CHALLENGES AND OPPORTUNITIES OF VALUE-BASED HEALTHCARE IN THE MEDICAL DEVICE INDUSTRY

By: Madhu Kiran PM/2023/408, Muskan Goel PM/2023/422

Guided By: Dr. B. Lakshmi, SaiKishore V

Department of Pharmaceutical Management, National Institute of Pharmaceutical Education and Research (NIPER) – Hyderabad

ABSTRACT

The medical device industry stands at the nexus of technological innovation, healthcare advancements, regulatory landscapes, and market dynamics. This review article systematically explores the multifaceted challenges and burgeoning opportunities shaping this pivotal sector. The ever-evolving landscape of technological innovations continues to revolutionize medical devices, propelling the industry forward. However, the exponential growth of sophisticated technologies introduces challenges in regulatory compliance, cybersecurity, interoperability, and ethical considerations. Balancing innovation with stringent regulatory frameworks and ensuring patient safety remains a paramount challenge.

Moreover, the globalization of markets presents both opportunities and challenges. Increased market access offers potential growth, but it also intensifies competition, necessitating adaptation to diverse regulatory environments and varying healthcare infrastructures across regions. This review delves into the intricacies of challenges associated with intellectual property rights, cost containment, and reimbursement models, which significantly impact market penetration and profitability. Additionally, the escalating demand for personalized and connected healthcare further complicates the landscape, demanding adaptive strategies and novel business models.

Notwithstanding these challenges, the medical device industry is ripe with opportunities. Emerging markets, technological convergence (such as AI, IoT, and 3D printing), and the paradigm shift toward value-based care offer avenues for growth and market expansion. Collaborations between industry players, healthcare providers, and regulatory bodies pave the way for innovation and addressing unmet clinical needs. This article synthesizes current literature, industry reports, and regulatory insights to comprehensively understand the complexities, hurdles, and potential pathways for growth in the medical device industry. It highlights the imperative for strategic foresight, adaptability, and innovation in navigating the intricate landscape, thereby fostering sustainable growth and improved patient outcomes.

Keywords *Medical Device Industry, Challenges, Opportunities, Healthcare Technology, Regulatory Compliance, Innovation, value-based healthcare, Market Trends, Research and Development, Quality Control, Global Market*

Introduction

In the pursuit of enhanced performance and accountability in healthcare, identifying shared goals is crucial, with achieving high value for patients recognized as the overarching objective. Despite its conceptual clarity, the measurement and understanding of value in healthcare have been largely uncharted territories, prompting the

development of various frameworks and guidance to assess and prioritize value, aligning diverse stakeholder interests for more informed decision-making and resource allocation **(Boscolo et al., 2020).** As healthcare systems shift towards "value-based healthcare" (VBHC) to enhance care quality, performance, and resource sustainability, understanding the impact on healthcare professionals, their contributions, experienced job demands, resources, and overall well-being remains fragmented. This systematic review aims to consolidate existing evidence, exploring the reciprocal relationship between VBHC and healthcare professionals **(van Engen et al., 2022).** The medical device industry operates within a framework of intricate regulatory requirements, demanding a delicate balance between innovation and compliance. A comprehensive understanding of these regulatory dynamics is essential for the industry to thrive in an era where technological advancements outpace regulatory frameworks **(Wagan et al., 2022)**.

The medical device industry faces the ongoing challenge of balancing the imperative for innovation with economic constraints. Navigating cost-effectiveness while delivering high-quality patient outcomes demands strategic foresight amid economic uncertainties **(Retraction: New Opportunities, 2023)**. The shift to value-based healthcare compels the medical device industry to redefine innovation with a strong emphasis on measurable patient outcomes. This provides fertile ground for the development of devices that not only meet clinical needs but also contribute substantively to improved health outcomes **(Burke et al., 2019)**. The integration of data analytics and advanced technologies opens avenues for enhanced decision-making in healthcare delivery. By harnessing real-time data from medical devices, stakeholders can make informed decisions, thereby optimizing care and improving patient outcomes **(Batko & Slezak, 2022).**

Value-based healthcare

Value-based healthcare has been implemented to tackle many health system issues, like as rising costs and variations in quality of life. Research indicated that value-based purchasing in hospitals can result in improved patient outcomes and increased cost-effectiveness. It also helps to create innovations. Value-based procurement needs continuous collaboration among stakeholders **(Rahm, n.d.).**

Achieving high value for patients—defined as the health outcomes attained per dollar spent—must become the primary objective of the delivery of health care. This objective aligns with the interests of all system participants and is what matters for patients. Value improvement can benefit patients, payers, providers, and suppliers while bolstering the healthcare system's financial viability **(Porter, 2010).**

Higher ages are associated with a higher incidence of numerous diseases, or comorbidity. Because of this, the need for care puts more strain on social care and health systems. The issue of investments in the medical device industry as a component of health care becomes increasingly important in light of this growth medical gadgets play a crucial role in disease diagnosis, prevention, monitoring, therapy, and quality of life enhancement for individuals with health issues **(European Committee n.d. (EC).**The flexibility and inventiveness of this sector greatly enhance the effectiveness and caliber of medical care. This article's primary goal is to examine and describe the state of the medical device sector at the moment, as well as any prospective advantages or disadvantages, in light of recent changes in the economy and population **(Maresova et al., 2015)**.

