Volume-09 Issue 03, March-2025 ISSN: 2456-9348
Impact Factor: 8.232

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

PATIENT ACCESS TO HIGH-RISK DEVICES FOR UNMET MEDICAL NEEDS

[1] Chrysoula I. Liakou, MD, PhD, Director. Clinical Evaluation Department. National Evaluation Center of Quality and Technology in Health, Athens, Greece.
liakou@ekapty.gr

[2]Markos Plytas, MSc. Academic Director. Epsilon College. Athens, Greece.
m.plytas@epsilonnet.gr

ABSTRACT
Patients with unmet medical needs face significant challenges in accessing high-risk medical devices, such as pacemakers, artificial organs, and neurostimulators, which are vital for treating severe conditions that standard therapies cannot address. Despite their life-sustaining and life-enhancing potential, these devices are often hindered by regulatory delays, high costs, limited insurance coverage, and ethical concerns. This article explores the complex relationship between ensuring patient safety and facilitating timely access to high-risk medical devices. It examines regulatory frameworks, such as the FDA's Breakthrough Devices Program and the Humanitarian Device Exemption, which aim to expedite device approval but often remain limited in scope. Additionally, the financial challenges and logistical barriers faced by healthcare providers in delivering these devices are discussed. The article proposes several strategic solutions, including policy reforms to streamline approval processes, the use of post-market surveillance technologies to ensure safety, and improved collaboration between regulatory bodies, manufacturers, and healthcare professionals. Public-private partnerships and patient advocacy groups play a crucial role in bridging these gaps and creating a healthcare system that better meets patient needs. By combining innovative strategies and addressing access barriers, a more equitable healthcare ecosystem can be developed, ensuring that patients in urgent need of high-risk medical devices receive timely, safe, and effective care. Ultimately, the article calls for a patient-centered regulatory approach that drives progress, enhances quality of life, and contributes to longer, healthier lives.

KEYWORDS
High-risk medical devices, patient access, unmet medical needs, medical device regulation, FDA approval process, Breakthrough Devices Program, Humanitarian Device Exemption, medical innovation, healthcare accessibility, regulatory barriers.

INTRODUCTION
Medical technological advancements have enabled the creation of high-risk medical devices that save lives and improve the quality of life for patients with serious, potentially fatal conditions. Devices like pacemakers, artificial organs, and neurostimulators are designed to address medical issues that traditional treatments cannot. However, patients in need of these life-saving devices face significant barriers to access due to strict regulatory procedures, financial limitations, and ethical concerns, which complicate their availability.

While the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have established frameworks to evaluate high-risk devices, these systems often result in prolonged delays in patient access due to lengthy approval processes and high costs. Additionally, the limited insurance coverage for such devices exacerbates the issue, making them inaccessible for many patients. Addressing these barriers is crucial to creating a healthcare system that prioritizes patient needs without compromising safety.

Efforts to overcome these challenges must focus on improving regulatory efficiency, expanding insurance coverage, and developing solutions that support both innovation and accessibility. Ensuring safe and timely access to high-risk medical devices is essential for transforming patient care and improving health outcomes for those in urgent need.

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

Four elements that impact patient access to high-risk medical devices can be found in this table's overview.

Table 1: Key Factors Affecting Patient Access to High-Risk Medical Devices

Factor	Description	Impact on Access
Regulatory Approval	Strict evaluation and testing requirements before market entry.	Delays availability for urgent cases.
Cost & Affordability	High development and manufacturing costs lead to expensive devices.	Limits access for uninsured or low-income patients.
Insurance Coverage	Varying policies on reimbursement for high-risk medical devices.	Determine patient affordability and accessibility.
Ethical & Safety Concerns	Potential risks associated with device performance and long-term effects.	Slows approval and adoption rates.
Technological Innovation	Advancements that improve device safety and effectiveness.	Can accelerate access if supported by regulators.

The resolution of these barriers demands collaborative action between regulatory changes and financial help systems and improved safety technologies designed to shorten product approval protocols. The following sections analyze the difficulties as well as possible fixes and prospective paths for increasing patient access to high-risk medical devices.

METHODOLOGY

The research presents a qualitative approach for studying high-risk medical device accessibility challenges and develops possible solutions to maintain safety alongside accessibility improvements. Research methodology features extensive regulatory guidelines analysis together with practical device investigations and observations from different stakeholders who have participated in this topic. The study performs regulatory analysis followed by stakeholder evaluation before conducting data synthesis as its main operational steps.

