

# Artificial Intelligence and ethics in radiology

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## ABSTRACT

Artificial Intelligence (AI) is reshaping radiology by enhancing diagnostic accuracy, optimizing workflows, and supporting clinical decision-making. Despite over 500 Food and Drug Administration (FDA)-approved algorithms, adoption remains limited due to ethical, legal, and operational challenges. Key concerns include data privacy, algorithmic bias, explainability, and accountability. Inadequate representation in training datasets can perpetuate healthcare disparities, while “black-box” decision-making undermines trust and complicates liability. Ethical governance must integrate transparency, fairness, and human oversight from system design through implementation. Data protection frameworks, such as GDPR and Türkiye’s KVKK, mandate anonymization, informed consent, and secure handling of imaging data. Privacy safeguards-metadata cleaning, pixel-level masking, and defacing-are essential to prevent re-identification. Commercial use of health data requires explicit consent, strict oversight, and equitable benefit-sharing. Explainable AI techniques and human-in-the-loop designs can improve trust and reliability. In Türkiye, AI-specific regulations are emerging, with the 2024 Draft AI Law introducing risk-based classification and governance requirements. Global frameworks, including FUTURE-AI and UNESCO guidelines, provide structured pathways for ethical integration. Ensuring AI in radiology is safe, fair, and socially responsible depends on embedding ethical principles into every stage of its lifecycle, fostering interdisciplinary collaboration, and maintaining active oversight to align technological progress with human dignity.

**Keywords:** Artificial intelligence, radiology, ethics, data privacy, algorithmic bias

## INTRODUCTION

Artificial Intelligence (AI) has initiated a transformative shift in medical imaging, with the potential to enhance diagnostic accuracy, reduce processing times, and increase efficiency. Deep learning-based models can analyze modalities such as computed tomography (CT), magnetic resonance imaging (MRI), and mammography with accuracy comparable to that of human experts, and in certain cases, even surpass their performance. However, despite more than 500 AI algorithms approved by the U.S. FDA, only approximately 2% have been widely integrated into routine clinical practice.<sup>1</sup> This indicates the existence of ethical, legal, and operational barriers that go beyond mere technical capability.

Recently, with the rise of technologies such as generative AI, tasks like automated reporting and patient communication have reduced the workload on clinicians, allowing radiologists to focus on more cognitive and interpretative processes.<sup>2,3</sup> Nevertheless, these advances also introduce a range of ethical challenges. Issues such as embedded algorithmic biases,

opaque decision-making mechanisms (“black box”), lack of explainability, and questions regarding accountability are directly linked to fundamental medical ethics principles.<sup>4,5</sup>

Imbalanced representation of variables such as gender, race, and age in training datasets risks exacerbating healthcare disparities, particularly among vulnerable patient groups.<sup>4,6</sup> Moreover, despite high performance, decisions generated by non-explainable models can undermine clinical trust and create uncertainty in legal accountability.<sup>2</sup> In high-risk fields such as radiology, it is imperative that decision-making is not solely delegated to algorithms but is reinforced through human oversight and adherence to explainability principles.

Thus, ethical implementation should be grounded not only in technical excellence but also in a multilayered governance framework encompassing justice, accountability, transparency, and respect for human dignity. Initiatives such as the European Commission’s Ethics Guidelines for



Trustworthy AI and the FUTURE-AI framework offer guidance toward this goal.<sup>7,8</sup> In addition, multinational ethics statements published by professional bodies such as the American College of Radiology (ACR), Radiological Society of North America (RSNA), and European Society of Radiology (ESR) have established comprehensive principles covering data usage, algorithm training, and shared accountability.<sup>2,9</sup>

In conclusion, the safe and equitable integration of AI into radiology requires not only software accuracy but also the establishment of robust ethical governance principles. This book chapter aims to examine the ethical dimensions of AI in radiology, focusing on data governance, algorithm reliability, shared accountability, and social justice.