Medical Device Industry

Medical devices encompass a broad category of instruments, apparatus, implements, machines, contrivances, implants, in vitro reagents, or analogous articles. These devices are designed and intended for use in diagnosing diseases and medical conditions. Medical device development entails lengthy lead times to market, high upfront costs, financial risk, and complexity **(Moultrie et al., 2015).**

Although there are few and dispersed domestic studies on the Medical Device Industry (MDI), it plays a unique role in the nation's economy and health **(Gholi Motlagh et al., 2022).**

The medical device industry in Asia has shown a consistent growth trajectory, with estimates indicating that it will reach $88.6 billion by 2020 from 67.5 billion in 2016. For the majority of the 2018–2023 period, this Asian market segment had a CAGR (composite annual growth rate) of 12.9% **(Jakovljevic et al., 2021).**

Despite the rapid rate of innovation, investment to develop new products is large and the environmental impact of devices is substantial. However, it is evident that the medical device industry is increasingly concerned about the environmental impact of their products and processes, as these are significant. For example, approximately 90% of medical device waste consists of either disposable or one-time-use products/components **(Moultrie et al., 2016).**

Usually, the idea for a medical condition is conceived by a doctor or bioengineer before an altogether new technology is developed. They construct the gadget or arrange for it to be constructed, and at the same time, they start the patent application procedure **(Brown et al., 2004)**. Animal testing comes after preliminary bench testing, and then the device goes through a testing and redesign cycle that usually lasts two to three years and costs between $10 million and $20 million. Today, rather than coming from university medical centers, the majority of genuinely innovative medical devices come from venture-backed startup firms, mostly due to these expenses **(Kaplan et al., 2004).**

Challenges For Medical Devices Industry

Significant advancements in medical technology in recent decades have allowed people to live longer, healthier lives and have contributed to earlier and more accurate diagnoses as well as more successful treatments. However, these advancements are not free; rather, new technology is the main source of the sharp increase in health care costs. Consequently, in clinical practice, a thorough assessment of medications, supplies, equipment, and even discharge criteria is becoming more and more important **(Lee Ventola, 2008).**

Since medical device software and SaMDs (Software as Medical Devices) are now recognized as "active medical devices," medical device laws have attempted to keep up with advancements in digital healthcare. But these legislative changes are also thought to be inadequate to address the issues with algorithmic integrity, data quality, and cybersecurity brought up by CIMDs (connected, intelligent medical devices) **(Brass & Mkwashi, 2022)**.

When medical devices first enter the market, there is frequently not much data to support an economic assessment. As a result, when assessing a new technology, one must strike a compromise between the timeliness of an economic review and the availability of data (and its quality) **(Kirisits & Redekop, 2013).**

Due to iterative developments, MDs often have a shorter lifespan than medication therapy. Additionally, the ability to circumvent patient safeguards frequently renders older generations of devices useless. The assessment of MDs at market debut typically depends on scant data to gauge their safety, efficacy, effectiveness, and value for money, which is a direct result of a shorter product lifespan. The necessary maintenance, the possibility of individual part instability that might affect the device's overall function, and potential dependencies on or interferences with other devices are further aspects of the medical device's lifetime **(Polisena et al., 2018)**.

Unlike pharmaceuticals, the approval to sell MDs may depend on factors other than the assessment of safety and effectiveness information from randomized clinical studies. For devices that the authorities have classified as high-risk, makers are obligated to conduct clinical trials on human subjects; however, there are no set standards for sample size, design, or duration of follow-up **(Sorenson et al., 2011)**.

While it's a good idea to streamline the medication and device approval process, it will always be difficult to do so without jeopardizing the FDA's capacity to guarantee the efficacy and safety of new products for patients **(Norman, 2016)**.

Technological Innovations

The progress in technology over the years has made it possible to use smaller devices, such as smartwatches, for health monitoring and illness detection. In addition, technology has made healthcare less hospital-centric and more patient-centric. For instance, a number of clinical tests (including blood pressure, blood glucose, pO2, level, and so on) may be completed at home without the assistance of a medical expert **(Yang et al., 2014).**

Healthcare apps employ sensors—either wearable or incorporated into the human body—to gather physiological data from patients' bodies, including temperature, blood pressure (ECG), electroencephalogram (EEG), and so on **(Pradhan et al., 2021)**.

