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Ethical and regulatory considerations in AI-driven medical imaging: A perspective overview

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Abstract

Artificial Intelligence (AI)-driven research aimed at improving critical clinical procedures and results has significantly increased during the last decade and a half. AI-powered systems that support decisions can improve clinical workflows, aid in diagnosis, and facilitate individualized care. However, implementing these innovative solutions presents some significant impediments in clinical and care settings, requiring a careful examination of the legal, ethical, and regulatory issues. A strong governance framework is essential to promote AI adoption and practical application in healthcare. By offering insightful suggestions for all parties interested in promoting the creation and application of cutting-edge AI systems, this review study seeks to address the present issues in digital healthcare, particularly as they relate to the ethical and regulatory considerations in AI-driven medical imaging (MI). Hence, this perspective overview explores the ethical and legal concerns arising when AI technologies are used in therapeutic settings. It makes a groundbreaking contribution to the subject by highlighting the function of AI technology and providing a perceptive viewpoint on the legal and ethical issues involved, particularly in MI.

Keywords: Artificial Intelligence; Ethical and Regulatory Issues; Healthcare; Medical Imaging

1. Introduction

Humanity has been impacted by several important stages of industrialization and digitalization (Dwivedi et al., 2021). Artificial Intelligence (AI), which is becoming increasingly prevalent, is one of the important stages of industrialization and digitalization. Over the past few decades, we have seen remarkable growth in the digitization of services across all sectors. Among the many sectors that AI technologies have significantly transformed is healthcare (Fuchs et al., 2024; Han et al., 2023; Gottlieb and Silvis, 2023; Habli et al., 2021). In the healthcare sector, AI refers to the use of algorithms and machine learning (ML) techniques to analyze complex medical data, make accurate diagnoses, support treatment decisions, and enhance patient care. By improving the outcomes of patients, simplifying treatment plans, and improving diagnosis accuracy, these advancements have the potential to fundamentally alter the healthcare sector (Alkayyali et al., 2024; Tiwari, 2023; Galkin and Zhavoronkov, 2023; Murphy et al., 2021).

AI is a key component that highlights many advancements and technologies in the healthcare development process (Macri and Roberts, 2023; Manickam et al., 2022), such as medical imaging (MI) and biomedical diagnostics, decision support and hospital monitoring, virtual assistant and chatbots, remote patient assistant, precision medicine and treatments, digital medicine and wearable technology, robotic technology assistant, drug discovery and research, as shown in Figure 1. Numerous fields, such as wearable technology and digital medicine, are made easier, enabling better decision-making and individualized health monitoring. While robotics and precision medicine aid in medication

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research and virtual assistance, AI-driven medical monitoring and diagnostic processes improve accuracy in MI and patient care. These uses demonstrate how AI revolutionizes contemporary technological advances and medicine (Khan et al., 2023; Manickam et al., 2022; Kashyap, 2018).