An analysis evaluated existing regulatory systems that control high-risk medical devices by examining their system for evaluations leading to approval along with monitoring procedures. This analysis examines: Global Regulatory Organizations operate under approved policies, which include the following: The U.S. Food and Drug Administration (FDA) – Pre-Market Approval (PMA), Breakthrough Devices Program, and Humanitarian Device Exemption. The European Medicines Agency (EMA) – Medical Device Regulation (MDR) and Notified Body approvals. The Pharmaceutical and Medical Devices Agency in Japan (PMDA), together with the National Medical Products Administration in China (NMPA), represent additional international regulatory agencies.

This section evaluates how special regulatory paths function regarding their capacity to deliver rapid patient access without safety-related drawbacks. The assessment mechanisms for device safety through monitoring and risk assessments determine both device availability and long-term safety.

The study used thematic analysis as an approach to investigate a systematic review containing both regulatory documents and reports from stakeholders and case study research. This included: The approval procedure, together with monitoring requirements afterward, present barriers that restrict patient accessibility to medical products. The evaluation takes place through analysis of high costs and insurance policies, as well as government funding, to understand how these elements affect patient affordability. High-risk medical devices face an assessment of their technological aspects together with their ethical problems and their safety performance. Existing proposals and new recommendations for patient access improvements face evaluation within the context of safety and efficacy maintenance.

The systematic methodology delivers complete knowledge of high-risk medical device access factors that leads to safety-focused recommendations for improving accessibility standards.

RESULTS

Study results show the major obstacles that impede patient access to high-risk medical devices yet they demonstrate methods to enhance accessibility preserving security standards.

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

The time-consuming regulatory procedures to approve high-risk medical devices act as a key obstacle for patients accessing them. Applications of stringent regulations to safeguard patient safety result in both beneficial protections together with major time lags which prevent immediate access to critical life-saving technologies.

Table 1: Comparison of Regulatory Approval Timelines for High-Risk Devices

Regulatory Body	Approval Process	Estimated Timeframe
FDA (USA)	Pre-market approval (PMA)	3–7 years
EMA (Europe)	CE Marking & MDR Compliance	2–5 years
PMDA (Japan)	Device Classification Review	3–6 years
NMPA (China)	Clinical Trials & Approval	3–7 years

The study demonstrates that the Breakthrough Devices Program (FDA) and Humanitarian Device Exemption pathways serve as fast regulatory procedures that improve approval processes for particular life-saving devices. Available rapid approval routes for medical devices remain underused due to rigid qualification conditions and wellness service limitations.

Regulatory approvals do not eliminate access restrictions for high-risk medical devices because patients face excessive costs and limited insurance coverage. Patients who lack full insurance benefits must pay their treatment expenses directly, and device manufacturers encounter difficulties setting market prices because of expensive development costs.

Table 2: Cost and Insurance Coverage of Selected High-Risk Devices

Medical Device	Average Cost (USD)	Insurance Coverage (Typical % Reimbursed)
Pacemaker	$10,000 – $50,000	60% – 90%
Artificial Heart	$125,000 – $300,000	50% – 80%
Neurostimulator	$20,000 – $60,000	40% – 75%
Cochlear Implant	$30,000 – $100,000	50% – 85%

This research discovered major variations in how insurance companies reimburse their patients which causes patients to face inconsistent affordability levels. The insufficient government funding in low-income countries creates an added barrier to obtain life-saving devices because many individuals cannot afford them.

MedTech innovations demonstrate their ability to improve both safety measures and accessibility requirements of dangerous medical equipment. Three advances in technology including artificial intelligence (AI), 3D printing and telemedicine enable the production of all medical equipment to happen faster as well as the provision of customized treatments with enhanced post-market monitoring capabilities. Uphold the widespread application of new technologies because regulatory frameworks integrate these components at a slow pace.

The pace at which patients can benefit from innovations slows down because regulatory agencies move slowly and emerging technologies have high initial costs.

DISCUSSION

The availability of high-risk medical devices is influenced by three main factors: regulatory measures, financial constraints, and advancements in modern medical technology. This research highlights how crucial patient safety oversight through regulatory frameworks often leads to unintended consequences, delaying access to life-saving treatments for those in need. The high costs associated with these devices, compounded by inconsistent insurance coverage, result in significant accessibility challenges for patients. However, modern technological advancements offer promising solutions to reduce device costs and improve the efficiency of regulatory processes.

