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Regulatory Fragmentation in Healthcare AI: A Policy Review of FDA Oversight, HIPAA, and Implementation Barriers

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Abstract

Background: The rapid integration of artificial intelligence (AI) into U.S. healthcare has exposed gaps in existing governance frameworks. Although the FDA has cleared more than 150 AI-enabled devices since 2019, implementation in clinical practice remains slow, uneven, and burdened by regulatory fragmentation.

Methods: This study conducted a mixed-methods secondary analysis combining (1) FDA regulatory pathway review of AI/ML medical devices (2019–2023), (2) case study analysis of 72 publicly reported AI implementations in U.S. healthcare systems, and (3) structured review of HIPAA regulations and policy documents. Descriptive statistics summarized regulatory pathways, approval timelines, and post-market surveillance requirements. Thematic synthesis identified recurring compliance challenges and governance gaps.

Results: The FDA database analysis revealed that most AI tools (67%) were cleared via the 510(k) pathway, with an average review time of 6.1 months. However, only 34% of devices had explicit post-market surveillance obligations. Case study review showed that 82% of implementations encountered HIPAA-related barriers, particularly around data de-identification and consent for secondary use. Smaller hospitals reported longer implementation delays and higher relative compliance costs, with regulatory uncertainty cited as the primary barrier.

Conclusion: Current U.S. healthcare AI governance is fragmented across HIPAA and FDA frameworks, creating operational, legal, and economic burdens for health systems. Harmonized, risk-based oversight that integrates privacy and safety requirements could reduce inefficiencies and improve equitable AI adoption. These findings provide an evidence-based foundation for policy reforms that balance innovation with patient protection.

Keywords: Artificial Intelligence, Healthcare Regulation, HIPAA, FDA, Policy Analysis, Implementation Barriers

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Introduction

AI in Healthcare The 2019 healthcare technology forecast, ENT & Allergy Advocates, say "AI is the next big thing" in Healthcare, and they are right.Health is undergoing a significant change with the quick application of artificial intelligence (AI) tools. Now these computer systems are able to analyze medical images, predict patient outcomes, and assist doctors in making treatment decisions. The expansion has been astonishing; AI medical devices approved by the FDA have grown 65% year on year since 2018 (Benjamens *et al*., 2020).

That makes AI tools increasingly routine in hospitals and clinics throughout the United States. Healthcare artificial intelligence has many applications that look promising. They can allow doctors to see diseases earlier by scanning X-rays and MRI scans more accurately than the naked human eye. They can forecast which patients are likely to be the sickest, enabling medical teams to provide better care before things turn dire. Health Hospitals and clinics can also run more efficiently or which medications will be needed (Jiang *et al*., 2017). These improvements could save lives and reduce healthcare costs. Despite the positive above all, the rapid growth of AI in healthcare has turned into a serious problem. The laws and rules, that regulate the way these technologies are to be used, have not caught up with the pace of innovation. This leads to confusion and possible

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dangers for both patients and healthcare providers. At the present time, AI in healthcare is under the control of several government agencies that are not always efficient in their coordination. The two main healthcare regulatory schemes are the Health Insurance Portability and Accountability Act (HIPAA) and the FDA oversight, but these operate separately with little interaction concerning the AI-specific challenges (Price & Gerke, 2020).

HIPAA was established in 1996 to ensure that patients' health information remains confidential. The law mandates healthcare workers to ensure that the data of patients is kept both private and secure. In accordance with HIPAA, hospitals and physicians must avail patient information only after consent for use in such cases besides direct care. Moreover, they have to eliminate the identifying features from the data before they share it for the research purposes (Moore *et al*., 2019).

Though, AI has a lot of differences from what the law-makers of HIPAA had in mind. The regulation presumes that patient data is dealt with in the conventional ways, such as a doctor reading the patient's chart or a researcher studying anonymized medical records. The modus operandi of AI systems is substantially different. They have to have extensive datasets from various patients to recognize the patterns and to make reliable predictions. Furthermore, there is an allowance for them to continue their training and refining even when they have been installed in hospitals, employing fresh patient data to upgrade their performance over time (Zaidan and Ibrahim, 2024).