## APPLICATIONS OF AI IN RADIOLOGY

AI and machine learning (ML) significantly enhance clinical efficiency in radiology by improving diagnostic accuracy and reducing workload. Systematic reviews have demonstrated that AI-assisted image analysis shortens diagnostic times, increases interpretation speed, and reduces false-positive and false-negative rates.<sup>10</sup> In modalities such as MRI, AI has the potential to save radiologists' time through tasks such as automated segmentation, reduction of scan times, and worklist prioritization.<sup>11</sup> In the diagnostic domain, AI tools are already employed in routine clinical practice with high sensitivity and specificity for detecting urgent findings such as lung nodules, intracranial hemorrhage, and pulmonary embolism.<sup>4</sup>

In treatment evaluation and monitoring, radiomics enables the analysis of parameters such as tumor heterogeneity, treatment response, and disease progression.<sup>12</sup> AI-assisted analyses allow prediction of therapeutic response, thereby enriching clinical decision-making processes.

In the reporting field, studies have shown that the automatic transfer of AI-generated findings into structured reporting templates reduces reporting times by approximately 20% while significantly improving report quality.<sup>13</sup> Furthermore, in Large Language Model (LLM)-based systems, such as those using GPT-4, draft reports refined by radiologists provide both time and quality advantages.<sup>14</sup> AI also optimizes workflow in structured reporting systems through functionalities such as auto-populating fields, error checking, and quality assurance, leading to substantial time savings and a marked reduction in human errors.

In the context of education, AI models can analyze reports prepared by radiology residents, provide targeted feedback, and accelerate learning processes.<sup>15</sup>

## UNIVERSAL ETHICAL PRINCIPLES FOR AI

The integration of AI into high-impact domains, particularly healthcare, has made it imperative to clearly define ethical principles and standards. In fields such as medicine, which directly affect human life, universal ethical principles for AI have been shaped by numerous international organizations, academic institutions, and policymakers.<sup>5,16</sup> These principles establish a

framework of responsibility that extends not only to technology developers but also to healthcare professionals using AI systems, patients, decision-makers, and society as a whole.<sup>17</sup>

Respect for human dignity and the protection of individual autonomy form the foundation of AI ethics. Ensuring patients' control over their own data and adopting dynamic informed consent processes are essential in this context.<sup>4</sup> The existence of continuously learning algorithms allows for repeated use of data, making it advisable that consent be ongoing and renewable over time. In addition, the confidentiality of personal data must be supported by legal frameworks such as the European Union's General Data Protection Regulation (GDPR) and Türkiye's Personal Data Protection Law (KVKK).<sup>16</sup>

The principles of non-maleficence and beneficence are directly linked to medical ethics. AI applications should not cause harm to individuals and should provide potential benefits. However, algorithms trained on biased datasets carry the risk of reinforcing systemic inequities. For example, a widely used healthcare algorithm in the United States was shown to assign disproportionately lower risk scores to Black patients.<sup>18</sup> Preventing such inequities requires representative diversity in datasets and rigorous oversight during algorithm training.<sup>19</sup>

The principle of justice aims to ensure equitable access to healthcare services. Universal ethical principles call for preventing algorithmic decisions that could lead to disparities among different socioeconomic and demographic groups.<sup>3</sup> In this regard, ethical design must be evaluated not only in terms of technological competence but also through a social justice perspective.

Transparency and explainability are prominent ethical concerns in modern AI systems. It is essential to provide external traceability regarding how algorithms reach decisions, along with understandable explanations for users and patients.<sup>20</sup> This facilitates both scientific auditability and the establishment of trust. However, the high parameter counts and complex architectures of contemporary deep learning models make explainability challenging.

According to the principle of accountability, ultimate responsibility for erroneous decisions made by AI systems still lies with humans. Clinicians and developers are expected to understand system risks, apply effective oversight during use, and maintain a role in the decision-making chain.<sup>2,17</sup> Awareness of issues such as automation bias and balancing decision-support tools with human judgment are critical for ethical compliance.

In conclusion, universal AI ethical principles are built on respect for human rights, non-maleficence, justice, explainability, and accountability. Binding ethical frameworks, such as UNESCO's 2021 Recommendation on the Ethics of AI and the Council of Europe's legally binding instrument enacted in 2024, demonstrate that these principles have evolved from guidance into normative regulatory structures.<sup>16,17</sup> Ensuring their applicability requires interdisciplinary collaboration, educational initiatives, and

the development of ethical oversight mechanisms. In high-risk domains such as radiology, regular review and updating of these principles is essential to ensure that technology advances with a human-centered and equitable approach (Figure 1).