By facilitating early diagnosis and management, as well as overseeing patients' treatment and rehabilitation, cloud-based telemedicine platforms, smart wearables, and remote health monitoring systems can all greatly reduce the risk of disease **(Papa et al., 2020).**

Biochemical sensors can measure body fluid electrolytes with the use of electrochemical transducers, offering valuable information about plasma volume status and analyte concentrations while biomechanical sensors incorporated into clothing or shoes, such as ballistocardiograms, seismocardiograms, and dielectric sensors, have been developed in an attempt to passively and continuously measure variables such as cardiac output, lung fluid volume and weight, which could be beneficial in managing conditions **(Bayoumy et al., 2021).**

Opportunities of the Medical Device Industry

There are many chances for innovation and success in the quickly expanding and changing medical device sector. Among the principal opportunities are:

Aging populations are driving up demand: It is anticipated that demand for medical gadgets will rise sharply as people age globally. This is because chronic diseases are more common and require more advanced medical equipment to identify and cure **(McEvoy & Rowan, 2019).**

Spending on healthcare is rising: By 2025, it is expected that global healthcare spending will total $12 trillion, which will further propel the growth of the medical device sector **(Kelly & Mcdermid, n.d.).**

Technical developments: Technological progress at a rapid pace is opening up new avenues for the creation of novel and more efficient medical equipment. Artificial intelligence (AI) and machine learning, for instance **(Lee & Lee, 2021)**.

Growing demand for healthcare: The global population is aging and the prevalence of chronic diseases is increasing, both of which are driving demand for healthcare services and medical devices **(Von Walterskirchen, n.d.)**.

Development of more personalized and targeted medical devices: This includes devices that are tailored to the individual needs of patients, such as 3D-printed implants and gene therapies **(Janssens et al., 2019).**

Regulatory Policies Of the Medical Device Industry

One of the global industries with the highest levels of regulation is the medical device sector. This is due to the fact that medical gadgets can significantly affect a patient's health and well-being and are used to diagnose, cure, and prevent diseases. Medical device safety and efficacy are guaranteed by regulatory policies **Jeffersons (n.d.).**

Classification: Depending on their level of risk, medical gadgets are usually divided into several groups. High-risk devices might need premarket approval and clinical studies, while low-risk devices might just need basic testing and registration.

Controls over design and manufacture: To guarantee that their devices are created and produced in accordance with safety and efficacy requirements, manufacturers need to have a quality management system in place **(Konishi et al., 2018).**

The regulatory policies for medical devices are constantly evolving to keep up with new technologies and the changing needs of patients. For example, the US Food and Drug

Administration (FDA) recently implemented new regulations for medical device software and cybersecurity **(Jefferys, n.d.).**

Regulatory policies play an important role in protecting patients from unsafe and ineffective medical devices. However, they can also add cost and complexity to the development and commercialization of new devices. It is important to strike a balance between protecting patients and promoting innovation **(Kelly & Mcdermid, n.d.).**

Methodology

The literature search was limited to articles published from 2004 - 2023. The search for articles was done online by using the search words ‘‘Medical Device Industry, Challenges, Opportunities, Healthcare Technology, Regulatory Compliance, Innovation, value-based healthcare, Market Trends’’ in the title and keywords in research databases at Wiley, Elsevier, Taylor & Francis, ERIC, Springer, SAGE, Frontiers.

Analysis

The method used is the Preferred Reporting Item for Systemic Reviews and Meta Analytics (PRISMA) method. All articles that have passed the selection process were then reviewed and summarised based on the objectives, year of publication, number of citations, and suggestions for further research.

