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Navigating regulatory and policy challenges for AI enabled combination devices

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Abstract

Artificial Intelligence (AI) has made it possible for traditional Combination Devices (CDs) to innovate in the healthcare industry by combining the technology and healthcare sectors in recent years. Nonetheless, the difficulties, such as dependence on predicate devices, are highlighted in the US Food and Drug Administration's (FDA) 510(k) process, particularly for AI that is constantly evolving. Even though software and AI are included by the European Union's (EU) new Medical Device Regulations, it is still challenging to incorporate adaptive algorithms into conformance evaluations. It is underlined how urgently frameworks aware of AI concerns such as model deterioration and data biases are needed. Manufacturers' difficulties with regulations are clarified by case studies and insights from recalled equipment. Proposed are flexible policy frameworks that provide a balance between quick innovation and patient protections. In order to facilitate the safe, efficient, and egalitarian deployment of AI, recommendations are made to regulators and policymakers, promoting worldwide standards.

Keywords: AI-enabled combination devices, AI regulatory frameworks, FDA AI regulations, AI-enabled medical devices, AI policy frameworks, AI regulatory challenges

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1. Introduction

Artificial intelligence (AI)-enabled Combination Devices (CD) are a major development in the technology and healthcare industries that integrate AI with traditional medical devices to increase their usefulness, accuracy, and adaptability. Unlike traditional medical devices, AI-enabled CDs can learn from data, adjust their performance over time, and make decisions on their own or with some degree of autonomy. Natural language processing in patient monitoring systems, machine learning algorithms for picture analysis in diagnostic equipment, and reinforcement learning in medication delivery devices are examples of common AI technologies found in CDs. Smart cardiac monitoring devices, AI-assisted surgical robots, and customized insulin delivery systems are just a few of the applications for these. Although integrating AI into medical devices has the potential to improve patient outcomes, lawmakers and regulatory bodies face obstacles. (1)

The integration of AI into medical devices presents difficulties for lawmakers and regulatory agencies, particularly in the areas of patient safety, algorithmic transparency, and data privacy. To prevent unauthorized access and unethical use of patient data, robust security measures are necessary to address data privacy issues. (2) Algorithmic transparency is required to preserve trust, requiring thorough documentation and explanations of AI decision-making processes. (3) To guarantee patient safety and effectiveness, AI-enabled medical devices must pass rigorous testing and validation procedures before being approved for commercial use. (4)

The Food and Drug Administration (FDA) in the United States and the European Commission in the European Union (EU) have created regulatory regimes especially for CDs. The FD's suggested framework for AI/ML-based Software as a Medical Device (SaMD) emphasizes finding a balance between pre-market evaluation for significant modifications and a simplified method for small adjustments because AI technology are always changing. (5) In contrast, stringent pre- and post-market procedures are established by the E's Medical Devices Regulation (MDR) and the in vitro Diagnostic Regulation (IVDR) to ensure high safety and performance criteria. (6) A flexible and knowledgeable regulatory and policy approach that puts safety, efficacy, and ethical considerations first is necessary to properly explore the possibilities of AI-enabled combination devices in healthcare.

2. US regulatory landscape and challenges

One important avenue for traversing the US regulatory landscape for medical devices, particularly those using artificial intelligence (AI), is the FD's 510(k) pathway. Even though this approach facilitates the introduction of innovative devices into the market, it poses unique challenges for AI-based medical devices. Significant regulatory obstacles need to be removed because AI is built with the ability to learn and adapt over time. In order to ensure safety and efficacy, new approaches are required. We are aware that the FDA regulates medical devices through additional channels. Novel devices without predicates that pose a low to moderate risk are classified using the De Novo classification process. Class III technologies that support or sustain human life must go through the strictest Premarket Approval (PMA) procedure. However, a lot of AI-enabled gadgets still use the 510(k) channel.