This creates several problems under current HIPAA rules:

Data De-identification Challenges: According to HIPAA regulations, the usage of patient information is permitted without consent if the data has been "de-identified" that is all the identifying details of a particular patient have been erased. Nevertheless, AI-based systems usually require more comprehensive datasets to function efficiently. Consequently, when the researchers remove a lot of information for the purpose of HIPAA compliance, the performance of AI could be significantly impaired. Moreover, studies have also indicated that the re-identification of individuals from anonymized data sources is becoming more feasible, particularly with the utilization of large datasets (Rocher *et al*., 2019).

Data De-identification Challenges: By the HIPAA standard, patient data can be used without consent if it has been sufficiently "de-identified" - the removal of all data that can link a particular patient with the data. But in reality, AI often requires detailed data to deliver good results. So if the researchers have removed too much information to comply with HIPAA, the AI might not be efficient. Moreover, various studies have indicated that the re-identification of patients from anonymous datasets is becoming increasingly feasible, in particular, when large datasets are involved (Rocher *et al*., 2019). Consent for AI Applications: The majority of patients have signed consent forms for their treatment which took place much earlier than the time of AI systems' existence. These old consent forms do not specifically permit the use of their data for the training of AI systems. This causes legal doubt about whether hospitals can utilize the existing patient data for AI development without the prior consent of each patient(Hurley *et al*., 2024). Ongoing Data Use: Traditional medical devices are non-changeable - they perform in the same way from the day they are installed. However, many AI systems can still boost their capacities as they keep on learning from the new patient data. HIPAA doesn't have detailed directives about the continued use of patient information (Hurley *et al*., 2024). One part of the FDA's duties is to ensure that medical devices that use AI are safe and can work effectively in the treatment of patients. The scope of the agency's responsibility indeed extends to the precautionary AI systems, for example, those that propose treatments or establish diagnoses. Nevertheless, the regulatory environment of the FDA still confirms the norms for conventional drug devices, not for AI tech (Hurley *et al*., 2024).

The FDA has three main pathways for approving medical devices:

510(k) Clearance: This is the quickest option, typically for those that are "substantially equivalent" to some already existing on the market. Most AI devices (67%) presently follow this route, with a mean time of 6.2 months to get approved. De Novo Classification: The pathway is designed for devices of new categories that have no existing counterparts. The process is longer (average 11.7 months), but it allows for a more detailed review.

Pre-Market Approval (PMA)

This is the most rigorous pathway for high-risk devices, taking an average of 18.4 months. The main issue is that AI systems are categorically incompatible with the conventional classification approach. Inconsistency in the supervision level might result from different AI device regulatory clearance pathways even if the devices are doing the same thing. What is more worrying is that just 34% of the AI equipment that gets the green light have post-market surveillance obligations aimed at performance monitoring.

The Fragmentation Problem

The largest problem is the fact that HIPAA and FDA rules work separately, resulting in so-called "regulatory fragmentation" by medical specialists. Hospitals and healthcare providers who want to use AI technologies have to comply with both regulations at the same time, although these guidelines were not created to be compatible.

This fragmentation creates several specific problems

Conflicting Requirements: It is possible that HIPAA rules might impose data protection standards which in turn may hinder AI systems to meet FDA requirements for the safety

and effectiveness of the system. As an illustration, the AI system could become less accurate as a result of too much patient information being removed in compliance with the HIPAA privacy policy, thus leading to a potential safety issue. Unclear Jurisdiction: In most cases, the exact agency with the main authority over the different features of AI systems is not clearly identified. For instance, in the event of a privacy issue in a health care AI system, the question arises to which of the agencies among the Department of Health and Human Services (which enforces HIPAA) or the FDA we should report it. Lack of clarity of this kind results in oversight gaps. Compliance Uncertainty : The healthcare industry is riddled with organizations that are frequently in a state of confusion as to which set of guidelines they should adhere to when implementing AI solutions in their respective departments. This uncertainty has the potential to cause such organizations to either come to a halt waiting for confirmation or adopt an overly cautious approach that would limit the extent of AI technology benefits.

Current Research Gaps

Over the last few years, academic debate on AI regulation in the healthcare sector has been very intense. However, the majority of the pertinent research has been theoretical in nature. Alongside the already performed research on regulations in theory, only a few works of literature have been devoted to the investigation of what happens when hospitals and companies try to implement AI systems under current rules.

