The Regulatory Imperative: Should AI in Medicine Face Stricter Oversight?

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Abstract

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The integration of Artificial Intelligence (AI) into medicine promises a revolution in diagnostics, personalized treatment, and operational efficiency. From sophisticated image analysis algorithms to predictive models for disease outbreaks, AI's potential to enhance patient care is undeniable. However, this rapid technological adoption introduces a complex set of ethical, legal, and technical challenges that demand a critical re-evaluation of the current regulatory landscape. The central question facing policymakers, clinicians, and the public is: **Should AI in medicine be regulated more strictly?**

The Dual Edge of Medical AI: Innovation vs. Risk

AI systems in healthcare are fundamentally different from traditional medical devices. They are often "black boxes," with decision-making processes that can be opaque, and they are inherently adaptive, meaning their performance can change over time as they interact with new data. This dynamic nature creates a unique regulatory dilemma.

On one hand, overly stringent regulation could stifle the innovation that is crucial for advancing patient care. The speed of technological development often outpaces the legislative process, and slow approval pathways could prevent life-saving tools from reaching the market. Innovation is often fueled by rapid iteration, which can be hampered by bureaucratic oversight.

On the other hand, the risks associated with unregulated or under-regulated AI are profound [1]. These risks fall into three primary categories, each demanding a targeted regulatory response:

Risk Category	Description	Regulatory Concern
Bias and Fairness	AI models trained on unrepresentative or skewed datasets can perpetuate and amplify existing health disparities, leading to unequal care for different demographic groups. This is particularly concerning in areas like diagnostic imaging or risk stratification, where biases can become deeply

embedded and difficult to detect post-deployment [4]. | Ensuring algorithmic fairness, equity in deployment, and mandatory bias audits. | | **Accountability and Liability** | When an AI system makes an error leading to patient harm, determining who is legally responsible—the developer, the prescribing clinician, or the implementing hospital—is often unclear. The complexity of modern AI supply chains further complicates the attribution of fault. | Establishing clear lines of legal accountability for AI-driven decisions and defining the scope of professional responsibility for clinicians using AI tools. | | **Safety and Efficacy** | The "drift" in AI performance over time (model degradation) and the lack of transparency (explainability) make it difficult to ensure continuous safety and efficacy post-deployment. A model's performance can degrade subtly as real-world data shifts away from its training data, posing a silent threat to patient safety [5]. | Developing robust mechanisms for continuous monitoring, mandatory post-market surveillance, and clear standards for model maintenance. |

The Current Regulatory Landscape: A Patchwork Approach

Regulatory bodies worldwide are grappling with how to classify and govern medical AI. The approach is often a patchwork, attempting to fit novel AI technologies into existing frameworks designed for static hardware and software. This has led to a divergence in global strategies.

In the United States, the Food and Drug Administration (FDA) has adopted an agile, risk-based approach, focusing on the concept of "Software as a Medical Device" (SaMD). Recognizing the adaptive nature of AI, the FDA has proposed a framework for "Predetermined Change Control Plans" (PCCP) to manage updates, allowing for pre-approved modifications without requiring a full new review for every iteration [2]. This strategy aims to balance safety with the need for rapid innovation.

Conversely, the European Union's landmark **AI Act** introduces a comprehensive, risk-based tiered system. AI systems used in medical devices are generally classified as "high-risk," subjecting them to rigorous conformity assessments, mandatory quality management systems, and extensive documentation requirements [3]. This approach emphasizes patient safety and fundamental rights, but its complexity has raised concerns about potential barriers to entry for smaller innovators and the speed at which new technologies can be deployed across the EU market.

The Case for Stricter, Smarter Regulation

The consensus among many experts is not simply for *more* regulation, but for *smarter, more adaptive* regulation that is commensurate with the risk. The current pace of innovation, coupled with the high-stakes environment of clinical care, necessitates a shift toward stricter oversight in key areas to ensure public trust and clinical reliability:

1. **Mandatory Transparency and Explainability:** Regulations should mandate a minimum level of explainability for high-risk AI systems, allowing clinicians to understand *why* a decision was made (e.g., why a specific lesion was flagged as malignant). This is essential for informed consent, for

challenging erroneous outputs, and for maintaining physician trust in the technology [6]. 2. **Continuous Post-Market Surveillance:** Given the potential for model drift, regulatory approval should be conditional on continuous, real-world performance monitoring and mandatory reporting of performance degradation or bias detection. This requires developers to build in robust monitoring tools and to actively manage the lifecycle of their AI models long after initial deployment. 3. **Standardized Auditing and Certification:** An independent, international body should be established to audit AI models for bias, robustness, and adherence to ethical guidelines before and after deployment. This would provide a necessary layer of external validation beyond the developer's internal testing.

The stakes are too high to rely solely on industry self-regulation. While innovation must be encouraged, it cannot come at the expense of patient safety and health equity. A stricter, more harmonized global regulatory framework is essential to build public trust and ensure that AI serves as a reliable, ethical partner in the future of medicine.

For more in-depth analysis on this topic, the resources at www.rasitdinc.com provide expert commentary and cutting-edge research on the intersection of digital health, AI, and policy.

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References

[1] M Chustecki, "Benefits and Risks of AI in Health Care: Narrative Review," PMC, *2024. [https://pmc.ncbi.nlm.nih.gov/articles/PMC11612599/] (https://pmc.ncbi.nlm.nih.gov/articles/PMC11612599/) [2] RegDesk, "The FDA vs. EU AI Act: What Regulatory Teams Must Know Now,"* RegDesk Blog, *Jul 28, 2025. https://www.regdesk.co/blog/the-fda-vs-eu-ai-act-what-regulatory-teams-must-know-now/ [3] E P Vardas, "Medicine, healthcare and the AI act: gaps, challenges and opportunities,"* European Heart Journal - Digital Health, *2025. [https://academic.oup.com/ehjdh/advance-article/doi/10.1093/ehjdh/ztaf041/8118685] (https://academic.oup.com/ehjdh/advance-article/doi/10.1093/ehjdh/ztaf041/8118685) [4] T Pham, "Ethical and legal considerations in healthcare AI,"* Royal Society Open Science, *2025. [https://royalsocietypublishing.org/doi/10.1098/rsos.241873] (https://royalsocietypublishing.org/doi/10.1098/rsos.241873) [5] EB Weiner, "Ethical challenges and evolving strategies in the integration of AI in healthcare,"* PMC, *2025. [https://pmc.ncbi.nlm.nih.gov/articles/PMC11977975/] (https://pmc.ncbi.nlm.nih.gov/articles/PMC11977975/) [6] C Mennella, "Ethical and regulatory challenges of AI technologies in clinical practice,"* PMC*, 2024. [https://pmc.ncbi.nlm.nih.gov/articles/PMC10879008/] (https://pmc.ncbi.nlm.nih.gov/articles/PMC10879008/)