>.

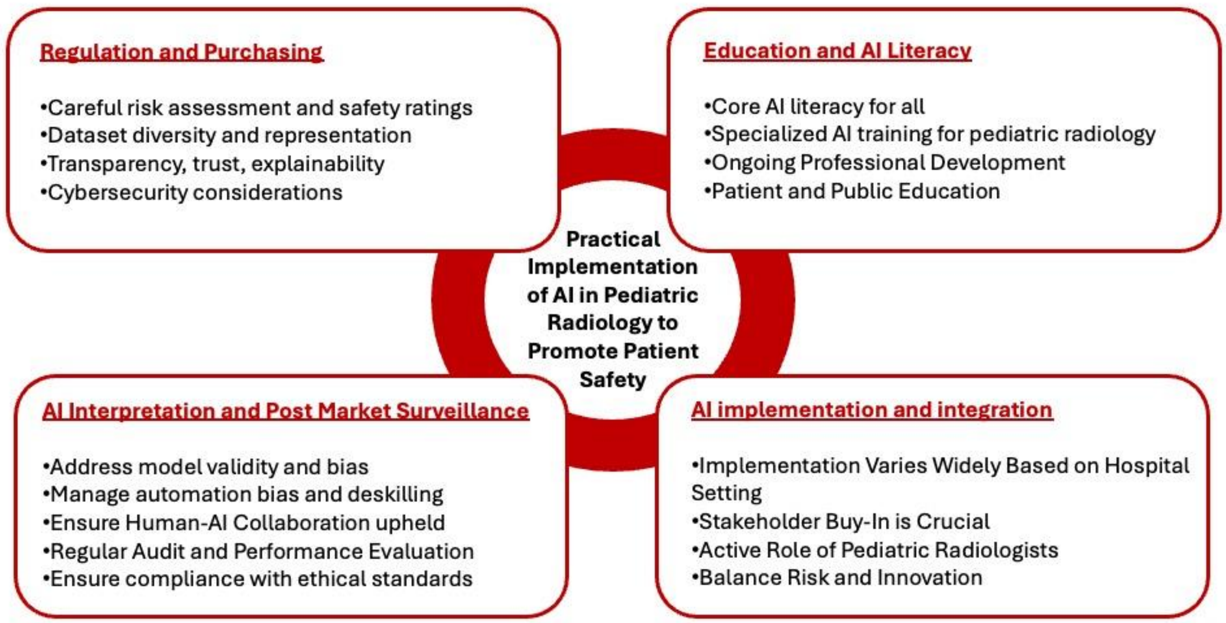
This article aims to guide responsible AI practices in pediatric radiology through four core pillars, emphasizing safety, regulatory oversight, effective implementation, and educational strategies. By fostering a deeper understanding of AI's limitations and potential, we hope to promote a child-centric approach to AI adoption, ensuring that children are not just seen as small adults but as a unique, diverse population deserving of tailored and responsible AI tools. We cover four core pillars divided into 1) regulation and purchasing of AI tools, 2) implementation and integration, 3) interpretation and post-market surveillance, and 4) education. Key take home points are outlined at the end of each subsection and in **Table 1 and Figure 1**.

Table 1. Summarized key statements across the four pillars for promotion of patient safety for AI use in pediatric radiology

Pillars	Subheading	Description
Regulation and Purchasing	**Careful risk assessment and safety ratings**	AI tools should include pediatric-specific labeling and safety ratings to guide critical appraisal and oversight by healthcare providers.
	Dataset diversity and representation	Comprehensive training datasets with diverse pediatric cases are essential to ensure consistent AI performance across subgroups or clarify its limitations.
	Transparency, trust, explainability	Clear communication of AI decision-making builds trust among healthcare providers, parents/guardians and the patients by ensuring outputs are understandable.
	Cybersecurity considerations	Follow best practices in line with GDPR, HIPAA and HITECH standards and ensure that strong data protection measures are in place.
AI implementation and Integration	**Implementation varies widely depending on setting**	AI integration in pediatric radiology must align with the institution's specific needs, whether a pediatric center or a shared facility.
	Stakeholder buy-in is crucial	Stakeholder buy-in, including pediatric radiologists, is crucial for AI integration, requiring concerns to be addressed, benefits demonstrated, and support secured.
	Active role of pediatric radiologists	Pediatric radiologists must actively guide AI implementation to ensure tools are clinically relevant and avoid premature use in shared or understaffed settings.
	Balance risk and innovation	AI advancements hold great promise but must be balanced with risks, requiring ongoing evaluation, monitoring, and adjustments to protect pediatric patients and maintain trust.
AI interpretation and post-market surveillance	**Address model validity and bias**	AI models for children must be trained with pediatric-specific data to minimize bias, supported by robust integration and surveillance strategies.
	Manage automation bias and deskilling	Over-reliance on AI risks staff deskilling; regular audits, feedback, and training on AI pitfalls should be part of governance measures.
	Ensure human-AI collaboration upheld	Human-in-the-loop approaches should ensure staff have adequate time and focus to manage technology without distractions or burnout.
	Regular audit and performance evaluation	Regularly evaluate AI outputs against human interpretations and patient outcomes to identify discrepancies, assess long-term impacts, and measure healthcare value.
	Ensure compliance with ethical standards	Healthcare professionals must apply institutional policies on consent, privacy, in line with ethical standards
Education and AI Literacy	**Core AI literacy for all**	Educate healthcare staff on AI design, limitations, and unique challenges in pediatric applications.
	Specialized AI training for pediatric radiology	Understand pediatric anatomy, diseases, and AI-specific pitfalls to ensure appropriate and safe application of AI tools in children’s imaging.
	Ongoing professional development	Regular updated training and certification in AI.