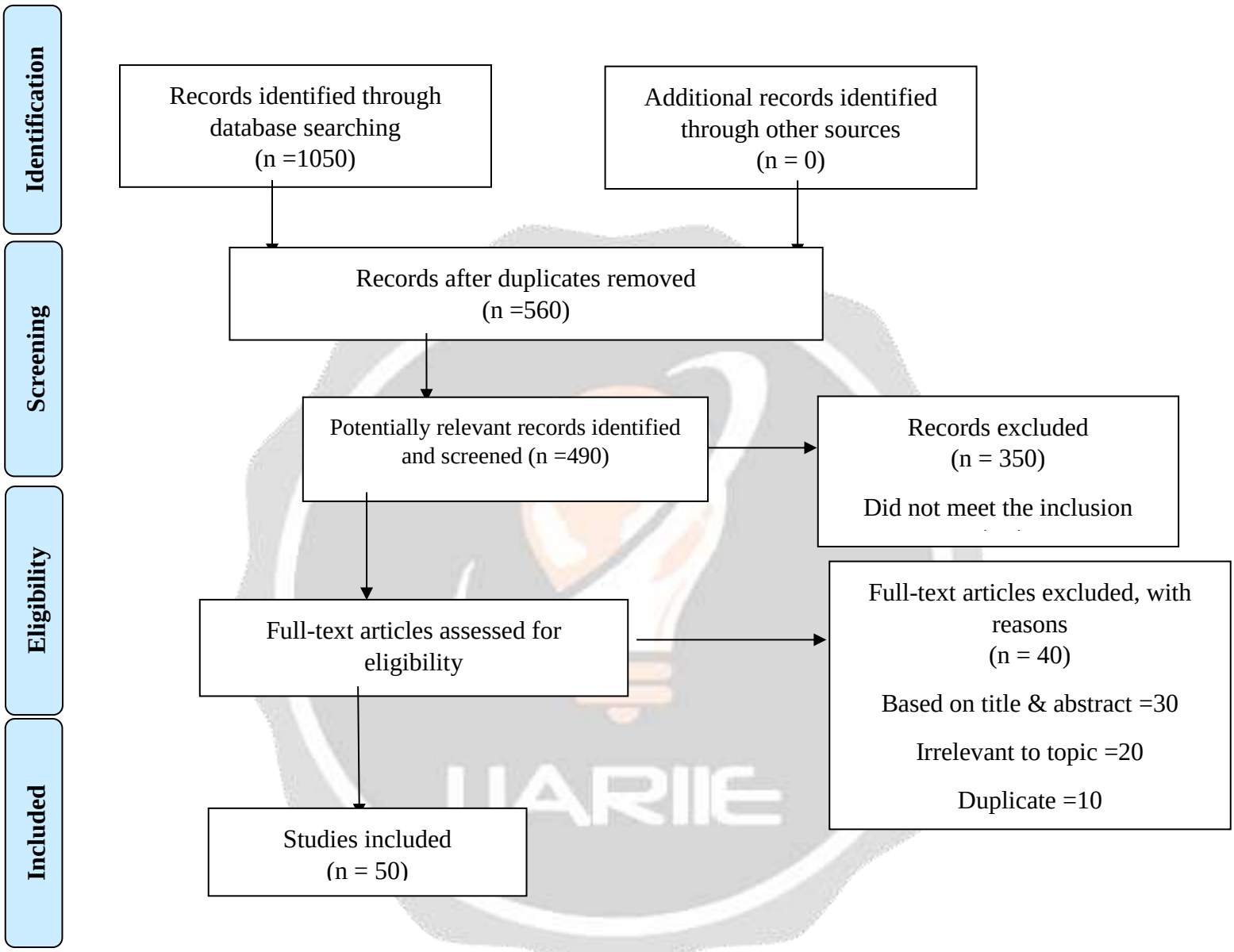
Inclusion & Exclusion criteria

Studies must fulfill certain requirements in order to be included in the present research:

(a) Studies have included some kind of selection criteria (Medical Device Industry, Challenges, Opportunities, Healthcare Technology, Regulatory Compliance, Innovation, Value-Based Healthcare). These criteria limited the number of studies

(b) Accordingly excluded the studies in which it based on irrelevant information there is no proper Title, Abstract,

PRISMA Flow Diagram



DISCUSSION

Navigating the landscape of value-based healthcare (VBHC) within the medical device industry presents a complex tapestry of challenges and opportunities that demand nuanced exploration. At its core, the adoption of VBHC represents a fundamental shift in healthcare delivery, placing paramount importance on patient outcomes while optimizing resource utilization. However, the industry encounters formidable challenges. Regulatory intricacies pose a significant hurdle, demanding a delicate balance between innovation and compliance to ensure the safety and efficacy of medical devices. Interoperability barriers impede seamless integration into healthcare ecosystems, hindering the holistic approach essential for VBHC success. Economic pressures add another layer of complexity, requiring the industry to innovate while managing costs effectively. Despite these challenges, opportunities abound.

Embracing patient-centric innovation allows for the development of devices that not only meet clinical needs but substantially enhance overall care quality. Leveraging data analytics and predictive technologies holds promise in optimizing care delivery and resource allocation. Collaborative ecosystems fostered through partnerships among stakeholders pave the way for cohesive healthcare solutions. As the industry navigates these challenges, strategic approaches to overcome regulatory barriers, address interoperability issues, and balance innovation with economic constraints will define its pivotal role in driving the realization of VBHC's ultimate goal—enhancing patient outcomes while ensuring sustainable healthcare practices.

CONCLUSION

The medical device industry is a dynamic and ever-evolving sector that plays a crucial role in improving patient care and outcomes. While the industry faces several challenges, it also presents significant opportunities for growth and innovation. By addressing the challenges related to regulatory requirements, supply chain disruptions, cybersecurity threats, and reimbursement models, medical device companies can capitalize on the opportunities offered by technological advancements, aging populations, and increasing demand for personalized healthcare. The future of the medical device industry is bright, and companies that can adapt to the changing landscape will be well-positioned for success.

The medical device industry faces a complex regulatory environment that can hinder innovation and product development. Supply chain disruptions have caused shortages and increased costs for medical devices. Cybersecurity threats are a growing concern as medical devices become increasingly interconnected. Reimbursement models are becoming more complex and challenging for medical device companies. Technological advancements offer opportunities for developing new and innovative medical devices. An aging population is driving demand for medical devices that address chronic conditions. Increasing demand for personalized healthcare creates opportunities for tailored medical devices.

