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Application Exploration of Artificial Intelligence Technology in the Innovative Development of Medical Equipment

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ABSTRACT

The use of AI in medical devices is one of the greatest technological revolutions in modern medicine. This review focuses on the mechanisms and dimensions of AI application to medical equipment innovation in four domains, such as AI-enabled medical imaging devices, AI-assisted surgical robotics, AI-integrated wearable monitoring devices, and federated learning-based data infrastructure for equipment development. A review of regulatory data, clinical evidence and emerging technical literature traces the evolution of AI-enabled device authorisations – from 27 FDA-cleared devices in 2017 to 235 in 2024 (with more than 1,000 cumulative authorisations) – and discusses the technology-specific drivers of this growth. A technology innovation diffusion framework and the human-AI collaboration concept are used to contextualise the systemic implications of AI integration at the equipment level. We tackle and evaluate major issues, including the lack of transparency in algorithms, differences in regulations between the U.S. Food and Drug Administration and China's National Medical Products Administration, restrictions on data privacy, algorithmic bias, and the development of governance frameworks. The assessment finishes with pragmatic thoughts on how to bridge the device-level AI performance with the system-level healthcare outcomes and on the development of internationally harmonised evaluation criteria for AI-enabled medical equipment.

KEYWORDS

Artificial intelligence; Medical equipment; Medical imaging; Surgical robotics; Wearable devices; Federated learning; FDA; NMPA; Algorithm transparency

1. INTRODUCTION

1.1. Research Background

The emergence of artificial intelligence in medical equipment marks a structural inflection point in the history of medical device innovation. The latter rounds of medical equipment innovation were mostly based on breakthroughs in materials science, precision manufacturing and sensor miniaturisation. The current wave is propelled by the integration of machine learning algorithms, especially deep learning and convolutional neural networks, empowering devices to execute sophisticated pattern recognition, predictive inference, and adaptive decision-support tasks that extend beyond the reach of rule-based software. The extent of this shift may be seen in regulatory authorisation statistics with the United States Food and Drug Administration (FDA) clearing or licensing a cumulative total of more than 1,250 AI-enabled medical devices by mid-2025 vs fewer than 100 in 2019. Of these, 956 (about 77%) of all authorisations were for radiology, showing the maturity of deep learning based image processing relative to other therapeutic areas. By the end of 2024, China's NMPA had approved 103 Class III AI medical device devices, the first being approved in 2020, and the approval volume has been expanding fast since then.

This growth indicates both the technological maturity of AI approaches available to medical data and the growing regulatory infrastructure capable of analysing AI-enabled devices as a separate device class. The FDA's release of its AI/ML Software as a Medical Device (SaMD) Action Plan in 2021, its guidance on Predetermined Change Control Plans in 2023 and 2024 and its comprehensive AI-Enabled Device Software Functions lifecycle management guidance in January 2025, is a regulatory framework increasingly calibrated to the adaptive and continuously learning characteristics of the AI systems. The NMPA has also been involved in the formalisation of AI-specific evaluation criteria in China's regulatory framework, with the publication of six AI-specific device recommendations in 2023.

1.2. Research Questions

The review answers three research questions. RQ1: What are the most transformatively integrating technological mechanisms of AI with contemporary medical equipment in clinical domains and what performance advantages are reported? RQ2: What are the novel data infrastructure, e.g., federated learning, that allow the development of clinically validated AI for medical devices in privacy-constrained healthcare environments? RQ3: What are the legislative, ethical and technical hurdles that hinder the full potential of AI in medical equipment innovation? What governance frameworks are emerging to respond to these difficulties?

2. THEORETICAL FRAMEWORK: TECHNOLOGY INNOVATION DIFFUSION AND HUMAN-AI COLLABORATION

Rogers' diffusion of innovations theory [5] provides a valuable macro-level framework to evaluate the different adoption pathways of AI-enabled medical devices across clinical specialities. The steep element of this diffusion curve is the quick rise in the number of FDA-cleared AI devices (27 in 2017 to 235 in 2024 [2]), as predicted by the notion that acceptance grows exponentially once a societal barrier is passed. The S-curve diffusion pattern may be observed in the data of FDA authorisations with radiology leading at 77% of approvals and behavioural health, pathology and interventional devices still in the early-adoption stages [2]. Relative advantage, compatibility with the work-flow, observability of outcomes and trialability are features that are strongly related to the difficulties of AI device adoption [5] and the speed of diffusion is affected by these features.

The concept of human-AI collaboration provides an operational paradigm for how AI capacity should be integrated into the design of medical equipment at the device-system interface. The human-AI collaboration model is not intended to substitute for clinical judgement, but to enhance clinician capacity. Topol refers to this paradigm as "high-performance medicine", where AI analyses high-dimensional data beyond the perception of unaided humans and provides structured decision support that clinicians can assess, override and contextualise [1, 6]. This approach has important consequences for device design, evaluation and regulation: it demands that AI-enabled devices be evaluated not merely on the basis of algorithm performance metrics, but on the clinical decision-making and patient outcomes delivered by the human-AI dyad.