	Patient and public education	Engage patients, guardians, and the public through outreach to build trust in AI use and address misconceptions

Figure 1. *Visual summary of the four pillars and summary statements in this multi-society document for the promotion of pediatric patient safety when using AI in children's imaging.*



Regulation and Purchasing

In June 2024, the U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) jointly published a set of guiding principles to ensure transparency on machine learning-enabled medical devices [4]. Amongst these principles, it is stated that AI products should be designed and validated using clinical study participants and data sets that are representative of the intended patient population, e.g., an AI product intended for pediatric population should have pediatric case examples in its training set. Concurrently, the American College of Radiology (ACR) advocates for clear statements on contraindications for pediatric use, specific authorization statements for use in children, and ongoing monitoring of AI model performance in clinical practice[3]. In Europe, the European Union (EU) aims to regulate the use of AI, including those used in healthcare (considered to be a high risk use of AI), via the EU AI Act [5]. This is the world's first comprehensive AI law, approved in March 2024 and to be fully applicable by March 2026. Within this AI act all medical AI tools are considered to be high risk and therefore providers must meet specific requirements. One of these requirements is that they should achieve appropriate levels of accuracy and robustness, and incorporate a human-in-the-loop. Building on these efforts, we propose additional recommendations to enhance the safety and efficacy of AI tools in pediatric radiology.

Risk assessments that differentiate AI tools based on their safety impact on children are recommended, and could be mandated by regulatory agencies. Inspired by the EU's AI Act [5] and various age rating systems (such as the Entertainment Software Rating Board (ESRB) for video games [6] and the Motion Picture Association (MPA) rating system for movies [7]), similar standards could be adapted for AI tools in healthcare. These approaches would help healthcare providers to identify those tools requiring more oversight, and be complementary to the 'model card' system that has been championed for all AI tools[8]. Additionally, ongoing quality improvement for AI systems through periodic license renewals is recommended. Continuous updates are essential to keep AI systems relevant, accurate, and inclusive of diverse patient populations [9].

When evaluating AI tools to purchase for potential pediatric use, several key considerations emerge. Ensuring dataset diversity and global representation is vital, necessitating comprehensive training data that encompasses a wide range of pediatric cases across different ages, geographic regions, and ethnicities [10-13], as outlined in the paediatric specific ACCEPT-AI guidelines relating to use of paediatric data in machine learning and AI [11]. Addressing class imbalances is equally important. These imbalances can pertain to the proportions of abnormal cases or types of abnormalities (versus 'normal' data points), gender, ethnicity, socioeconomic status and other demographic factors. This challenge is particularly relevant in pediatric radiology, where datasets often have limited sizes across age groups, and certain conditions may be rare, making it difficult to achieve balanced representation in the data for each stage of child development.

To mitigate such limitations, the development and maintenance of open-source radiology data registries for rare diseases – overseen by national and international organizations – are crucial [14]. These registries align with the objectives of the European Health Data Space (EHDS) an initiative in development that is aimed at facilitating the secure and standardized sharing of health data across Europe [15].

AI tools should be evaluated on their performance across underrepresented classes, employing techniques such as resampling, synthetic data generation, and algorithm adjustments to address these imbalances. Collaboration with AI vendors who prioritize ethical considerations is essential in this process [11]. Specifically, AI software vendors should provide detailed performance metrics, including how the tool performs across different paediatric subgroups (similar to the MRI safety checklist [16]). This includes metrics for various age groups, gender, ethnicities, and geographic regions [9, 11, 12]. Finally, the presence of class imbalances (where certain data classes are underrepresented or uneven distribution of data across different classes) can skew AI performance so it is crucial to evaluate how the AI tool handles such imbalances prior to purchase, and definitely prior to deployment, to provide suitable metrics to accurately reflect the algorithm's performance [9, 13, 17-19].

Transparency and explainability in AI decision-making healthcare processes are vital for building trust amongst patients, their carers, and healthcare providers. This should be integral to decision making aided with AI-enabled tools, and should allow users to trace and verify how conclusions are made. Additionally, it is recommended that as far as possible, healthcare facilities establish a governance structure compromised of multidisciplinary stakeholders to oversee the use of AI tools in children. Stakeholders should include radiologists, data scientists, ethicists, and legal experts. This ensures that the evaluation process considers all relevant aspects, from technical and clinical performance to ethical implications [11]. Examples of these collaborations are already happening, such as in the Boston Children’s Hospital (BCH) AI and Machine Learning working group, and the Great Ormond Street Hosptial Data Research, Innovation and Virtual Environments unit (DRIVE) facilitating cross-department discussions on responsible AI deployment.

