

OPINION



# Artificial intelligence in radiology: safeguarding patients' rights in the digital era

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Artificial intelligence (AI) is now firmly embedded in radiology practice. From automated abnormality detection on chest radiographs to workflow optimization in triage, AI is increasingly shaping diagnostic processes. Its promise is substantial: improved efficiency, faster reporting, and better diagnostic accuracy. Yet these benefits come with risks that extend beyond technical performance. For radiologists, the critical challenge is to ensure that integration of AI into clinical practice does not compromise patients' fundamental rights.

This is not only a professional duty, but also a legal obligation. Under the recently adopted EU Artificial Intelligence Act (AI Act), hospitals and clinicians deploying “high-risk” AI systems, including most radiology applications, are required to demonstrate adequate AI literacy [1, 2]. Radiologists must be equipped not only to understand technical aspects but also to assess risks for patients.

## Bias and beyond: multiple risks to patients

Recent studies in breast cancer screening illustrate one well-known problem: the performance of AI systems can vary according to patient characteristics such as age, race/ethnicity, and breast density [3]. Women from minority backgrounds and older women are more likely to receive false-positive results compared with white, middle-aged women [4]. These disparities reflect biases in training datasets and design choices, raising the possibility that AI amplifies existing health inequities.

But bias is only one part of the story. Even a technically “accurate” AI system may still create new risks for patients

if its functioning undermines autonomy, obscures information, compromises privacy, or blurs accountability [5]. Radiologists need to think about AI not just in terms of performance metrics, but in terms of how it interacts with the rights and expectations of patients [6].

## Patients' rights under pressure

AI integration in radiology places five established patients' rights at risk:

- (1) **Right of access to care:** If algorithms perform less reliably for certain groups, patients face unequal diagnostic quality. For example, studies of AI in mammography have shown higher false-positive rates in women with dense breast tissue or in Black women compared with white women of the same age [3, 4].
- (2) **Right to autonomy:** Informed consent is weakened if AI-driven outputs are accepted without explanation or clinician oversight. A patient undergoing CT lung cancer screening may never know an AI algorithm flagged or dismissed a nodule, leaving no meaningful opportunity for informed decision-making [7].
- (3) **Right to information:** Black-box systems make it difficult for radiologists to explain to patients how a diagnosis was reached. For example, heatmaps may highlight suspicious areas without justifying why, leaving radiologists unable to fully explain results [8].
- (4) **Right to privacy:** The development of radiology AI depends on massive datasets of CT, MRI, and X-ray images. Hospitals face mounting pressure to pool or commercialize these datasets, sometimes through partnerships with technology companies. This raises concerns about genuine consent, reuse of data beyond care (e.g., insurance or marketing), and cross-border data safeguards [9].

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- (5) **Right to redress:** When harm occurs, accountability is unclear. Imagine a case where an AI algorithm fails to detect a cerebral aneurysm on CTA, leading to delayed treatment. Was the error the responsibility of the radiologist for relying on the tool, the hospital for approving its use, or the developer for deficiencies in training data? Without transparency and clearly defined liability frameworks, patients may find it nearly impossible to pursue compensation [10].

### European regulation: progress but not yet enough

In Europe, several legal instruments govern AI in healthcare, but their protections remain fragmented. The General Data Protection Regulation (GDPR) provides safeguards against automated decision-making, yet its application to clinical diagnostic processes remains ambiguous [11]. The Medical Device Regulation (MDR) focuses on product safety and performance but does not directly address patients' rights, such as autonomy or redress [10, 12]. The recently adopted AI Act introduces new requirements for "high-risk" AI systems, including medical imaging applications, but its provisions remain general. They create no new enforceable rights for patients affected by algorithmic decision-making. Current frameworks tend to view AI risks through a narrow lens of product conformity and safety, rather than the experiences and rights of patients [1].

### Toward stronger safeguards in radiology practice

Radiologists are uniquely positioned at the interface between patients, technology, and regulation. To ensure that AI strengthens rather than weakens patient trust, three complementary safeguards are essential.

First, a European Charter of Digital Patients' Rights should clarify rights for the digital era, such as the right to explainability, human oversight, and protection against automated discrimination [10]. This also means that patients should be involved in the entire AI lifecycle, from design to post-market surveillance [13]. Radiologists, as the link between AI medical imaging systems and patients, play a key role in putting patients' rights into practice.

Second, professional guidelines for AI in radiology are needed. Beyond law, professional societies should provide practical guidance. This could cover when and how AI outputs should be recorded in medical records, how radiologists should address false-positive results, and what information must be shared with referring physicians, radiographers, and patients. Radiologists' direct involvement in guideline development, together with ethicists and legal experts, will help ensure that safeguards are tailored to clinical realities [14, 15].

Third, continuous education and AI literacy are crucial. The EU AI Act explicitly requires that deployers of high-risk AI systems, including hospitals and clinicians, ensure adequate AI literacy. For radiologists, this means structured training not only in technical dimensions but also in ethical and legal implications. Embedding AI literacy into training at all levels will ensure radiologists remain equipped to use AI responsibly [16].

Together, these measures can help ensure that AI strengthens patient trust and safeguards radiology's commitment to quality and safety.

### Conclusion

The expansion of AI in radiology represents both an opportunity and a responsibility. Bias is an important challenge, but not the only one: opacity, threats to autonomy, data pressures, and unclear accountability all place patients' rights under strain. By proactively addressing this broader spectrum of ethical and legal risks, radiologists can ensure that technological innovation translates into safer, more equitable patient care. Rather than viewing patients' rights and AI as opposing forces, we should treat them as mutually reinforcing: only by safeguarding rights can AI deliver on its promise to improve radiology for all patients.

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### Methodology

- Legal analysis (opinion piece)

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