



Development Of Health Technology Methodologies: An Indepth Study Based On Medical Devices

1st Dong Yuqing , 2nd Noraisyah Binti Tajudin, 3rd Mohammad Nizamudin Inamdar

Abstract

Finding methods by which current medical technology may enhance healthcare delivery by enabling treatment that is more targeted, accurate, and efficient is the major objective of the project. It is imperative that the researcher incorporate these technologies into the researcher's operational and clinical processes if the researcher want to achieve improved outcomes for everyone in the healthcare system. The reason for this initiative is that, over the course of the next several years, the advancement of medical technology will continue to proceed at a tremendous speed. This study investigates a wide range of medical equipment, including diagnostic, monitoring, and therapeutic tools, to name just a few of the many distinct categories of medical apparatus. To evaluate the influence that various kinds of medical equipment have on the development and enhancement of health technology practices, the purpose of this study is to investigate the repercussions of the many effects that are created by these practices. It is important to consider how the technology may enhance patient care and clinical decision-making, as well as how simple it is to use and how effectively it handles the integration of data. It is the objective of this research project to assess medical devices based on three criteria: the degree to which they are able to expedite operations, the frequency with which they eliminate medical errors, and the degree to which they properly prescribe medicines. To do this, the researcher have relied on methods that are part of quantitative research. Within the scope of the researcher's investigation, the researcher used both qualitative and quantitative methods to accomplish this goal. They argue for improved interoperability, real-time monitoring, and individualised treatment; they also stress the strategic use of medical equipment. This approach is a significant advance in the field of health technology techniques.

Keywords: healthcare efficiency, medical equipment effectiveness, health information technology, healthcare system performance, patient treatment results.

1. Introduction

It is critical to assess the value of medical equipment before making decisions on coverage and adoption. Some have produced frameworks to assess medical treatments, while others have highlighted the challenges of applying such frameworks to medical equipment. Results cannot be extrapolated to the broader patient population due to the steep learning curves and frequent device updates linked with medical devices. It is difficult to make broad assumptions on the worth of any one technology due to the wide variety of devices available and the fact that many stakeholders will have different objectives. All relevant parties, including payers, hospital purchasing departments, gpos, senior management, structured value assessment committees, physicians, and patients, must be considered when medical device businesses make their products (viceconti et al., 2021). Reimbursement, product pricing, device use, market structure, technical specifications, and equipment quality are just a few of the many factors that influence the incentives for each of these categories. Hospital buying departments, value assessment committees, and large-scale buyers may take into account factors such as reimbursement payments, device pricing, and the total effect on operating and capital budgets. Also considered may be the device's complexity, the doctor's personal choice, and how it impacts patient results. Contrarily, hospital staff members often aren't the ones who decide which medical devices



patients use. By only visiting institutions that have already made an investment in a certain system, both patients and physicians may limit their ability to influence the matter. Information compiled by organisations devoted to health technology methodology is useful when deciding which medical devices to purchase. This study intends to establish the veracity of this claim by doing an extensive literature assessment. The major objective of the research was to learn how medical device companies may go about purchasing health technologies. Using this method, companies may ensure that the data they gather is relevant to stakeholder demands and use it to direct their future moves. Health technology method groups and companies will be able to convey key problems to procurement authorities more effectively and efficiently as a result of this study, saving time and effort. Sponsors and organisations working on health technology techniques would benefit from information on what data to submit and how to disseminate that data. Buying and procurement mean the same thing in this context (tareq et al., 2021).

2. Background of the study

To make the most of available resources, it is critical to thoroughly assess health technology assessment methodologies before making any purchases of medical equipment. Regardless of how important this way of prioritising is, nobody has resolved on it. Because of this, it is crucial that the researcher carefully considers adaptable techniques. Developing countries' healthcare systems are totally ineffectual due to a lack of sufficiently trained medical professionals. This is because wealthy countries are severely understaffed in the medical field. The world health organisation predicts that by 2035, up to 12.9 million people employed in healthcare would be unemployed. Even though they made up only 3% of the world's healthcare workers, developing african countries caused more diseases than any other region. Emerging countries lacked the medical expertise needed due to the large emigration of their citizens to the west in pursuit of better job opportunities. Prominent who experts have speculated that medical advancements powered by modern technology may one day allow for a higher level of health care equality. More and more, healthcare systems in developed countries are using ai into their systems to enhance medical technology (who, 2025). The foundation for emerging countries might be laid by patient-centered care, if it is recognised and implemented. Potential game-changers for patient-centered care in rural china include wearable tech, chatbots, online booking systems, and remote monitoring. Considering the widespread usage of mobile devices throughout the african continent, this is especially true there. Via better communication between doctors and patients and via interoperability with existing medical devices, modern technology has the ability to significantly transform healthcare delivery. Ai based medical technology advancements can greatly enhance the efficacy and efficiency of healthcare systems in underdeveloped nations. Tele monitoring has made it possible for physicians in developing nations to see patients with hypertension and other chronic diseases (mbunge et al., 2022).