Cybersecurity considerations are paramount to protect sensitive patient data [20]. Pediatric patient data is should be considered highly sensitive, as infants and children are unable to give their consent to its use and to fully understand the ramifications of data breaches [11, 21]. For all patients, AI implementation requires careful consideration of cybersecurity issues and risk mitigation. The “CIA Triad” (confidentiality, integrity, availability) provides guiding principles for information and network security [20, 22]. This involves protecting patient data privacy in compliance with regulations including those in the U.S. Health Insurance Portability and Accountability Act (HIPAA) Security Rule, the U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act, and the European Union General Data Protection Regulation (GDPR)[22]. Best security practices for maintaining confidentiality during AI implementation, whether local or cloud-based solutions, include limiting physical and/or digital access, transmitting only the minimum necessary protected health information for proper functioning, encrypting data at rest and in transit, and managing minimum and maximum data retention time on servers. Vendor service agreements should clearly define security practices and provide evidence of regulatory compliance which may include System and Organization Controls 2 (SOC 2) certification [20], Digital Clinical Standards (e.g. DCB0129 and DCB0160)[23], and healthcare organizations should regularly audit vendors for compliance with International Organization for Standardization (ISO) (e.g. ISO27001) [24].

AI Regulation and Purchasing Key Statements

- **Careful risk assessment and safety ratings**: AI tools should have specific labelling and, where applicable, safety ratings for pediatric use. These can guide healthcare providers in understanding which tools require more critical appraisal and oversight.
- **Dataset diversity and representation**: Ensuring comprehensive training datasets that include pediatric cases across ages, ethnicities and geography are crucial. The tools should perform consistently across these subgroups, or specify which groups it can be used.
- **Transparency, trust, explainability**: Clear communication of AI-aided decision-making processes will help build trust amongst healthcare providers and patients, and should be understandable when providing outputs.

- **Cybersecurity considerations:** Follow best practices in line with GDPR, HIPAA and HITECH standards and ensure that strong data protection measures are in place.

AI Implementation and Integration

Implementing AI in radiology has the potential to significantly impact radiology care for children, particularly by enhancing diagnostic accuracy, and increasing access to specialized interpretations and freeing up pediatric radiologists to focus on more complex radiology tasks or quality time with patients and their families explaining imaging results. This can be achieved by streamlining workflows, potentially improving patient outcomes and subsequently quality of care. However, integrating AI into pediatric radiology requires careful consideration given the specific physiological, pathological and developmental characteristics of children. AI for automating tasks exist to enhance pediatric radiology workflows for non-interpretive tasks, such as assistance with motion correction artefacts, reduction in radiation dose or intravenous contrast administration in cross sectional imaging examinations however these do need to be carefully evaluated [2]. Finally, the willingness and culture for innovation to implement AI tools, including allocation of resources required to succeed, plays a crucial role. This section outlines the scope of AI implementation in pediatric radiology and some of the important steps to ensure its safe and effective integration.

A fundamental consideration in implementing AI tools in pediatric clinical practice is the recognition that tools developed for adults are not automatically valid for pediatric use. In fact, AI models trained predominantly on adult data may not perform accurately in pediatric radiology [25]. For example, an AI model developed to identify lung nodules in adults may not accurately detect similar anomalies in pediatric patients due to differences in lung development and pathology presentation [26]. AI techniques may need to be modified in children to improve sensitivity but may come with trade-offs. For instance, adult lung computer-aided detection has shown better performance when applied to pediatric CT examinations for images with thinner CT slice thickness but also higher radiation doses[26].

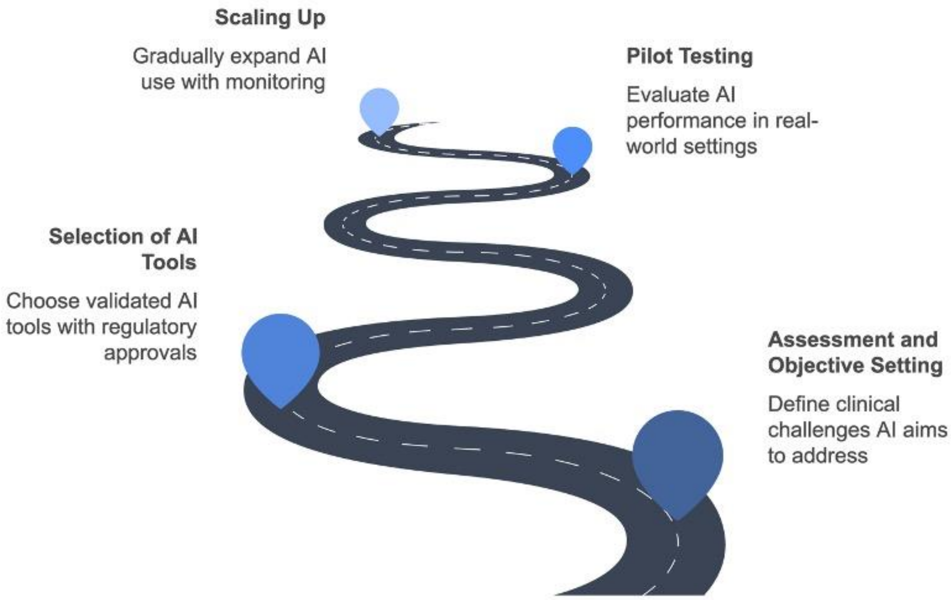
To effectively integrate AI into pediatric radiology practices, a structured, stepwise approach to AI implementation is recommended. Organisations such as the Royal College of Radiologists [27, 28] and the British Medical Association [29] have published guidance for AI implementation into practice, and these implementation steps can be guided by established frameworks such as the ACR's ARCH-AI (ACR

Recognized Center for Healthcare-AI) program[30], however approaching these with a child-centric focus is required. A phased implementation strategy allows for early identification and resolution of issues, minimizing disruptions to clinical workflows.