Medical device companies should prioritize collaboration with regulatory agencies to streamline the approval process. Diversifying supply chains and investing in manufacturing capabilities can mitigate supply chain disruptions. Implementing robust cybersecurity measures and adopting industry best practices can protect medical devices from cyberattacks. Engaging with healthcare providers and payers can help ensure that medical devices are reimbursed fairly. Investing in research and development can lead to the creation of groundbreaking medical devices. Developing devices that address specific patient needs can capture a growing market share. The medical device industry is poised for continued growth and innovation in the years to come. By addressing the challenges and seizing the opportunities, medical device companies can make a significant impact on the lives of patients worldwide.

References

Batko, K., & Ślęzak, A. (2022). The use of Big Data Analytics in healthcare. *Journal of Big Data*, *9*(1). https://doi.org/10.1186/s40537-021-00553-4

Bayoumy, K., Gaber, M., Elshafeey, A., Mhaimeed, O., Dineen, E. H., Marvel, F. A., Martin, S. S., Muse, E. D., Turakhia, M. P., Tarakji, K. G., & Elshazly, M. B. (2021). Smart wearable devices in cardiovascular care: where we are and how to move forward. In *Nature Reviews Cardiology* (Vol. 18, Issue 8, pp. 581–599). Nature Research. https://doi.org/10.1038/s41569-021-00522-7

Boscolo, P. R., Callea, G., Ciani, O., & Tarricone, R. (2020). Measuring Value in Health Care: A Comparative Analysis of Value-based Frameworks. In *Clinical Therapeutics* (Vol. 42, Issue 1, pp. 34–43). Excerpta Medica Inc. https://doi.org/10.1016/j.clinthera.2019.11.017

Brass, I., & Mkwashi, A. (2022). Risk Assessment and Classification of Medical Device Software for the Internet of Medical Things Challenges arising from connected, intelligent medical devices. *ACM International Conference Proceeding Series*, 171–178. https://doi.org/10.1145/3567445.3571104

Brown, S. L., Bright, R. A., & Tavris, D. S. (2004). Medical device epidemiology and surveillance: Patient safety is the bottom line. In *Expert Review of Medical Devices* (Vol. 1, Issue 1, pp. 1–2). Future Drugs Ltd. https://doi.org/10.1586/17434440.1.1.1

Burke, M. D., Keeney, M., Kleinberg, R., & Burlage, R. (2019). Challenges and Opportunities for Patient Centric Drug Product Design: Industry Perspectives. In *Pharmaceutical Research* (Vol. 36, Issue 6). Springer New York LLC. https://doi.org/10.1007/s11095-019-2616-5

DEFINING VALUE IN "VALUE-BASED HEALTHCARE" Expert Panel on effective ways of investing in Health (EXPH). (n.d.). https://doi.org/10.2875/872343

Gholi Motlagh, M., Ghasemi, H., Mohammad Hosseini, B., Masaeli, R., Fazli, S., & Author Publisher, T. (2022). Future Scenarios of Industry (Case Study: Iran Medical Device Industry). *Semiannual Journal of Iran Futures Studies*, *6*(2), 79–109. https://doi.org/10.30479/jfs.2022.16157.1331

Jakovljevic, M., Wu, W., Merrick, J., Cerda, A., Varjacic, M., & Sugahara, T. (2021). Asian innovation in pharmaceutical and medical device industry–beyond tomorrow. In *Journal of Medical Economics* (Vol. 24, Issue S1, pp. 42–50). Taylor and Francis Ltd. https://doi.org/10.1080/13696998.2021.2013675

Janssens, R., Huys, I., Van Overbeeke, E., Whichello, C., Harding, S., Kübler, J., Juhaeri, J., Ciaglia, A., Simoens, S., Stevens, H., Smith, M., Levitan, B., Cleemput, I., De Bekker-Grob, E., & Veldwijk, J. (2019). Opportunities and challenges for the inclusion of patient preferences in the medical product life cycle: A systematic review. In *BMC Medical Informatics and Decision Making* (Vol. 19, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12911-019-0875-z

Jefferys, D. B. (n.d.). *The regulation of medical devices and the role of the Medical Devices Agency*.

Kaplan, A. V., Baim, D. S., Smith, J. J., Feigal, D. A., Simons, M., Jefferys, D., Fogarty, T. J., Kuntz, R. E., & Leon, M. B. (2004). Medical device development: from prototype to regulatory approval. In *Circulation* (Vol. 109, Issue 25, pp. 3068–3072). https://doi.org/10.1161/01.CIR.0000134695.65733.64

Kelly, T. P., & Mcdermid, J. A. (n.d.). *A systematic approach to safety case maintenance*. www.elsevier.com/locate/ress

Kirisits, A., & Redekop, W. K. (2013). The economic evaluation of medical devices: Challenges ahead. In *Applied Health Economics and Health Policy* (Vol. 11, Issue 1, pp. 15–26). https://doi.org/10.1007/s40258-012-0006-9

Konishi, A., Isobe, S., & Sato, D. (2018). New Regulatory Framework for Medical Devices in Japan: Current Regulatory Considerations Regarding Clinical Studies. In *Journal of Vascular and Interventional Radiology* (Vol. 29, Issue 5, pp. 657–660). Elsevier Inc. https://doi.org/10.1016/j.jvir.2017.12.022

Lee, S. M., & Lee, D. H. (2021). Opportunities and challenges for contactless healthcare services in the post-COVID-19 Era. *Technological Forecasting and Social Change*, *167*. https://doi.org/10.1016/j.techfore.2021.120712

Lee Ventola, C. (2008). *Challenges in Evaluating and Standardizing Medical Devices in Health Care Facilities* (Vol. 33, Issue 6).

