IMPROVEMENT IN HEALTH TECHNOLOGY METHODOLOGIES: AN EXTENSIVE ANALYSIS TARGETED ON OBSTETRICAL MEDICAL DEVICES

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ABSTRACT

With an emphasis on tools used during pregnancy, this research aims to analyze the evolution of different approaches to health technology. Considering the growing need for novel approaches to maternal healthcare, this article surveys the state of medical device research and development and assesses possible ways to improve the devices' usability, security, and effectiveness. Innovative approaches to maternal care were desperately needed. The study delves into the current state of technology and emerging developments to reveal significant possibilities and threats in the industry. A multidisciplinary approach may help understand the development process by looking at legal frameworks, integration approaches, and stakeholder views. The objectives of this study were to provide the framework for future research and practice in obstetric healthcare technology and best practices with the goal of improving healthcare delivery and patient outcomes. Obstetrics and other highly specialized professions have been greatly transformed by the application of current medical technologies. This research looks closely at cutting-edge health technology, particularly as it pertains to obstetrical medical equipment. Contemporary instruments that aim to improve the health of mothers and infants are a great boon in the field of obstetrics, which places a premium on accuracy and new ideas. Wearables, imaging breakthroughs, and AI-powered apps are just a few of the noteworthy developments in diagnostic, therapeutic, and monitoring technologies covered in this article.

Keywords: *Medical, Technological, Health-Related, Approaches.*

1. INTRODUCTION

Its advising function for decision-makers includes suggesting medical device reimbursement and providing advise on the correct utilization and significance of these equipment in therapeutic, diagnostic, or disability compensation systems. It is essential that CNEDiMTS guarantees CE marking before commencing its scientific assessment activities. In order for a medical equipment to acquire CE certification, it must pass this extra assessment. It considers the product's efficacy

and safety, as well as its influence on public health and its place in France's present treatment alternatives. Final clinical trials are the only way to find out if MDs work. When patients asked CNEDiMTS to register them for payment, the views were based on the available clinical data, which was typically from studies, and the current state of medicine and research. Although it may be difficult, conducting randomized, controlled clinical trials for medical devices is the gold standard for proving a health product's efficacy according to the principles of Evidence-Based Medicine. The field's acknowledged characteristics, such as its rapid expansion, operator-dependent or organization-of-care-related character, and sometimes very small target populations, have necessitated the necessity for appropriate evidence collection methodologies. New methods of evaluation are required due to developments in technology, the dynamic nature of the medical device industry, the proliferation of AI-driven tools, and the expansion of access to real-world health data. Included in this update will be a technology-specific assessment that makes use of appropriate rigorous procedures. The committee required to update its 2013 recommendations, which were formerly titled Methodological Choices for the Clinical Development of Medical Devices, since the area is constantly evolving, as the committee recognized. This guide will now be known as "Methodology for the Clinical Development of Medical Devices" due to the committee's decision to rebrand it as a tool for companies to use in creating business plans. As an expansion of the long-standing services offered to companies by HAS, this revised guidebook is now available. Particularly for complicated development initiatives, businesses often do preliminary communication to ascertain the viability of clinical research before implementing it (Santos et al., 2020).