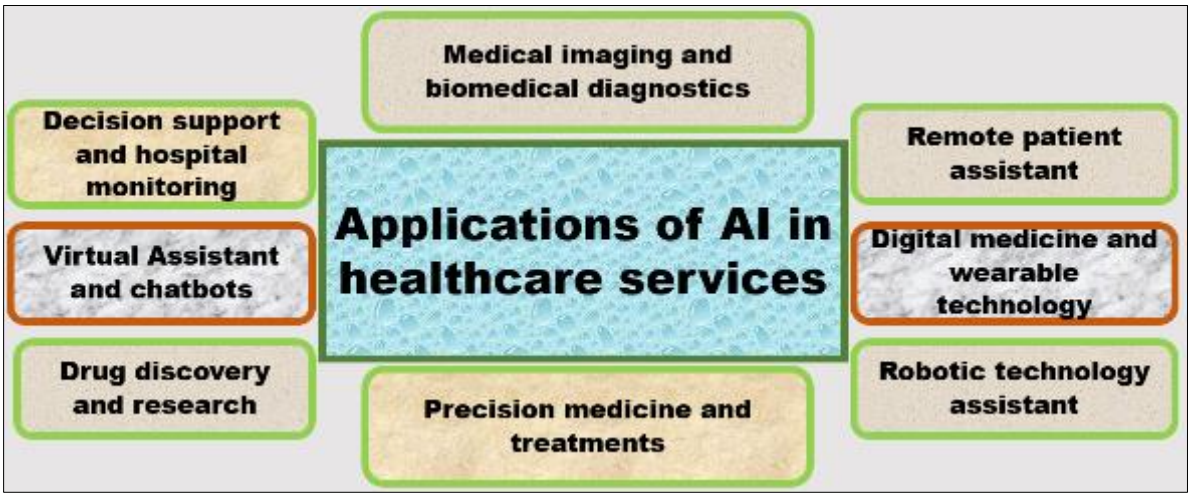

Figure 1 Applications of AI in healthcare services

By expanding the capabilities of imaging technology and increasing precision in diagnosis, the use of AI-driven medical imaging (MI) and other advanced technological procedures is transforming the healthcare system generally (Alkayyali et al., 2024; Herington et al., 2023; Ukhurebor et al., 2022; Onyancha et al., 2021). AI is increasingly used in medical imaging procedures to analyze and interpret complicated visual data, especially ML and deep learning algorithms (Mennella et al., 2024; Liao et al., 2023; Mak and Pichika, 2019). As a branch of AI, ML entails training algorithms for identifying patterns in massive datasets and generating predictions based on fresh information. These algorithms can recognize and categorize features in MI, including cancers, lesions, and anatomical structures, because they have been trained on a variety of image datasets. A more sophisticated type of ML called deep learning uses multi-layered neural networks, or deep neural networks, for analyzing images with extreme precision (Manickam et al., 2022). X-rays, computed tomography (CT) scans, magnetic resonance imaging (MRI), and ultrasound are just a few imaging modalities that use AI approaches. AI systems, for instance, can improve image quality, identify anomalies, and automate repetitive processes like measuring and segmenting an image. These features assist individualized treatment regimens, lessen radiologists' burdens, and enable a faster and more precise diagnosis. AI-driven IM helps with predictive analytics and speeds up the diagnosis process, allowing medical professionals to forecast patient outcomes and adjust interventions accordingly (Sáez et al., 2024; Visan et al., 2024; Secinaro et al., 2021; Zhavoronkov et al., 2021). AI-based technology is anticipated to play a bigger part in MI as it develops, strengthening diagnostic capacities and improving patient care.

AI and ML systems are a promising field of study in nuclear medicine (NM) vis-à-vis MI. The development and advancement of medical devices and other healthcare services based on AI holds the potential to increase diagnosis precision, speed up medical interventions, reduce expenses, and enhance patient outcomes (Herington et al., 2023; Petersson et al., 2022).

The privacy of data subjects, the possibility of unintentional injury to patients, and equity for marginalized groups are some of the ethical issues brought up by the development of these medical devices from AI (Williamson and Prybutok, 2024). Before medical devices from AI were widely used in NM/MI, scientists had to deal with these ethical concerns. By separating the creation and implementation of medical devices from AI, the Society of NM/MI's AI task group aims to clarify inventors, physicians, and supervisory bodies' roles and responsibilities. Herington et al. (2023) study looked at the development of medical devices from AI for applications in NM, and their study was structured around three different stages in the medical devices from the AI pipeline, as summarized in Table 1.

Table 1 Dimensions of ethical issues of medical devices from AI according to collection of data, development and assessment

Classification	Collection of data	Development	Assessment
Welfare	Encourage initiatives that are likely to have a positive social impact; avoid designing models and collecting data that could lead to re-identification.	Encourage performance to be generalizable across healthcare settings.	Make sure to assess the medical benefits as well as in silico performance.
Autonomy	Verify consent before collecting data, and explore notifying others when it will be used subsequently.	Steer clear of hard-coding developers' assessments regarding dangerous trade-offs; make sure clinicians can understand algorithmic ambiguity.	Make sure medical professionals are informed understandably and straightforwardly of performance and constraints.
Justice	Evaluate whether the data is reflective of the task (particularly by gender, ethnic background, etc.); support initiatives that result in rewards that are widely distributed.	Minimize performance differences by race, sex, etc.; meticulously defend the application of personally identifiable information attributes (race, sex, etc.) as input characteristics.	Make sure that the population's subgroups (by sex, race, etc.) have their performance assessed.