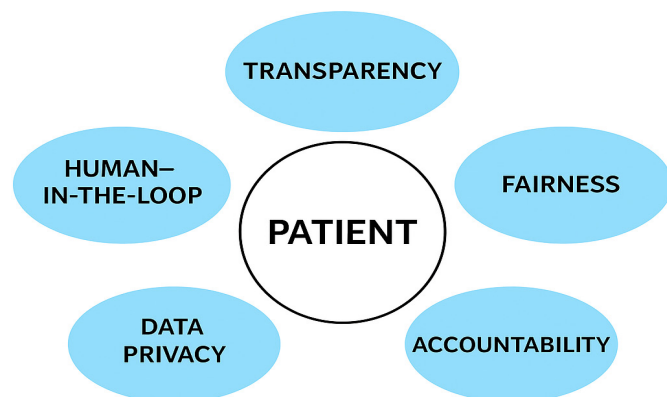


Figure 1. Core ethical principles of ai in radiology

## DATA PROTECTION AND PRIVACY

Given that applications of AI in healthcare require the processing of highly sensitive medical data, data protection and privacy constitute one of the most fundamental components of the ethical framework. Because AI algorithms are typically trained on large volumes of patient data, such data must be appropriately anonymized or, at a minimum, processed in a purpose-limited and pseudonymized manner. The EU's GDPR incorporates core principles such as data subject consent, data minimization, accountability, and transparency.<sup>4,6</sup>

In Türkiye, amendments to the KVKK in 2020 introduced certain exceptions for the use of health data in scientific research. Specifically, if data have been appropriately pseudonymized and the research serves the public interest, they may be used for scientific purposes without obtaining explicit consent from individuals, provided that approval from an ethics committee is obtained and adequate data protection measures are implemented.<sup>21</sup>

In radiology, the use of imaging data in AI projects necessitates more specific regulations. For instance, personal identifiers within the metadata of DICOM-format images must be removed, and any information such as patient names or identification numbers displayed on the images should be masked. Additionally, in three-dimensional imaging, body contours are often removed to prevent the possibility of personal identification.

Nevertheless, the contribution of data sharing to scientific advancement should not be overlooked. Organizations such as the ICMJE define the sharing of clinical research data as an ethical obligation, emphasizing that the accessibility of datasets used in AI research is essential for transparency and reproducibility.<sup>5</sup>

In conclusion, safeguarding personal data in AI research is not only a legal obligation but also an essential ethical responsibility to ensure research integrity, protect

participants' rights, and maintain public trust. Within this scope, data controllers must reinforce technical infrastructure, conduct regular audits of research processes, and comply with both national and international ethical guidelines.

## PRIVACY OF IMAGING DATA AND MASKING METHODS

Medical imaging data not only contain clinical information but may also include elements that can directly or indirectly reveal an individual's identity. In DICOM-format images, header (metadata) fields may contain identifiers such as patient name, date, device, and protocol numbers; moreover, in scans of the facial region, re-identification can be achieved through pixel-level anatomical details.<sup>22</sup>

Therefore, two levels of measures are necessary to ensure image privacy: metadata-level and pixel-level. At the metadata level, de-identification or pseudonymization techniques are used to either completely remove identifying fields or replace them with random identifiers.<sup>23</sup> At the pixel level, identifiers such as patient names, faces, or wristbands are rendered unrecognizable through blurring, masking, or regional deletion techniques.<sup>24</sup>

However, in 3D images of the head and face, these methods may be insufficient, as facial contours can still be used for re-identification. To mitigate this risk, approaches such as defacing (face removal), algorithms that distort facial modeling, or segmentation-based automatic masking are recommended.<sup>25</sup> Recently developed machine learning-based systems aim to automatically conceal identity-related features while preserving clinical information.

Nonetheless, studies published in 2024 and 2025 have emphasized that despite the high accuracy rates of automated DICOM anonymization tools, human oversight remains indispensable in sensitive cases. According to the final report of the NIH's Medical Imaging De-Identification (MIDI) Project in June 2025, the ethical use of DICOM data should incorporate human-supervised processes alongside automated masking systems.<sup>26</sup>

In conclusion, privacy in medical imaging data is not only a legal requirement but also an ethical necessity. Therefore, a combined approach involving metadata cleaning, pixel-level masking, 3D face removal, machine learning-based concealment systems, and human verification processes is recommended. Ethics committees should technically assess these procedures and document them in accordance with traceability principles, ensuring that AI-assisted image analysis is conducted both safely and within the legal framework.