3. APPLICATION DOMAINS

3.1. AI-Enabled Medical Imaging Devices

AI medical imaging is the most mature and validated area of AI medical device development. Convolutional neural networks (CNNs) trained on large annotated datasets of radiological images have shown diagnostic performance at least equal to that of specialist clinicians on a variety of imaging tasks including chest X-ray pathology detection, diabetic retinopathy screening, skin lesion classification and mammography screening [6]. A systematic review and meta-analysis published in

The BMJ reviewed 69 deep learning systems across various imaging modalities. Deep learning systems had similar mean diagnostic accuracy to clinicians, with deep learning systems achieving 87.0% sensitivity and 92.5% specificity compared with clinicians' sensitivity of 86.4% and specificity of 90.5%. The authors, however, warned that methodological limitations in the main literature reduce confidence in these estimations [6]. The most mature domains for clinical translation of imaging AI are ophthalmology and radiology, including scalable AI-assisted chest CT analysis for COVID-19, lung nodule detection and stroke triage in clinical practice.

China's NMPA has included review of imaging AI devices in its 2023 recommendations and also needs demonstration of performance robustness across multi-centre clinical validation datasets before Class III clearance [3]. From the device design perspective, imaging AI requires the incorporation of explainable AI modules, which are used to generate saliency maps to identify portions of images responsible for the diagnostic outputs (addressing the interpretability challenge), and continuous performance monitoring systems to detect distribution shifts of input data that are likely to result in degradation in algorithm accuracy in the deployment environments different from the training settings [4]. The FDA's Predetermined Change Control Plan framework introduced in 2023 addresses the challenge of managing the lifecycle of imaging AI devices trained or fine-tuned on post-deployment data by providing pathways to regulation for approved performance changes that do not require a full re-submission [4].

3.2. AI-Assisted Surgical Robotics

The clinical application and commercial investment in the integration of AI with surgical robotics is quickly expanding. The global medical robots and computer-assisted surgery market was valued at USD 15.0 billion in 2025 and is expected to reach USD 52.4 billion by 2034, at a CAGR of 14.9% [7]. AI supplements surgical robots in the entire operation continuum, from pre-operative anatomy segmentation, intra-operative real-time tissue identification and guidance, to post-operative outcome analysis and skills assessment [8]. The da Vinci robotic platform is an example of AI-enabled computer vision integration with robotic instrument control, which allows three-dimensional visualisation, motion scaling and tremor reduction for minimally invasive therapies [7]. There is a development of AI-based skill evaluation systems with computer vision analysis of robotic instrument kinematics which has the ability to standardise the assessment of surgical competency [8].

Evidence suggests that robotic assisted prostatectomy and ventral hernia repair have similar or better outcomes but long term benefits are not yet assured and they are costly compared to laparoscopy [7]. In March 2024, Medtronic's Hugo robotic-assisted surgery system received FDA approval, contributing to the competitive landscape and accelerating the adoption of AI capabilities [7].

3.3. AI-Integrated Wearable Monitoring Devices

AI-enabled wearables are the fastest expanding segment of consumer-facing medical technology, providing continuous, longitudinal health monitoring at a scale and granularity that episodic physician contacts cannot. The global wearable healthcare technology market size was valued at USD 42.6 billion in 2023 and is projected to reach USD 169 billion by 2029 [9]. The combination of AI with continuous data streams from wearable sensors such as photoplethysmography, accelerometry and continuous glucose monitoring, offer predictive analytics that could help to detect clinically relevant events before patients develop symptoms. Data privacy, algorithmic bias, and the need for large diverse training datasets are ongoing challenges, despite the potential for glycaemic monitoring, adaptive insulin management and prediction of diabetes-related complications identified in a systematic review of AI-powered wearable devices in Nature npj Digital Medicine [10]. Wearable-derived multimodal data streams have been used to detect anomalies in cardiac arrhythmia, sleep problem diagnosis and early sepsis warning in hospital monitored patient populations with

demonstrated clinical benefit utilising gradient boosting trees and support vector machine algorithms [9].

3.4. Federated Learning as Data Infrastructure for AI Device Development

The training data for clinically certified AI for medical devices cannot be collected from one institution. But there are major legal, security and privacy challenges to sharing health data between organisations. Federated learning (FL) overcomes this shortcoming by enabling multi-institutional collaborative model training without centralising raw patient data. Instead of sharing patient records, model parameters are shared between a central server and participating institutions. This preserves data residency and enables aggregate learning that cannot be achieved by single-institution datasets [11]. A survey on privacy-preserving FL in healthcare concludes that FL is a technically feasible solution to the data silo problem in medical AI development, while documenting that FL introduces novel privacy risks – including gradient inversion attacks through which participating institutional data can be partially reconstructed from exchanged model updates – that require differential privacy, secure aggregation, and trusted execution environment mitigations [11]. FL is particularly relevant for medical device development in rare diseases, where no single institution can gather enough training datasets, and for harmonisation of international regulations, where FL frameworks can facilitate the validation of a model across regulatory jurisdictions while respecting national data sovereignty regulations [3, 11].

