

EVALUATING THE IMPLEMENTATION AND IMPACT OF FETAL MONITORING DEVICE

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in

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By

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Under the Supervision and Guidance of

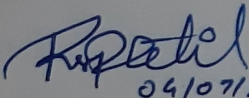
Mr. Rahul Sharma

2024

DECLARATION BY THE STUDENT

I hereby declare that this dissertation titled **“Evaluating the implementation and impact of fetal monitoring Device”** is the bonafide record of my original research work.

I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in this text.


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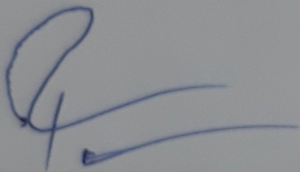
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CERTIFICATE

This is to certify that the dissertation titled **"Evaluating the implementation and impact of fetal monitoring Device"** is a record of the research work undertaken by **Rupesh Patil** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

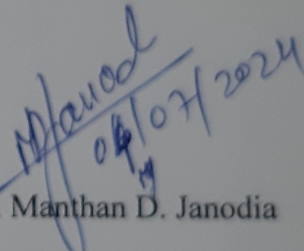


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Abstract

Title: Evaluating the implementation and impact of fetal monitoring Device

Author name: Rupesh Patil

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Keywords: Fetal Heart Rate, Maternal Heart Rate, Uterine Contractions, Fetal Monitoring devices, Non-stress Test, Cardiotocography, etc.

Background: Fetal monitoring devices are crucial for ensuring maternal and neonatal health, providing vital information during pregnancy and childbirth. In India, high maternal and neonatal mortality rates highlight the need for effective monitoring technologies. However, challenges such as limited access in rural areas, a shortage of trained professionals, and economic constraints hinder their widespread use. Innovations like portable and wireless devices, as well as AI integration, offer potential solutions to these challenges by enhancing accessibility and accuracy. This dissertation explores the current state of fetal monitoring devices in India, examining the challenges, innovations, and implications for improving maternal and neonatal health outcomes.

Objective: To critically assess the current state of fetal monitoring devices in India, identify key challenges and innovations, and evaluate their implications for maternal and neonatal health outcomes.

Methodology: This study aims to provide a detailed look at the current state of fetal monitoring devices in India, examining how effective these devices are in clinical settings, how widely they are adopted, and what barriers exist to their use, such as cost, accessibility, and training. It will also explore disparities in access to these technologies among different socio-economic groups and regions. The research will highlight the latest advancements, like wearable devices and AI-enhanced monitoring, and their potential to improve health outcomes for mothers and newborns. Additionally, the study will offer policy recommendations, suggest strategies for better training healthcare professionals, and propose areas for future research to enhance the use and impact of

these devices within India's maternal and child health programs. Information will be gathered from academic articles, industry reports, surveys, and regulatory documents, with data analysis conducted using MS Excel.

Results: The survey of 175 gynecologists reveals significant insights into the use and perception of fetal monitoring devices (FMDs). Among the respondents, 120 gynecologists are using FMDs, while 55 are not, possibly due to reliance on traditional methods or practices. The frequency of FMD usage is high, with most doctors frequently using these devices, as indicated by the ratings: 60 rated 3, 49 rated 5, 31 rated 4, 20 rated 2, and 15 rated 1. Furthermore, FMDs are employed more frequently in high-risk pregnancies compared to general routine checkups, with 83 rating 5, 43 rating 3, 29 rating 4, 15 rating 2, and 5 rating 1. Despite their widespread use, technical challenges are a concern for many, with 60 doctors reporting such issues. However, there is a strong belief in the efficacy of FMDs, as 140 gynecologists believe these devices improve neonatal health outcomes. Additionally, the healthcare system's support for adopting new fetal monitoring technologies is acknowledged by over 150 doctors.

Conclusion: The survey of 175 gynecologists reveals that 120 are using fetal monitoring devices (FMDs) while 55 are not, possibly due to traditional practices. Satisfaction levels vary, with most finding these devices satisfactory and frequently used, especially in high-risk pregnancies. Technical challenges are a significant barrier, as reported by 60 gynecologists. Despite this, 140 believe FMDs improve neonatal health outcomes, and over 150 recognize healthcare system support for adopting new technologies. Continuous efforts to address challenges, enhance accessibility, affordability, training, and supportive policies are essential to further improve maternal and neonatal health in India.