3. Purpose of the study

The present inquiry is now being conducted under the working title of a comprehensive evaluation of health technology methodologies via the utilisation of medical devices. The primary purpose is to investigate healthcare systems as well as the medical equipment that is used to power medical systems. The primary objective of this research is to determine how successfully, safely, and advantageously the technology is currently functioning. These technologies have been thoroughly investigated by researchers, who have evaluated their capabilities, as well as their advantages and disadvantages. The stated purpose of this research is to discover novel approaches to improve the usability of medical equipment and the manner in which it is connected to digital health organisations. To do this, it is necessary to conduct an exhaustive study into the matter at issue. The program's objectives are to enhance clinical



results, develop solutions that are focused on patients, and achieve improvements in health technology technologies. An additional purpose of the effort is to exert an effect on the legislative and regulatory processes that will be implemented in the future regarding healthcare.

4. Literature review

Medical devices are essential in modern medicine due to their ability to assist in the identification, tracking, and management of many health conditions. As a result of technical advancements throughout the years, electronic devices have become more intricate. Blood pressure monitors and probes are examples of some of the inexpensive equipment that are now accessible. Additionally, automated surgical instruments and transplanted atrial defibrillators are easily accessible. Plenty of such examples are currently available to the general audience. These innovative breakthroughs have improved the precision and efficacy of healthcare operations, which in turn has led to happier patients and better treatment outcomes. Healthcare delivery has been radically altered by the incorporation of electronic gadgets into medical equipment. With the advent of smart gadgets that can track, inform, and perform remote diagnostics in real time, these technologies have opened the door to preventative and personalised treatment. For example, vital sign monitoring has become a reality because to wearable electronics. This makes it possible to detect problems earlier and provide the right treatment at the right time (stoumpos et al., 2023). Diagnostic technologies that use ai and ml have improved decision-making. These developments are a direct result of the fact that these technologies have made evaluations more precise and less prone to human mistake. Some problems with medical device design, use, and government regulation remain, even if there have been great improvements. People may find it challenging to effectively use new technology due to several concerns, including those around privacy, integrity, usability, and cost. The rapid development of new concepts makes it difficult for regulators to follow up, which in turn raises questions about the gadgets' dependability and safety. Also, medical devices need to undergo strict clinical testing and have their performance tracked over time to make sure they keep up with what doctors and patients anticipate. Thanks to the global push for evidence-based healthcare, the significance of gathering clinical feedback while developing and improving medical technology is now readily apparent. Also influencing this is the worldwide movement for evidence-based healthcare. To create products that are creative, practical, and easy to use, engineers, healthcare professionals, and end users must work together. The capacity of gadgets to cooperate is critical to their manufacturing. The importance of putting the patient's requirements first all the way through the design phase is growing. Hence, top-notch medical gear need to be user-friendly, comfy, and adjustable to suit different consumers (ming et al., 2022).

5. Research question

- What is the impact of manufacturability in health technology methodologies?

6. Research methodology

6.1 Research design: the quantitative data analysis was conducted with spss version 25. The odds ratio and 95% confidence interval were used to assess the magnitude and direction of the statistical link. The researchers set a statistically significant threshold of $p < 0.05$. A descriptive analysis was performed to identify the key elements of the data. Quantitative approaches are often used to evaluate data obtained from surveys, polls, and questionnaires, as well as data modified by computational tools for statistical analysis.

6.2 Sampling: the experiment used a fundamental sampling technique. The research used questionnaires to gather data. The rao-soft program determined a sample size of 1263. A total of 1456 questionnaires were distributed; 1357 were collected, and 52 were rejected due to incompleteness. A total of 1,305 questionnaires were used for the study.