2. BACKGROUND OF THE STUDY

Healthcare systems in developing countries are facing challenges due to a lack of qualified medical professionals caused by the increasing demand for healthcare workers in developed nations. In 2035, the World Health Organization (WHO) projected that there will be a global shortfall of around 12.9 million healthcare workers. Developing African nations were accountable for almost 25% of the world's ailments, although only making up 3% of the healthcare workforce overall. There was a critical shortage of doctors and other medical experts in developing nations since so many people emigrated to the West in quest of economic opportunity. Medical technologies powered by artificial intelligence (AI) have the potential to level the health playing field, according to the World Health Organization's higher echelons (Amin & Hossain, 2020). The healthcare systems of developed nations are increasingly using AI to drive technological improvements in medical technology. If patient-centered care is recognized and implemented in developing nations, they might be able to lay the foundation for it. Innovations in AI-powered medical devices, such as wearables, chatbots, electronic reservation systems, and remote monitoring, have the potential to revolutionize patient-centered care in China's distant areas, particularly in African nations where mobile device use is common. With its integration into different medical devices, AI has the potential to transform healthcare delivery and the doctor-patient interaction. Artificial intelligence (AI) medical device advancements might improve performance while decreasing delivery costs, which would be a huge boon to healthcare systems in developing nations. Using telemonitoring and related technology, doctors may now reach out to individuals in underdeveloped countries who deal with hypertension and other chronic conditions. By leveraging these tools to forecast when infectious diseases will arise,the researcher may potentially stop their spread before they even start. If this were to occur,the researcher may potentially be able to treat patients faster. Medical device

advancements driven by artificial intelligence are reshaping healthcare by improving the delivery of medication regimens, patient monitoring, and data analysis from large datasets. Keeping this background in mind, the researcher decided to research how other nations' healthcare systems have used AI to better cater to the individualized requirements of China's enormous population (Alshehri & Muhammad, 2020).

3. PURPOSE OF THE STUDY

Specifically addressing the topic of "How are medical devices developed?" as it pertains to birthing aids, this research aimed to provide a solution. By studying the current practices, challenges, and innovations in this field,the researcher may find practical solutions to improve the design, deployment, and management of these devices. Improving maternal healthcare outcomes is the main goal of this project. To do this,the researcher will create technologies that emphasize efficacy, safety, and user-centric design. Careful consideration of stakeholder perspectives and regulatory issues may direct future developments in prenatal health technologies and impart best practices.

4. LITERATURE REVIEW

The global rise of alternative patient care practices was impacting healthcare systems throughout the globe. New research shows that healthcare providers no longer follow their patients' daily activities in the hospital as they did before the advent of AI, big data analytics (BD), blockchain,

and the IoT. The development of medical device technology powered by AI is driven by the goal of making healthcare more accessible and personalized. Anybody may benefit from a therapeutic tool, therefore it's important to foster an atmosphere that encourages open dialogue, teamwork, and inclusion. The use of AI-powered medical technology has the potential to increase efficiency while decreasing costs for healthcare providers. In addition to enhancing digital knowledge, diagnostic capabilities, treatment options, prevention strategies, and rehabilitation programs, medical device technologies based on AI influence the structure, culture, professions, treatments, and outcomes of health care (Dhanvijay & Patil, 2019). Improvements in detection may be possible with new medical imaging technologies, and clinicians may benefit from AI-enabled medical device tech that helps them with diagnosis, treatment, and prognosis. There is some indication that medical devices powered by artificial intelligence might improve the efficacy, efficiency, and quality of care physicians provide their patients, but the real-world uses of this technology in hospitals and clinics are yet unknown (Mutlag et al, 2019). The healthcare landscape is changing as a result of AI technologies that are making new treatment options feasible. The study's findings suggest that with the incorporation of AI into medical devices, physicians may become more involved in their patients' treatment. Despite the many benefits, healthcare organizations have been slow to embrace AI-based device solutions. Medical device solutions based on artificial intelligence have been stymied by the present healthcare system's many flaws. There are several issues with the healthcare system, including high patient medical costs, insufficient doctors in low-income areas, incorrect diagnoses by primary care physicians, excessively extended training durations for doctors, and an unequal distribution of senior doctors. Improvements in artificial intelligence (AI) medical devices may have to wait until specific problems in the healthcare industry are solved (Dang et al., 2019).

5. RESEARCH QUESTION

- What is the impact of Technological Innovation on medical devices in health technology methodologies?

6. RESEARCH METHODOLOGY

Quantitative research refers to studies that examine numerical readings of variables using one or more statistical models. The social environment may be better understood via quantitative research. Quantitative approaches are often used by academics to study problems that impact individuals. Objective data presented in a graphical format is a byproduct of quantitative research. Numbers are crucial to quantitative research and must be collected and analyzed in a systematic way. Averages, predictions, correlations, and extrapolating findings to larger groups are all possible with their help.