The 510(k) submission process for medical devices was originally designed for devices with static functioning, but it now requires new devices to be substantially identical to a legally sold item known as a "predicate device." However, A's dynamic learning capabilities, which allow post-market adjustments based on new data, make this criterion more challenging to execute. The FDA is currently looking on regulatory frameworks that maintain stringent safety and efficacy standards while permitting incremental improvements to AI systems. One of the biggest challenges in this area is regulating AI systems that are constantly evolving. The rapid iteration cycle of artificial intelligence technologies is too rapid for traditional regulatory frameworks to handle. In its regulatory proposals, the FDA has responded by considering a “predetermined change control plan” that allows manufacturers to modify AI algorithms after they have been approved without submitting a new 510(k) application, provided that the changes remain within the parameters of the original plan. (7)

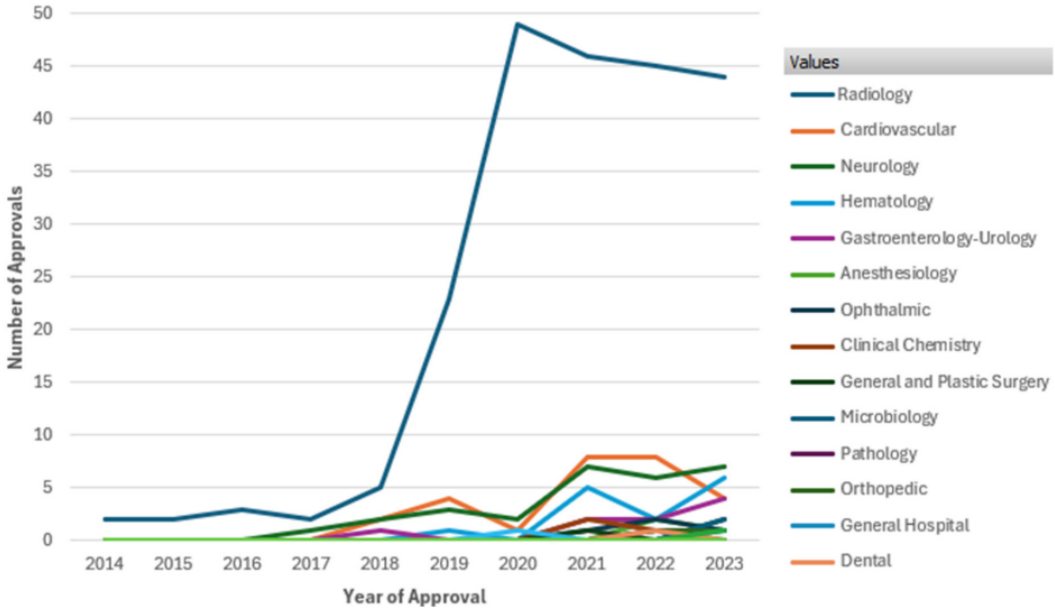

FIGURE 1
FDA approvals of AI/ML enabled devices by therapeutic area from 2014 to 2023. Data Source (8): U.S. Food and Drug Administration, Artificial intelligence and machine learning (AI/ML) enabled medical devices available online at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices, last accessed on Sept. 2024.

Figure 1. FDA approvals of Al/ML enabled devices by therapeutic area from 2014 to 2023

The number of FDA-approved AI/ML-enabled medical devices over the previous ten years is shown in Figure 1. It demonstrates a notable general increase in approvals that began in 2018 and peaked in 2020 at about 50 approvals. Other therapeutic areas including cardiology, neurology, hematology, and gastroenterology and urology show consistent but lesser growth, while radiology leads the approvals with a sharp increase from 2018 onward. This information highlights the increasing regulatory acceptability and integration of AI/ML technology in medical devices, particularly in radiology. (8) Important insights on the difficulties in regulating AI in healthcare can be gained from case studies and recalled devices. For example, the recall of an AI-based diagnostic tool due to failures in real-world scenarios highlights the need for strict post-market surveillance and the likely need for recalibration of AI algorithms based on real-world outcomes. These instances highlight the discrepancy between clinical trial conditions and actual use, highlighting the necessity of both stringent and adaptable regulatory systems to track and handle these kinds of problems. The FDA is putting more emphasis on real-world performance monitoring for AI/ML technologies, even though many of these devices have been approved under the 510(k) pathway without clinical studies. (9)

