

## Introduction

The integration of Artificial Intelligence (AI) into clinical practice holds the potential to significantly improve patient care, but it also introduces complex legal and ethical challenges that must be navigated carefully. Existing legal frameworks do not address the unique challenges posed by AI in healthcare, particularly in cases of malpractice, leading to unclear areas of liability. Specifically, generative large language models (LLMs) like OpenAI's ChatGPT can generate articulate contextual language, raising concerns for its applications in clinical decision making<sup>1</sup>. This work explores the ramifications of AI on medical malpractice and the necessity for policy evolution to manage these challenges effectively. As regulation catches up to AI capabilities, legal precedents that could inform future AI-related malpractice cases and proposed policy recommendations are also discussed to foster a safe integration of AI into clinical care.

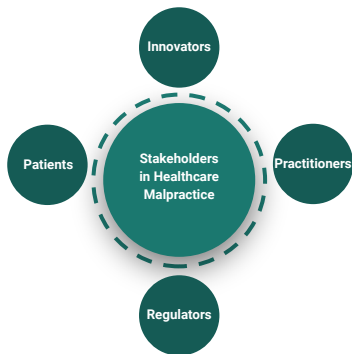
## Background

**Healthcare Practitioners:** Potential users who utilize AI to assist with administrative tasks, clinical decision making support, and more.

**Patients:** Beneficiaries of AI-enhanced healthcare.

**Regulators:** Oversee responsible marketing and commercialization of new healthcare technologies.

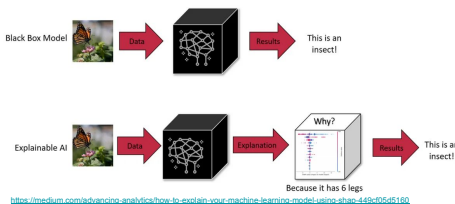
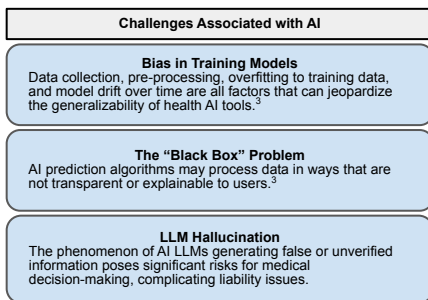
**AI Researchers and Developers:** Create and train AI technologies.<sup>2</sup>



## Materials and Methods

**Mixed-Methods Approach:** Utilization of legal case studies and policy reviews for a robust synthesis of challenges associated with AI, AI regulation, and legal analogues related to AI in healthcare. Analysis of literature from recent years related to these topics were supplemented with legislation to relate to medical malpractice liability in AI.

## Results



## A Framework for Policy Reform

**Clarify Standard of Care:** Explicitly address AI-influenced medical decisions, offering clarity on liability issues

**Mandatory Validation:** Independent FDA or similar validation of algorithms to ensure algorithmic transparency, reliability, and patient safety over the long term and monitor model drift

**Innovative Insurance Models:** New insurance solutions tailored to accommodate AI's unique risks in healthcare

**Specialized Legal Frameworks:** Establish adjudication channels for AI malpractice claims

**Liability Reform and Shared Responsibility:** Tort reform to potentially sharing liability among AI developers, manufacturers, and healthcare providers.

## Conclusion

Given the absence of existing litigation in AI-related medical malpractice, there is a pressing need for legal and regulatory policy development. The transformative role of AI in healthcare necessitates an evolution of tort law and ethical frameworks. Existing regulations addressing LLM AI's liability in medical decisions are scarce and unsystematic, presenting unique challenges for traditional legal approaches. The FDA is starting to evaluate AI systems as medical devices, but significant legislative gaps remain.

Physicians may face increased liability for uncritical acceptance of AI recommendations, while employing institutions or technology developers may also face vicarious liability for errors. Policymakers, alongside healthcare professionals and AI developers, must work together to establish clear, equitable liability systems that protect patients and encourage the prudent use of AI in medicine. Through collaborative effort, the legal system can support the revolutionary potential of AI in healthcare while maintaining patient safety and trust in the medical profession.

## References