AI-driven research has significantly increased over the last ten years, focusing on improving important clinical procedures and results. It is becoming clearer how AI-powered decision support systems may improve clinical workflows, aid diagnosis, and allow individualized care (Mennella et al., 2024). However, the implementation of these innovative solutions presents some significant challenges in clinical and care settings, requiring a careful examination of legal, ethical, and regulatory issues (Wang et al., 2024; Abujaber and Nashwan, 2024; Abdullah et al., 2021; Ganapathy, 2021).

A strong governance framework is essential to promote the adoption and effective application of AI in healthcare. This article explores the ethical and legal issues arising when AI-driven technologies are used in MI settings. This study sheds light on the present situation of AI-driven MI as well as possible future developments, and this will show how AI-based technologies are still developing and how important they are to improving healthcare diagnosis and treatment approaches. It makes a groundbreaking contribution to the subject by offering a basic review of the function of AI technology and a perceptive viewpoint on the ethical and legal issues involved. By offering insightful suggestions for all parties interested in promoting the creation and application of cutting-edge AI systems, this study seeks to address the present issues in the digital/electronic healthcare system.

2. Regulatory Frameworks for AI-Driven MI

2.1. Ethical Principles and Guidelines in AI-Driven MI

The cornerstone of medical ethics is a collection of core values that direct medical personnel to provide patient-centred, compassionate medical attention (Herington et al., 2024; Adetunji et al., 2022; Gerke et al., 2020). Consideration for patient autonomy, which recognizes people's right to make knowledgeable healthcare decisions, is fundamental to these ideals. In keeping with the principle of benevolence, this emphasizes the healthcare provider's need to behave in the patients' most beneficial interests, fostering their overall well-being and working to optimize benefits while limiting harm (Mennella et al., 2024; Herington et al., 2024; Ukhurebor and Balogun, 2022; Beauchamp and Childress, 2001).

In medical ethics, justice refers to the fair allocation of resources for healthcare, prospects, and treatments to resolve inequalities and provide all individuals access. While protecting patient privacy, veracity and confidentiality emphasize the value of open and sincere communication (Char, 2022). Professional faithfulness, sometimes known as fidelity, emphasizes how dedicated healthcare professionals are to carrying out their responsibilities and upholding confidence in the healthcare professionals-patient relationship and the larger healthcare system. Together, these values create the ethical compass that directs medical decision-making, guaranteeing harmony between patient rights, social justice, and

the integrity of the medical field. These guidelines continue to be crucial as the healthcare industry changes, encouraging moral behavior that puts the needs of patients first and preserves the fundamental ideals of the medical field. Healthcare workers can handle the difficulties of medical practice with integrity, compassion, and an unshakeable dedication to ethical norms if they regularly reflect on these ethical issues in mind (Mennella et al., 2024; Amedior, 2023).

The need to track the safety of patients, confidentiality, traceability, accountability, and privacy must be considered when creating electronic healthcare approaches. Strategies should also be put in place to deal with any potential violations. In 2019, the WHO started establishing a framework to help integrate technology and digital advancements into healthcare. According to the WHO's guidelines for technological interventions in healthcare, it is crucial to assess these technologies using criteria including "benefits, possible negative effects, acceptableness, feasible, utilization of resources as well as considerations of equity". These suggestions emphasize that these digital tools ought to be viewed as vital resources in the pursuit of long-term sustainability and broad healthcare coverage (Mennella et al., 2024).

The fundamental framework of medical ethics is a collection of core values that direct medical personnel to provide patient-centred, compassionate medical attention. Support for patient autonomy, which recognizes people's right to make knowledgeable choices regarding their health, is fundamental to these ideals. In keeping with the principle of non-maleficence, the principle of beneficence emphasizes the medical services provider's need to behave in the patients' most beneficial interests, fostering their well-being and working to optimize benefits while limiting harm (Mennella et al., 2024; Herington et al., 2024; Beauchamp and Childress, 2001).

In medical ethics, justice refers to the fair allocation of resources for healthcare, possibilities and treatments in order to resolve inequalities and provide everyone with access to healthcare. While protecting patient privacy, veracity and secrecy emphasize the value of open and sincere communication (Mennella et al., 2024).