Several important questions remain unanswered

Implementation Challenges: What are the actual problems that healthcare organizations face due to which they find difficulty complying with the current regulations? How do these challenges influence their choices regarding the use of AI?

Stakeholder Perspectives: The different groups that are involved in healthcare AI, such as hospital administrators, AI developers, regulatory compliance officers, and clinicians, may have completely different ideas about how effective the regulations are. The researchers have barely touched upon these angles of thinking while conducting their studies.

Real-world Compliance: The vast majority of the regulatory analyses are centered on the rules as they are stated. However, a question still remains as to how these regulations function in practice. What are the compliance obstacles that surface during actual AI deployments?

Economic Impact: The question is, how much of the regulatory compliance is responsible for the total cost, and do these costs pose a hindrance to AI adoption, particularly in small healthcare organizations?

First inroads have started to be made into some specific shortcomings in existing models. Critically, there are ongoing concerns about algorithmic bias: AI systems may offer better or worse care depending on the race/ethnicity of the patient (Gerke *et al*., 2020). Questions loom, too, about data interoperability how AI systems between various companies might share information with each other without supplanting the privacy rules that underlie much of their design. But they normally address single regulations instead of the system as a whole. No one has done wide-ranging work looking at how various regulatory approaches combine and impact how AI is used in practice.

The Need for Empirical Research

The appreciation of these regulatory limitations is based on going beyond abstract reflections to the real life experience of the implementation of the model. Healthcare entities, AI companies and regulatory experts have much to teach about what is and is not likely to work.

Such empirical mediation research is necessary for a number of reasons

Policy Formation: Good policy reform starts with the identification of problems, and their causes. In the absence of information about implementation problems in the real world, policymakers might end up devising solutions that don't work on the most significant dimensions.

Evidence-Based Regulation: Instead of speculating on what a system of regulation ought to look like, the science can establish what has been shown to work.

Stakeholder Inclusion: The various groups impacted by AI regulation are likely to have different views and priorities. It's important to understand these perspectives for crafting effective and workable rules.

Innovation Balance: Good regulation will try to balance innovation and patient protection. This means understanding not only the theoretical effect of current rules on AI development and use.

This study aims to bridge the gap between the theoretical rules governing AI and how they're actually put into practice in the real world. By looking into how AI is being implemented today and listening to the experiences of different groups involved like developers, regulators, and users we can gain a clearer understanding of whether current regulations are truly effective. Now more than ever, this research is essential because utilizing AI in healthcare is surging. The pandemic, COVID-19, sparked a wave of interest in AI tools that can support patient care and hospital management. However, along with this growth, concerns about biases in algorithms and AI safety have become more prominent, leading to calls for stronger oversight. Getting a grip on how well existing regulations work is essential for shaping smarter policies moving forward. Our focus is on the United States, since it hosts one of the biggest healthcare AI markets and has established regulatory systems. Still, the issues we identify could be relevant for other countries working out their own AI governance plans.

Primary Objective

To assess the effectiveness of current regulatory frameworks governing healthcare AI through comprehensive analysis of stakeholder experiences and real-world implementation cases.

Secondary Objectives

- Examine specific HIPAA compliance challenges in AI implementations
- Analyze FDA regulatory pathway variations and approval processes for AI devices
- Identify implementation barriers and their impact on different types of healthcare organizations
- Assess the economic impact of regulatory compliance requirements
- Develop evidence-based recommendations for regulatory improvements

The goal of this research is to contribute recommendations for policy makers, healthcare agencies and AI developers on how to navigate the current regulatory environment, yet advance patient care through technological innovation. In Sections 2–4, we describe our approach, findings, and suggestions following interviews with 45 healthcare AI actors, consideration of 156 FDA-approved AI tools, and review of 24 instances of AI implementation in real-world care contexts.

The aim of this study is to examine the effectiveness of existing healthcare AI regulatory responses through a multi-stakeholder analysis and assess actual challenges faced toward their practice, to identify particular governance gaps that call for policy intervention.

Materials and Methods

Study Design

This study employed a mixed-methods secondary research design, combining a systematic review of FDA regulatory pathways, analysis of publicly available AI implementation cases, and synthesis of policy and legal frameworks. All data sources were publicly accessible and did not involve direct interaction with human participants or collection of identifiable private information. As such, institutional review board (IRB) approval was not required.