Under the new regulatory framework, pre-market testing and post-market monitoring must be balanced to promote innovation while preserving patient safety. By interacting with stakeholders through open workshops and guidance materials, the FD demonstrates its adaptive regulatory approach, which attempts to stay up with technological

advancements. Regulation of AI-enabled medical devices poses unique challenges for the FD's 510(k) procedure, necessitating an adaptable and progressive regulatory approach. By combining stringent safety and efficacy regulations with adaptability to account for A's iterative character, the FDA seeks to safeguard public health and foster AI innovation. (10) In an effort to interact with different stakeholders about the use of artificial intelligence (AI) in drug safety, the FDA recently launched the Emerging Drug Safety Technology Meeting (EDSTM) program. The EDSTM program emphasizes the FD's proactive role in promoting communication and mutual learning, which is essential for creating regulatory frameworks that can adapt to new technologies. (11)

3. European Union's regulatory landscape and challenges

The regulatory environment and difficulties of the European Union A framework for ensuring the efficacy and safety of medical devices, including those that employ artificial intelligence (AI), is provided by the European Union's Medical Device Regulation (MDR). The MDR, which come into effect in May 2021, is a major update from its predecessors with the aim of improving clinical safety and enabling the rapid advancement of technology in the healthcare sector. (12) The use of AI into medical devices presents significant obstacles, particularly with regard to conformance assessments for adaptive algorithms. Because these algorithms are dynamic, a regulatory approach that protects patients while allowing for their development in response to new data is required. The MDR requires manufacturers to provide comprehensive clinical data and to continuously monitor the efficacy of their devices in an attempt to address these concerns. It also places a larger emphasis on clinical evidence and post-market surveillance. (13) One of the primary challenges in conformance evaluations is predicting how adaptive AI algorithms will behave as they learn from new data. This unpredictability complicates the standard regulatory technique, which relies on set device properties to establish compliance. The MDR recommends a risk-based approach to address this issue, where the level of scrutiny is proportionate to the potential risk the device presents. In their respective guidance documents, regulatory agencies such as the FDA and the E's MDR describe their risk-based strategy, which is a sophisticated method of evaluating devices that adjusts the level of scrutiny and its scope according to the possible risk a device poses to patient safety. (12) In actuality, this means that AI-enabled devices with greater risk profiles—like those utilized for autonomous treatment decision-making or in critical care settings—are subjected to more thorough testing. Comprehensive post market surveillance programs, in-depth algorithm validation, and large clinical trials may all be necessary for this. On the other hand, less rigorous review procedures might apply to lower-risk AI applications, such as those employed for administrative duties or non-essential decision assistance. The intended use and clinical context of the device, the degree of autonomy of the AI system in decision-making, the possible repercussions of AI errors or malfunctions, the transparency and explainability of the AI algorithm, and the caliber and representativeness of the training data are some of the factors considered in the risk assessment for AI-enabled devices. This approach necessitates that manufacturers implement robust risk management and quality control protocols to guarantee that any alterations made by the AI do not compromise the device's operation or safety. (14) Resolving privacy and data protection concerns is another aspect of removing regulatory obstacles in the EU for medical devices that include AI. The General Data Protection Regulation (GDPR) specifies stringent rules for the management of personal data, including health data used by AI systems. GDPR, which requires open data processing practices and the protection of data subjects' rights, must be followed by manufacturers of AI-integrated devices. (15)

4. Regulatory challenges with AI-enabled medical devices FDA 510(k) pathway challenges

The IDx-DR case raises concerns about the issues with the FDA's dependence on precedent devices when approving AI-based technologies under the 510(k) pathway. While this has helped products deemed "substantially equivalent" to already-marketed devices gain market approval more quickly, it is a laborious procedure for adaptive AI systems. Under a 510(k) framework based on static technologies, the ability of IDx-DR to continuously learn and improve after deployment through updates from real-world experience revealed significant hurdles. Once more, this example will show how an adaptive algorithm that requires updates cannot coexist with the predicate-based process's static nature. This raises concerns regarding the applicability of the 510(k) procedure for such dynamic technologies and necessitates continuous postmarket surveillance. The inherent difficulty of implementing a conventional regulatory framework for AI technologies that are not "fixed" at the time of approval but instead develop over time with an increasing risk of model drift or degradation is illustrated by this example (16-19) The difficulties presented by AI-enabled medical equipment were compiled in Table 1.

5. Challenges of EU MDR conformity assessment

An excellent illustration of how challenging it is to prove an AI algorithm's long-term safety and effectiveness under EU MDR is the Heart Flow FFR act case.

