Regulatory Needs for Radiation Protection Devices based upon Artificial Intelligence - State task or leave unregulated?

Stefanie Garni[1], Nando Mertineit[2], Gerd Nöldge[1], Keivan Daneshvar[1], Frank Mosler[1]

1Department of Diagnostic, Interventional and Pediatric Radiology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland

2Institut für Medizinische Radiologie (IMR) Bürgerspital Solothurn, Solothurn, Switzerland

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1Corresponding author: stefanie.garni@insel.ch - received: 20.01.2024 - published: 24.02.2024

Abstract

Artificial intelligence (AI) is increasingly employed in radiation protection, encompassing both medical devices and software. These technologies are integrated with AI throughout their manufacturing and application processes. This article underscores the imperative for comprehensive regulation in the utilization of AI. Decisions regarding AI application should not solely rest with manufacturers, medical professionals, or patients. Instead, an overarching "neutral" authority must be engaged to regulate, review, and enforce adherence to established protocols. The authors contend that relying on "self-regulation" within the free market, absent clear guidelines, proves to be inadequately effective and leads to patient's radiation protection safety issues.

Keywords: artificial intelligence, radiation protection, regulations, ensuring compliance

Introduction

The differentiation between Artificial Intelligence (AI), machine learning (ML), and deep learning (DL) is initially irrelevant for radiation protection in radiology (8). It is important to emphasize that any application of such methods in radiation protection inevitably leads to a somewhat ambiguous responsibility in the event of errors.

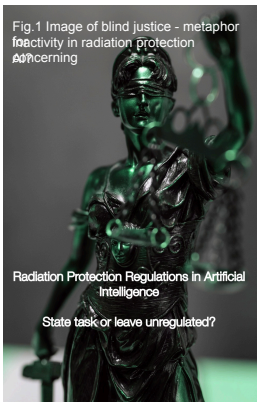


Fig.1 Image of blind justice - metaphor for activity in radiation protection concerning AI

AI applications in radiology include image analysis and assistance with report drafting (10). In a study using nine predefined distal radius fracture cases, Bosbach et al. evaluated ChatGPT-generated reports based on structured textual input and found both promising report quality and shortcomings in terminology and medical interpretation (2). This work concerns report generation; it does not establish safe autonomous radiation-dose control or quantify productivity gains in routine clinical practice.

As a hypothetical application scenario, consider an AI-enabled CT system that uses protocol data and patient-specific information to assist in selecting exposure settings. This example does not establish the capabilities or safety of a particular device.

Radiology, as a service provider within interconnected modern medicine, must not be overlooked when evaluating patient outcomes and patient's radiation exposures. The capacity for improvement can be achieved, in our belief, through enhanced facilities and increased productivity. One tool that offers significant opportunities is information technology (IT) based on artificial intelligence (AI).

US regulatory context as of February 2024

AI/ML-enabled software that qualifies as a medical device is subject to the applicable US medical-device regulatory framework. Questions concerning AI-specific oversight and discrepancies between device marketing and FDA clearance documentation should therefore be distinguished from an absence of regulation. Clark et al. identified discrepancies between marketing claims and publicly available 510(k) clearance summaries (3).

The 2021 Good Machine Learning Practice guiding principles provide a framework for responsible development, but do not replace applicable statutory and regulatory requirements (12). By February 2024, US legislation had expressly provided for FDA authorization of predetermined change control plans (PCCPs). FDA had published draft recommendations on PCCPs for AI/ML-enabled device software in April 2023, followed by joint PCCP guiding principles with Health Canada and the MHRA in October 2023 (15,16). These documents represented guidance development rather than a final, binding AI-specific rule. The authors advocate further clarification and effective oversight of AI applications in radiation protection within this evolving framework.

Challenges of AI in Radiology

The rationale underlying the design of AI must also be taken into account, as certain systems can be programmed to behave unethically. For instance, Uber's algorithmic tool 'Greyball' was developed to predict which ride-hailers might be undercover law enforcement officers, enabling the company to

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US-FDA & Health Canada & UK-MHRA - 10 Guiding principles for AI-based software development for medical devices	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Good Software Engineering and Security Practices Are Implemented	Focus Is Placed on the Performance of the Human-AI Team
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Training Data Sets Are Independent of Test Sets	Users Are Provided Clear, Essential Information
Selected Reference Datasets Are Based Upon Best Available Methods	Deployed Models Are Monitored for Performance and Re-training Risks Are Managed

