PROGRESS IN HEALTH TECHNOLOGY METHODOLOGIES: A THOROUGH ANALYSIS CENTERED ON OBSTETRICAL MEDICAL DEVICES

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ABSTRACT

The purpose of this study is to examine the development of various approaches to health technology with a focus on devices used during pregnancy. Considering the increasing need for innovative methods of maternal healthcare, this paper examines the current landscape of medical device development and evaluates potential solutions to enhance the devices' use, safety, and efficacy. There was a significant need for novel methods of maternity care. The research uncovers major challenges and opportunities in the sector by conducting an in-depth analysis of the present technology and the developing trends. By delving into legal frameworks, integration methodologies, and stakeholder viewpoints, a multidisciplinary approach may provide a thorough grasp of the development process. In order to improve healthcare delivery and patient outcomes, these findings were intended to provide the groundwork for future study and practice in obstetric healthcare technology and best practices. The use of modern medical technology has revolutionized several fields, including obstetrics and other highly specialized ones. This study delves deeply into the latest health technology methods, with a focus on obstetrical medical equipment. In obstetrics, where precision and novel concepts are of the utmost importance, modern tools that seek to enhance maternal and infant health are a tremendous advantage. Some of the significant advancements in diagnostic, therapeutic, and monitoring technologies discussed in this article include wearables, advances in imaging, and applications powered by artificial intelligence.

Keywords: *Diagnostic, Technology, Health, Methodologies.*

1. INTRODUCTION

Recommending the reimbursement of medical devices and offering advice on their proper usage and importance in therapeutic, diagnostic, or disability compensation systems are all part of the advising role it plays for decision-makers. Prior to beginning its scientific evaluation duties, CNEDiMTS must ensure CE marking. This examination is an additional step before a medical device may get CE certification. It considers the item's safety and effectiveness, as well as its impact on public health and how it fits into France's current treatment options. The effectiveness of MDs can only be determined by definitive clinical trials. Clinical data available, often from

studies, and the status of medicine and research were the basis for CNEDiMTS's opinions when patients requested registration for payment. The gold standard for demonstrating the effectiveness of a health product in accordance with the principles of Evidence-Based Medicine is to conduct randomized, controlled clinical trials for medical devices, which may be challenging. The quick growth, operator-dependent or organization-of-care-related nature, and sometimes very tiny target populations are recognized features of the field that have prompted the need for suitable methods of evidence collecting. Technological advancements, the ever-changing medical device sector, the rise of AI-driven technologies, and the improvement of access to real-world health data all need new approaches to assessment. As part of this change,the researcher will include a technology-specific evaluation based on suitable rigorous methodologies. The committee acknowledged that the field is always changing, thus it needed to revise its 2013 recommendations, which was originally called Methodological Choices for the Clinical Development of Medical Devices. The committee decided to change the name of this guide to "Methodology for the Clinical Development of Medical Devices" to make it more clear that it is a tool that firms may use to develop their project plan. This updated manual is an extension of the services that HAS has provided to businesses for a long time. Before implementing clinical research, companies typically conduct preliminary communication to determine its feasibility, especially for complex development projects (Li et al., 2019).

2. BACKGROUND OF THE STUDY

The rising demand for healthcare personnel in wealthy nations has led to a shortage of trained doctors, which is putting a strain on healthcare systems in developing nations. Worldwide, there would be a shortage of around 12.9 million healthcare professionals, according to the World Health Organization's (WHO) 2035 prediction. Even though they only accounted for 3% of the global healthcare workforce, developing African countries were responsible for more than 25% of all diseases. The great migration of individuals from poor countries to the West in search of better life caused a severe scarcity of medical professionals in those countries. The World Health Organization's upper echelons reasoned that artificial intelligence (AI) in medical devices may level the playing field in terms of health (Karthick & Pankajavalli, 2020). The use of AI to fuel medical technology advancements is becoming more common in industrialized countries' healthcare systems. Developing countries may be able to provide the groundwork for patient-centered care if it is accepted and implemented there. Wearables, chatbots, electronic reservation systems, and remote monitoring are just a few examples of the AI-powered medical device innovations that could transform patient-centered care in China's outlying regions, thanks to the abundant mobile device usage in African countries. AI has the ability to revolutionize healthcare delivery and the relationship between doctors and patients via its incorporation into various medical equipment. Developing country healthcare systems would greatly benefit from medical device innovations based on artificial intelligence, since they have the potential to increase performance while cutting delivery costs. Doctors may now reach out to people in developing nations who suffer from hypertension and other chronic illnesses using telemonitoring and similar technologies.the researcher may be able to halt the spread of infectious illnesses before they even start by utilizing these technologies to predict when they will emerge.the researcher could also

treat patients more swiftly if this happened. Healthcare is being revolutionized by AI-powered medical device innovations that enhance treatment regimen administration, patient monitoring, and data analysis from massive datasets. With this history in mind, the researcher set out to learn how other countries' healthcare systems had integrated AI to better meet the needs of China's vast population in terms of individual attention (Kamruzzaman et al., 2022).