Table 1. EU MDR Heart Flow FFR act case.

Sr.no.	Challenge	Description	Case study example
1.	FDA 510(k) pathway challenges	Reliance on predicate devices for Al-based medical technologies, limiting the accommodation of adaptive Al algorithms.	IDx-DR (Al for Diabetic Retinopathy)
2.	EU MDR conformity assessment challenges	Demonstrating safety and efficacy for adaptive Al algorithms under MDR is difficult due to their evolving nature.	HeartFlow FFRct (Al-based coronary diagnostics)

3.	Post-market surveillance challenges	Continuous monitoring and updating of Al algorithms are required to ensure ongoing compliance and functionality.	Aidenc's veye lung nodules (AI for lung cancer detection)

The company faced a new kind of issue because the Heart Flow AI system was dynamic, and the regulatory environment expects devices to remain unchanged after being approved for sale. The scenario highlights the difficulty adaptive AI presents for conventional conformance tests. The AI system's clinical performance could not be assessed at a particular moment in time, as the MDR had required, due to the algorithm's continuous changes. Rather, the AI system's learning capability necessitated ongoing evaluation and updating, which is incompatible with the EU's current legislative framework. Using a flexible and iterative approach to regulation, the instance exemplifies the more general issue of trying to apply invariant regulatory norms to a technology that is always changing and adapting (20, 21)

6. Challenges of post-market surveillance

One of the many instances that still require post-market management and monitoring of AI technology is the use of Aidenc's Veye Lung Nodule AI to detect lung cancer nodules. The accuracy and efficacy of the AI system will need to be continuously updated and monitored as long as it is learning from real-world data and new situations. The intricacy involved in maintaining adaptive AI systems' clinical effectiveness over time is aptly demonstrated by this scenario. AI systems, like veye, will inevitably need to be upgraded and recalibrated after the market, aside from the majority of medical equipment that remain stationary. Since the initial permission did not take these iterative learning processes into consideration, such continuous surveillance presents serious regulatory issues. This scenario demonstrates how post-market surveillance becomes an essential component of an AI device's life cycle, which is required for them to remain compliant and functioning as they continuously evolve. (19)

7. Addressing AI risks in healthcare

The term artificial intelligence (AI) in healthcare refers to a range of technological developments that enable Large Language Models (LLs) to do tasks that typically require human intelligence, including as learning, problem-solving, and decision-making. Creating robust frameworks is necessary to handle AI challenges in healthcare effectively. These frameworks should consider not only technology issues but also sociological, legal, and ethical challenges. Building on pre-existing frameworks such as the FD's Software Precertification (Pre-Cert) Program, healthcare stakeholders must collaborate to establish regulations specific to the development, validation, and implementation of AI models. (22) and the European Union’s Ethics rules for Trustworthy AI which encourage the development of new technologies while offering standards for the moral, legal, and reliable creation of trustworthy AI. In order to ensure the reliability and security of AI models over the course of their lifecycle, these frameworks ought to prioritize accountability, transparency, and continuous model monitoring. An examination of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database shows that, between 2021 and June 2024, there were 32 experiences with artificial intelligence devices. A closer look reveals that none of the user experiences specifically attribute the malfunction to AI. AI was utilized to plan the AI-guided ablation in some circumstances, like an ablation catheter, and to create a 3D model for a total hip replacement in other cases, such a femoral stem. (23)

AI models used in healthcare may deteriorate over time because to changes in patient demographics, modifications to medical practices, or changes in the distribution of data. Understanding and responding to model deterioration is necessary to maintain the effectiveness of AI applications. With continuous monitoring, regular updates, and feedback loops involving medical specialists, degradation issues can be promptly detected and resolved. Model degradation poses a serious problem for AI-enabled medical devices, especially those that use machine learning algorithms, since it can compromise patient safety and the device's overall effectiveness. When used in real-world situations, these models' performance may gradually deteriorate because they are frequently trained on data gathered from controlled conditions. Data drift, or changes in the statistical characteristics of input data following model deployment, is the main cause of this degradation. Data drift can result from a variety of factors, including changing patient demographics, changes in the prevalence of diseases, and adjustments to clinical procedures. This can lead to less precise forecasts and potentially harmful or ineffective medical consequences. For instance, when applied to multiple patient groups with varied features, predictive models that were first created for particular populations may perform poorly, increasing the possibility of incorrect diagnosis or wrong treatment choices. (24, 25)

