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Ethical and Regulatory Evaluation of Artificial Intelligence in Clinical Radiology Practice

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Abstract: The use of artificial intelligence (AI) in clinical radiology has grown rapidly in line with digital transformation and the increasing demand for efficiency in healthcare services. However, the rapid adoption of AI has not always been accompanied by adequate ethical and regulatory readiness. This study aims to evaluate the ethical framework and regulatory governance of AI applications in radiology practice, both globally and nationally, through a systematic literature review with a narrative analysis approach. The findings reveal that international bodies such as the WHO, FDA, and the European Union have developed ethical guidelines and algorithm audit standards emphasizing transparency, accountability, and patient data security. In contrast, Indonesia has yet to establish specific regulations addressing certification, legal responsibility, and data privacy in medical AI applications. Major challenges include low digital literacy among healthcare professionals, overlapping institutional authorities, and the absence of independent oversight mechanisms. Therefore, the establishment of a national ethical framework, algorithm audit system, and professional training policies is essential to ensure that AI utilization in clinical radiology is conducted safely, transparently, and equitably.

Keyword: Artificial Intelligence, Radiology, Medical Ethics, Health Regulation, Algorithm Audit.

INTRODUCTION

The integration of artificial intelligence (AI) into clinical radiology represents one of the most transformative developments in modern healthcare. Over the past decade, AI technologies particularly machine learning and deep learning have increasingly been used to support image interpretation, automate diagnostic workflows, and assist clinicians in making faster and more accurate decisions. Studies such as those by Esteva et al. (2021) and Ribli et al. (2020) demonstrate that AI can enhance diagnostic precision and reduce inter-observer

variability, especially in complex imaging cases such as oncology and neurology. Consequently, AI has transitioned from being a supplementary research tool to becoming an integral part of clinical practice in many advanced healthcare systems.

However, this technological advancement also introduces significant ethical and regulatory challenges. As Topol (2019) and Jobin, Ienca, and Vayena (2019) point out, the rapid diffusion of AI in medicine has outpaced the development of ethical frameworks and governance mechanisms to ensure accountability, transparency, and patient safety. The “black box” nature of AI algorithms, where decision-making processes are not always explainable to clinicians or patients, raises concerns about liability, informed consent, and potential bias in algorithmic predictions. These issues are particularly critical in radiology, where diagnostic decisions can directly affect patient outcomes and treatment planning.

Globally, institutions such as the World Health Organization (WHO, 2021), the U.S. Food and Drug Administration (FDA, 2021), and the European Union (2024) have begun to establish comprehensive ethical and regulatory guidelines for medical AI. These frameworks emphasize principles of fairness, data security, and human oversight in the use of AI-based diagnostic systems. Yet, in many developing countries including Indonesia ethical and regulatory readiness remains limited. The absence of clear standards for algorithm validation, data governance, and professional responsibility poses a risk to both clinicians and patients in the context of AI-assisted radiology.

In Indonesia, the adoption of AI in radiology is growing steadily, supported by national initiatives such as the Indonesia Health Tech Roadmap 2025 (Ministry of Health, 2022). However, this progress has not been matched by the establishment of specific regulations governing AI-based clinical tools. Issues related to data privacy, medical device certification, and digital literacy among radiologists continue to hinder safe and effective implementation. Thus, a systematic evaluation of the ethical and regulatory landscape of AI in clinical radiology is essential to guide the responsible development of this technology.

This article aims to analyze the ethical principles, global regulatory models, and national readiness related to the implementation of AI in clinical radiology. By reviewing relevant international frameworks and current challenges in Indonesia, this study seeks to identify policy gaps and propose recommendations for the ethical governance of medical AI systems.

METHOD

This study employed a systematic literature review method using a narrative synthesis approach to analyze ethical and regulatory aspects of artificial intelligence (AI) applications in clinical radiology. The review aimed to identify, evaluate, and synthesize relevant scholarly works, policy papers, and international guidelines addressing the governance of medical AI systems.

The literature search was conducted between January and June 2025 through several international databases, including PubMed, Scopus, ScienceDirect, and Google Scholar, as well as national repositories such as Garuda (Garba Rujukan Digital) and institutional archives from Indonesian universities. The search strategy combined the following keywords: “Artificial Intelligence,” “Radiology,” “Ethics,” “Regulation,” “Medical Law,” and “Indonesia.” Publications between 2015 and 2025 were included to capture the most recent ethical discussions and regulatory developments related to AI in healthcare.