This road map for clinical AI implementation and integration involves several key steps (**Figure 2**):

1. **Assessment and Objective Setting:** Define the clinical challenges AI aims to address within pediatric radiology. This step ensures that the AI tools developed are relevant and beneficial to children [31]
2. **Selection of AI Tools and Decision-making:** Choose AI tools validated with pediatric datasets. It is essential to consider regulatory approvals and evidence of clinical efficacy specific to pediatric use [31, 32]
3. **Pilot Testing:** Conduct pilot studies to evaluate AI performance in real-world pediatric settings. This step involves monitoring the tool's accuracy, compatibility with existing infrastructure, ease of integration into existing workflows, and collecting feedback from clinical users [32]. This could be retrospective in nature, or operating in a shadow (‘silent trial’) mode [33].
4. **Scaling Up:** Gradually expand the use of AI tools, incorporating continuous monitoring of defined performance benchmarks and quality assurance measures to maintain high standards of care [32].

Figure 2. A simplified road map for AI implementation in radiology



Securing buy-in from all stakeholders is crucial for successful AI implementation. In children and infants, this includes pediatricians, radiologists, radiographers, imaging technologists, hospital administrators, IT personnel, parents and other caregivers, and patients. Engaging multidisciplinary teams composed of a variety of stakeholders in pilot testing phases can provide diverse perspectives and enhance the robustness of AI integration [32], whilst also addressing resistance to change. In some children's hospitals, such as Great Ormond Street Hopsital for Children in the UK a local active Young Person's Advisory Group (YPAG) and Parent and Carer Advisory Group (PCAG) provide regular feedback and public involvement on topics relating to digital innovation. In The Hosptial for Sick Children (Sick Kids) in Toronto, a "Children's Council" has previously been set up to ensure children's voices are front and centre to AI related changes in their care pathways.

Each group will have different motivations and concerns, which must be addressed to ensure their support. For instance, patients and their families may prioritize safety and accuracy, while hospital administrators may focus on cost-effectiveness and efficiency. A recent study showed that children and young adults favor AI involvement with human oversight, seek assurances for safety, accuracy, and clear accountability in case of failures [34]. Determining what constitutes as "adequate/accurate performance" is inherently context dependent. Acceptable thresholds for accuracy, reliability, and error tolerance may differ upon the clinical setting, patient population, use case and current standard of care. As such, these standards should not be universally imposed but locally defined through a multidisplinary governance committee that includes both clinical and managerial leadership. Such a group would be best placed to determine when pilot testing is sufficient, whether in-house or commercial tools are appropriate, and what validation is needed prior to full scale implementation.

The impact of AI on job security is an important matter of concern among radiologists and other healthcare providers [35, 36]. Clear communication about the AI's role in enhancing rather than replacing human expertise is crucial to fostering acceptance [34, 37].

Implementation processes can be costly and exploring funding options through grants and institutional budgets is important [38]. Available resources, financial and otherwise, significantly influence the scope and pace of AI implementation [31]. Demonstrating the tangible benefits of AI, such as optimized workload and improved diagnostic accuracy, can help alleviate apprehensions. This approach, coupled with timely monitoring and result validation, fosters a culture of continuous improvement by actively seeking and using feedback to enhance AI tools based on real-world experiences [32].

Implementation approaches may also vary substantially across healthcare settings. For instance, the strategy used in academic pediatric hospitals is likely to be different from that in community (non-specialist) hospitals, which primarily care for adults but also treat children. This diversity underscores the need for careful oversight to account for pediatric patient needs, regardless of the setting. Adverse events should be clearly documented (using incident management systems), with plans in the AI protocols for further evaluation in order to prevent future similar occurrences. Safeguards such as regular audits blinded to human or AI generated reports, mandatory human review of AI-generated results and continuous professional development, may mitigate the risks associated with over-reliance on AI. This approach ensures that radiologists remain engaged and vigilant in their diagnostic processes [25].

Establishing criteria for the appropriate use of AI, including specific indications and contraindications, can guide clinical practice and ensure the responsible deployment of AI technologies. For example, AI is not ready to be used in medico-legal cases or abuse investigations (although solutions do exist [39]), as human judgment is critical and require careful multidisciplinary clinical assessment for both diagnosis and next steps. Defining high, medium, and low-risk use cases for AI in children can help prioritize the safest and perhaps most effective applications [25].