3. PURPOSE OF THE STUDY

This study set out to answer the question, "How are medical devices developed?" with a focus on the tools used during childbirth. Practical strategies that increase the design, deployment, and administration of these devices may be discovered via an investigation of present practices, difficulties, and breakthroughs in this sector. The overarching objective of this study is to enhance maternal healthcare outcomes via the development of technologies that prioritize effectiveness, safety, and user-centric design. Future advancements in prenatal health technology may be guided and best practices can be taught by thoroughly examining stakeholder viewpoints and regulatory concerns.

4. LITERATURE REVIEW

Alternative patient care techniques were gaining traction throughout the world, and this was having an effect on the healthcare industry. Artificial intelligence (AI), big data analytics (BD),

blockchain, and the internet of things (IoT) have changed the way healthcare professionals track their patients' everyday activities in hospitals, according to new study. Making healthcare more accessible and individual is the driving force behind the development of AI-powered medical device technology. By creating an environment that values open communication, collaboration, and inclusion, it may be feasible to develop a therapeutic tool that can be used by anybody. Healthcare providers may be able to save costs and improve efficiency by using AI-powered medical equipment (Qadri et al., 2022). Medical device technologies based on artificial intelligence (AI) have an impact on the structure, culture, professions, treatments, and outcomes of health care, in addition to increasing digital knowledge, diagnostic capabilities, treatment options, prevention strategies, and rehabilitation programs. Medical imaging innovations may improve detection, and AI-enabled medical device tech can improve patient care by guiding doctors through the diagnostic, treatment, and prognosis processes. While there is some evidence that AI-enabled medical devices could enhance the efficiency, effectiveness, and quality of treatment doctors provide their patients, the practical applications of this technology in healthcare facilities remain unclear. Because AI technologies are making novel treatment methods viable, the healthcare environment is shifting. According to the research, doctors may take a more active part in their patients' care now that AI is used in medical devices. Healthcare companies have been hesitant to adopt AI-based device solutions, even though they provide several advantages (Qayyum et al., 2020). There are a number of problems with the current healthcare system that have made it difficult to implement AI-based medical device solutions. Exorbitant patient medical bills, a lack of doctors in low-income regions, inaccurate diagnoses made by primary care physicians, overly long training periods for doctors, and an uneven distribution of senior doctors are all problems in

the healthcare system. Artificial intelligence (AI) medical device advancements may be postponed until certain healthcare sector challenges are resolved (Yang et al., 2022).

5. RESEARCH QUESTION

- What is the impact of legal frameworks 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.

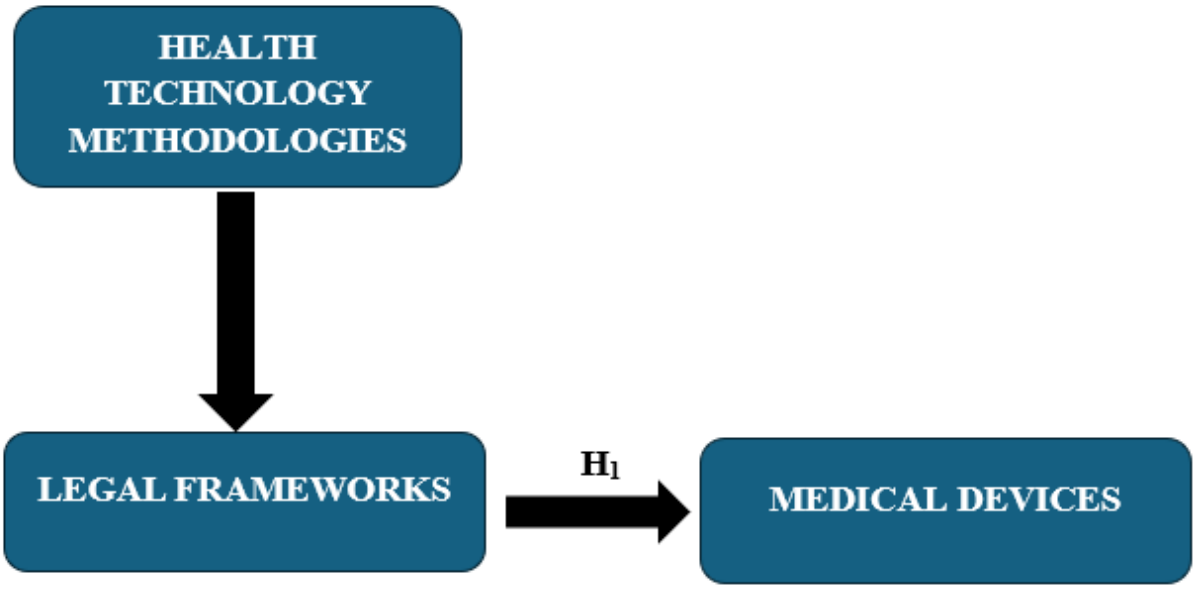
6.2 Sampling: Research participants filled out questionnaires to provide information for the research. Using the Rao-soft programme, researchers determined that there were 941 people in the research population, so researchers sent out 1165 questionnaires. The researchers got 1092 back, and they excluded 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: .869