Changes in the environment and hardware that impact data collecting are another major factor contributing to model degradation. Diagnostic equipment that use AI algorithms, for example, might collect lower-quality input data due to changes in lighting, sensor calibration, or other environmental factors. These circumstances can raise the risk of device breakdown and drastically lower the accuracy of AI predictions. (26) The dynamic nature of AI models, which necessitate constant updates and recalibration to sustain performance over time, makes this issue worse. In order to address possible degradation issues before they jeopardize patient safety, regulatory agencies like the FDA support the establishment of strong post-market surveillance systems that continuously monitor the mode's performance in the real world and allow for controlled updates.

Long-term device efficacy is also at danger from the deterioration of AI models, particularly as treatment procedures or clinical guidelines change. When standards change, a model that was trained using one set of criteria may become outdated, decreasing the device's effectiveness. The significance of flexible legal regimes that permit prompt upgrades and adjustments to AI algorithms without sacrificing security is highlighted by this situation. The necessity of pre-established change

control procedures is emphasized in the FD's advice on Software as a Medical Device (SaMD), which permits manufacturers to make the required modifications while preserving the device's regulatory clearance. (27) The insights learned from medical device recalls brought on by unanticipated issues like the accuracy of drug lists based on EMs can be applied to preemptive model assessment and improvement initiatives. (28)

In line with the need for preemptive model assessment and improvement efforts previously discussed, these projects seek to identify points in the AI development lifecycle where bias can be introduced and investigate ways to address it through risk management. The FDA also intends to support initiatives that consider health inequities related to AI use in medical product development, leveraging ongoing diversity, equity, and inclusion efforts. By using representative and varied datasets, this method supports industry efforts to lessen biases in AI applications.

The FDA also stresses how crucial it is to continuously evaluate AI tools used in the creation of medicinal products. The need of ongoing attention in tackling AI hazards in healthcare is shown by this focus on guaranteeing standard adherence and preserving performance and dependability throughout the AI lifespan. As demonstrated by the lessons learnt from medical device recalls, it emphasizes the necessity of thorough testing standards and rapid reaction procedures to handle unforeseen challenges.

Data biases provide a number of difficulties for AI in the healthcare industry and can lead to differences in diagnosis and treatment recommendations. Because they recognize the value of objective data, healthcare professionals and AI engineers can work together to identify and minimize biases in data collection, reprocessing, and model training. Fairness-aware algorithms and representative and diverse datasets can help reduce biases in AI applications. (29) Analyzing case studies related to medical device recalls offers valuable insights into the potential consequences of deploying technology that have not been adequately assessed in the healthcare sector. The recall of certain imaging devices due to inaccurate readings is an example of a cautionary tale regarding the importance of extensive testing and validation before widespread adoption. In order to swiftly handle unforeseen challenges by learning from such circumstances, we advise AI stakeholders to set up thorough testing requirements, post-market surveillance, and rapid response systems. (30)

8. Conclusion

The incorporation of AI in CDs and its potential to transform healthcare through enhanced functionality, accuracy, and adaptability were the subjects of this study. Personalized care, real-time monitoring, and improved diagnostic capabilities are all made possible with AI-enabled CDs. Adoption of these technologies, however, also poses special difficulties for regulatory and policy frameworks, requiring these frameworks to change in order to address important concerns like patient safety, algorithmic transparency, and data privacy. Initiatives by the FD, like the EDSTM program, highlight the significance of ongoing discussions and flexible regulatory strategies to stay up with technology developments. The EDSTM initiative, which has promoted debates leading to the formulation of recommendations for the safe and successful use of CDs, could help AI-enabled devices. The regulatory environment can effectively facilitate the safe and equitable adoption of AI-enabled combination devices by encouraging stakeholder collaboration and placing a strong emphasis on a balanced approach between innovation and patient safety. Maintaining a flexible and progressive approach to regulation is crucial as technology develops in order to fully fulfill AI's potential to improve patient outcomes and advance medical technologies.

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Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The author(s) declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

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