The development of more sophisticated AI algorithms brings new challenges with it as well, such as the rise of AI tools becoming capable of integrating data from various imaging modalities (e.g., MRI, CT, ultrasound) teamed with clinical data from electronic health records to provide comprehensive insights (i.e. multimodal models) [40]. These new tools can streamline some pediatric radiological workflows, reducing the time and effort required for image acquisition, processing, and interpretation [41, 42] whilst also proposing more personalized solutions. For instance, recently developed imaging tools can analyze bronchial disease and be used to validate treatment effects of new drugs, as well as generating normal values in health children [43, 44]. Synthetic and AI-based reconstruction MRI techniques have potential for reducing the utilization of gadolinium-based MRI contrast agents in the pediatric population and for optimizing protocols through efficient acquisition and reconstruction techniques [45, 46]. This is key to improve cooperation of young children to examinations and reduce the likelihood of future complications, particularly in patients with compromised renal function and those related to the long-term deposition of gadolinium material in different parts of the brain and body [47], however with multiple data inputs, and multiple tasks automated, managing and evaluating the quality of output also becomes more complex and even more necessary to maintain high standards of care.

AI Implementation Key Statements

- **Implementation Varies Widely Based on Hospital Setting:** The integration of AI in pediatric radiology should be tailored to the specific needs and resources of the institution, whether it is a dedicated pediatric center or a shared adult-pediatric facility.

- **Stakeholder Buy-In is Crucial:** Achieving buy-in from all relevant stakeholders, including pediatric radiologists, is essential to ensure the successful integration of AI. This involves addressing concerns, demonstrating benefits, and securing financial and institutional support [36, 38].
- **Active Role of Pediatric Radiologists:** Pediatric radiologists must take an active role in the implementation process to prevent the premature incorporation of inappropriate AI tools, in particular when introduced into workflows in shared adult-pediatric facilities, and understaffed centers. The expertise of pediatric radiologists is vital in ensuring that AI tools are clinically relevant and beneficial for pediatric patients [25, 48].
- **Balance Risk and Innovation:** While AI developments offer significant potential benefits, it is crucial to balance these advancements with the inherent risks, particularly for the vulnerable pediatric population. Ongoing evaluation, monitoring, and adjustments are necessary to safeguard patient safety and maintain trust in AI technologies [34].

AI Interpretation and Post-Market Surveillance

The aim of post-market surveillance is to ensure that tools continue to perform reliably and safely in real-world settings. It is vital that in the ongoing evaluation of implemented AI tools that pediatric radiologists and other pediatric healthcare specialists are involved and consulted regarding whether these tools address the clinical needs and issues at play for their patients, and that adverse incidents or near misses are minimized as far as possible, and dangers raised in a swift manner. On-going audit and evaluation are essential.

AI assisted image detection and diagnosis

AI has various applications in pediatric imaging, however integrating interpretative AI tools into clinical practice can be challenging [34, 49]. A significant issue is "training data bias," where biases present in training data can inadvertently disadvantage children. This bias often arises from unrepresentative training datasets, which may not adequately cover all patient ages or include normative data [50]. To mitigate this, promoting national and international databases, including normative data per anatomical region, is essential.

In mixed adult-pediatric hospitals, ensuring pediatric scans are not overlooked in AI triage systems is paramount. AI models trained predominantly on adult data may not perform accurately for children, leading to potential misdiagnoses or overlooked conditions, and potentially downgrade the urgency of children's cases if used as a triage tool. Continuous monitoring and updating of AI models with pediatric-specific data are necessary to maintain their effectiveness [25, 34, 51]. Additionally, AI can improve patient outcomes through double reading, theoretically leading to more accurate diagnoses, enhancing patient experiences. However, the lack of adequate metrics to evaluate the impact of AI remains a challenge [52].

Continuous Monitoring and Adjustment

Continuous improvement and monitoring of AI tools in pediatric radiology requires robust feedback loops between clinicians and AI developers, ensuring that AI systems remain effective and reliable. This can be achieved through regular performance audits, updates, and structured feedback collection and analysis [53]. Robust post-market surveillance systems to track AI performance and make necessary adjustments based on real-world data is a key part to this process [31, 51, 54]. Quality registries such as ACR Assess-AI™ play a curcial role in this monitoriting process by capturing real-world performance data of AI algorithms across different settings [55]. Such registries are especially important for pediatric applications, where they can help track algorithm performance across different age groups and developmental stages. Having these in place and having transparency in reporting AI tool performance is also crucial for maintaining trust [31, 53, 54]. tructured feedback from radiologists should be welcomed to guide further improvements in AI systems, making them more reliable and effective over time [31, 51, 54].

Automation Bias and Deskilling in Pediatric Radiology

Automation bias, where clinicians over-rely on AI recommendations, poses a significant risk to the quality and safety of patient care and can risk radiologist de-skilling [25]. Radiologists may become complacent, potentially missing errors or anomalies not detected by AI. This phenomenon can be exacerbated by the greater reliance on AI in understaffed or resource-constrained settings where human oversight may be minimal [25, 34]. Addressing automation bias requires a multifaceted approach. Radiologists should be trained to critically evaluate AI outputs [56] and make independent diagnostic decisions, conduct regular audits and review feedback mechanisms for improvement [31, 51]. When AI provides results that cannot be independently verified (e.g., risk stratification score based on non-visible elements), the potential limitations of such data should be clearly stated. Human-in-the-loop approaches for interpretive tasks are prudent until AI models have been extensively tested [31, 51].