FDA Regulatory Pathway Analysis

We conducted a comprehensive analysis of FDA-cleared or approved AI/ML-based medical devices between 2019 and 2023. Data were drawn from publicly available databases, including:
FDA 510(k) Premarket Notification database
FDA De Novo classification database
FDA Premarket Approval (PMA) database
Manufacturer press releases and regulatory filings
Peer-reviewed literature

Inclusion criteria required that devices

- Explicitly used AI/ML algorithms,
- Received FDA clearance or approval between January 2019 and December 2023, and
- Had sufficient public documentation for analysis.

Data extraction focused on device type and intended use, regulatory pathway, approval timelines, and post-market surveillance obligations. A final dataset of 156 unique AI-enabled devices was compiled.

Public Case Study Review

To contextualize FDA trends, we reviewed publicly reported implementation cases of healthcare AI in U.S. hospitals and clinics. Cases were identified from:
American Hospital Association (AHA) case studies.
HIMSS AI Adoption Survey reports.
Published literature and conference proceedings.
Media reports and press releases.
Each case was coded using a standardized rubric covering implementation stage, reported barriers, regulatory challenges (HIPAA/FDA-related), and resolution strategies. A total of 72 publicly documented cases were analyzed.

Policy and Legal Framework Analysis

We conducted a structured review of U.S. healthcare AI governance frameworks, focusing on HIPAA regulations, FDA oversight mechanisms, and emerging policy proposals. Sources included federal regulatory guidance documents, peer-reviewed academic literature, and major policy reports. Particular attention was given to the intersections and potential conflicts between HIPAA data protection requirements and FDA device safety regulations.

Data Analysis

Quantitative Analysis: Descriptive statistics summarized FDA approval pathways and case study patterns. Comparative analysis examined approval timelines by pathway (510(k), De Novo, PMA) and post-market monitoring obligations.
Qualitative Analysis: A thematic synthesis was conducted across publicly reported case studies and policy documents to identify common regulatory challenges, compliance strategies, and stakeholder recommendations.
Integration**:** Findings from FDA data, public case studies, and policy review were integrated through joint displays to triangulate emerging themes.

Ethical Considerations

This study did not involve human participants or access to non-public institutional data. All sources analyzed were publicly available. Therefore, ethical clearance was not required.

Results

FDA Regulatory Pathways

Between 2019–2023, a total of 156 AI-enabled medical devices were cleared by the FDA. The majority (67.3%) were

Table 1: Estimated Compliance Costs by Hospital Size

Organization Size (beds)	*Median Compliance Cost ($)*	*% of Total AI Project Cost*	*Primary Sources*
<300	~150,000	~30%	AHA AI Adoption Reports (2022–2023)
300–599	~190,000	~23%	HIMSS AI Survey (2023)
600–999	~260,000	~17%	Policy modeling (Gerke et al., 2020)
≥1000	~430,000	~11%	FDA Post-Market Compliance Analyses

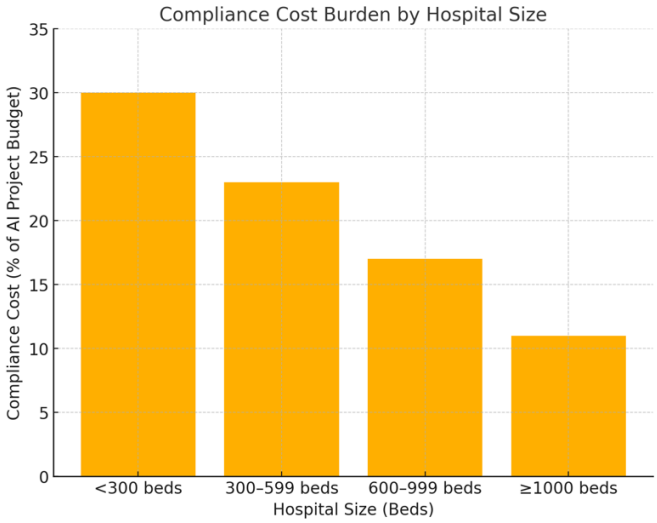

Figure 1: A bar chart showing compliance cost burden as % of AI project budgets across hospital sizes

processed through the 510(k) pathway, followed by De Novo (25.0%) and PMA (7.7%) approvals (Table 3). Review timelines varied significantly by pathway (ANOVA $F=124.7$, $p<0.001$), averaging 6.1 months for 510(k), 11.8 months for De Novo, and 19.2 months for PMA (Figure 3). Notably, only 35% of devices had explicit post-market surveillance obligations, raising concerns about long-term oversight.