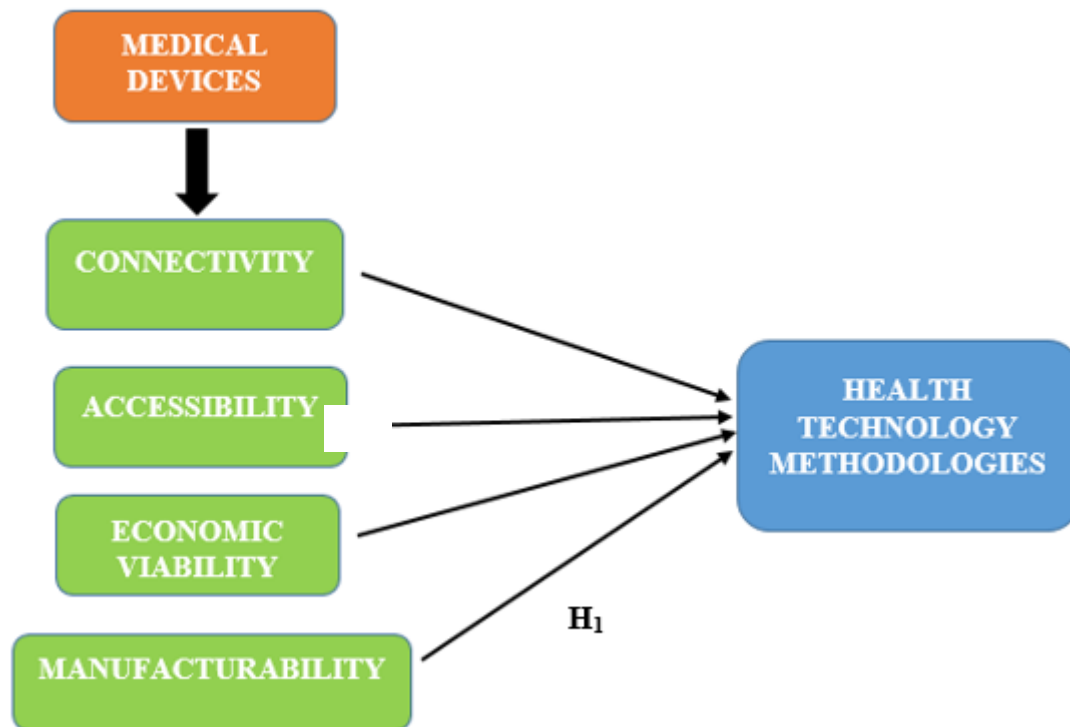


6.3 Data and measurement: the primary source of information for the research was a questionnaire survey conducted via direct contact or a google form. The questionnaire had two independent sections: (a) demographic data collected from both online and offline sources, and (b) responses to various traits evaluated using a 5-point likert scale. Secondary data was acquired using several online techniques.

6.4 Statistical software: statistical analysis was performed with spss 25.

6.5 Statistical tools: a descriptive analysis was conducted to understand the data's underlying structure. A descriptive analysis was performed to understand the essential properties of the data. Validity was assessed by factor analysis and anova.

7. Conceptual framework



8. Result

❖ Factor analysis

A prevalent use of factor analysis (fa) is to validate the intrinsic component structure of a set of measurement items. Unobserved factors are believed to directly influence the scores of the assessed variables. Accuracy analysis (fa) is contingent upon models. The primary objective of this study is to elucidate causal relationships among visible occurrences, underlying causes, and measurement mistakes. The kaiser-meyer-olkin (kmo) method may be used to assess the appropriateness of data for factor analysis. Researchers assess the adequacy of the sample for the overall model and for each specific variable. The statistical analysis quantifies the probable extent of common variation across many variables. Factor analysis is often better suitable for data sets with lower percentages.

kmo produces a value for integers ranging from 0 to 1. A kmo value ranging from 0.8 to 1 indicates a suitable sample. Should the kmo fall under 0.6, indicating inadequate sampling, remedial actions must be undertaken. The range is 0.5 to 0.6, allowing researchers flexibility; yet, some authors see 0.5 as definitive.



the researchers note that the partial correlations substantially surpass the overall correlations when the kmo approaches 0. Pronounced correlations provide a considerable impediment to component analysis.

the criteria used by kaiser to evaluate acceptability are as follows:

a negligible quantity ranging from 0.050 to 0.059.

- substandard by 0.60 to 0.69

the normative range for middle school is 0.70 to 0.79 cm.

ranging from a quality point value of 0.80 to 0.89.

it notably varies between 0.90 and 1.00.

Table1: KMO and Bartlett's Test

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.930
Bartlett's Test of Sphericity	Approx. Chi-Square	3252.968
	df	190
	Sig.	.000

Bartlett's test of sphericity also validated the relevance of the correlation matrices. The kaiser-meyer-olkin metric of sampling adequacy is at 0.930. Utilising bartlett's sphericity test, researchers obtained a p-value of 0.00. The results of bartlett's sphericity test indicated that the correlation matrix is defective.