6.1 Research design: In order to analyse quantitative data, SPSS version 25 was used. When analysing the statistical association, the odds ratio and 95% confidence interval were used to determine its direction and size. A statistically significant threshold was suggested by the researchers at $p < 0.05$. The primary features of the data were identified by a descriptive analysis. Mathematical, numerical, or statistical evaluations using quantitative methodologies are often used for data gathered from surveys, polls, and questionnaires, or by modifying existing statistical data using computing tools.

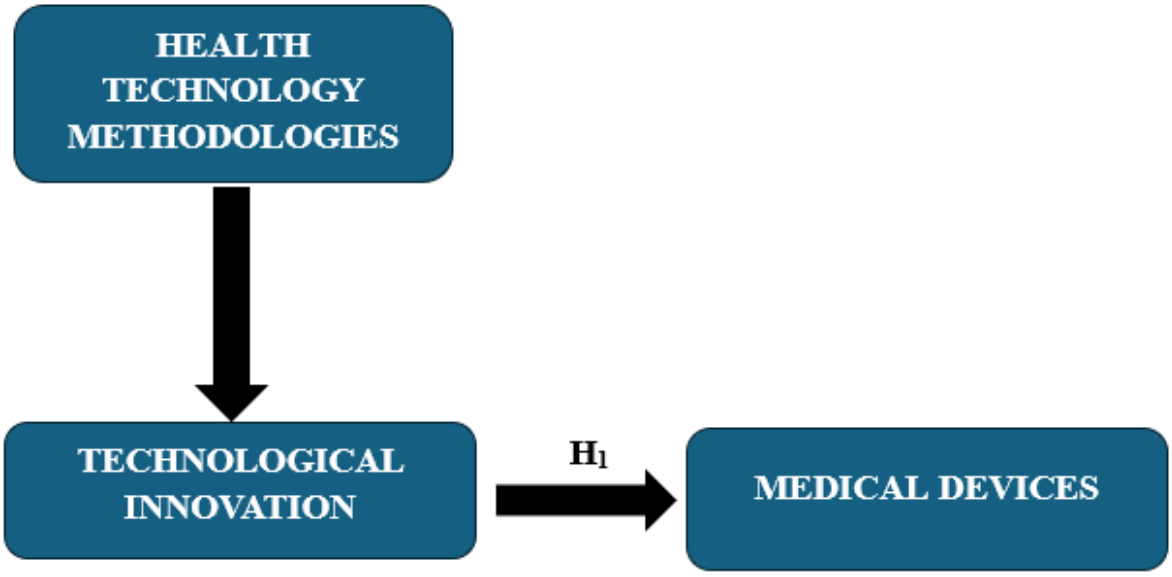
6.2 Sampling: Research participants filled out questionnaires to provide information for the research. Using the Rao-soft programme, researchers determined that there were 941 people in the research population, so researchers sent out 1165 questionnaires. The researchers got 1092 back, and they excluded 37 due to incompleteness, so the researchers ended up with a sample size of 1055.

6.3 Data and Measurement: A questionnaire survey functioned as the primary data collection instrument for the investigation. The survey had two sections: (A) General demographic information and (B) Responses on online and non-online channel factors on a 5-point Likert scale. Secondary data was obtained from many sources, mostly on internet databases.

6.4 Statistical software: The statistical analysis was conducted using SPSS 25 and MS-Excel.

6.5 Statistical Tools: To grasp the fundamental character of the data, descriptive analysis was used. The researcher is required to analyse the data using ANOVA.