4. CHALLENGES AND GOVERNANCE FRAMEWORKS

4.1. Algorithmic Opacity and Explainability

Deep learning models are opaque, high-dimensional function approximators whose core computational paths are resistant to human interpretation, a major barrier for clinical trust, regulatory review and liability attribution of AI-enabled medical devices. The black-box aspect is especially essential for AI tools whose outputs directly impact clinical decisions with implications for patient safety. Here, clinicians' ability to evaluate the plausibility of an AI output in light of clinical context is the key safeguard against algorithmic error. Explainable AI (XAI) methods as Grad-CAM, LIME and SHAP value analysis, give clinical users post-hoc explanations although the truthfulness of their explanation to the actual computing process of the model is still debatable [1, 4]. The FDA's June 2024 Transparency for Machine Learning-Enabled Medical Devices guidance addresses the challenge by providing transparency recommendations including descriptions of the AI/ML model's intended use, training data characteristics, and known performance limitations—these recommendations help inform clinical use but do not address the core challenge of interpretability [4].

4.2. Regulatory Heterogeneity and International Harmonisation

The parallel development of AI medical device regulation in the US, the EU and China has resulted in a fragmented global regulatory landscape which makes compliance difficult for multinational device producers and hinders the international generality of clinical validation findings. The FDA approves 97% of AI medical devices via the 510(k)-dominated approach based on the significant equivalence to predicate devices, a paradigm that does not work well for adaptive AI systems and encourages incremental rather than breakthrough AI device innovation [2, 4]. Yoon et al. conducted a comparative analysis of regulatory responses across different jurisdictions, finding systematic differences in approval timelines and submission requirements for AI-enabled devices among the FDA, the EU's Medical Device Regulation and Asian regulatory systems, with consequences for the international availability of approved devices [12]. China's NMPA has taken a different regulatory strategy, having certified 103 Class III AI devices by the end of 2024 and published six specialised

AI device evaluation guidelines in 2023, including a special focus on the examination of dynamic algorithm performance in post-market situations [3]. The NMPA's experiment with a regulatory sandbox model — a technique employed by FinTech regulators to test AI device technical compliance in controlled settings — is an innovative governance experiment that aims to strike a balance between facilitating innovation and controlling risks, and is worth noting as a potential blueprint for the adaptive regulation of AI medical devices around the world [3].

4.3. Data Privacy, Bias, and Equity

AI medical devices trained on datasets that do not adequately represent the demographic, phenotypic, and clinical diversity of their intended deployment populations are susceptible to systematic bias – performance disparities across patient subgroups that lead to differential diagnostic accuracy and unequal clinical benefit [6, 10]. Differential performance across racial and socioeconomic groups has been observed in deployed AI diagnostic devices, with the source of this difference being the under-representation of diversity in training datasets for medical imaging, which has the potential to exacerbate rather than mitigate existing health disparities [6]. To tackle algorithmic bias, diversifying the datasets used during the development stage and persistently tracking bias in post-market surveillance are crucial.

5. DISCUSSION: PRACTICAL PERSPECTIVES ON AI-ENABLED MEDICAL EQUIPMENT INNOVATION

For RQ1: Imaging devices where AI diagnostic accuracy is equivalent to specialist clinicians, surgical robotics where AI precision enhancement and skill assessment are redefining surgical ability, and wearables where continuous AI-driven predictive analytics are extending clinical monitoring into the patient environment are identified as the most disruptive applications of AI into medical devices.

Answer to RQ2: federated learning allows cross-institutional model training without data centralisation, although there is a need for differential privacy mitigations to address gradient leaking concerns [11].

In response to RQ3: algorithmic opacity and regulatory heterogeneity are the main governance challenges. For practical advancement, this means convergent effort to set up benchmarking standards that evaluate AI devices on human-AI dyad results, not just algorithm performance metrics.

6. CONCLUSION

This analysis has highlighted the AI technology revolutionising medical equipment innovation in imaging, surgical robots, wearable monitoring, and data infrastructure. The motor of the revolution is the ability of deep learning to do high dimensional pattern identification. The regulatory framework is the catalyst that is being fine-tuned more and more to the AI-specific gadget characteristics. As of 2024, we have 1250+ AI-enabled devices approved by the FDA and 103 Class III products approved by the NMPA, illustrating the shift from proof-of-concept to clinical deployment at scale." Key impediments to harnessing the full potential of AI in medical devices are structural rather than technical, including algorithmic opacity, regulatory heterogeneity, data privacy limits and algorithmic bias. This will require governance innovation in transparency frameworks, worldwide regulatory harmonisation and post-market surveillance methods to follow the ongoing technical maturation of AI algorithms. The practical objective for the subject is to develop standards of evaluation that will examine AI-enabled medical devices not only as algorithmic artefacts, but as components of human-AI healthcare systems whose value is ultimately determined by patient outcomes.

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