❖ Independent variable

➤ Medical devices

Anything with the potential for use in the medical field might be considered a medical device, whether it is software, hardware, an instrument, or a mix of these elements (as specified by the manufacturer). In medicine, a broad range of assistive devices are categorised as medical devices. Universal health care, better community health, and the management of health emergencies all hinge on people's ability to readily access affordable and appropriate health commodities. Bandaging an ankle injury, diagnosing hiv/aids, implanting a prosthetic hip, or performing any kind of surgery would be very difficult without medical equipment. Home, in distant clinics for screening and prevention, and in palliative care are just a few of the various settings where medical devices are used by patients, paramedical staff, opticians, dentists, and healthcare practitioners. Possible future improvements in the detection, treatment, and monitoring of both acute and chronic health issues may result from new breakthroughs in healthcare information technology. The advances in question may be useful for everyone, including those with disabilities. All throughout the world, people may today buy about two million individual pieces of medical equipment, falling into more than seven thousand different generic device categories. A medical device may be defined as any tool that is specifically designed for use in the medical field, whether it is utilised independently or in combination



with other equipment. Software, materials, appliances, implants, and reagents for use in vitro are just a few examples of the numerous things that fall under this category (rahman et al., 2023).

❖ **Factor**

➤ **Manufacturability**

The degree to which a product may be readily manufactured is referred to as its manufacturability. This term takes into consideration a variety of factors, including design, materials, techniques, and pricing. It is the belief of this concept that designers should create items that can be mass-produced in a cheap way without compromising quality or significantly increasing pricing. Mastering the concept of manufacturability may help engineers improve their production efficiency and reduce the amount of waste they produce (rehman et al., 2022).

❖ **Dependent variable**

➤ **Health technology methodologies**

All sorts of medications, assistive devices, and equipment fall under the umbrella term "health technologies" when discussing medical tools and procedures. This technology is prevalent in all types of healthcare facilities and influences the treatment that patients receive; it is thus crucial to modern healthcare systems. Having said that, they work best when paired with skilled doctors and organised healthcare systems. By using proven approaches, health technology methodology is an interdisciplinary endeavour that aims to determine the value of health technologies throughout their existence. If the powers that be can use this data to build a healthcare system that the researchers can be proud of, then everyone will be happy (shahrubudin et al., 2020).

❖ **Relationship between manufacturability and health technology methodologies**

The connection between manufacturability and health technology methods is an extremely important factor to consider when it comes to the process of inventing, growing, and implementing medical breakthroughs. The frameworks and methods that are used to assess the value, safety, efficacy, and cost-benefit of medical technologies are referred to as health technology methodology. On the other hand, manufacturability refers to the simplicity, efficiency, and cost-effectiveness of creating a medical product or device at a large scale. When developing novel health technologies, it is essential to take into account challenges related to their capacity to be manufactured throughout the design and evaluation phases. In the event that a product is not able to make it to market in a timely manner owing to a design that is not suitable for scalable production, it is irrelevant how beneficial the product is in the clinical setting. On the other hand, methods such as health technology assessment have the potential to provide insights into the elements that influence manufacturing choices, such as economic constraints, regulatory requirements, and user desires, and therefore drive design decisions. When powerful health technology procedures are matched with manufacturability, innovations that are both economically practical and accessible to the target populations are more likely to be clinically useful. This is because of the fact that these innovations possess both of these characteristics (soekhai et al., 2019).

Subsequent to the above debate, the researcher developed the following hypothesis, which analyses the link between manufacturability and health technology methodologies.

" h_{01} : there is no significant relationship between manufacturability and health technology methodologies."

" h_1 : there is a significant relationship between manufacturability and health technology methodologies."



Table 2: H₁ ANOVA Test

ANOVA					
Sum					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	39588.620	590	5308.836	765.623	.000
Within Groups	492.770	714	6.934		
Total	40081.390	1304			

This investigation has produced substantial results. The f statistic is 765.623, demonstrating significance with a p-value of .000, which is below the .05 alpha threshold. The hypothesis "*h₁: there is a significant relationship between manufacturability and health technology methodologies*" is accepted, whereas the null hypothesis is rejected.