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The ethical guidelines for using AI for healthcare purposes are intended to help developers, users, and regulators improve the way these advanced technologies are conceived and used while maintaining appropriate checks and balances (Mennella et al., 2024; Herington et al., 2024; Ganapathy, 2021).

Human dignity and the inherent value of every person are at the core of all ethical beliefs. The ethical standards that delineate obligations and responsibilities in the domain of creating, deploying, and continuously assessing AI technology for healthcare are grounded in these fundamental principles. The European Regulation, which went into effect on April 21, 2021, precisely classifies AI products according to the risks they pose to fundamental rights like data privacy, freedom, equality, democracy, dignity, health and safety, and the right to be free from discrimination (Mennella et al., 2024)

Considering this category, ethical standards play an essential function for all parties engaged in the appropriate advancement, implementation, and assessment of AI-based technologies for healthcare systems. This encompassing group covers physicians, system developers, medical facility managers, healthcare authority policymakers, and also local and national governments. Through legislation and regulation, ethical standards should act as catalysts, assisting and motivating governments and public sector organizations to adjust to the swift advancement of AI technologies.

Furthermore, these guidelines ought to enable medical practitioners to use AI technologies responsibly in their work (Mennella et al., 2024).

From the literature, six essential criteria are highlighted that support the ethical development of AI-based technologies within a broad framework for their application in the service of society. Some of these are basic principles that are frequently applied in bioethics: justice (ensuring equality and that no person or group is vulnerable to discrimination, neglect, manipulation, dominance, or exploitation), autonomy (the respect for one's own best interests while making decisions), and beneficence and non-maleficence (that is, to do nothing that harms and reduce the benefit/risk trade-off). Conversely, other principles are derived from legal and moral ideals. Sustaining the epistemological component of intelligibility is emphasized by these principles, which cover both the obligation to trace cause-and-effect links emerging from technology's actions and the requirement for concise explanations of how technology operates. They also emphasize the significance of protecting and maintaining personal privacy in order to enable people to maintain control over private information about themselves, maintaining their ability to make decisions for themselves and, consequently, their autonomy (Mennella et al., 2024).

A complete collection of indications, recommendations, and guidelines regarding the development, use, and implementation of AI-based technologies in healthcare systems was established in June 2021 as part of a recent WHO project (Mennella et al., 2024). The WHO study thoroughly examined core moral precepts intended to direct the creation and application of AI technologies. A detailed evaluation of the main ethical criteria outlined by WHO for a more in-depth analysis of the subject, strongly supporting the adoption of this updated document within the AI-based domains, is highlighted in Mennella et al. (2024). However, a diagrammatic summary of the suggested ethical standards and guidelines for AI-driven MI vis-à-vis the general healthcare system is given in Figure 2 (Mennella et al., 2024).