Foundation Models and Generative AI

The rise of foundation models and generative AI poses new challenges for pediatric radiology. These general purpose models, often developed outside traditional healthcare settings, may be used ad hoc without institutional approval (both by healthcare professionals and patients), leading to inconsistent practices, demands and potential safety risks [51]. Some tools, such as large language models (LLMs) for generating AI-driven content such as medical note summarization may not be classified as medical devices [57], but may still hallucinate introducing errors from which critical decisions are made. Additionally clinicians may use widely available tools (e.g. Chat GPT, Claude, Gemini) for medical purposes, such as aiding in differential diagnosis or image interpretation, even when they were not designed for such applications. AI tools used without proper medical validation can produce inaccurate or misleading results, posing significant risks to patient safety [58, 59]. As AI tools become more accessible to consumers (i.e. doctors, patients to use themselves) without specialist oversight, it will be crucial to educate users on their safe use, data privacy, and limitations – especially when these tools may be used in clinical practice without proper auditing (e.g. patients or doctors using ChatGPT without governance [60]).

Institutional Guidelines

Institutions should establish clear policies and guidelines for the use of AI tools. All AI tools should undergo rigorous validation and approval processes before being integrated into clinical practice that include pediatric-specific data, if the intention is to use the tool for children [58, 59]. Clear rules regarding the use of web based or personal subscription based AI tools should also be highlighted. It is also worth highlighting that some online meetings are attended by 'AI scribes' which may be helpful in taking minutes, but when patient data is being discussed in the setting of a multidisciplinary meeting, the data protection, privacy and cybersecurity of these tools may not have been fully evaluated by the institution and this should be also recognised as a possible risk to data and privacy issues.

Institutions should have protocols in place to regularly review and update AI tools based on new data and clinical feedback [31, 54, 58]. This approach helps maintain the clinical relevance and safety of AI tools in pediatric radiology.

<u>AI Interpretation and Post-Market Surveillance Key Statements</u>

- **Address model validity and bias:** AI models for intended children should be trained or fine-tuned with pediatric specific data to avoid biases, and reflect the diverse pediatric populations. AI teams who are responsible for integration and post-market surveillance should have a robust strategy in place to monitor and evaluate any unexpected reduction in diagnostic performance of the tools.
- **Manage automation bias and deskilling:** Over-reliance on AI can lead to deskilling amongst healthcare staff. Regular audits and structured feedback on the model and staff performance with supported training on common AI pitfalls should be incorporated into local governance measures.
- **Ensure Human-AI Collaboration upheld:** Human in the loop approaches should be the standard, and methods employed to ensure staff are given sufficient time and focus to oversee the technology without unnecessary distractions or burnout.
- **Regular Audit and Performance Evaluation:** Ongoing evaluation of AI outputs against human interpretations or patient outcomes should be undertaken not only to evaluate for discrepancies but to understand the longer term outcomes, return on investment and value to healthcare brought through the investment of AI deployment.

- **Ensure compliance with ethical standards:** Healthcare professionals with responsibility over children should ensure that institutional guidelines and policies regarding patient consent, privacy and transparency of tools being used are well relayed to patients to foster trust and awareness.

Education & AI Literacy

The EU AI Act [61] states that providers and deployers of AI systems should take measures to ensure that their staff (and other persons dealing with the operation and use of AI systems) have a sufficient level of AI literacy, taking into account their education, technical knowledge, and the type of AI system to be used. This will require further work, clarification and adaptation across the radiology workforce. Currently, the 2024 European Training Curriculum for Radiology mentions AI only once in the chapter on principles of medical informatics (to understand basic principles of AI tools) [62] and at present, many healthcare institutions are not equipped to provide the expected level of training. Some countries have implemented a national digital AI literacy education program via free online e-training modules to address this new legislation (e.g. NHS Digital Skills Assessment Tool [63]), however most do not include any training highlighting the dangers or need for awareness when implementing and using AI tools for children's healthcare. A more unified effort is needed to integrate pediatric-specific consideration into both basic AI training for all healthcare staff and specialized programs for those directly caring for children (**Figure 3**).

Figure 3. *Different components that could be applicable to AI education for paediatric radiology for healthcare professionals divided into core and advanced competencies and knowledge requirements.*

Core (basic) components of AI literacy for all healthcare staff should include:

- **Overview of AI model development:** How AI models are developed (data collation, privacy and consent, data ‘cleaning’) [38, 64].
- **Basic regulatory documentation:** Understanding of the conformity regulatory documentation (to understand the intended use case and intended population and whether this is pediatric relevant)
- **Limitations of the AI model and potential for bias**: Focus on why adult AI tools may lack generalisability and not perform equally across diverse populations. For instance, healthcare staff need to understand that due to the nuances of paediatric anatomy and pathology, AI tools may not perform adequately if they were primarily trained on adult data [25, 34].
- **Safety risks:** Recognizing when AI tools may not be suitable for some clinical pathways that involve both adults and children, reflecting on possible impacts of errors made by the AI or misunderstandings by staff [51].

