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PERSPECTIVE article

Ethical and legal challenges of Artificial Intelligence-based medical diagnostics: A perspective

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Abstract: Artificial intelligence systems are quickly becoming part of clinical diagnostics in areas like imaging, pathology, genomics, and point-of-care testing. They promise to improve the speed, accuracy, and availability of easy diagnoses. However, integrating them presents significant ethical and legal challenges. Key ethical concerns include algorithmic bias, lack of transparency, known as the black box problem, threats to patient autonomy and consent, data privacy, and trust issues. Legal issues focus on assigning liability, ensuring that regulations fit adaptive algorithms, complying with data protection across different regions, intellectual property rights, and managing cross-border governance. This article highlights common failure modes and suggests practical steps for deploying artificial intelligence diagnostics in an ethical and legal manner. These steps include developing regulatory pathways, requiring bias audits, establishing explainable standards, monitoring throughout the lifecycle, and clarifying liability frameworks.

Introduction

Artificial intelligence (AI) is becoming increasingly applicable in healthcare due to the growth of big data in the fields of medicine and healthcare. Medical AI is currently employed in various medical domains, including medical image analysis, disease screening and prediction, clinical decision support, surgical operations, health management, virtual medical assistants, and assisting in the screening of drug targets. These applications range from early rule-based algorithms to machine learning (ML) to deep learning (DL) [1-3]. Technological advancements in medical AI are also constantly being propelled by commercial value. The health-related AI market is estimated to grow tenfold from 2020 to 2026, reaching $ 45.2 billion in 2026 [4]. The quick development and use of medical AI portend more accurate and convenient medical care as well as more universal and effective medical aid, which will revolutionize traditional medicine on many fronts. However, the majority of modern medical AI does not take the job of human physicians; rather, it speeds up and aids in diagnosis [5], with the final decision still coming from humans. AI, especially ML and DL, is changing medical diagnostics by automating or assisting with tasks including interpreting medical images, reading pathology slides, triaging patients, and predicting risks. AI systems can increase speed, improve consistency, and provide better detection for conditions that are hard for humans to identify. The World Health Organization (WHO) and other international groups see the clinical benefits and the need for careful management to prevent harm and service inequality [6, 7]. However,

the rapid growth of AI diagnostics has surpassed the current ethical guidelines and legal systems. It is crucial to adopt ethical AI practices in healthcare to ensure human oversight, fairness, transparency, and strict data protection (**Figure 2**). This perspective looks at the main ethical and legal issues related to AI diagnostics and offers practical solutions.

Use of AI in healthcare: AI is the act of teaching a computer system to make judgments and forecast results when given new data by employing intricate and sizable data sets [8]. Millions of patient data sets are put into AI models created for the healthcare industry. For instance, an AI model may use data from previous patients with comparable medical issues to determine which treatment option is most likely to succeed and which treatment will yield the greatest results for the new patient. The genomic data enables AI to make highly informed decisions regarding diagnosis and therapy because each individual has a unique collection of DNA and AI models can recognize similarities and differences [9]. AI is now a useful tool because of its potential. AI makes it easier for medical professionals to determine the stage of cancer and the best course of treatment. A clinician can use AI models to make a diagnosis and recommend the best course of therapy (**Figure 1**) by simply feeding the genomic data obtained from tissue biopsies, reports of blood test results, and X-ray images of the liaisons [10]. AI has improved the healthcare sector more than before, paving the way for extremely sophisticated and widely available precision medicine. It has become a potent instrument for low-income nations such as India. India continues to struggle with resource scarcity and healthcare accessibility due to the "Iron Triangle" of access, equity, and cost [11].