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 0.869 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.		.869
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 0.869. 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**

It is fair to use the term "health technology methodologies" when describing the systematic procedures utilized in healthcare IT development, implementation, and assessment. Included in these strategies are practices like complying with regulations, conducting user-centered design, agile development, and research based on evidence. They were on a mission to guarantee that health innovations enhanced patient outcomes while also satisfying user demands. These methods aid in the development of trustworthy, effective, and user-friendly medical devices by incorporating the perspectives of relevant stakeholders, including patients and healthcare

providers. Innovation in healthcare and an improvement in treatment quality were both made possible by health technology approaches (Karatas et al., 2022).

- **FACTOR**

- **Legal Frameworks**

A jurisdiction's legal framework is its predetermined set of laws, regulations, and institutionalized norms for doing business, enforcing rights and responsibilities, and resolving disputes. It is the bedrock upon which the making, interpretation, and enforcement of policies and regulations rest. Economic and social stability, the protection of individual rights, the resolution of conflicts, and the regulation of social interactions all depend on well-established legal frameworks (Alshamrani, 2022).

- **DEPENDENT VARIABLE**

- **Medical Devices**

Machines, implants, and other equipment that may detect, diagnose, treat, prevent, or monitor a variety of medical diseases are all part of what is often referred to as a "medical device" in the healthcare industry. All sorts of devices are included, from basic thermometers to advanced MRI scanners and surgical robots.the researcher may sort these devices according to their complexity, lifespan, and function. These gadgets may do anything from monitoring vital signs to detecting and identifying ailments to administering real therapies or being surgically implanted for therapeutic purposes. Bodies responsible for overseeing medical device safety and clearance processes make sure these devices are up to snuff when it comes to providing patients with effective and safe treatment (Krishnamoorthy et al., 2021).

❖ **Relationship between Legal Frameworks and Medical Devices**

All stages of a medical device's lifecycle—from inception to research, production, marketing, and post-market monitoring—are influenced by several legal frameworks. To safeguard the public's health, authorities and international organizations set up these organized systems of rules and regulations to make sure that medical devices are safe, effective, and of good quality. Assuring the public's health and safety relies on the connection between legal frameworks and medical equipment. From initial concept to final product, legal frameworks offer a systematic collection of laws and regulations that control every step of a medical device's lifetime. Before they hit store shelves, these frameworks make sure medical equipment are risk-free, efficient, and up to par. The categorization and authorization of medical equipment by regulatory bodies is an important component. Depending on the degree of risk and the device's intended use, regulatory agencies like the FDA in the US and the EMA in Europe categorize them. In order to prove their safety and effectiveness, higher-risk devices are subjected to rigorous premarket studies, which may include clinical trials. By categorizing devices according to their possible effects on patients, this method facilitates more efficient monitoring and guarantees the right actions are taken.Adherence to quality management systems (QMS) is also emphasized by legal frameworks. In order to keep quality constant all, the way through manufacturing, manufacturers must follow international standards like ISO 13485. The identification, assessment, and mitigation of hazards connected with devices is an essential part of risk management, which is frequently governed by ISO 14971 (Nahavandi et al., 2022).