Tab.1 Good machine learning practice for medical device development - Guiding principles (3,12)

detect and evade local regulations. Similarly, Volkswagen's algorithm enabled vehicles to pass emissions tests by reducing their nitrogen oxide emissions during testing.
Likewise, designers in the private sector tasked with creating AI algorithms for clinical applications may face similar ethical dilemmas, potentially programming AI systems to steer users towards clinical actions that would boost profits for their purchasers (such as by recommending medications, tests, or medical devices in which they have a financial interest or by modifying referral patterns), without necessarily ensuring better patient care (9).
Another concern for policymakers is timing. Presently, companies recognize the potential of machine / deep learning and are consistently amassing new forms of data for analysis and exploitation. In a rapidly evolving and unpredictable environment such as the technology sector and AI, regulations must be promptly enacted to remain pertinent (9,10).

Regulatory needs?

Examples of AI-based radiation protection devices still to be regulated in Switzerland

"Simple" Questions

All components of a medical device in radiation protection should be labeled or assessed regarding the use of AI. This applies to both hardware and software. As an example, consider the user manual *of any X-ray device.*

In Switzerland, product information, including instructions for use, must generally be provided in German, French and Italian. Article 16(3) of the Medical Devices Ordinance permits fewer languages or English for devices supplied exclusively to healthcare professionals, provided that users have the necessary professional and language skills and agree to this arrangement, the protection of patients, users and third parties is ensured, and effective use and device performance are not compromised. Additional information in an official language must be supplied on request under Article 16(4) (17). Against this background, the use of AI-assisted translation raises questions about how the accuracy and safety of translated instructions are assured.

- Should it be labeled as a "AI-driven translation"?

- Who bears responsibility when dubious translations result in user errors and incorrect radiation protection for patients?

- Are there quality control measures implemented by the manufacturer? What are the protocols?

- If quality control protocols exist, who oversees their implementation? Humans or AI?

These questions above mentioned among many others are the so called "easy ones" to answer. Of course the correct answers depend on the insight and the striking will of the politics and the earnest pursuit towards implementation by the officially responsible authorities which would have substantially more of hard administrative workload than ever before.

Key Inquiries (not simple)

The complexity and criticality of these questions escalate significantly when AI-based software is responsible for determining the dosage of radiation administered to individual patients during X-ray or CT examinations. This intricate matter poses considerable challenges due to liability concerns, responsibilities, and other technical inquiries.

AI-based medical software does not necessarily learn continuously during clinical use. A distinction should be made between models that remain fixed during deployment and are updated through manufacturer-controlled retraining and validation, and adaptive systems designed to learn from new data during use (14). The degree of operational autonomy is a separate characteristic and depends on the device's intended purpose and implementation. In radiation protection, oversight should therefore address the specific system's behaviour, update process and safeguards. Incorrect or misleading dose information and failures of control mechanisms should be examined as potential hazards; intentional deception should not be assumed to be an inherent property of medical AI.

Against this background, we propose the following safety and accountability questions for AI-enabled systems used in radiation protection:

- How is it ensured that the AI-based software accurately presents the human technician with the correct results of radiation exposure during a CT examination?

- Could dose information be incorrect or misleading in the event of excessive exposure or an inadequate protocol?

- Who bears final responsibility for the radiation exposure?

The manufacturer? The operator? The radiologist? The patient? The X-ray device with AI?

- What controls detect and prevent incorrect reporting of radiation-dose information?

- How can control protocols detect and prevent failures or circumvention of safeguards?

Ethical Considerations

(FAT) paradigm of AI ethics:
- Fairness
- Accountability
- Transparency

Many ethical concerns related to AI in healthcare can be grouped into three main categories: fairness, accountability, and transparency. This has led some researchers to discuss the fairness, accountability, and transparency (FAT) paradigm of AI ethics. While it may not be feasible or desirable to eliminate all biases, it is essential to acknowledge them and consider their implications for both machine and human decision-making processes. Biases can arise from the utilization of datasets that either overrepresent, underrepresent, or entirely miss certain relevant characteristics for the task at hand.
Additionally, there is a risk of "automation bias", where humans begin to overly rely on machine outputs without exercising their own critical judgment and scrutiny. Furthermore, there is the potential for spurious correlations that, if acted upon, could result in harm to patients (4,5).

Presently, there is limited experience employing AI for patient care across its various demanding and diverse settings. Extensive research is still needed to comprehend the optimal utilization of AI in clinical practice and the essential operational characteristics it should possess. The approach to addressing these issues will be influenced not only by technical factors but also by the ethical considerations within the community. Individuals engaged in any phase of an AI product's life cycle must possess a thorough understanding of it.
It is our responsibility to comprehend the risks associated with the products we utilize, to communicate any potential pitfalls to patients and stakeholders as necessary, and to continuously monitor AI products to mitigate harm. Moreover, we are obligated to ensure not only that the overall use of the product is beneficial but also that the distribution of benefits among potential stakeholders is fair and equitable (5).