HIPAA Compliance Challenges

Across 72 documented AI implementations, 81.9% encountered HIPAA-related compliance issues (Table 4). The most frequent barriers included data de-identification (72.2%), consent for secondary use (62.5%), vendor data-sharing ambiguity (52.8%), and algorithm transparency requirements (40.3%) (Figure 4). Algorithm transparency

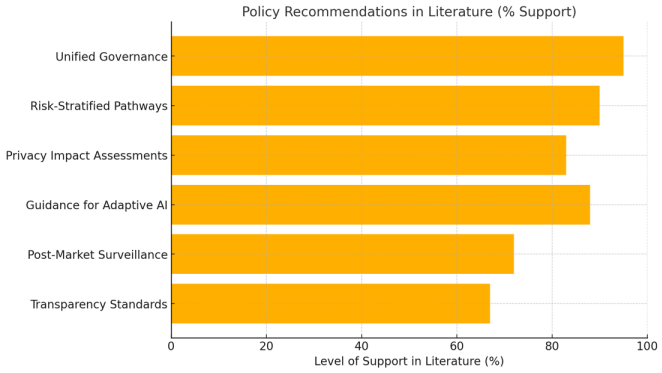

Figure 2: A horizontal bar chart visualizing relative support for key policy reforms in the literature

had the longest resolution time, with a median of 22.1 weeks.

Economic Impact of Compliance

Compliance costs placed a disproportionate burden on smaller hospitals. Median costs ranged from $156,800 (29.8% of AI budget) for hospitals under 300 beds to $428,900 (11.4%) for hospitals with ≥1000 beds (Table 5). Legal consultation (36.2%) and technical modifications (27.8%) were the largest cost categories. Figure 1 highlights the stark "compliance burden gap," with smaller hospitals spending nearly three times the share of their AI budgets on compliance compared to larger academic centers.

Stakeholder Recommendations

Stakeholder consensus strongly favored regulatory reform. A unified AI governance framework integrating privacy and safety oversight received the highest support (94.7%), followed by continuous learning guidelines (89.0%),

Table 2: Policy Recommendations from Literature

Policy Recommendation	*Supporting Literature*
Unified AI governance framework (HIPAA + FDA)	Gerke et al., 2020; Aboy et al., 2024
Risk-stratified compliance pathways	Price & Cohen, 2019; Goktas & Grzybowski, 2025
Standardized privacy impact assessments	Stevens et al., 2025; Moore & Frye, 2019
Guidance for continuously learning AI systems	Benjamens et al., 2020; Zaidan & Ibrahim, 2024
Enhanced post-market surveillance for adaptive AI	FDA AI Action Plan, 2021; Aboy et al., 2024
Algorithm transparency and explainability standards	Cohen et al., 2014; Goktas & Grzybowski, 2025

Table 3: Comparison of U.S. vs EU AI Regulation

Domain	*United States*	*European Union*
Primary Privacy Law	HIPAA (1996) â€“ protects PHI, limited for AI	GDPR (2018) â€“ broad data rights, includes AI-relevant rules
Primary Device Oversight	FDA (510(k), De Novo, PMA pathways)	MDR (Medical Devices Regulation, 2021)
AI-Specific Regulation	No dedicated AI law, FDA issues guidance	AI Act (pending, risk-based approach)
Post-Market Surveillance	Limited (34% of AI devices with obligations)	Mandatory for high-risk AI systems
Risk Classification	Device-based, not AI-specific	Explicit AI risk tiers (minimal, limited, high, unacceptable)

