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LIABILITY IN AI DIAGNOSTICS IN THE MEDICAL FIELD

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ABSTRACT

Artificial Intelligence (AI) systems are increasingly integrated into medical diagnostics, promising enhanced efficiency, accuracy and predictive capabilities. However, the rapid deployment of these tools raises complex legal and ethical questions regarding liability when diagnostic errors occur. This paper critically examines the current regulatory landscape for medical AI, identifies principal liability theories applicable to diagnostic failures, and analyzes how responsibility could be apportioned among developers, healthcare providers and institutions. We argue that traditional frameworks-product liability, medical malpractice and regulatory compliance-are insufficient on their own to address AI's unique challenges, including opaque decision processes and continuous learning. We propose a hybrid liability model incorporating strict liability for developers, shared responsibility for clinicians and mandatory transparency standards. Implications for policy, clinical practice and future research are discussed.

KEYWORDS

Artificial intelligence, Medical diagnostics, Data privacy, Liability and Ethics.

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INTRODUCTION

Artificial Intelligence has transformed medical diagnostics by enabling automated image analysis, predictive modeling, and decision support systems (Topol, 2019)[1]. From radiology to pathology and genomics, machine learning algorithms assist clinicians by identifying patterns invisible to the human eye (Esteva *et al*, 2017)[2]. However, AI systems can err due to biased training data, algorithmic misclassification, and unforeseen edge cases (Amann *et al*, 2020)[3]. When an AI diagnostic tool contributes to patient harm, a central question arises: Who is legally liable?

Liability in medical diagnostics has traditionally been governed by well-defined doctrines such as medical malpractice and product liability. However, AI introduces features-opacity, non-deterministic outputs and continuous learning-that strain existing legal categories (Price and Cohen, 2019)[4]. The absence of consensus on responsibility allocation could deter innovation or leave patients without redress.

This paper examines existing liability frameworks applicable to AI diagnostics, identifies gaps, and proposes a hybrid model that balances innovation incentives with patient protection.

Background and Legal Context

AI in Medical Diagnostics

AI diagnostic systems can be broadly categorized into:

Rule-based systems: Preprogrammed logic with explicit rules.

Machine learning models: Algorithms that learn patterns from data.

Deep learning systems: Neural networks trained on large clinical datasets (Rajkomar, Dean, Kohane, 2019)[5].

Clinical AI systems are regulated as medical devices in many jurisdictions (FDA, 2021)[6]. Regulatory frameworks mandate safety validation, but they typically address static products, not adaptive algorithms that evolve post-deployment.

Existing Liability Frameworks

Product Liability

Product liability holds manufacturers accountable for defective products that injure users. Traditionally, three defects are actionable: design, manufacturing, and inadequate warnings (Tingle and Criddle, 2017)[7]. The challenge in AI arises when algorithms display emergent behavior not foreseeable by developers, complicating assessments of design defect.

Medical Malpractice

Medical malpractice requires demonstration of a breach of standard of care resulting in harm (Brennan *et al*, 1991)[8]. When clinicians rely on AI advice, the scope of professional judgment, and whether using the AI itself constitutes a breach, become contested.

Regulatory Compliance and Standard Setting

Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have frameworks for software as a medical device (SaMD) (FDA, 2021)[6]. However, certification does not shield actors from liability arising from harm.

Challenges in Assigning Liability for AI Diagnostics

Opacity and Explainability

Many AI models, especially deep learning systems, function as "black boxes" (Holzinger *et al*, 2017)[9]. This opaqueness complicates fault tracing. Was the error due to training data bias, algorithm design, or improper use by the clinician?

Adaptive Learning and Dynamic Behavior

AI systems that adapt post-deployment challenge static definitions of product defects (European Commission, 2020)[10]. If an algorithm updates itself, who bears responsibility for errors introduced after initial validation?

Shared Decision-Making

AI diagnostics often augment clinician judgment (Shortliffe and Sepulveda, 2018)[11]. Liability could therefore be diffused across developers, healthcare institutions and individual providers.

Data Quality and Bias

Bias in training datasets can lead to disparate diagnostic accuracy across populations (Obermeyer *et al*, 2019)[12]. Determining whether bias constitutes a design defect is legally and technically complex.

Analysis: Liability Regimes and Applicability

Strict Liability for Developers

Under strict product liability, developers should bear liability for harms caused by defective AI diagnostic tools, regardless of intent or negligence. Given AI's complexity, strict liability incentivizes rigorous pre-market validation and post-market surveillance.

Advantages

Promotes high safety standards.

Simplifies patient recourse.

Challenges

Could stifle innovation due to increased legal risk.

Requires clear standards for what constitutes a defect in AI.

Modified Medical Malpractice

Clinicians should retain accountability for appropriate use of AI tools. This recognizes the clinician's duty to interpret AI outputs within clinical context.

Advantages

Preserves clinician responsibility for patient care.

Encourages informed use of AI support.

Challenges

Determining reliance vs. independent judgment is complex.

Regulatory and Institutional Safeguards

Regulators must define standards for explainability, validation data diversity, and real-world performance monitoring. Hospitals should implement governance frameworks for AI deployment, including training and oversight.

Proposed Liability Framework

We propose a hybrid model

Strict liability for developers and vendors for defects in AI diagnostic tools, especially in algorithmic design and training data bias.

Shared liability for clinicians and healthcare institutions when AI is misused or interpreted incorrectly.

Mandatory explainability and monitoring requirements imposed by regulators.

Adaptive learning oversight

Algorithms that continue learning post-deployment should undergo incremental certification.

This model achieves accountability while preserving innovation capability.

DISCUSSION

The legal treatment of AI diagnostics must reconcile patient safety with technological progress. Sole reliance on traditional product liability or malpractice doctrines is insufficient given AI's distinct attributes. A hybrid model aligns legal responsibility with actors' roles in the development and clinical use of diagnostic AI.

Figure No.1: Graphical abstract

CONCLUSION

AI diagnostic tools offer transformative potential, but unresolved liability concerns may impede their safe adoption. A hybrid liability regime that incorporates strict liability for developers, clinician responsibility for use and robust regulatory oversight could provide clarity, protect patients and support innovation.

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None.

CONFLICTS OF INTEREST

There are no conflicts of interest.

ETHICAL DECLARATION

This material is the authors' own original work, which has not been
previously published elsewhere.

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