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List of abbreviations:

S.NO	Abbreviations	Full Form
1.	FMD	Fetal monitoring device
2.	FHR	Fetal heart rate
3.	CDSCO	Central Drugs Standard Control Organization
4.	MHR	Maternal heart rate
5.	USD	United States dollar
6.	CAGR	Compound Annual Growth Rate
7.	UC	Uterine contraction
8.	US	Ultrasound
9.	EFM	Electronic fetal monitor
10.	INR	Indian rupee
11.	NST	Non-stress Test
12.	CTG	Cardiotocography

Research Objective:

<u>Objective</u>	<u>Method</u>	<u>Result</u>
Assess the use of electronic fetal monitoring devices in current medical practice.	Primary research	The majority of gynecologists surveyed use fetal monitoring devices, while a smaller group does not, possibly due to adherence to traditional practices and methods.
Determine the frequency of use of fetal monitoring devices during routine check-ups	Primary research	Most gynecologists expressed positive satisfaction with fetal monitoring devices, frequently rating them highly.
Evaluate the frequency of using fetal monitoring devices during high-risk pregnancies.	Primary research	Fetal monitoring devices are more commonly used in high-risk pregnancies compared to routine checkups, according to survey findings.
Investigate the prevalence of technical issues encountered with fetal monitoring devices.	Primary research	Many gynecologists reported facing technical challenges with fetal monitoring devices, highlighting a significant barrier to their broader adoption.
Assess the use of fetal monitoring devices to enhance the neonatal health outcomes	Primary research	Most gynecologists believe that fetal monitoring devices improve neonatal health outcomes, underscoring their perceived importance for newborn health.
To assess the healthcare system's support for the adoption of new fetal monitoring technologies	Primary research	Most doctors believe the healthcare system supports the adoption of new fetal monitoring technologies, suggesting a favorable environment for integrating these devices into clinical practice.

Chapter 1 – Introduction

The care is very important in its maintenance of expectant moms and their unborn babies to perfect health and happiness. Among the numerous facets of this care, though, is the use of fetal monitoring devices that need no introduction about their essentiality in keeping an eye on the health of the baby and realizing problems that may arise during pregnancy and at birth. Certainly, where healthcare is much diversified and varies with socio-economic factors, India needs to evaluate these monitoring devices so that existing challenges in handling the betterment of mothers' and newborns' health can be improved through an ongoing challenge.

Although the situation has improved to some extent in recent times, India is still riddled with myriad problems as far as mom and baby health goes. According to the World Health Organization, in 2019, only India accounted for nearly 15% of all global maternal deaths and 20% of neonatal ones. All these figures truly underscore the need for an improvement in prenatal care standards and the introduction and proper working of advanced fetal monitoring technologies that could revolutionize the way the whole process is done now.

Evaluation of fetal monitoring devices in India therefore calls for a look into many diverse things: new technologies that are purporting to make monitoring more accurate and accessible, obstacles that hamper diffuse use, and the overall impact on the health of moms and babies. The availability and use vary considerably, whether it be a metropolitan city of large dimensions or a far-flung rural area. These will depend on the quality of available health facilities, money availability, and in some cases, cultural approaches toward prenatal care and technology.

Fetal monitoring devices, wearable sensors, and even AI-based analytical tools—these have been some of the most outstanding experiments in the field of innovation. These innovations really revolutionized the monitoring and management of the health of an unborn baby by providing early detection solutions that could help enable better decision-making to reduce the mortality rate for mothers and babies.

Bringing these technologies to India is not free of difficulties, as access to healthcare facilities in itself could be limited, there are differences in healthcare resources available at urban and rural levels, and further concerns over the issue of affordability. These notwithstanding, cultural beliefs

and traditional practices during pregnancy and childbirth may influence the will and willingness of the expectant mother and practitioners in adopting these technologies.

Chapter 2 - Literature Review

Early Developments: The practice of monitoring fetal health had its beginning in the early 20th century when physicians would use a stethoscope to listen to the baby's heartbeat. This approach was helpful but depended much upon the doctor's skills and only provided intermittent monitoring

Electronic Fetal Monitoring: In the 1960s, electronic fetal monitoring came to be, and it really did revolutionize obstetrical care. According to Mires et al. (2001), EFM provided for the continuous recording of the FHR and UC during labor, which greatly facilitated early detection of any signs of distress. A cardiotocograph became a staple in delivery rooms, providing a visual record of the heartbeat of the baby and the contractions.