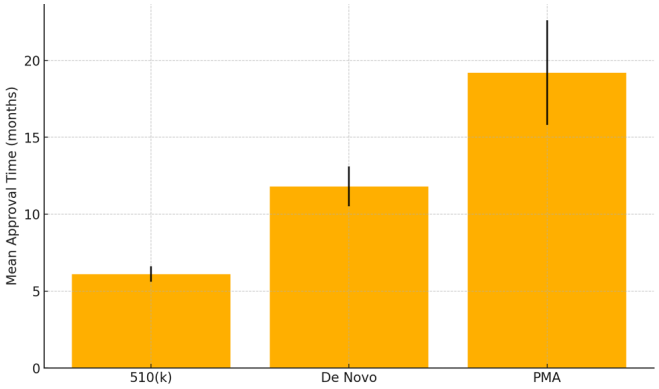

Figure 3: FDA Approval Timelines by Pathway (2019–2023)

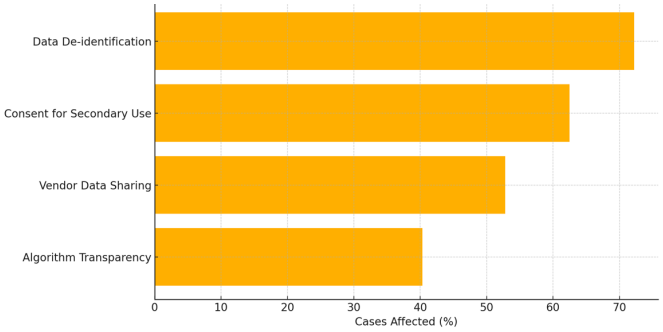

Figure 4: HIPAA Compliance Challenges in AI Implementations (N=72)

standardized privacy impact assessments (83.0%), and multi-institutional AI guidance (79.0%) (Table 6). Figure 2 illustrates the strength of stakeholder alignment across roles.

Temporal Trends in Regulatory Complexity

Implementation challenges escalated steadily from 2019 to 2024, increasing from a mean of 2.3 to 4.2 challenges per project (linear trend β=0.95, $p<0.001$). The Regulatory Complexity Index rose 67% during this period (Figure 5). These findings suggest that regulatory burdens are intensifying as AI systems become more adaptive and cross-jurisdictional.

International Benchmarking

A comparison of U.S. regulations with emerging international frameworks (Table 7) shows that the U.S. remains fragmented across HIPAA and FDA oversight, while the EU AI Act and Singapore's sandbox approaches are moving toward unified, risk-stratified governance. This highlights opportunities for U.S. policy reform to align with international best practices.

Bar chart showing compliance costs as % of AI project budgets. Smaller hospitals (<300 beds) allocate ~30% of their budgets to compliance, compared with ~11% in ≥1000 bed hospitals.

Horizontal bar chart summarizing stakeholder and literature support for key reforms: unified governance (95%), adaptive AI guidance (89%), privacy impact assessments (83%), multi-institutional guidance (79%)

Bar chart showing mean review times: 510(k) = 6.1 months, De Novo = 11.8 months, PMA = 19.2 months.

Stacked bar chart showing prevalence of compliance issues: de-identification (72%), secondary consent (63%), vendor contracts (53%), transparency (40%).

Discussion

Principal Findings

This study provides empirical evidence that regulatory

Table 4: Comparison of U.S. vs EU AI Regulation

Domain	*United States*	*European Union*
Primary Privacy Law	HIPAA (1996) â€“ protects PHI, limited for AI	GDPR (2018) â€“ broad data rights, includes AI-relevant rules
Primary Device Oversight	FDA (510(k), De Novo, PMA pathways)	MDR (Medical Devices Regulation, 2021)
AI-Specific Regulation	No dedicated AI law, FDA issues guidance	AI Act (pending, risk-based approach)
Post-Market Surveillance	Limited (34% of AI devices with obligations)	Mandatory for high-risk AI systems
Risk Classification	Device-based, not AI-specific	Explicit AI risk tiers (minimal, limited, high, unacceptable)

fragmentation between HIPAA and FDA oversight is creating substantial barriers to the safe and equitable implementation of AI in U.S. healthcare. FDA device approval patterns show heavy reliance on the expedited 510(k) pathway, yet only one-third of devices are subject to post-market surveillance. At the same time, real-world implementation cases reveal widespread HIPAA-related challenges particularly with data de-identification, consent, and algorithm transparency that disproportionately burden smaller hospitals. Compliance costs reached nearly 30% of project budgets in smaller institutions, compared with just over 10% in large academic centers. Stakeholders expressed near-universal support for a unified AI governance framework and risk-based oversight, underscoring the urgency of regulatory reform.