Recommendations

AI in healthcare is best conceptualized as a socio-technological practice, where humans and machines do not vie against each other, but rather where machines augment the abilities of humans.
Innovations in AI within radiology are likely to be propelled by academic healthcare organizations collaborating with industry. Guidelines are essential to govern these partnerships in an ethical manner.
Bias stands out as one of the foremost ethical concerns associated with AI in radiology. While not all biases are detrimental (such as purposefully oversampling critical characteristics or tailoring algorithms for specific contexts), all applications of AI should undergo scrutiny for potential impacts stemming from various forms of bias.
Guidelines for the ethical utilization of imaging AI must be established, with radiologists collaborating with ethicists at the forefront of this initiative.
For the responsible integration of AI into clinical practice, robust validation strategies are imperative. One approach is to align AI use cases, as defined by clinical end-users (including labeled data), with challenges designed to objectively evaluate and compare algorithm performance (7,10).
To train resilient AI algorithms, diverse datasets are essential. Standards are required to facilitate the efficient utilization and sharing of these datasets through clinical trials.
Data sharing holds the potential to advance the development of clinically relevant AI tools, provided that barriers to data sharing are addressed and appropriate incentives are established (3).
Radiologists will need varying levels of proficiency in AI depending on their roles, but it is crucial for all radiologists to acquire a fundamental understanding of AI, encompassing both its capabilities and limitations.
Developing the educational resources necessary for an AI curriculum will necessitate collaborative efforts among multiple stakeholders, including national and international societies, regulatory officials and academic radiology departments.

Discussion

In the pertinent scientific literature, three critical areas of intervention in AI can be discerned: ethical concerns, the international regulatory framework, and bottlenecks in regulatory development. Specifically, bottlenecks have been pinpointed, particularly regarding workload, indicating that regulating it without a scientific foundation may pose greater risks than having no regulation at all (6).

Evidence on AI-related knowledge and educational needs should be interpreted in relation to the populations surveyed. Barreiro-Ares et al. studied students rather than the full range of stakeholders involved in radiation protection (1). In a regional French survey, 270 radiologists responded to 617 invitations; 73.3% reported insufficient previous information about AI, 94.4% would consider general AI training, and 79.3% expected a positive impact on their future practice (11). These findings describe respondents' perceptions and expectations; they do not establish knowledge deficits across regulatory officials, medical physicists, technicians or patients, nor do they demonstrate improved care. We recommend education tailored to the responsibilities and needs of each stakeholder group.

Regulations, standards, and codes of conduct must be established and consistently revised. Central to these codes of conduct is an ongoing focus on transparency, safeguarding patient interests, and robust oversight of data versions and utilization (5). Continuous postimplementation monitoring is essential to detect unintended consequences and potential declines in quality, with established protocols for identifying causes and implementing corrective measures (7).

Important and uncomfortable questions need to be answered. Therefore, it is incumbent upon policy-makers and official regulatory bodies to ensure the continuous reliability of medical radiation protection for the general public, especially in the face of regulatory vacuums created by new technologies such as AI. Entrusting this task to the so-called free market is not considered conducive to achieving this goal.

Conflict of interest:

The authors declare that there were no conflicts of interest within the meaning of the recommendations of the International Committee of Medical Journal Editors when the article was written.

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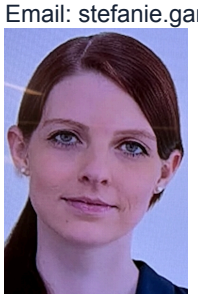
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Acronyms

AI Artificial Intelligence
DR Digital radiology
MD Medical Device
SaMD Software as Medical Device
FDA Food and Drug administration
ML Machine Learning
ACR American College of Radiology
NMPD National Medical Products Administration
IMDRF International Medical Device Regulators Forum
FHIR Fast Healthcare Interoperability Resource
HL7 Health Level seven

Correspondence address:

Dr. sc. nat. Stefanie Nicole Garni
Medical Physicist, SGSMP
University Institute of Diagnostic, Interventional and Paediatric Radiology
University Hospital Bern, Inselspital
University of Bern
Freiburgstrasse 18
CH-3010 Bern
Switzerland
Email: stefanie.garni@insel.ch



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