

The Medical and Legal Implications of Artificial Intelligence in Health Care – An Area of Unsettled Law

What are the medical and legal implications of using artificial intelligence in healthcare, and how does unsettled law affect liability and patient care?

This study by Samuel Hodge, published in the Richmond Journal of Law and Technology, explores the transformative impact of artificial intelligence (AI) in healthcare and the unresolved legal challenges it presents.

AI enhances medical diagnostics, treatment, and emergency care by processing vast data and aiding decision-making. While AI improves accuracy and efficiency, it also raises complex liability issues due to its autonomous, 'black box' nature. Traditional legal frameworks struggle to assign responsibility among physicians, manufacturers, and healthcare institutions when AI errors cause harm.

The article examines FDA regulation of AI as medical devices and the evolving standards for software approval. It discusses products liability, medical malpractice, and vicarious liability doctrines as applied to AI in medicine. Key legal questions include whether AI software qualifies as a product or service, the applicability of the learned intermediary doctrine, and the extent of physicians' duty of care when using AI. The study also addresses informed consent challenges related to AI-assisted care.

Cases illustrate courts' current uncertainty in allocating responsibility for AI-related medical errors, highlighting the need for ongoing legal development. The article emphasizes that healthcare providers remain liable for decisions made with AI assistance, and that standards of care may evolve to reflect AI's growing role. Ultimately, the paper calls for clarity in legal standards to balance innovation benefits with patient safety and accountability.

MAJOR TAKEAWAYS:

- AI in healthcare improves diagnostics and treatment but raises complex liability and regulatory challenges.
- Legal responsibility for AI-related errors is unclear, involving manufacturers, physicians, and healthcare institutions.
- Courts and regulators must develop clear standards balancing innovation with patient safety and accountability.

WHO NEEDS TO KNOW:

- Healthcare Providers
- Medical Device Manufacturers
- Legal Professionals and Policymakers

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