Maresova, P., Penhaker, M., Selamat, A., & Kuca, K. (2015). The potential of medical device industry in technological and economical context. In *Therapeutics and Clinical Risk Management* (Vol. 11, pp. 1505–1514). Dove Medical Press Ltd. https://doi.org/10.2147/TCRM.S88574

McEvoy, B., & Rowan, N. J. (2019). Terminal sterilization of medical devices using vaporized hydrogen peroxide: a review of current methods and emerging opportunities. In *Journal of Applied Microbiology* (Vol. 127, Issue 5, pp. 1403–1420). John Wiley and Sons Inc. https://doi.org/10.1111/jam.14412

Moultrie, J., Sutcliffe, L., & Maier, A. (2015). Exploratory study of the state of environmentally conscious design in the medical device industry. *Journal of Cleaner Production*, *108*, 363–376. https://doi.org/10.1016/j.jclepro.2015.06.014

Moultrie, J., Sutcliffe, L., & Maier, A. (2016). A maturity grid assessment tool for environmentally conscious design in the medical device industry. *Journal of Cleaner Production*, *122*, 252–265. https://doi.org/10.1016/j.jclepro.2015.10.108

Norman, G. A. Van. (2016). TRANSLATIONAL TOOLBOX Drugs, Devices, and the FDA: Part 2 An Overview of Approval Processes: FDA Approval of Medical Devices. In *Basic Trans Science* (Vol. 1).

Papa, A., Mital, M., Pisano, P., & Del Giudice, M. (2020). E-health and wellbeing monitoring using smart healthcare devices: An empirical investigation. *Technological Forecasting and Social Change*, *153*. https://doi.org/10.1016/j.techfore.2018.02.018

Polisena, J., Castaldo, R., Ciani, O., Federici, C., Borsci, S., Ritrovato, M., Clark, D., & Pecchia, L. (2018). Health technology assessment methods guidelines for medical devices: How can we address the gaps? The International Federation of Medical and Biological Engineering perspective. In *International Journal of Technology Assessment in Health Care* (Vol. 34, Issue 3, pp. 276–289). Cambridge University Press. https://doi.org/10.1017/S0266462318000314

Porter, M. E. (2010). *What Is Value in Health Care?*

Pradhan, B., Bhattacharyya, S., & Pal, K. (2021). IoT-Based Applications in Healthcare Devices. In *Journal of Healthcare Engineering* (Vol. 2021). Hindawi Limited. https://doi.org/10.1155/2021/6632599

Rahm, K. (n.d.). *Rev Value-Ba*. https://doi.org/10.47176/m

Retraction: New Opportunities, Challenges, and Applications of Edge-AI for Connected Healthcare in Internet of Medical Things for Smart Cities (Journal of Healthcare Engineering (2022) 2022 (2950699) DOI: 10.1155/2022/2950699). (2023). In *Journal of Healthcare Engineering* (Vol. 2023). Hindawi Limited. https://doi.org/10.1155/2023/9823658

Sorenson, C., Tarricone, R., Siebert, M., & Drummond, M. (2011). Applying health economics for policy decision making: Do devices differ from drugs? *Europace*, *13*(SUPPL. 2). https://doi.org/10.1093/europace/eur089

van Engen, V., Bonfrer, I., Ahaus, K., & Buljac-Samardzic, M. (2022). Value-Based Healthcare From the Perspective of the Healthcare Professional: A Systematic Literature Review. In *Frontiers in Public Health* (Vol. 9). Frontiers Media S.A. https://doi.org/10.3389/fpubh.2021.800702

Von Walterskirchen, M. (n.d.). *The U.S. Market for Medical Devices-Opportunities and Challenges for Swiss Companies Chicago 2004*. www.swissbusinesshub.org

Wagan, S. A., Koo, J., Siddiqui, I. F., Attique, M., Shin, D. R., & Qureshi, N. M. F. (2022). Internet of medical things and trending converged technologies: A comprehensive review on real-time applications. In *Journal of King Saud University - Computer and Information Sciences* (Vol. 34, Issue 10, pp. 9228–9251). King Saud bin Abdulaziz University. https://doi.org/10.1016/j.jksuci.2022.09.005