7. CONCEPTUAL FRAMEWORK



8. RESULT

❖ Factor analysis

One typical use of Factor Analysis (FA) is to verify the existence of latent components in observable data. When there are not easily observable visual or diagnostic markers, it is common practice to utilize regression coefficients to produce ratings. In FA, models are essential for success. Finding mistakes, intrusions, and obvious connections are the aims of modelling. One way to assess datasets produced by multiple regression studies is with the use of the Kaiser-Meyer-Olkin (KMO) Test. They verify that the model and sample variables are representative. According to the numbers, there is data duplication. When the proportions are less, the data is easier to understand. For KMO, the output is a number between zero and one. If the KMO value is between 0.8 and 1, then the sample size should be enough. These are the permissible boundaries, according to Kaiser: The following are the acceptance criteria set by Kaiser:

A dismal 0.050 to 0.059, subpar 0.60 to 0.69

Middle grades often range from 0.70 to 0.79.

Exhibiting a quality point score between 0.80 and 0.89.

They are astonished by the range of 0.90 to 1.00.

Table 1: KMO and Bartlett's Test for Sampling Adequacy Kaiser-Meyer-Olkin measurement: .895

The outcomes of Bartlett's test of sphericity are as follows: Approximately chi-square degrees of freedom = 190 significance = 0.000

This confirms the legitimacy of claims made just for sampling purposes. Researchers used Bartlett's Test of Sphericity to ascertain the significance of the correlation matrices. A Kaiser-Meyer-Olkin value of 0.895 indicates that the sample is sufficient. The p-value is 0.00 according to Bartlett's sphericity test. A positive outcome from Bartlett's sphericity test indicates that the correlation matrix is not an identity matrix.

Table: KMO and Bartlett's

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.895
Bartlett's Test of Sphericity	Approx. Chi-Square	3252.968
	df	190
	Sig.	.000

The overall importance of the correlation matrices was also validated by Bartlett's Test of Sphericity. The Kaiser-Meyer-Olkin sampling adequacy is 0.895. Utilizing Bartlett's sphericity test, researchers obtained a p-value of 0.00. A notable result from Bartlett's sphericity test indicated that the correlation matrix is not valid.

- **INDEPENDENT VARIABLE**
  - **Health Technology Methodologies**

When referring to the methodical processes used in healthcare IT testing, deployment, and evaluation, the phrase "health technology methodologies" is appropriate. Some of the tactics that fall under this category are evidence-based research, agile development, user-centered design, and regulatory compliance. They set out to ensure that health innovations met user desires while improving patient outcomes. Medical device developers may benefit from these techniques since they take into account the needs of patients and healthcare professionals to create products that are reliable, efficient, and easy to use. Approaches based on health technology have enabled innovation in healthcare and enhanced the quality of treatment (Darwish et al., 2019).

❖ **FACTOR**

➢ **Technological Innovation**

When new or better technology, goods, services, or processes are created and put into use, they generate value, increase functioning, and solve certain problems or requirements. This process is called technological innovation. It comprises turning concepts and innovations into workable Innovation may manifest in many ways, such as the launch of brand-new goods, the refinement of existing ones, the provision of better services, or the introduction of game-changing technology that reshape whole sectors. In the end, technical innovation is what propels development, molds industries, and enhances living standards by addressing complicated issues and changing requirements. Software that is used by people, companies, or industries. The originality, usefulness, and capacity to provide observable gains in performance, use, or comfort define this invention (Kamruzzaman et al., 2022).

❖ **DEPENDENT VARIABLE**

➢ **Medical Devices**

In medicine, a "medical device" may be anything from a machine or implant to tools that can detect, diagnose, treat, prevent, or monitor a wide range of medical conditions. Included are a wide variety of tools, from simple thermometers to high-tech magnetic resonance imaging (MRI) scanners and surgical robots.the researcher may categorize these gadgets based on how complicated they are, how long they last, and what they do. These devices have a wide range of potential applications, including the detection and identification of diseases, the administration of actual medicines, and even surgical implantation for therapeutic reasons. To ensure that patients get safe and effective treatment, the entities in charge of medical device safety and clearance procedures make sure that these devices are up to standard (Maurya et al., 2021).