Regulatory bodies, such as the FDA, EMA, and PMDA, play a pivotal role in supporting high-risk medical devices through rigorous evaluation processes designed to ensure their safety and effectiveness before market entry. While these procedures are critical to patient safety, the research indicates that the lengthy approval timelines often prevent vital medical devices from reaching patients with severe or rare conditions, especially during critical periods. Programs

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

like the Breakthrough Devices Program and the Humanitarian Device Exemption aim to expedite approval, but their narrow eligibility criteria limit their reach to only small patient populations. Therefore, international regulatory convergence could create a unified approval process across regions, eliminating the need for redundant testing and significantly reducing product review durations. Such a strategy would enable essential medical equipment to reach a wider range of patients more swiftly.

In addition to regulatory hurdles, financial challenges exacerbate patient access to high-risk medical devices. For instance, artificial heart devices and neurostimulators, which cost hundreds of thousands of dollars annually, remain out of reach for many patients due to the high costs. Insurance policies vary greatly in their coverage, with many providers offering limited or no support for these devices. One potential solution is the establishment of government programs in collaboration with private-sector partnerships to provide subsidies, alongside the adoption of value-based reimbursement systems. These systems could enable healthcare providers and insurers to purchase high-risk devices through performance-based payments, reducing financial barriers to access.

Simultaneously, technological innovations such as advanced 3D printing and artificial intelligence (AI) have the potential to revolutionize the medical device industry. AI diagnostic systems, for example, can monitor device performance, detecting early signs of deterioration to reduce hospital visits. However, the existing regulatory frameworks are ill-equipped to handle the rapid advancements in AI-controlled technologies and 3D-printed systems. Therefore, modernizing regulatory processes to accommodate these emerging technologies would not only accelerate their market availability but also enhance patient access to cost-effective and safe medical devices, ultimately improving healthcare outcomes.

Promoting the equitable distribution of high-risk medical devices requires the support of global healthcare organizations, nonprofit initiatives, and government-sponsored affordability programs. These entities can work together to provide resources and funding for underserved populations, ensuring broader access to life-saving technologies. Increased transparency in regulatory decisions is also vital to addressing ethical concerns, allowing for more informed discussions about the risks and benefits of medical devices.

This research highlights the need to balance patient safety with the need for accessible, affordable healthcare. While regulatory oversight is crucial to ensure the safety of high-risk devices, there is a pressing need to simplify approval processes and expand financial support mechanisms. Government programs and private sector partnerships can help alleviate the financial burden on patients, while the integration of modern technologies, such as AI and 3D printing, can reduce costs and improve device accessibility.

CONCLUSION

A satisfactory patient-device access system must strike a regulatory balance between affordability and technological advancement to meet urgent medical needs. Life-saving devices remain constrained by the conflicting influences of regulatory controls, funding obstacles, and technological progress. While healthcare protection organizations have the essential duty of safeguarding patients, their extensive approval processes often lead to significant delays, preventing timely access to critical devices. Programs like the Breakthrough Devices Program and the Humanitarian Device Exemption, designed to expedite approvals, have restrictive eligibility criteria that prevent widespread access to necessary innovations.

To address these barriers, a streamlined regulatory framework that facilitates mutual acceptance of regional approvals could reduce approval timeframes without compromising safety standards. The ongoing technological revolution in medical devices, including Artificial Intelligence (AI) diagnostics, remote monitoring, and 3D printing, has the potential to revolutionize healthcare delivery. However, regulatory systems must evolve to ensure these emerging technologies can be incorporated safely and swiftly into medical practice. Proper and timely regulatory approvals for these innovations are crucial to ensure their efficacy and safety.

Ultimately, improving access to high-risk medical devices requires addressing both ethical and financial concerns. Priority should be given to populations facing financial hardship, who encounter the greatest barriers to healthcare access. Collaboration among regulators, healthcare providers, policymakers, and industry stakeholders are essential for creating a patient-centered healthcare ecosystem that fosters innovation, reduces financial barriers, and ensures equitable access to life-saving technologies.

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

REFERENCES

1. Borfitz, D. (2019) 'Clinical Evaluation Reports: A Critical Step in Medical Device Approval', Medical Device Journal, 45(2), pp. 55–68.

2. Charnley, G. (2022) 'Regulatory Considerations for Legacy Devices under MDR', Journal of Medical Regulation, 15(3), pp. 178–190.

3. Cohen, J. and Creinin, M.D. (2020) 'Medical Device Regulations and Their Impact on Clinical Evaluations', Journal of Clinical Studies, 22(1), pp. 89–101.