9. Discussion

Technology advancements in the medical field, particularly in the field of obstetric medical equipment, are very necessary in order to provide superior care to pregnant women and their unborn children. When it comes to product creation, the results of the research emphasise the importance of using agile development methodologies and user-centred design wherever it is feasible to do so. In the event that the researcher has a solid comprehension of these methods, it is possible to discover the most effective strategies for enhancing performance. Participating in conversations with people who came from a variety of different backgrounds, had different interests, and had different points of view was a crucial part of the process. Participants in this group included individuals and organisations from the government, healthcare providers, patients, and information technology companies. There is a greater likelihood that the gadgets will function as anticipated and meet all of the requirements if their thoughts are taken into consideration. In order to improve the chances of the regulatory environment management program being successful, it was essential to guarantee that the development procedures were in line with the official guidelines. In order to get access to new markets in a more expedient manner and to expedite clearance processes, it was essential to make this shift, which was tough but necessary. The transition, whatever the difficulties it presented, had to take place. The dizzying pace of technological advancement was yet another significant issue that was elaborated upon in great detail over the course of the conversation. Some examples of how technology is revolutionising the treatment of obstetric problems include telemedicine, data analytics, and wearable devices. Additionally, telemedicine is becoming increasingly popular.

10. Conclusion

Only via the development of innovative strategies for the use of health technology that are centred on obstetric medical equipment will it be possible to make progress in the field of maternal healthcare. In light of the findings, it is important to adopt a research methodology that allows for the inclusion of data-driven techniques, agile development, and user-centred design. The involvement of a greater number of individuals from the very beginning of the design process may make it simpler to guarantee that the final product satisfies the requirements of both the regulatory agency and the demands of the actual world. In the end, it will be much simpler to ensure that the final product will fulfil both sets of standards. As a consequence of this, they evolve into methods that are both safer and more effective. Because dealing with the complexities of regulatory systems continued to be a significant obstacle, it



was essential to cut down on the number of approval procedures in order to achieve these goals. By accomplishing all of this, it was guaranteed that the conditions would be satisfied. In order to stay up with the benefits and drawbacks that have been brought about by the exponential expansion of technology, it is essential to improve the procedures that are used for development. Because it is impossible to afford to fall behind the technological curve, this is an absolute need. This expansion has resulted in an increase in the number of options; nevertheless, it has also resulted in an increase in the number of limits. Organisations, businesses, and people that are employed in the healthcare industry are required to collaborate on a constant basis in order to achieve success in the future. The availability of consistent finance for education and infrastructure, which helps to cultivate an environment that is open to new ideas, may make it simpler to manufacture cutting-edge obstetric medical equipment that improves the results of maternal healthcare. Under these circumstances, the development of innovative medical technology is more likely to take place.

References

1. mbunge, e., batani, j., gaobotse, g., & muchemwa, b. (2022). Virtual healthcare services and digital health technologies deployed during coronavirus disease 2019 (covid-19) pandemic in south africa: a systematic review. *Global health journal*, 6(2), 102-113.
2. Ming, j., he, y., yang, y., hu, m., zhao, x., liu, j., ... & chen, y. (2022). Health technology assessment of medical devices: current landscape, challenges, and a way forward. *Cost effectiveness and resource allocation*, 20(1), 54.
3. Rahman, a., hossain, m. S., muhammad, g., kundu, d., debnath, t., rahman, m., ... & band, s. S. (2023). Federated learning-based ai approaches in smart healthcare: concepts, taxonomies, challenges and open issues. *Cluster computing*, 26(4), 2271-2311.
4. Rehman, a., abbas, s., khan, m. A., ghazal, t. M., adnan, k. M., & mosavi, a. (2022). A secure healthcare 5.0 system based on blockchain technology entangled with federated learning technique. *Computers in biology and medicine*, 150, 106019.
5. Shahrubudin, n., koshy, p., alipal, j., kadir, m. H. A., & lee, t. C. (2020). Challenges of 3d printing technology for manufacturing biomedical products: a case study of malaysian manufacturing firms. *Heliyon*, 6(4).
6. Soekhai, v., whichello, c., levitan, b., veldwijk, j., pinto, c. A., donkers, b., ... & de bekker-grob, e. W. (2019). Methods for exploring and eliciting patient preferences in the medical product lifecycle: a literature review. *Drug discovery today*, 24(7), 1324-1331.
7. Stoumpos, a. I., kitsios, f., & talias, m. A. (2023). Digital transformation in healthcare: technology acceptance and its applications. *International journal of environmental research and public health*, 20(4), 3407.
8. Tareq, m. S., rahman, t., hossain, m., & dorrington, p. (2021). Additive manufacturing and the covid-19 challenges: an in-depth study. *Journal of manufacturing systems*, 60, 787-798.
9. Viceconti, m., pappalardo, f., rodriguez, b., horner, m., bischoff, j., & tshinanu, f. M. (2021). In silico trials: verification, validation and uncertainty quantification of predictive models used in the regulatory evaluation of biomedical products. *Methods*, 185, 120-127.
10. World health organization. (2025). Health technology assessment of medical devices. World health organization.