## DATA OWNERSHIP, SHARING, AND ETHICAL LIMITS OF COMMERCIAL USE

Data ownership is a central ethical issue, particularly in the context of health data used in AI applications, as it directly relates to the protection of individual rights. The ability of individuals to exercise control over their own

data is intrinsically linked to both privacy and the principle of autonomy. However, the replicable, reproducible, and shareable nature of digital data creates an ethical debate distinct from traditional concepts of property rights.<sup>27</sup>

While the sharing of medical data for scientific research purposes generally offers a more ethically acceptable framework, data sharing with commercial entities requires far stricter oversight, transparency, and explicit consent mechanisms. The use of publicly available datasets for commercial purposes without the informed consent of data owners can lead to ethical concerns such as erosion of trust, risk of discrimination, and the commodification of personal information.<sup>28</sup> In particular, when large technology companies utilize patient data for financial gain in AI development processes, it raises questions about the boundary between public interest and market-driven benefits.

A prominent recent approach, the concept of data commons, advocates for the open sharing of data for societal benefit. However, even within this model, data ownership, intended use, access conditions, and sharing limitations must be clearly defined, ensuring adherence to principles of fairness and inclusivity.<sup>29</sup> Furthermore, in cases where data generate revenue, increasing attention is being paid to whether data owners are adequately informed and included in benefit-sharing arrangements.

In conclusion, the ethical boundaries of data ownership and sharing should be defined not only by legal frameworks but also by principles of societal trust, individual rights, and transparency. A careful balance must be struck between supporting scientific progress and safeguarding individual rights, with explicit consent, robust oversight, and strict adherence to ethical guidelines being essential—particularly in commercial use cases.

### ALGORITHM ETHICS AND TRANSPARENCY IN DECISION-MAKING SYSTEMS

AI-assisted decision-making systems are increasingly used in healthcare, finance, and law, yet their “black box” nature and risk of bias raise significant ethical concerns. To address these, explainable AI (XAI) methods—such as feature importance ranking, decision tree surrogates, and SHAP—can enhance transparency and user understanding, while human-in-the-loop designs improve reliability and oversight.<sup>30,31</sup>

Transparency also fosters trust and societal acceptance, as studies show it reduces opposition to AI and increases stakeholder confidence. However, the “right to explanation” recognized in frameworks like the GDPR has limited applicability to deep learning models, and excessive regulation may hinder innovation. A balanced strategy—combining independent audits, diverse training datasets, ethical standards, and robust transparency processes—is essential to ensure fairness and accountability (Figure 2).<sup>32</sup>

In breast MRI, when a deep learning model predicting pCR was rendered explainable using SHAP, it was demonstrated that the decision primarily relied on early enhancement

patterns around the tumor; this explanation increased confidence in altering treatment intensity during the oncology board discussion.<sup>30,32</sup>

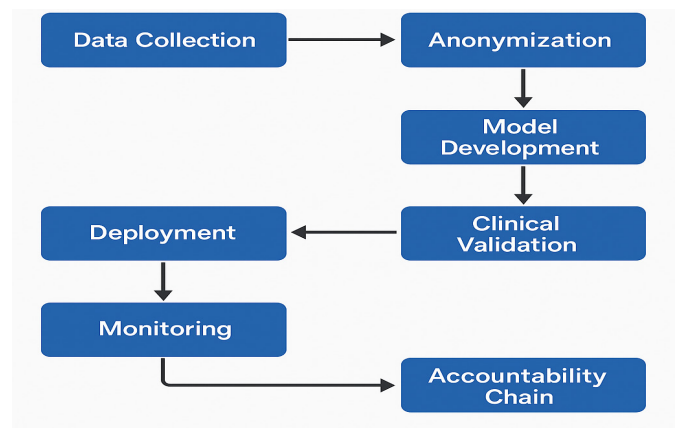


Figure 2. Ethical lifecycle of ai in radiology

### ETHICAL DILEMMAS OF AI IN CLINICAL PRACTICE

In the practical implementation of AI-assisted clinical systems, ethical dilemmas often center on critical areas such as decision-support systems, algorithmic bias, patient privacy, and the allocation of responsibility. AI-CDSS tools have begun to be used in clinical processes such as resource allocation and care prioritization, which requires careful evaluation in terms of fairness, reliability, and patient trust.<sup>33</sup>

Deep learning–based systems often operate as “black boxes,” with decision-making logic that may not be externally interpretable. This lack of transparency can undermine the confidence of both clinicians and patients, while also making it more difficult to identify the mechanisms underlying errors.