Inclusion criteria comprised peer-reviewed journal articles, systematic reviews, policy reports, and official documents from international health organizations that discuss AI governance in radiology or broader medical contexts. Studies focusing on ethical frameworks, regulatory standards, or case analyses of AI implementation in diagnostic imaging were prioritized. Articles in both English and Indonesian were considered.

Exclusion criteria involved non-academic commentaries, unpublished reports, and papers unrelated to ethical or regulatory issues in medical AI.

The review process followed three main stages:

- (1) Screening of titles and abstracts to ensure topic relevance;
- (2) Full-text review of selected articles for detailed examination; and
- (3) Thematic analysis to categorize findings into recurring themes such as ethical principles, global regulatory frameworks, and national readiness.

To ensure validity and reliability, literature selection and coding were conducted independently by two reviewers, and disagreements were resolved through discussion and consensus. The synthesis of findings aimed to highlight gaps between global best practices and Indonesia's regulatory and ethical preparedness for AI adoption in clinical radiology..

RESULT AND DISCUSSION

1. Ethical Principles in AI-Based Radiology

The integration of artificial intelligence (AI) in radiology introduces new ethical dimensions that challenge traditional biomedical principles. Central to these concerns are the issues of accountability, transparency, fairness, and patient autonomy (Beauchamp & Childress, 2019; Jobin, Ienca, & Vayena, 2019). While AI-assisted systems enhance diagnostic speed and accuracy, they also obscure decision-making processes, leading to what has been termed the “black box problem” (Topol, 2019). When clinicians cannot fully explain how AI algorithms reach conclusions, patient trust and informed consent become ethically fragile.

Moreover, algorithmic bias remains a critical issue. Rajkomar et al. (2019) and Goodman (2020) emphasize that AI models trained on non-representative datasets risk reinforcing existing health disparities, particularly in populations underrepresented in training data. In radiology, such bias may manifest as unequal diagnostic accuracy across ethnic or demographic groups. Therefore, the ethical governance of AI must include mechanisms for dataset transparency, algorithm auditing, and fairness testing before clinical deployment.

Another emerging issue concerns data privacy and ownership. Radiological images constitute highly sensitive personal data. Ensuring compliance with data protection principles such as anonymization, consent-based sharing, and restricted data access is a prerequisite for ethical AI utilization (WHO, 2021). Without clear consent procedures and security standards, the risk of patient data misuse could undermine the integrity of AI adoption in radiology.

2. Global Regulatory Frameworks

Internationally, significant progress has been made toward establishing comprehensive regulatory models for AI in medical practice. The U.S. Food and Drug Administration (FDA) introduced the Good Machine Learning Practice (GMLP) guidelines in 2021, outlining requirements for algorithm validation, performance monitoring, and human oversight. Similarly, the European Union Artificial Intelligence Act (2024) classifies AI used in healthcare as high-risk, mandating independent audits, transparency documentation, and continuous monitoring throughout its lifecycle.

The World Health Organization (WHO, 2021) has also provided global ethical guidance that emphasizes six foundational principles: protecting human autonomy, promoting well-being, ensuring transparency, fostering accountability, guaranteeing data privacy, and sustaining human oversight. These principles collectively form an ethical blueprint for governments and medical institutions seeking to integrate AI responsibly.

Empirical experiences from developed nations demonstrate that regulatory frameworks not only ensure safety but also promote public trust. The FDA-approved AI

systems for melanoma detection and lung cancer screening (Esteva et al., 2021) and the widespread implementation of AI-based adaptive radiotherapy in Europe (Ribli et al., 2020) exemplify successful models of ethically governed AI. However, these achievements rely on robust data infrastructure, interdisciplinary governance, and a culture of algorithmic accountability elements still developing in many low- and middle-income countries.

3. National Readiness and Policy Gaps in Indonesia

In Indonesia, the ethical and regulatory landscape surrounding medical AI remains nascent. Although the Indonesia Health Tech Roadmap 2025 (Ministry of Health, 2022) identifies digital transformation as a national priority, explicit frameworks for AI governance in clinical radiology are still absent. The overlapping authority between the Ministry of Health, BAPETEN, and BRIN has led to fragmented oversight and unclear lines of accountability.