Yang, G., Xie, L., Mäntysalo, M., Zhou, X., Pang, Z., Xu, L. Da, Kao-Walter, S., Chen, Q., & Zheng, L. R. (2014). A Health-IoT platform based on the integration of intelligent packaging, unobtrusive bio-sensor, and intelligent medicine box. *IEEE Transactions on Industrial Informatics*, *10*(4), 2180–2191. https://doi.org/10.1109/TII.2014.2307795

Batko, K., & Ślęzak, A. (2022). The use of Big Data Analytics in healthcare. *Journal of Big Data*, *9*(1). https://doi.org/10.1186/s40537-021-00553-4

Bayoumy, K., Gaber, M., Elshafeey, A., Mhaimeed, O., Dineen, E. H., Marvel, F. A., Martin, S. S., Muse, E. D., Turakhia, M. P., Tarakji, K. G., & Elshazly, M. B. (2021). Smart wearable devices in cardiovascular care: where we are and how to move forward. In *Nature Reviews Cardiology* (Vol. 18, Issue 8, pp. 581–599). Nature Research. https://doi.org/10.1038/s41569-021-00522-7

Boscolo, P. R., Callea, G., Ciani, O., & Tarricone, R. (2020). Measuring Value in Health Care: A Comparative Analysis of Value-based Frameworks. In *Clinical Therapeutics* (Vol. 42, Issue 1, pp. 34–43). Excerpta Medica Inc. https://doi.org/10.1016/j.clinthera.2019.11.017

Brass, I., & Mkwashi, A. (2022). Risk Assessment and Classification of Medical Device Software for the Internet of Medical Things Challenges arising from connected, intelligent medical devices. *ACM International Conference Proceeding Series*, 171–178. https://doi.org/10.1145/3567445.3571104

Brown, S. L., Bright, R. A., & Tavris, D. S. (2004). Medical device epidemiology and surveillance: Patient safety is the bottom line. In *Expert Review of Medical Devices* (Vol. 1, Issue 1, pp. 1–2). Future Drugs Ltd. https://doi.org/10.1586/17434440.1.1.1

Burke, M. D., Keeney, M., Kleinberg, R., & Burlage, R. (2019). Challenges and Opportunities for Patient Centric Drug Product Design: Industry Perspectives. In *Pharmaceutical Research* (Vol. 36, Issue 6). Springer New York LLC. https://doi.org/10.1007/s11095-019-2616-5

DEFINING VALUE IN "VALUE-BASED HEALTHCARE" Expert Panel on effective ways of investing in Health (EXPH). (n.d.). https://doi.org/10.2875/872343

Gholi Motlagh, M., Ghasemi, H., Mohammad Hosseini, B., Masaeli, R., Fazli, S., & Author Publisher, T. (2022). Future Scenarios of Industry (Case Study: Iran Medical Device Industry). *Semiannual Journal of Iran Futures Studies*, *6*(2), 79–109. https://doi.org/10.30479/jfs.2022.16157.1331

Jakovljevic, M., Wu, W., Merrick, J., Cerda, A., Varjacic, M., & Sugahara, T. (2021). Asian innovation in pharmaceutical and medical device industry–beyond tomorrow. In *Journal of Medical Economics* (Vol. 24, Issue S1, pp. 42–50). Taylor and Francis Ltd. https://doi.org/10.1080/13696998.2021.2013675

Janssens, R., Huys, I., Van Overbeeke, E., Whichello, C., Harding, S., Kübler, J., Juhaeri, J., Ciaglia, A., Simoens, S., Stevens, H., Smith, M., Levitan, B., Cleemput, I., De Bekker-Grob, E., & Veldwijk, J. (2019). Opportunities and challenges for the inclusion of patient preferences in the medical product life cycle: A systematic review. In *BMC Medical Informatics and Decision Making* (Vol. 19, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12911-019-0875-z

Jefferys, D. B. (n.d.). *The regulation of medical devices and the role of the Medical Devices Agency*.

Kaplan, A. V., Baim, D. S., Smith, J. J., Feigal, D. A., Simons, M., Jefferys, D., Fogarty, T. J., Kuntz, R. E., & Leon, M. B. (2004). Medical device development: from prototype to regulatory approval. In *Circulation* (Vol. 109, Issue 25, pp. 3068–3072). https://doi.org/10.1161/01.CIR.0000134695.65733.64

Kelly, T. P., & Mcdermid, J. A. (n.d.). *A systematic approach to safety case maintenance*. www.elsevier.com/locate/ress

Kirisits, A., & Redekop, W. K. (2013). The economic evaluation of medical devices: Challenges ahead. In *Applied Health Economics and Health Policy* (Vol. 11, Issue 1, pp. 15–26). https://doi.org/10.1007/s40258-012-0006-9

Konishi, A., Isobe, S., & Sato, D. (2018). New Regulatory Framework for Medical Devices in Japan: Current Regulatory Considerations Regarding Clinical Studies. In *Journal of Vascular and Interventional Radiology* (Vol. 29, Issue 5, pp. 657–660). Elsevier Inc. https://doi.org/10.1016/j.jvir.2017.12.022

Lee, S. M., & Lee, D. H. (2021). Opportunities and challenges for contactless healthcare services in the post-COVID-19 Era. *Technological Forecasting and Social Change*, *167*. https://doi.org/10.1016/j.techfore.2021.120712

Lee Ventola, C. (2008). *Challenges in Evaluating and Standardizing Medical Devices in Health Care Facilities* (Vol. 33, Issue 6).