Another concern is that the datasets used to train AI systems may contain demographic imbalances or biased patterns. Such limitations can lead to misdiagnosis and inappropriate treatment planning, particularly for minority groups, thereby contributing to clinical inequities. Some dataset-based analyses have demonstrated higher error rates for non-white populations.<sup>34</sup>

Informed consent is another important yet insufficiently addressed ethical issue in clinical scenarios involving AI. Patients may not fully understand how AI operates, what data it uses, or how it makes decisions, potentially undermining their right to autonomy. In addition, responsibility must be clearly defined. When AI contributes to an error, there must be explicit ethical and legal guidelines determining whether the developer, clinical personnel, or the institution is accountable.<sup>33</sup>

A widely used U.S. healthcare algorithm disproportionately assigned lower risk scores to Black patients, limiting access to additional care; similar biases may threaten equity in radiology triage models.<sup>18</sup>

In a case where an AI-CDSS suggested chemotherapy modification, limited training data led to misclassification, underscoring the need for defined human-in-the-loop oversight and shared accountability.<sup>33</sup>

To address these ethical challenges, three strategies stand out: continuous system monitoring and evaluation (silent evaluation), feedback loops incorporating clinician input, and the active involvement of multidisciplinary, multi-stakeholder ethics committees.<sup>35</sup>

## ETHICAL OVERSIGHT, REGULATIONS, AND THE SITUATION IN TURKIYE

The integration of AI into medicine necessitates a redefinition of ethical oversight and regulatory frameworks. The use of AI systems in decision-making processes introduces new dimensions—such as transparency, accountability, and data privacy—beyond the traditional ethical principles of autonomy, beneficence, non-maleficence, and justice.<sup>2</sup>

At the international level, several key documents, including the European Commission's Trustworthy AI ethics guidelines, the Asilomar Principles, and the Montreal Declaration, set standards for ensuring that AI is reliable, transparent, and human-centered.<sup>5</sup> These frameworks emphasize that algorithms should not produce bias, decision-making processes should remain traceable, and human oversight must be maintained. The FDA has also established distinct regulatory models for “locked” and “adaptive” AI-based software, requiring both ethical and technical monitoring throughout the product life cycle.<sup>36</sup>

In radiology, a multi-institutional international consortium's Ethics of AI in Radiology report addresses data ethics, algorithm auditing, and the ethical principles necessary for the clinical implementation of AI. This report underscores that humans should remain the ultimate decision-makers in clinical workflows, with ethical responsibility shared among developers, implementers, and decision-makers.<sup>9</sup>

In Turkiye, the KVKK provides the fundamental legal framework for the collection, processing, and sharing of health data. Under this law, anonymization of imaging data, establishment of dynamic consent procedures, and obtaining informed consent for data sharing are mandatory. However, AI-specific ethics committees or independent regulatory frameworks are still in early stages of development. Some university hospitals have nonetheless introduced dedicated review protocols for AI-based clinical research within their ethics committees.

In clinical use, an adaptive AI software exhibited performance drift following a protocol change, prompting notification to the manufacturer; in line with the FDA's lifecycle approach, recalibration with real-world data and post-market surveillance were initiated.<sup>36</sup>

At a university hospital, the ethics committee began requiring an additional ‘AI methodology appendix’—including data flow, anonymization, XAI outputs, and human-in-the-loop plans—for clinical studies involving AI.<sup>9</sup>