Advanced (Specialised) Paediatric AI Literacy:

- **Advanced decision making in AI tool evaluation**: Understanding of how applicable the AI tool is for the pediatric population (through real-world performance from AI registries or peer reviewed publications)
- **Strategic planning for safe integration**: the ability to identify when AI tools are not performing and making necessary adjustments [51, 64].
- **Active influence and engagement with key stakeholders**: Explain the involvement of the AI in patient care, promoting transparency of use in practice. It is imperative that radiologists are well-equipped to manage risks associated with AI usage, and communicate them effectively to patients and their families [53].
- **Ethical practices for use of AI in clinical work:** This includes consideration for informed consent, privacy, and transparency, as well as recognizing potential biases in AI systems and understanding the legal and ethical implications of AI use in clinical practice [31, 51].
- **Acknowledging and reporting adverse incidents:** Healthcare professionals should be made aware of their role and responsibilities for human oversight and how to report adverse incidents. This can include an awareness of human factors such as automation bias, alarm fatigue, algorithm aversion, learning effect and possible risks of deskilling through overreliance of AI systems [65].
- **Change management and staff engagement:** This includes an understanding of care pathways where AI is being deployed and awareness of likely changes to roles and responsibilities, and how to adapt to these [36, 66].

Outreach and public engagement

Raising awareness and educating healthcare professionals, patients, parents/carers and the public about the benefits and limitations of AI in pediatric radiology is essential for building trust and acceptance for clinical adoption [35]. Educational initiatives outside of healthcare staff could consider creating informative resources for patients and their families. Public awareness campaigns should utilize various media to disseminate information about the use of AI in pediatric radiology, address common misconceptions, and engage with patient communities. These campaigns should address misconceptions and fears about AI, ensuring that the information presented is accurate and balanced [67] given that children are wary of how their data is used and what the implications of AI in their care may be [34]. Some work is being conducted to ensure children's priorities are being heard, such as at the Paris AI Action Summit 2025 where 'The Children's Manifesto for the Future of AI'[68] was discussed, but more should be done to ensure the conversation is ongoing.

Key AI Educational Considerations:

1) **Core AI literacy for all**: Include basic understanding amongst healthcare staff on how AI tools are designed, their limitations and the unique challenges of using AI in pediatric settings.
2) **Specialized AI training for pediatric radiology**: Knowledge regarding specific aspects of pediatric anatomy, diseases and common pitfalls of AI tools in children's imaging. Awareness of how and whether AI tools are intended for children's imaging and potential dangers in practice should be addressed.
3) **Ongoing Professional Development**: regular updated training and certification in AI.
4) **Patient and Public Education**: outreach and stakeholder meetings for patients, guardians and the wider public to build trust and awareness of how AI is being used, and to tackle any misconceptions.

Conclusion

AI in pediatric radiology holds immense potential to improve diagnostic accuracy, efficiency, and personalized care but requires cautious implementation. Collaboration between pediatric radiologists, AI vendors, healthcare institutions internationally is crucial to develop child-specific AI models with rigorous training, robust regulation, and continuous monitoring. Transparency, ethical practices, and education are essential to ensure safe and effective use, minimizing bias and harm. A child-centric framework – grounded in data protection, consent, and human oversight can safeguard young patients while advancing equitable, inclusive pediatric healthcare.

Acknowledgements

(1) This article is a co-publication (*doi numbers of accompanying publication will be included at production).*

(2) Both journals (JACR and Pediatric Radiology) have peer reviewed this manuscript. None of the co-authors on this manuscript were involved in the peer review process or selecting peer reviewers. All senior board committee members and research representative members of the affiliated societies on this multi-society statement article were involved in reviewing the final manuscript prior to endorsement and publication, which includes board members of ACR, ESPR, SPR, AOSPR, SLARP and SPIN.

Funding:
<blinded>

Figure Legends

Figure 1

Visual summary of the four pillars and summary statements in this multi-society document for the promotion of pediatric patient safety when using AI in children's imaging.