Non-Invasive Technologies: Over the years of developments, Fetal monitoring techniques have definitely shifted to Non-Invasive methods. According to Alfirevic, Devane and Gyte, the invasive methods like fetal scalp electrodes are substituted by Doppler Ultrasound and external CTG. These technological developments improve the comfort level of patients with enhanced safety features.

Clinical Efficacy and Outcomes:

Meta-Analyses and Systematic Reviews: Studies on the Effectiveness of Fetal monitoring devices highlight conflicting results. Alfirevic et al. (2006) conducted a meta-analysis comparing continuous EFM against intermittent auscultation. In their results, the authors reported no significant reduction in infant mortality with continuous EFM; however, it significantly increased rates of cesarean and instrumental deliveries. Grivell et al. (2012) also confirm these findings that state EFM improves the detection of fetal distress and yet has no significant effect on such outcomes as seizures or cerebral palsy.

Intervention Rates: Studies by Thacker, Stroup, and Chang, 2001 link continuous EFM with increased rates of interventions, including cesarean sections and assisted deliveries. This may be interpreted as providing even more reason to reinforce careful interpretation of EFM data so that non-necessary interventions can be avoided.

Innovations in Fetal Monitoring:

Wearable and Portable Devices: Wearable fetal monitoring devices have recently been developed. Chen et al. (2020) outline how, by using these more recent devices, it is now possible to have the continuous monitoring of the fetus without restricting the movement of the mother, which provides greater convenience and might improve compliance.

Telemedicine Integration: The integration of fetal monitoring with telemedicine has been of particular relevance during the COVID-19 pandemic. García et al. note, "By remote monitoring, high-risk pregnancy could be taken care of with continuity while keeping the visits to the hospital at minimum.

Artificial Intelligence: AI and machine learning are paving their way into fetal monitoring. Rosen et al. (2018) discuss the role of artificial intelligence in improving the interpretation of fetal monitoring data and the accuracy of prediction of an adverse outcome, hence facilitating personalized prenatal care.

Market Dynamics in India:

Market Growth: The Indian market for fetal monitoring devices has witnessed high growth. This surge could be based on increased awareness regarding maternal health, the willingness of people to spend more on healthcare, and subsequent augmentation by policy decisions of the government. Saxena et al. (2019) report significant growth in both urban and rural markets, which would be based on increasing demand for advanced technologies for fetal monitoring.

Access and Equity: Despite the growth of this market, there is still a palpable access inequality to fetal monitoring devices. Patel et al. (2017) point out this inequality between urban and rural settings, showing that rural areas many times lack infrastructural facilities and appropriate personnel for the efficient use of such equipment.

Challenges and Barriers:

Cost and Affordability: The high costs of advanced fetal monitoring have significant implications for Maternal and Neonatal Health.

In Training and Expertise: Due to less number of trainers, it becomes a challenge for FMD.

Implications for maternal and neonatal health:

Improved Patient Outcomes: Effective fetal monitoring can significantly improve maternal and neonatal outcome by enabling early detection, intervention for fetal distress and other complications. Studies like **Dawes et al. (1992)** show that timely interventions based on fetal monitoring data can reduce perinatal mortality and morbidity.

Holistic Care Approach: Integrating fetal monitoring into broader maternal health programs can provide holistic care. **Verma and Agarwal (2020)** advocate for a comprehensive care model that addresses not only fetal health but also maternal nutrition, mental health, postpartum care.

Future Directions:

Affordable and Portable Solutions: We need to develop fetal monitoring devices that are both cost-effective and easy to carry around. This is really important because it will make it easier for people in areas with limited resources to access these devices. Rao et al. (2018) came up with some innovative ideas specifically designed for rural healthcare needs. They suggest using monitors that are low-cost and run on batteries, which sounds pretty practical, right?

Better Training and Education: We can't forget about the people who will be using these devices. It's crucial to improve the skills and knowledge of healthcare providers through enhanced training programs. Gupta and Prakash (2021) have a great suggestion: we should have standardized curricula and certification programs to make sure healthcare professionals are well-prepared to use fetal monitoring technologies. That way, they'll know exactly what they're doing.

Working Together: It's all about teamwork! To make the most of fetal monitoring, we need to integrate it with existing health systems. This will allow for better sharing of data and coordination

of care. Verma and Agrawal (2020) suggest that using interoperable systems can really improve the efficiency and effectiveness of prenatal care. It's all about making things work together seamlessly.