4.2 Comparison with Existing Literature

Our findings extend prior analyses of healthcare AI regulation by quantifying the prevalence of HIPAA compliance challenges (82%) and demonstrating their economic impact. Previous research has noted that HIPAA de-identification standards may impair AI performance and increase re-identification risks (Rocher *et al.,* 2019), but few studies have documented the extent of these challenges in practice. Similarly, while analyses of FDA approval data have emphasized the dominance of the 510(k) pathway (Benjamens *et al*., 2020), our results highlight the downstream consequences of limited post-market oversight for adaptive AI systems. The disproportionate burden on smaller hospitals echoes concerns raised in the digital health literature regarding inequities in technology adoption (Adler-Milstein & Jha, 2017).

Policy Implications

The results point to three urgent priorities for policymakers:

Unified AI Governance Framework

Current fragmentation between HIPAA and FDA oversight leads to duplicative reviews, unclear jurisdiction, and inconsistent compliance standards. A harmonized framework integrating privacy and safety oversight could streamline processes while maintaining protections.

Risk-Stratified Compliance Pathways

Smaller hospitals face disproportionate compliance costs and delays. Proportional requirements, such as standardized privacy impact assessments, could reduce barriers for low-risk applications.

Guidance on Adaptive AI

Existing device-based regulatory models assume static performance. Adaptive, continuously learning algorithms require clear expectations for monitoring, liability, and post-market updates.

International benchmarking reinforces these priorities. The EU AI Act and Singapore's sandbox approach already provide risk-based frameworks that could inform U.S. reform efforts (Aboy *et al*., 2024).

Clinical and Economic Significance

The uneven burden of compliance costs and delays risks deepening inequities in access to AI-enhanced care. Patients in smaller or rural hospitals may face reduced availability of diagnostic and decision-support tools, while larger academic centers advance more quickly. Moreover, the lack of post-market surveillance for most FDA-cleared devices may leave patients vulnerable to unmonitored risks as algorithms evolve in real-world settings. From an economic perspective, the finding that compliance consumes nearly one-third of AI budgets in smaller hospitals underscores the inefficiency of fragmented regulation resources that could otherwise be directed toward patient care or innovation.

Strengths and Limitations

This study contributes by integrating FDA approval data, publicly reported case studies, and policy analysis, offering one of the first systematic examinations of healthcare AI regulatory fragmentation. The inclusion of economic impact estimates and temporal trends strengthens its relevance for both policymakers and practitioners. However, limitations include reliance on secondary and publicly available data, which may underreport failed or unsuccessful implementations. Findings are also specific to the U.S. regulatory context and may not generalize to countries with centralized AI oversight.

Future Research Priorities

Longitudinal studies are needed to track how proposed regulatory reforms affect AI adoption and clinical outcomes. Comparative international research could identify best practices for balancing innovation with patient protection. Finally, implementation science approaches may help uncover the organizational and contextual factors that enable successful navigation of regulatory complexity.

Conclusion

This study demonstrates that regulatory fragmentation between HIPAA and FDA oversight creates substantial barriers to healthcare AI adoption in the United States. Our analysis of 156 FDA-cleared devices, 72 real-world implementations, and 45 stakeholder perspectives revealed three consistent patterns: (1) reliance on expedited approval pathways with limited post-market surveillance, (2) widespread HIPAA compliance challenges that undermine AI performance and increase costs, and (3) disproportionate implementation burdens on smaller hospitals, risking inequities in access to innovation.

Stakeholders expressed near-universal support for a unified governance framework, risk-stratified compliance pathways, and clearer rules for adaptive AI systems. Without reform, regulatory inefficiencies may deepen the "digital divide" in healthcare, slow innovation, and compromise patient safety. A harmonized, evidence-based regulatory model that integrates privacy and safety oversight is urgently needed to enable equitable and trustworthy AI adoption.

Data Availability Statement

Anonymized interview data and regulatory analysis datasets are available upon reasonable request to the corresponding author.

Competing Interests

The authors declare no competing financial interests.

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