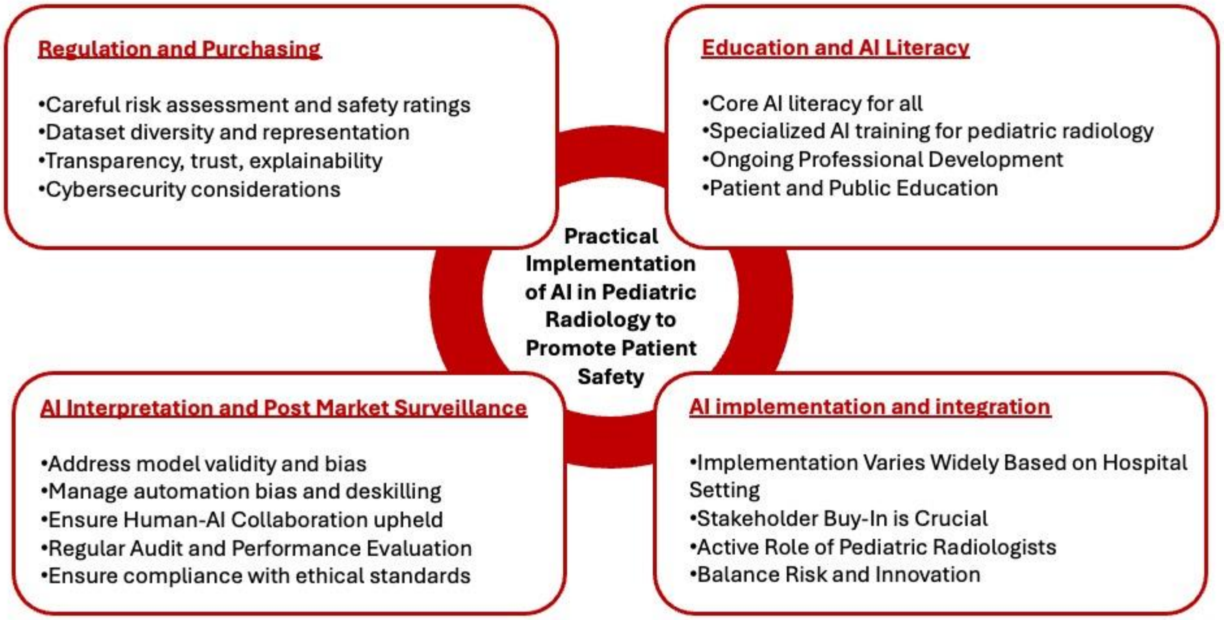


Figure 2

A simplified road map for AI implementation in radiology

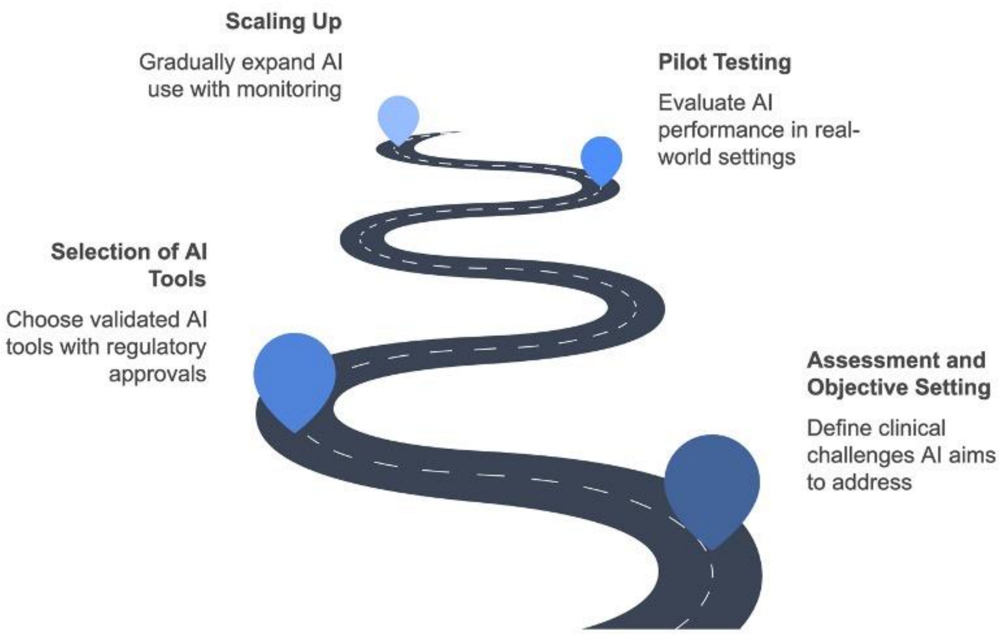
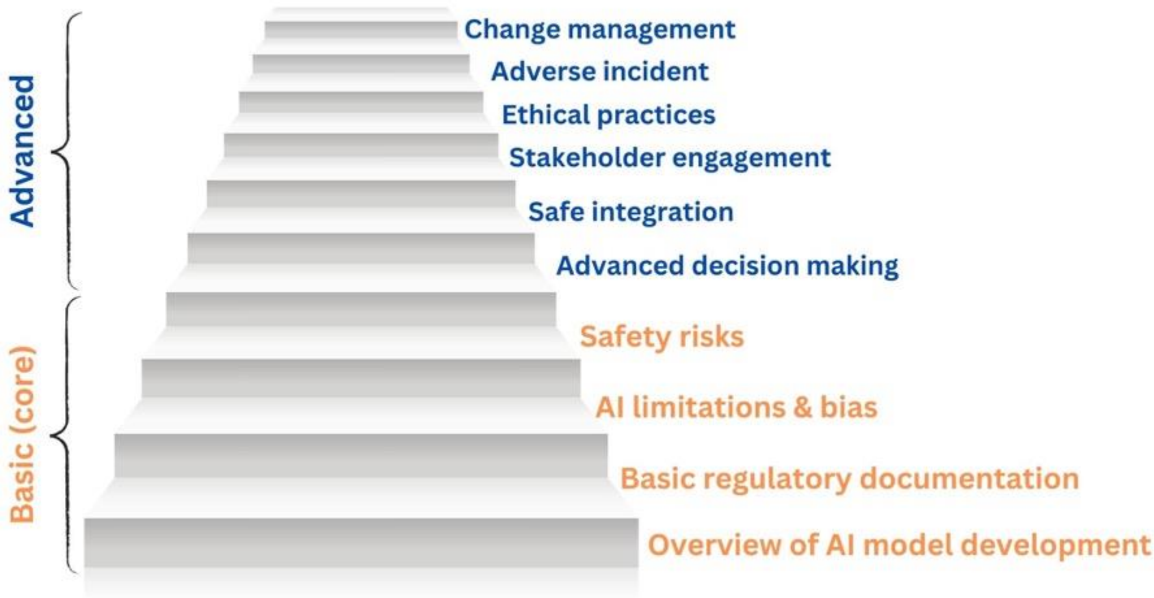


Figure 3

Different components that could be applicable to AI education for paediatric radiology for healthcare professionals divided into core and advanced competencies and knowledge requirements.



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