Challenges in adapting fetal monitoring devices:

1. Lack of Monitoring in Maternal and Newborn Care:

- Every day, around 800 mothers lose their lives.
- Only 58.1% of pregnant women get the recommended 4 antenatal visits.
- In 2020, 14.7% of worldwide births resulted in low birth weight.

2. Delayed Early Detection of Complications:

- There are only 37.5 health workers per 10,000 people in India, which is less than the recommended ratio by WHO of 44.5.
- There is a global deficit of 50% in health workers.

3. Economic Constraints:

- High Costs: The fetal monitoring devices, such as continuous electronic fetal monitors and cardiotocographs, can be very expensive and are unaffordable to most healthcare facilities.
- Inadequate Funding: Govt funding towards healthcare is always inadequate, and the amount allocated to advanced maternal and fetal healthcare technologies is pretty less.

4. Infrastructural Constraints:

- Lack of Infrastructure: Most healthcare centers, especially in backward and far-flung areas lack adequate infrastructure to support advanced fetal monitoring devices.
- Maintenance and Repairs: Proper maintenance and ensuring timely repairs of the fetal monitoring devices is quite a problem, especially in rural areas.

5. Educational and Training Challenges:

- Inadequate Training: This is primarily observed in peripheral health institutions for the majority of healthcare professionals; they are not adequately trained for the advanced fetal monitoring devices.

- **Continuing Education and Professional Development:** There is a need for continuing or up-gradation training programs to keep the healthcare professionals updated about the latest development and best practices in the domain of Fetal Monitoring

6. Technological Barriers:

- **Local Condition Adaptability:** Most of the fetal monitoring devices are constructed for use in well-equipped healthcare settings situated in urban areas and may not work perfectly in rural conditions.
- **Data Management:** The crux of the matter here is functional data management systems, but most health facilities lack the IT infrastructure necessary for managing and analyzing data coming from these devices.

Innovations in FMD

Evolution of fetal monitoring devices has come of age in making prenatal care much more efficient, accurate, and readily available, especially in the resource-constrained regions of rural India. These were driven primarily by technology and a need for affordable solutions with a rising concern for the health of both mother and baby. Therefore, let us discuss some of the recent significant innovations in fetal monitoring devices:

1. Portable and Wireless Devices:

- **Hand-held Doppler Ultrasound Devices:** These portable devices are useful in readily acquiring the baby's heart rate on numerous locations, like domestic visits and peripheral clinics. They are cheap, user-friendly, and at the same time, do not require much training.
- **Wireless Fetal Monitors:** No more hassling cables! Wireless devices use Bluetooth or other wireless technologies to send data over to a smartphone or tablet; continuous monitoring is possible without a hitch. Thus, providing moms-to-be comfort and liberty during labor.

2. Wearable Technology:

Wearable Sensors: Patch or belt devices that monitor the heart rate and uterine contractions of the baby continuously. Because these are non-invasive devices, they measure data in real-time, which healthcare providers can monitor for accuracy without invading personal space.

- **Smart Clothing:** Science fiction! Embedding sensors in maternity belts or shirts to track the fetus continuously and non-invasively. This type of intelligent clothing records vital signs and transmits information to the practitioners remotely.

3. Mobile and Telemedicine Solutions:

- **Mobile Apps:** It seems everything comes with an app these days, and fetal monitoring is no exception either. These are mobile applications accompanying portable fetal monitoring devices.

Health providers can track metrics of fetal health, record data as needed, and integrate with other medical professionals to ensure better care.

- **Telemedicine platforms:** Distance is no longer a barrier. Telemedicine solutions will make remote monitoring and consultations possible for women who earlier did not have an access to services in distant and backward places of high morbidity and mortality, thereby making prenatal care possible. Healthcare providers can take a review of data from the fetal monitors to aid advice or timely interventions.

4. Advanced Data Analytics and AI:

- **Predictive analytics:** AI and machine learning can use large amounts of data gathered from these monitoring devices in order to identify trends as well as predict any potential issues. Early identification would therefore give doctors time to respond and thus improve care and outcomes for both mom and baby.

- **Automated Interpretation:** Advanced Fetal Monitors using AI can read automates fetal heart rate patterns and uterine contractions. They provide real-time alerts to healthcare providers concerning possible problems such as fetal distress, so that timely intervention could be made.