Turkiye's regulatory framework, particularly the KVKK and the 2024 Draft AI Law, shows substantial parallels with international instruments. Similar to the GDPR, the KVKK emphasizes consent, anonymization, and accountability

in health data use.<sup>16</sup> Likewise, the draft law adopts a risk-based classification approach comparable to the EU AI Act.<sup>37</sup> However, while EU frameworks provide institutionalized oversight through dedicated AI governance bodies, Turkiye's mechanisms remain in early development, with ethics committees at university hospitals serving as the primary oversight structures. In contrast to global initiatives such as UNESCO's 2021 Recommendation on the Ethics of AI and the FUTURE-AI framework, which prioritize universal values and human rights, Turkiye's regulations currently place stronger emphasis on data protection and compliance.<sup>8</sup>

Looking ahead, establishing a common ethical language at both national and international levels will be crucial for the safe and equitable integration of AI. For Turkiye, aligning with this evolving ethical infrastructure will require the creation of independent oversight bodies encompassing both medical and engineering expertise.

## FUTURE DIRECTIONS AND ETHICAL ROADMAP

For the safe integration of AI technologies into healthcare systems, a dynamic and continuously updated roadmap—rather than static principles—should be established. From the model development stage onward, ethical design principles must systematically incorporate core values such as transparency, fairness, accountability, and human oversight.

At the international level, the FUTURE-AI ethical framework is structured around six core principles—Fairness, Universality, Traceability, Usability, Robustness, and Explainability—and outlines 28 best practices covering the design, validation, regulation, and field implementation of medical AI systems.<sup>8</sup> This model promotes reliable system development through risk-based assessments.

Recommendations from global organizations such as the United Nations (UN) and UNESCO emphasize the adoption of human rights-based, transparent, and accountable systems. The UN advisory group has proposed initiatives such as a “global AI standards exchange platform,” an “international capacity-building network,” and a “global AI data framework.”<sup>2</sup> UNESCO's recommendations highlight algorithmic transparency, anti-discrimination system design, and accountable governance frameworks as key ethical action areas.<sup>16</sup>

In Turkiye, the Draft AI Law prepared in 2024 classifies systems by risk level, mandates the registration of high-risk AI applications, and requires the preservation of algorithmic transparency and human oversight.<sup>37</sup> Additionally, the National AI Strategy—which includes objectives such as developing domestic language models, promoting green AI solutions, and enabling the secure sharing of public data—aims to strengthen ethical governance.<sup>38</sup>

The proposed ethical roadmap is summarized in [Table](#). This roadmap offers a sustainable framework to ensure that AI systems are developed not only with technical reliability but also with ethical soundness and a human-centered approach.

**Table.** Proposed ethical roadmap and implementation phases for AI systems

Phase	Recommended ethical measures
Design & development	Ethical-by-design approach, algorithmic impact assessment, bias testing
Regulation & compliance	AI system classification, conformity assessment for high-risk systems
Institutional oversight	AI-specific ethics committees, independent audit mechanisms
Social engagement	Stakeholder-based decision-making processes, collaboration with international ethics networks
Education & capacity	Integration of clinical and ethical training, performance and awareness education
Monitoring & updating	Continuous observation, adaptive feedback systems, local and global compliance monitoring

AI: Artificial Intelligence

## CONCLUSION

The rapid rise of AI in radiology is shaped not only by technological advancements but also by the need for robust, multi-layered ethical approaches. Integrating AI into clinical decision-making requires reinterpreting principles such as transparency, explainability, fairness, and accountability so that they offer practical guidance in addressing issues like data privacy, algorithmic bias, responsibility allocation, and social justice. Ethical governance should place human-centered design at its core, ensuring that clinicians retain ultimate responsibility for patient care. A human-in-the-loop approach can preserve clinical autonomy, support professional accountability, and maintain system explainability.

In Türkiye, where AI-related regulations are still emerging, national strategies should be strengthened by interdisciplinary collaboration and the formation of independent ethical oversight structures. Governance models must be inclusive, engaging not only technical experts but also ethics committees, clinicians, patients, and the wider public.

Ultimately, the safe, fair, and effective use of AI in radiology will depend on more than algorithmic accuracy. Embedding ethical principles into the foundation of AI system design and deployment is essential to ensure that these technologies advance societal benefit, safeguard patient interests, and respect human dignity.

## ETHICAL DECLARATIONS

### Peer Review Process

This review was externally peer-reviewed.

### Conflict of Interest

The author declare no conflicts of interest.

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### Author Contributions

The author is solely responsible for the conception, data collection, analysis, and writing of this manuscript.

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