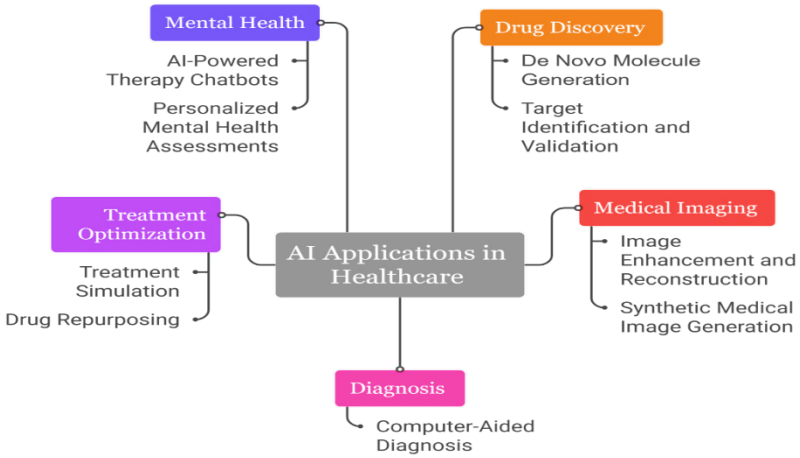

Figure 1: Generative Artificial Intelligence use in different healthcare sectors

Figure 2: Major ethical issues of AI to be considered in healthcare management

Ethical challenges

Algorithmic bias: AI models use training data to identify trends. The models may replicate and exacerbate inequality if the data does not accurately reflect particular groups or reveal biases in healthcare practice. Bias in diagnostics may manifest as inadequate calibration across clinical sites, varying performance across age or gender, or reduced sensitivity for diseases in minority ethnic groups [12, 13]. In imaging, differences in demographics and changes in datasets can lead to misclassification and varying diagnoses. These biases may be subtle and can show up only after being used in a new clinical setting [12]. From an ethical standpoint, biased AI threatens fairness and can cause harm to already disadvantaged groups of patients.

Transparency and explainability: Many high-performing diagnostic models use deep neural networks, but their internal functions are not easy for clinicians to interpret. This "black box" feature raises ethical issues related to informed consent, clinician trust, and error investigation. Patients and clinicians have the right to understand the reasons behind diagnostic results, especially when those results significantly influence treatment decisions [14]. The literature on explainable AI stresses the need for methods that offer clear, clinically relevant explanations without falsely suggesting that they provide definitive causal answers [15]. Explainability can increase clinician acceptance and support accountability, but it has its limits. Explanations can be misleading, incomplete, or misinterpreted if shared without the necessary clinical context.

Autonomy and human oversight: AI diagnostic tools have the potential to alter decision-making authority. Concerns around clinician autonomy and the proper ratio of automation to human control are caused by this. Over-reliance on AI may lead to deskilling and cognitive offloading. Clinicians may eventually become unable to read or recognize the characteristics that the AI emphasizes. Clear role definitions and "human-in-the-loop" designs are typically necessary for using AI ethically. Particularly in crucial situations where erroneous positives or negatives could have detrimental consequences, AI should function as an auxiliary tool rather than an autonomous decision-maker [14].

Patient privacy, data governance, and consent: AI models need a lot of health data for training and validation. Using clinical data, which is often collected for care instead of research, raises ethical issues about informed consent, data minimization, and data ownership. Laws like the EU GDPR consider health data a special category that needs extra protection. However, using this data for AI training could fall into legal gray areas if the initial consent did not clearly cover those uses [16]. Large tech partnerships with health systems, such as past controversies over data sharing, highlight the risks of poor transparency and lack of patient awareness, which can undermine trust in institutions [17]. Ethical governance should include strong de-identification, when possible, clear information and consent processes for patients, governance structures for data access, and ways for patients to opt out or control secondary uses.

Trust issue: A sensitive but essential component of clinical adoption is trust. Mainly, when commercial companies develop or host diagnostic models, patients may be wary of algorithmic conclusions. To use AI ethically, it must be made explicit how it operates, what the advantages and risks are, and who is responsible for making judgments. Practical measures to establish and maintain confidence include incorporating patients and physicians in co-design, utilizing straightforward language precises, and providing channels for inquiries and complaints.

Legal challenges

Liability and accountability: Traditional and conventional malpractice frameworks hold clinicians and institutions responsible for liability. The rise of AI creates tricky questions. Who is legally responsible if a clinician acts on an incorrect diagnosis made by an AI model-the clinician, the hospital, the AI developer, or all of them? Multi-

party responsibility can be handled by current tort rules, but they frequently fail to address AI that is constantly learning or has ambiguous training data and origins [18]. Courts and regulators are attempting to determine whether software qualifies as a medical device and how to assign liability when multiple parties, such as developers, model trainers, and data sources, share responsibility. According to certain ideas, AI companies should use product-liability models with clinician responsibilities to verify results.

Regulatory framework: Regulatory systems for medical devices usually assume a product that is stable and validated. Many modern AI systems, however, can update continuously after they are deployed or adjust to local data. Regulators like the U.S. Food and Drug Administration (FDA) have released action plans and draft guidelines focusing on AI/ML as Software as a Medical Device (SaMD). They suggest lifecycle approaches that involve monitoring, change control plans, and post-market surveillance [19, 20]. The EU's AI Act, which took effect in 2024, places stricter requirements on certain high-risk AI systems, including many medical diagnostic tools. These include obligations for risk management, data governance, documentation, and human oversight [21]. However, creating consistent global requirements remains difficult; varying standards across different regions make multinational deployments more complicated.

Intellectual property and ownership of models and outputs: Ownership of training data, models, and their outputs brings up legal and ethical problems. Hospital authority might claim rights over data produced from patient care. Meanwhile, tech developers may insist on rights over trained models and proprietary algorithms. There are also questions about whether model outputs can be considered protectable inventions or if some algorithmic artifacts should be available for verification. Intellectual property laws were not created for systems that rely on combined personal data. This leads to conflicts between encouraging innovation and ensuring public benefit [22].