❖ **Relationship between Technological Innovation and Medical Devices**

Medical equipment and technical innovation have a deep and mutually beneficial connection, with the former propelling the latter in terms of development, usefulness, and efficacy. Smaller, more portable, and implantable devices such as insulin pumps, neurostimulators, and pacemakers have been developed thanks to advancements in microelectronics and nanotechnology. Prosthetics, implants, and other devices that blend in with the body have been made possible by the development of biocompatible materials, which decrease the likelihood of rejection and problems. Improving patient outcomes and allowing early identification of abnormalities are both made possible by the real-time monitoring of physiological data by advanced sensors. Wearable health monitors and other connected devices allow for the sending of real-time data to healthcare practitioners for remote monitoring and diagnoses. via the use of AI algorithms, imaging systems (e.g., CT, MRI) and other diagnostic tools are improved, and individualized treatment plans are made possible via predictive analytics. Better decision-making, more effective treatments, and more efficient operations are all possible thanks to data analytics that are integrated with patient data (Mamdiwar et al., 2021).

Based on the above discussion, the researcher formulated the following hypothesis, which was to analyze the relationship between Technological Innovation and Medical Devices .

H_{01}: "There is no significant relationship between Technological Innovation and Medical Devices"

H_1: "There is no significant relationship between Technological Innovation and Medical Devices"

Table 2: H_1 ANOVA Test

ANOVA					
Sum					
	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	39588.620	504	5655.517	486.699	.000
Within Groups	492.770	550	5.356		
Total	40081.390	1054			

In this study, the result is significant. The value of F is 486.699 , which reaches significance with a p-value of .000 (which is less than the alpha level). This means the ***"H_1: There is a significant relationship between Technological Innovation and Medical Devices"*** is accepted and the null hypothesis is rejected.

9. DISCUSSION

To improve the standard of care for mothers and infants, healthcare IT approaches for obstetric medical equipment must be established. The results of this research show how important it is to employ techniques like agile development and user-centered design while making gadgets. Mastering these methods thoroughly enables one to identify the most effective tactics that may enhance results. An essential part of the process was communicating with people from many walks of life, including patients, government regulators, healthcare providers, and IT companies. The chances of the gadgets meeting actual demands and complying with all applicable regulations are increased when their comments and suggestions are implemented. Aligning development processes with regulatory standards was crucial for handling the regulatory environment. This difficult but essential change was needed to streamline clearance procedures and enter new markets. Another prominent subject that emerged throughout the conversation was the very rapid

development of new technologies. Telemedicine, data analytics, and wearable devices are just a few examples of how technology is reshaping obstetric care. Still, current practices will have to change to ensure these new technologies work and are safe to use. More collaboration and research between healthcare professionals, businesses, and universities is required, according to the results. Investing in training and resources is the only way to foster a culture of innovation in the design of obstetric medical equipment.

10.CONCLUSION

Innovations in obstetric medical equipment are at the heart of new health technology strategies aimed at bettering maternal healthcare. Based on the results, it is vital to combine evidence-based methods with user-centered design and agile development. Many different types of stakeholders should be included in the design process from the start to make sure the final product meets both real-world needs and regulatory standards. Their productivity and safety are both enhanced by this. Given the continued difficulty in understanding and complying with various regulatory frameworks, it was essential to standardize and simplify approval processes in line with these requirements. Development approaches need to change to stay up with the opportunities and risks presented by technology's exponential growth. Collaboration between healthcare providers, businesses, and other organizations is crucial to the industry's long-term viability. Consistent funding for education and infrastructure fosters an innovation-friendly atmosphere, which in turn leads to the development of novel obstetric medical equipment that substantially enhances the results of maternal healthcare. At the end of this article, the protocols that will govern the future of research and development of obstetric medical devices were outlined. Improved health

technology that better fits the evolving needs of maternity healthcare might be the result of stakeholder collaboration to confront challenges and exploit new potential.

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