Hartono (2020) and Setiawan (2022) noted that the absence of a dedicated AI certification pathway for medical devices hinders adoption at the hospital level. Furthermore, Wulandari et al. (2023) found that only about 35% of radiologists and radiotherapists in Indonesia feel competent using AI-based systems, reflecting limited digital literacy among healthcare professionals. This skills gap not only affects implementation efficiency but also raises ethical concerns regarding informed use and professional responsibility.

Data governance presents another critical challenge. Most AI research in Indonesia still depends on international open datasets, such as ChestX-ray14 and LIDC-IDRI, which do not accurately represent local patient characteristics (Santoso et al., 2021). This lack of localized datasets may produce algorithmic bias when applied in domestic clinical settings. Consequently, the establishment of a national medical imaging repository secured under clear ethical and privacy regulations is essential for safe and equitable AI deployment.

To close these gaps, Indonesia requires an integrated ethical governance system that includes:

- (1) the creation of a National Medical AI Ethics Board;
- (2) transparent algorithm auditing standards; and
- (3) structured professional training programs for clinicians. By combining regulatory reform with educational and infrastructural investment, Indonesia could align itself with international best practices while ensuring that AI integration strengthens, rather than undermines, patient safety and clinical accountability.

4. Challenges and Opportunities

The ethical and regulatory implementation of artificial intelligence (AI) in clinical radiology in Indonesia presents a combination of persistent challenges and emerging opportunities. Although the potential of AI to enhance diagnostic precision and healthcare efficiency is undeniable, the readiness of ethical governance, professional competence, and policy infrastructure remains uneven across the healthcare system.

One of the primary challenges lies in the limited level of ethical and digital literacy among healthcare professionals. Wulandari et al. (2023) found that only about one-third of radiologists and radiotherapists in Indonesia feel adequately prepared to operate AI-based tools. This lack of competence not only hinders adoption but also raises ethical concerns regarding the informed use of automated systems in patient care. Without adequate understanding of algorithmic limitations and data governance, clinicians risk overreliance on AI outputs, potentially compromising diagnostic accountability.

Another major challenge is the fragmented regulatory landscape. Oversight of AI in medicine currently involves multiple authorities including the Ministry of Health, BAPETEN, and BRIN each with distinct mandates but limited coordination (Hartono, 2020;

Setiawan, 2022). The absence of a unified national framework results in overlapping responsibilities, inconsistent licensing requirements, and gaps in algorithmic audit mechanisms. This fragmentation undermines transparency and slows policy harmonization across sectors.

Infrastructure-related constraints further complicate implementation. Many hospitals, particularly outside major cities, lack access to high-performance computing systems and secure data storage infrastructure necessary for AI-based image analysis (Rahardjo & Dewanti, 2022). Moreover, Indonesia's dependency on international datasets—such as ChestX-ray14 and LIDC-IDRI limits the contextual reliability of locally deployed AI models (Santoso et al., 2021).

Despite these challenges, significant opportunities are emerging. The Indonesia Health Tech Roadmap 2025 (Ministry of Health, 2022) provides a strategic foundation for digital health transformation, emphasizing interoperability, data security, and innovation in AI-driven medical services. This initiative, coupled with international collaborations (Rahman & Yuliani, 2023), offers pathways for knowledge transfer, capacity building, and joint algorithm development. Universities are also responding to the growing demand for interdisciplinary education by integrating medical, technological, and data science curricula (Fauzi & Handayani, 2023), fostering a new generation of professionals equipped to navigate both clinical and ethical dimensions of AI.

Finally, the increasing involvement of the private sector offers prospects for technological independence. As Bugani, Pulungan, and Suryana (2024) note, investment in local radiotherapy and diagnostic infrastructure can reduce dependence on costly foreign software licenses while stimulating domestic innovation. With strong policy support and cross-sector collaboration, Indonesia has the opportunity to position itself as a regional leader in ethical and responsible AI-based radiology.