5. Integration with Electronic Health Records:

- **Integrated data:** The latest generation fetal monitoring devices can be integrated with EHRs. Fetal health data is therefore auto-recorded and made available to all health professionals concerned. The integration would increase the continuity of care and quality of decision-making.

6. Affordable Inventions:

- **Low- Cost Fetal Monitors:** Researchers and companies have been striving to develop low-cost fetal monitoring devices for healthcare centers with meager resources. The low-cost fetal monitors come equipped with the very basic features and are economically more affordable.

- **DIY Fetal Monitoring Kits:** In this regard, some innovations are oriented towards integrating do-it-yourself fetal monitoring kits that expectant mothers can use in the comfort of their own homes. Such a kit is equipped with usable basic monitoring equipment, together with instructions, to further enable moms-to-be to detect any sign of problems at the very first instance.

7. Improved User Experience:

- **User-Friendly Interfaces:** The new generation of fetal monitoring devices has been designed with easy-to-operate user interfaces, reducing operational complexity for healthcare professionals and expectant mothers with clear visual and auditory cues to achieve correct monitoring and interpretation.

- **Real-Time Feedback:** Devices that give real-time feedback and guidance help healthcare providers and expectant mothers.

Implications on Maternal Neonatal Health:

Better Maternal Health Outcome:

Early Detection of Complications: Advanced fetal monitoring devices aid in the earlier detection of motherly issues such as preeclampsia gestational diabetes, and placental insufficiency. Dawes et al. (1992) point out that continuous monitoring allows for rapid action, which forms the basis for managing these disorders and preventing serious outcomes like maternal death or emergency cesarean sections.

Reducing Mother's Health Problems: Effective monitoring of the unborn child can lower the mother's health problems by improving how labor and childbirth are managed. **Grivell et al. (2012)** observed that immediate data from baby monitoring devices can guide healthcare workers to make informed choices regarding the progress of labor, which might lessen the need for procedures like using forceps or a vacuum, and these procedures can lead to issues for the mother.

Better Mental Health for Mothers: Keeping a constant watch on the fetus can calm expecting mothers lessening worry and stress during pregnancy and childbirth.

García et al. (2021) show that remote surveillance and devices you can wear help mothers-to-be stay more in touch with their doctors and feel better .

Better Health of Newborns:

Spotting Trouble in Babies: One big plus of better baby monitoring is catching problems . **Alfirevic et al. (2006)** show that watching the baby's heart rate all the time can spot signs of low oxygen or other problems letting doctors act fast by giving oxygen, medicine, or doing an urgent delivery.

Lower Perinatal Mortality: Effective fetal monitoring helps lower death rates before and after birth. **Dawes and his team (1992)** show that acting based on the data from fetal monitoring can prevent deaths of newborns and unborn babies by dealing with fetal distress.

Better Outcomes for Newborn Health: Advanced equipment for fetal monitoring can decrease newborn illnesses by spotting urgent issues like umbilical cord prolapse or placental abruption. **Rosen and colleagues (2018)** explain how using AI to enhance fetal monitoring increases the precision of detecting these problems, which improves the health of newborns.

Market Analysis:

India's market for neonatal and prenatal devices is set to grow, with a projected CAGR of 5.9% in the upcoming years. The COVID-19 pandemic disturbed maternal healthcare due to travel limits scarce public transport, and fear of catching the virus stopping many women from getting needed

services. A March 2022 study by PubMed Central noted a 2.26% drop in hospital births and a 22.91% decrease in antenatal care services during the pandemic. Despite these obstacles, the market is likely to bounce back and grow as the pandemic lessens.

Several vital factors are fueling the growth of this market. Increasing cases of preterm infants, a boost in public knowledge about prenatal and neonatal healthcare, and different government efforts to enhance newborn care are crucial. Babies born before 37 weeks termed preterm babies often need incubators because their organs are not developed. The Times of India report from July 2022 says that the higher number of diabetes, obesity, and fertility treatments in women are leading to more premature births. UNICEF information from July 2021 shows that India sees about 3.5 million preterm births every year, with 1.7 million infants born with birth defects and a million leaving Special Newborn Care Units (SNCUs) . These babies risk death, growth delays, and developmental problems highlighting the vital need for better neonatal and prenatal devices.