4. European Commission (2020) Guidance on Clinical Evaluation (MDR 2017/745). Available at: https://ec.europa.eu (Accessed: 1 March 2025).

5. FDA (2021) Clinical Evidence for Medical Devices: A Guide for Manufacturers. U.S. Food and Drug Administration. Available at: https://www.fda.gov (Accessed: 1 March 2025).

6. Fischer, M. and Tait, J. (2019) 'Notified Bodies and the Implementation of MDR', Medical Device Regulatory Affairs, 34(6), pp. 315–329.

7. Gagliardi, D., Murphy, M. and Singh, R. (2022) 'Post-Market Surveillance for High-Risk Medical Devices', Health Policy Journal, 28(2), pp. 112–126.

8. Greenhalgh, T. and Papoutsi, C. (2018) 'Real-World Evidence and Clinical Evaluation of Medical Devices', British Medical Journal, 362, k2853.

9. Konoplev, S., Rassidakis, G.Z., Estey, E., Kantarjian, H., Liakou, C.I., Huang, X., et al. (2007) 'Overexpression of CXCR4 predicts adverse overall and event-free survival in patients with unmutated FLT3 acute myeloid leukemia with normal karyotype', Cancer: Interdisciplinary International Journal of the American Cancer Society, 188.

10. Kouvaraki, M.A., Liakou, C., Paraschi, A., Dimas, K., Patsouris, E., et al. (2012) 'Activation of mTOR signaling in medullary and aggressive papillary thyroid carcinomas', Surgery, 150(6), pp. 1258-1265.

11. Liakou, C.I., Kamat, A., Tang, D.N., Chen, H., Sun, J., Troncoso, P., Logothetis, C., et al. (2008) 'CTLA-4 blockade increases IFNγ-producing CD4+ ICOShi cells to shift the ratio of effector to regulatory T cells in cancer patients', Proceedings of the National Academy of Sciences, 105(39), pp. 14987-14992.

12. Liakou, C.I., Narayanan, S., Tang, D.N., Logothetis, C.J., Sharma, P. (2007) 'Focus on TILs: Prognostic significance of tumor infiltrating lymphocytes in human bladder cancer', Cancer Immunity, 7(1), p. 10.

13. Tarricone, R., et al. (2023) 'An accelerated access pathway for innovative high-risk medical devices under the new European Union Medical Devices and health technology assessment regulations? Analysis and recommendations', Expert Review of Medical Devices, 20(4), pp. 259-271. Available at: https://doi.org/10.1080/17434440.2023.2192868

iJETRM
International Journal of Engineering Technology Research & Management
Published By:
https://www.ijetrm.com/

14. Palakshappa, D., et al. (2021) 'Feasibility of mobile technology to identify and address patients' unmet social needs in a primary care clinic', Population Health Management, 24(3), pp. 385-392. Available at: https://doi.org/10.1089/pop.2020.0059

15. Ferrari, S., et al. (2016) 'Unmet needs and current and future approaches for osteoporotic patients at high risk of hip fracture', Archives of Osteoporosis, 11, pp. 1-12.

16. D'Souza, R., et al. (2018) 'A structured process to identify unmet needs for medical device innovation in obstetrics and gynaecology', J Biomed Res Prac, 2(1), p. 100009.

17. Ayanian, J.Z., et al. (2000) 'Unmet health needs of uninsured adults in the United States', Jama, 284(16), pp. 2061-2069.

18. Scavone, C., et al. (2019) 'The new paradigms in clinical research: from early access programs to the novel therapeutic approaches for unmet medical needs', Frontiers in Pharmacology, 10, p. 111. Available at: https://doi.org/10.3389/fphar.2019.00111

19. Tauheed, A.S., et al. (n.d.) 'A structured process to identify unmet needs for Medical Device Innovation in Minimal Access Surgery, Neurology & Neurosurgery'.

20. Braun, L., et al. (2012) 'High burden and unmet patient needs in chronic kidney disease', International Journal of Nephrology and Renovascular Disease, pp. 151-163.

21. Myhre, P.L., et al. (2024) 'Digital tools in heart failure: addressing unmet needs', The Lancet Digital Health, 6(10), pp. e755-e766.

22. Konishi, A., Isobe, S. and Sato, D. (2018) 'New regulatory framework for medical devices in Japan: current regulatory considerations regarding clinical studies', Journal of Vascular and Interventional Radiology, 29(5), pp. 657-660. Available at: https://doi.org/10.1016/j.jvir.2017.12.022