Maresova, P., Penhaker, M., Selamat, A., & Kuca, K. (2015). The potential of medical device industry in technological and economical context. In *Therapeutics and Clinical Risk Management* (Vol. 11, pp. 1505–1514). Dove Medical Press Ltd. https://doi.org/10.2147/TCRM.S88574

McEvoy, B., & Rowan, N. J. (2019). Terminal sterilization of medical devices using vaporized hydrogen peroxide: a review of current methods and emerging opportunities. In *Journal of Applied Microbiology* (Vol. 127, Issue 5, pp. 1403–1420). John Wiley and Sons Inc. https://doi.org/10.1111/jam.14412

Moultrie, J., Sutcliffe, L., & Maier, A. (2015). Exploratory study of the state of environmentally conscious design in the medical device industry. *Journal of Cleaner Production*, *108*, 363–376. https://doi.org/10.1016/j.jclepro.2015.06.014

Moultrie, J., Sutcliffe, L., & Maier, A. (2016). A maturity grid assessment tool for environmentally conscious design in the medical device industry. *Journal of Cleaner Production*, *122*, 252–265. https://doi.org/10.1016/j.jclepro.2015.10.108

Norman, G. A. Van. (2016). TRANSLATIONAL TOOLBOX Drugs, Devices, and the FDA: Part 2 An Overview of Approval Processes: FDA Approval of Medical Devices. In *Basic Trans Science* (Vol. 1).

Papa, A., Mital, M., Pisano, P., & Del Giudice, M. (2020). E-health and wellbeing monitoring using smart healthcare devices: An empirical investigation. *Technological Forecasting and Social Change*, *153*. https://doi.org/10.1016/j.techfore.2018.02.018

Polisena, J., Castaldo, R., Ciani, O., Federici, C., Borsci, S., Ritrovato, M., Clark, D., & Pecchia, L. (2018). Health technology assessment methods guidelines for medical devices: How can we address the gaps? The International Federation of Medical and Biological Engineering perspective. In *International Journal of Technology Assessment in Health Care* (Vol. 34, Issue 3, pp. 276–289). Cambridge University Press. https://doi.org/10.1017/S0266462318000314

Porter, M. E. (2010). *What Is Value in Health Care?*

Pradhan, B., Bhattacharyya, S., & Pal, K. (2021). IoT-Based Applications in Healthcare Devices. In *Journal of Healthcare Engineering* (Vol. 2021). Hindawi Limited. https://doi.org/10.1155/2021/6632599

Rahm, K. (n.d.). *Rev Value-Ba*. https://doi.org/10.47176/m

Retraction: New Opportunities, Challenges, and Applications of Edge-AI for Connected Healthcare in Internet of Medical Things for Smart Cities (Journal of Healthcare Engineering (2022) 2022 (2950699) DOI: 10.1155/2022/2950699). (2023). In *Journal of Healthcare Engineering* (Vol. 2023). Hindawi Limited. https://doi.org/10.1155/2023/9823658

Sorenson, C., Tarricone, R., Siebert, M., & Drummond, M. (2011). Applying health economics for policy decision making: Do devices differ from drugs? *Europace*, *13*(SUPPL. 2). https://doi.org/10.1093/europace/eur089

van Engen, V., Bonfrer, I., Ahaus, K., & Buljac-Samardzic, M. (2022). Value-Based Healthcare From the Perspective of the Healthcare Professional: A Systematic Literature Review. In *Frontiers in Public Health* (Vol. 9). Frontiers Media S.A. https://doi.org/10.3389/fpubh.2021.800702

Von Walterskirchen, M. (n.d.). *The U.S. Market for Medical Devices-Opportunities and Challenges for Swiss Companies Chicago 2004*. www.swissbusinesshub.org

Wagan, S. A., Koo, J., Siddiqui, I. F., Attique, M., Shin, D. R., & Qureshi, N. M. F. (2022). Internet of medical things and trending converged technologies: A comprehensive review on real-time applications. In *Journal of King Saud University - Computer and Information Sciences* (Vol. 34, Issue 10, pp. 9228–9251). King Saud bin Abdulaziz University. https://doi.org/10.1016/j.jksuci.2022.09.005

Yang, G., Xie, L., Mäntysalo, M., Zhou, X., Pang, Z., Xu, L. Da, Kao-Walter, S., Chen, Q., & Zheng, L. R. (2014). A Health-IoT platform based on the integration of intelligent packaging, unobtrusive bio-sensor, and intelligent medicine box. *IEEE Transactions on Industrial Informatics*, *10*(4), 2180–2191. https://doi.org/10.1109/TII.2014.2307795