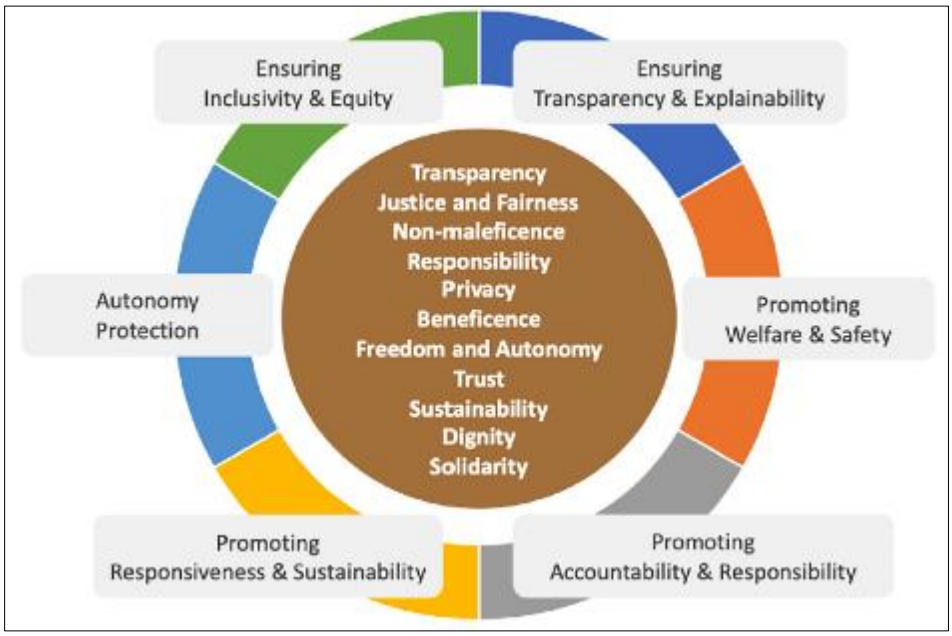

Figure 2 A diagrammatic summary of the suggested ethical standards and guidelines for AI-driven MI vis-à-vis the general healthcare system as adopted from Mennella et al. (2024) with permission from "Elsevier. Open access article distributed under the Creative Commons Attribution License (CC BY 4.0)"

2.2. Implications of Ethical Issues in AI-Driven MI

Like any other AI-driven healthcare, Tiwari (2023); Amedior et al. (2023); Mehrabi et al. (2021); Murphy et al. (2021); Panch et al. (2019), highlighted the following implications of ethical issues in AI-driven MI like any other AI-driven healthcare.

2.2.1. Fairness

Fairness is one of the major ethical issues in AI-driven MI. By offering varying degrees of care to various demographic groups, AI algorithms could accidentally contribute to the persistence of current MI inequities. The regulatory structures have to focus on fairness to guarantee that AI systems are not discriminatory on the basis of gender, ethnicity, or other sensitive traits.

2.2.2. Bias

AI bias is an alarming issue in AI-driven MI. AI models may inherit biases in the training data, which could result in inaccurate diagnoses or therapy suggestions. To reduce such dangers, regulatory requirements should require rigorous data screening and bias reduction techniques (Challen et al., 2019).

2.2.3. Accountability

In AI-driven MI, accountability has some complexities. It highlights the question of accountability when an AI system produces a recommendation that is damaging or inaccurate. Rules for assessing responsibility and liability need to be established by regulatory frameworks; these rules may apply to developers, providers of health care, or both.

2.2.4. Explainability

Since patients and healthcare providers must understand the logic behind AI-generated suggestions, explainability is essential for AI-driven MI. Regulatory agencies should stress the importance of providing clear justifications for AI decisions to enable patients to make knowledgeable decisions about their care.

Innovation and regulation have to be carefully balanced for AI to be used in MI. Data protection, security, and transparency are regulatory issues surrounding AI in MI. Building trust and confidence in these advancements requires transparency in AI decisions and ensuring patient data privacy and security. Regulatory frameworks and standards are essential for AI models and algorithms used in MI to remain safe and effective. They guarantee that these systems comply with the ethical values of responsibility, explainability, fairness, and bias mitigation measures, as well as satisfy predetermined precision and consistency criteria and thorough validation. The ethical ramifications of AI in MI emphasize how crucial it is to avoid prejudice and make sure AI-based medical solutions are open, transparent, and accountable. Robust regulations and these factors are necessary for AI's ethical and responsible development in MI, which will subsequently assist patients, healthcare professionals, and society at large (Tiwari, 2023).

2.3. The Existing Regulations and Guidelines for AI-Driven MI

As it is in any other AI-driven healthcare, the regulatory settings for AI-driven MI are complex and developing rapidly. Owing to the nature of the study, it will not be possible to provide much write-up on the existing regulations and guidelines for AI-driven MI. Hence, below is list of some foremost regulations and guidelines that are pertinent to AI-driven MI as adapted from Tiwari (2023):

- The United States (US) Food and Drug Administration (FDA) Guidance for AI in Healthcare
- The Health Insurance Portability and Accountability Act (HIPAA) and Data Privacy
- The General Data Protection Regulation (GDPR)
- The European Union (EU) Medical Devices Regulation (MDR)
- The US Federal Anti-Kickback Statute and Stark Law
- The AI Ethics and Guidelines
- The WHO AI Guidelines
- The Cyber Security and Health IT Regulations
- The FDA Pre-Certification Programme
- The State and Local Regulations
- The Ethical Considerations
- The Real-World Evidence and Post-Market Surveillance
- The International Collaboration

3. Challenges and Overview of Future Perspectives on the Ethical and Regulatory Considerations in AI-Driven MI

Several issues arise as AI is increasingly used in the healthcare sector vis-à-vis AI-driven MI. These challenges include technology improvements, regulatory factors to consider, and ethical considerations (Mennella et al., 2024; Petersson et al., 2023). Mennella et al. (2024) study emphasized the complex effects of AI technology on clinical practice in general, concentrating on two crucial aspects: "the doctor-patient relationship and AI-driven clinical decision-making." Furthermore, they highlighted issues pertaining to health record data, providing information about contemporary procedures for the use of medical data, which were also emphasized in their review study.