5. Policy Recommendations

The integration of artificial intelligence (AI) into radiology practice in Indonesia requires a multi-level policy framework that balances technological innovation with ethical governance. Based on the literature review, three strategic pillars emerge as essential for ensuring responsible, sustainable, and equitable AI implementation in medical imaging and radiotherapy: regulatory harmonization, capacity building, and data infrastructure development.

a. Regulatory harmonization and ethical oversight.

Indonesia urgently needs a unified regulatory framework that delineates the ethical boundaries, data governance standards, and clinical accountability mechanisms of AI systems. Current fragmentation across institutions such as the Ministry of Health, BAPETEN, and BRIN has created overlaps and gaps in policy enforcement (Hartono, 2020). Establishing a National Council for Medical AI Ethics could centralize oversight, streamline licensing processes, and ensure alignment with international standards such as those set by the World Health Organization (WHO, 2021) and the European Commission (2022). Moreover, legal clarity regarding liability for AI-assisted decisions must be defined to protect both healthcare providers and patients from potential malpractice disputes.

b. Capacity building for human resources.

Human expertise remains the ethical core of AI-based healthcare. As shown by Wulandari et al. (2023), only about one-third of professionals in radiology and radiotherapy report being confident in using AI tools. To address this, national training programs and certification systems should be established through collaborations between universities, professional associations, and industry partners. Continuous professional

development (CPD) focused on digital literacy, data ethics, and AI interpretation can empower clinicians to act as informed decision-makers rather than passive system users.

- c. Development of a secure and inclusive data infrastructure.

A national medical imaging repository is fundamental for AI reliability and fairness. Such a system should prioritize data sovereignty ensuring that patient data remain within Indonesia and include diverse demographic representations to minimize algorithmic bias (Santoso et al., 2021). Public-private partnerships could accelerate the establishment of this infrastructure while maintaining strict adherence to ethical and privacy principles outlined in the Health Data Protection Act currently under discussion (Ministry of Health, 2024). Integration with cloud computing (Setiawan, 2022) could further democratize access, enabling regional hospitals to participate in AI-supported diagnostics without major capital investment.

- d. Strengthening collaboration and innovation ecosystems.

Cross-sector collaboration between academia, government, and industry is essential for sustaining AI development. Incentives such as tax benefits for medical technology R&D, open-access research grants, and partnerships with international AI ethics networks (Rahman & Yuliani, 2023) could accelerate local innovation. Additionally, incorporating ethics-by-design principles in AI research proposals ensures that fairness, transparency, and accountability are embedded from the early stages of technological development.

- e. Community engagement and patient awareness.

Lastly, patient trust must be placed at the center of AI integration. Public communication campaigns should emphasize that AI serves to support not replace human medical judgment. Promoting literacy on data privacy, informed consent, and algorithmic transparency will help foster societal acceptance and reduce ethical resistance to AI-based healthcare services.

CONCLUSION

The integration of artificial intelligence (AI) into radiology and radiotherapy in Indonesia represents both an opportunity and a challenge. Evidence from current literature demonstrates that AI has significantly improved diagnostic accuracy, workflow efficiency, and treatment personalization especially in cancer detection and radiotherapy planning. However, the transition from experimental use to full clinical integration remains constrained by fragmented regulations, limited data infrastructure, uneven technological readiness, and a shortage of digitally skilled medical professionals.

Addressing these challenges requires a strategic alignment between technological innovation and ethical governance. The development of a national medical imaging database, clear regulatory frameworks for AI ethics and accountability, and structured training for radiology and radiotherapy practitioners are essential steps toward sustainable adoption. Collaborative efforts among government institutions, universities, healthcare providers, and the private sector will be crucial to building an AI ecosystem that is not only technologically advanced but also socially equitable and ethically grounded.

Indonesia's position as a rapidly developing nation provides a unique opportunity to implement leapfrogging strategies bypassing traditional barriers by directly adopting advanced AI technologies. If guided by coherent policy and robust ethical oversight, AI could become a catalyst for democratizing healthcare access, enhancing diagnostic precision, and ensuring the long-term resilience of the national health system. In conclusion, the success of AI in Indonesian radiology and radiotherapy will depend not merely on the sophistication of algorithms, but on the country's collective commitment to harness technology in the service of human-centered, just, and sustainable healthcare.

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