Cross-border governance and standards: AI diagnostic systems frequently operate in many legal jurisdictions. International consensus is required on performance reporting, safety requirements, and accountability. Although ethical principles have been proposed by organizations like the EU and WHO, it is still a work in progress to turn these into legally binding worldwide standards. There are chances for regulatory uncertainty that could be exploited or leave patients vulnerable due to the gap between rapid technological improvements and slower legislative processes [23].

Case illustrating failures: When 1.6 million patient records were transferred for app development without a clear legal basis, the DeepMind, Royal Free NHS data sharing controversy exposed privacy and governance flaws. This lack of access resulted in reputational harm and regulatory scrutiny [24]. The episode emphasizes the necessity of robust data-sharing agreements, transparent patient communication, and explicit legal justifications for data use. AI tools have been rapidly embraced by radiology, and numerous algorithms have received FDA approval. Premarket evidence, generalizability, and tracking performance across several sites have been the main topics of regulatory discussions. Due to domain shift, real-world performance frequently deviates from experimental outcomes. This discrepancy emphasizes the necessity of post-market monitoring and calibration processes [25].

Artificial intelligence in the pharmaceutical sector: Drug discovery, clinical trials, pharmacovigilance, and personalized medicine have all undergone significant improvements as a result of the use of AI in pharmaceutical research and development. AI-based systems are being utilized more frequently than conventional techniques to identify adverse drug reactions, optimize chemical structures, and anticipate drug-target interactions [26, 27]. Despite these developments, the use of AI raises difficult moral and legal issues that current pharmaceutical governance frameworks could not address. The sustainability of AI-driven pharmaceutical research in terms of the environment represents one new ethical issue. According to Strubell et al. [28], large-scale AI models

necessitate substantial computational resources, which increases energy consumption and carbon emissions. This shows ethical concerns in the pharmaceutical industry over whether gradual increases in research efficiency outweigh the environmental costs of AI-assisted drug discovery. Regulatory bodies give little thought to the environmental effects of AI infrastructures employed in pharmaceutical research, and instead, they concentrate on drug safety, efficacy, and quality [29]. Also, AI has an influence on decision-making authority in pharmaceutical research and clinical pharmacology. Predictive algorithms are becoming more and more important in risk assessment, dose optimization, patient selection, and trial design. While these tools boost outcomes, an over-reliance on algorithmic outcomes may compromise human competence and professional judgment [30]. This raises moral concerns regarding physician autonomy and informed consent. Legally, liability becomes unclear when AI-supported decisions contribute to adverse outcomes, as responsibility may be attributed among clinicians, pharmaceutical sponsors, software developers, and regulators [31, 32].

Figure 3: Artificial intelligence regulation and development process

Recommendations: Conventional drug treatments often cure symptoms but do not address the root causes. Future therapies might focus on prompt diagnostic tools and drug discovery [33-37]. Al has the potential to be used with modern diagnostic tools. Regulators need to address the lifecycle nature of AI. Methods include demanding monitoring and change control plans for adaptive systems, requiring premarket proof that corresponds with the degree of risk, and establishing precise criteria for external testing and validation. Developers should evaluate the effects of bias and report performance by important clinical subgroups and demographics. Transparency will be increased, and independent assessment will be possible if model cards or datasheets detailing training data, performance metrics, constraints, and intended applications are made publicly available [38, 39]. Models should, where feasible, include explainability elements like highlighted image regions and important contributing variables that provide doctors with actionable justifications. Clear patient disclosure, opportunities for consent or opting out, and empirical and stringent restrictions on secondary commercial usage are all necessary components of data use governance (**Figure 3**). Policymakers should clarify who is liable by balancing responsibilities among clinicians, institutions, and manufacturers. They should consider sector-specific solutions like requiring disclosure of training and validation materials, mandatory product liability coverage for high-risk AI diagnostics, or no-fault compensation for AI-related harms. AI diagnostics should undergo continuous monitoring to catch performance drift, emerging biases, and safety issues. Regulators may need to implement reporting systems for adverse events, maintain registries, and periodically reassess model performance in different clinical contexts.

Conclusion: Artificial intelligence diagnostics have the potential to diagnose disease and transform medicine, but they also present significant moral and legal issues. Important steps include developing robust data governance procedures, clarifying accountability, enhancing legal frameworks, and mandating clear performance reports. Careful policy design encompassing several disciplines and a persistent commitment to evaluating artificial intelligence systems in actual healthcare settings are necessary to strike the correct balance between innovation and patient wellbeing. When implemented properly, artificial intelligence diagnostics can improve the quality of treatment while upholding moral obligations relevant to safety, autonomy, justice, and trust.

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