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

H_{01}: "There is no significant relationship between Legal Frameworks and Medical Devices"

H_1: "There is no significant relationship between Legal Frameworks and Medical Devices"

Table 2: H_1 ANOVA Test

ANOVA					
Sum					
	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	39588.620	514	5655.517	693.487	.000
Within Groups	492.770	540	5.356		
Total	40081.390	1054			

In this study, the result is significant. The value of F is 693.487 , 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 Legal Frameworks and Medical Devices"*** is accepted and the null hypothesis is rejected.

9. DISCUSSION

Healthcare IT methods for obstetric medical equipment have to be put in place to raise the bar for maternal and infant care. This study's findings highlight the importance of methods such as agile development and user-centered design in the creation of safe and efficient devices. Learning these techniques inside and out allows one to find the best approaches that can improve outcomes. Interacting with individuals from many backgrounds, including patients, government regulators, healthcare providers, and IT businesses, was a crucial aspect of the process. Implementing their views and recommendations increases the likelihood that the devices will fulfill real needs and comply with all relevant rules. It was critical to handle the regulatory environment by aligning development processes with regulatory requirements. Streamlining clearance processes and

expanding into new markets required this painful but necessary move. The lightning-fast evolution of new technology was another major theme that surfaced over the course of the discussion. Obstetric care might be drastically altered by technological advancements like as telemedicine, data analytics, and wearable gadgets. To guarantee the effectiveness and safety of these new technologies, however, existing procedures will need to be modified. The findings show that healthcare providers, companies, and academic institutions need to work together more and do more research. The only way to encourage a culture of innovation in the creation of obstetric medical equipment is to invest in training and resources.

10.CONCLUSION

Improving maternal healthcare requires new approaches to health technology that center on obstetric medical equipment. Results show that an approach combining user-centered design, agile development, and processes based on evidence is essential. Making ensuring the end product satisfies both real-world demands and regulatory criteria may be easier if many different kinds of stakeholders are involved in the design process from the beginning. This improves their efficiency and safety. It was critical to streamline approval procedures in accordance with these standards as navigating the complexities of regulatory systems remained a challenge. To keep up with the benefits and threats posed by technology's exponential expansion, development methods must

likewise evolve. Future success will depend on healthcare professionals, companies, and institutions consistently working together. Novel obstetric medical equipment that greatly improves the outcomes of maternal healthcare is developed when there is consistent support for education and infrastructure, which creates an environment that is receptive to innovation. This essay concluded by outlining the procedures that will ultimately dictate the future of obstetric medical device research and development. Collaboration among stakeholders to tackle obstacles and seize innovative possibilities might lead to improved health technology that better suits the changing demands of maternity healthcare.

REFERENCE

Li J., Ma Q., Chan A.H., Man S. Health monitoring through wearable technologies for older adults: Smart wearables acceptance model. Appl. Ergon. 2019;75:162–169.

Kamruzzaman M., Alrashdi I., Alqazzaz A. New Opportunities, Challenges, and Applications of Edge-AI for Connected Healthcare in Internet of Medical Things for Smart Cities. J. Healthc. Eng. 2022;2022:2950699.

Yang Y., Wang H., Jiang R., Guo X., Cheng J., Chen Y. A Review of IoT-enabled Mobile Healthcare: Technologies, Challenges, and Future Trends. IEEE Internet Things J. 2022;9:9478–9502.

Karatas M., Eriskin L., Deveci M., Pamucar D., Garg H. Big Data for Healthcare Industry 4.0: Applications, challenges and future perspectives. Expert Syst. Appl. 2022;200:116912.

Alshamrani M. IoT and artificial intelligence implementations for remote healthcare monitoring systems: A survey. J. King Saud Univ. -Comput. Inf. Sci. 2022;34:4687–4701.

Krishnamoorthy S., Dua A., Gupta S. Role of emerging technologies in future IoT-driven Healthcare 4.0 technologies: A survey, current challenges and future directions. J. Ambient Intell. Humaniz. Comput. 2021:1–47.

Nahavandi D., Alizadehsani R., Khosravi A., Acharya U.R. Application of artificial intelligence in wearable devices: Opportunities and challenges. Comput. Methods Programs Biomed. 2022;213:106541.

Qadri Y.A., Nauman A., Zikria Y.B., Vasilakos A.V., Kim S.W. The future of healthcare internet of things: A survey of emerging technologies. IEEE Commun. Surv. Tutor. 2020;22:1121–1167.

Qayyum A., Qadir J., Bilal M., Al-Fuqaha A. Secure and robust machine learning for healthcare: A survey. IEEE Rev. Biomed. Eng. 2020;14:156–180.

Karthick G., Pankajavalli P. A review on human healthcare internet of things: A technical perspective. SN Comput. Sci. 2020;1:198.