Implementing ethics and regulations in AI-driven MI effectively is a challenging task fraught with difficult circumstances. First of all, because technology is frequently expanding more quickly than legal frameworks, it might be difficult to keep up with the quickly evolving uses of AI. Additionally, there are problems with the interpretability and transparency of AI algorithms, which could hinder efforts at regulation due to the fact that comprehending the way these systems make decisions is crucial for safety and transparency. Data security and privacy issues also pose significant hurdles, especially when sharing MI data to train AI models. Finding a balance between the need for data access and privacy considerations is challenging (Mennella et al., 2024; Petersson et al., 2023)

Since AI systems need to readily interface with existing instruments and platforms, interoperability and standardization issues arise when integrated into diverse healthcare ecosystems. AI systems for MI should easily interface with other clinical systems, including current electronic health records (EHR). For AI-driven MI to be delivered effectively, interoperability will need to be guaranteed. To close these regulatory gaps, further research and development are needed. The need for strong AI evaluation methods that can assess the safety and effectiveness of AI-powered MI applications is growing. Establishing consistent standards and certification processes for AI algorithms could be quite beneficial in this regard. Also, for regulators to better understand and justify their decisions, more research is required to make AI systems more visible and understandable (Mennella et al., 2024; Petersson et al., 2023).

Adopting a risk-based procedure, in which regulations are customized to any potential damage AI systems could cause, is one of the emerging trends and future perspectives in AI-driven MI legislation. It will be crucial to concentrate on ongoing monitoring and regulatory adaption as AI technologies advance. To guarantee a comprehensive strategy for regulation, partnerships between regulatory agencies, MI facilities, and AI developers are anticipated to increase. Finally, given the global nature of MI and AI development, the creation of global standards and frameworks would assist in harmonizing rules across national boundaries (Mennella et al., 2024; Petersson et al., 2023).

4. Conclusion

An innovative development that has the potential to revolutionize healthcare is the incorporation of AI into MI. AI has proven to significantly increase diagnostic accuracy, efficiency, and individualized patient care through the use of sophisticated algorithms such as CNNs and deep learning models. Applications of AI are found in a wide range of fields, from picture segmentation and tumor identification to diagnostic support, demonstrating its effect and adaptability. Case examples from the real world demonstrate how AI may improve early detection, lower diagnostic mistakes, and expedite clinical operations. These developments help physicians by lowering manual labor and offering useful decision-making tools, in addition to helping patients by enabling more precise and quicker diagnosis. But there are still difficulties, such as problems with the quality of the data, the capacity for the interpretation of the model, and concerns about ethics. For AI in medical imaging to continue to advance and be widely used, these issues need to be resolved. More developments in the performance of models, analysis in real time, and clinical procedure integration are anticipated in the future, opening the door to a medical system that is more accurate and effective.

The accuracy and effectiveness of MI could be significantly increased with the development of medical devices from AI. However, researchers ought not to disregard their responsibility to consider the autonomy and welfare of data subjects, medical professionals, and patients in their desire to build novel resources. They should additionally keep in mind that medical devices from AI can only reduce health disparities if they are built with justice in mind, and only then. This perspective review study highlights the unique ethical issues that AI developers ought to be mindful of at every level of medical devices from the AI process. The potential of this novel technology is achievable by medical devices from AI developers through the meticulous development of their own understanding of justice in cooperation with ethical scholars, inequality in health researchers, and community members. In conclusion, the further development of AI in MI has the potential to enhance patient outcomes greatly. AI can continue progressing the medical industry and providing patients and healthcare providers with revolutionary advantages by addressing the present challenges and adopting new trends.

Compliance with ethical standards

Disclosure of conflict of interest

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