UNICEF matches the efforts of the Government of India's "India Newborn Action Plan" aiming to cut preventable newborn deaths and stillbirths to single digits by 2030. UNICEF played a key role in expanding SNCUs throughout India and created a global real-time online database to track sick newborns. They take the lead in 39 of the 115 aspirational districts pinpointed by NITI Aayog for focused efforts.

Challenges continue. Developed regions face low birth rates, India sees economic issues and lack of awareness slow down market growth. Yet many organizations and the government are working hard, which leads to big improvements in health for mothers and newborns.

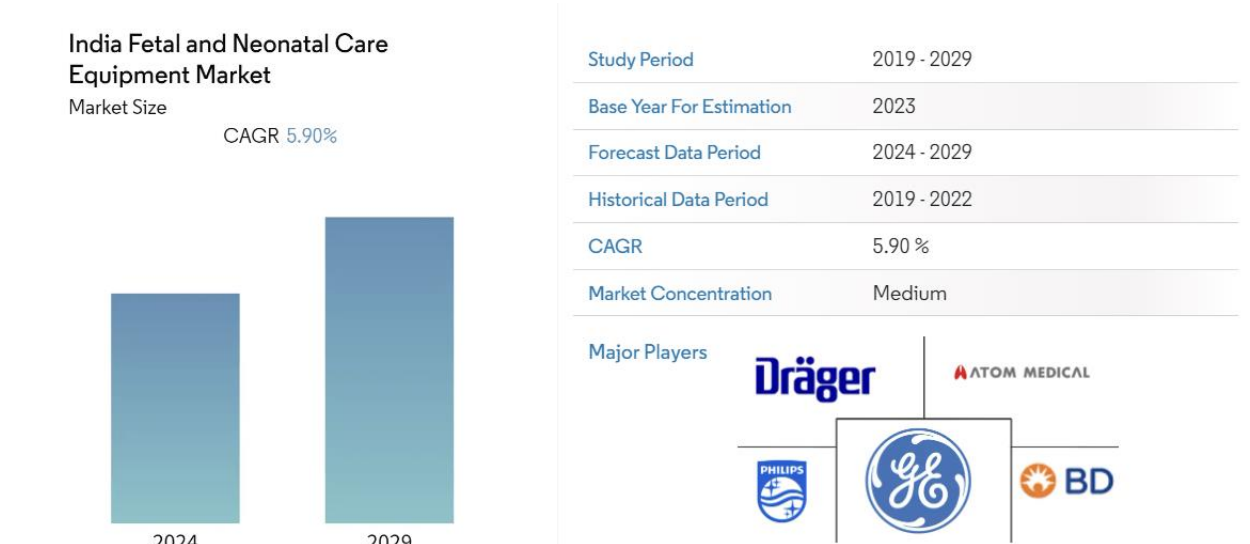


Figure-1

Trends in an Indian Fetal Monitoring Device:

Neonatal Incubators Expect Big Growth:

In the next few years, the neonatal incubator segment will grow a lot. Neonatal incubators are essential for babies who need help breathing. They provide everything from extra oxygen to continuous positive airway pressure (CPAP) or mechanical breathing help. Keeping the right temperature is very important in these incubators. If the temperature changes a lot, it can cause newborns to lose heat, get hypothermia, or have apnea. Companies focus a lot on managing the temperature, which is tied to how air flows and moves inside the incubator, to keep these babies safe.

In countries like India affordable neonatal incubators like MiraCradle and Embrace Nest are getting more popular. These cheap options help hospitals and patients access life-saving technology, which boosts this market segment. Also, the country's high birth rate plays a big role in the predicted strong growth rate for neonatal incubators.

A study in PubMed from July 2022 showed that the Medciti Institute of Medical Sciences recorded 135 premature births out of 1,243 (10.86%) pointing out a greater need for neonatal incubators. With more early births happening and more of these key machines available, the market for incubators is set to grow during the forecast period.

Estimated Number of Births in India (in million), India, 2022



Figure-2

Respiratory support and monitoring tools will have a big part in the market during the forecast period. Their important function in maintaining the health and safety of babies makes them key in offering specialized care during crucial infancy stages across India:

Devices for neonatal respiratory monitoring help newborns breathe well during important times while keeping lung damage low. Top clinical guidelines suggest using volume control that protects lungs and monitors CO2 for ventilating neonates.

The need for respiratory help and tracking tools in baby care is likely to boost segment growth. For instance, a June 2022 study from PubMed Central underlined the need for unbroken tracking of heart and breathing in premature babies in India. These tools keep an eye on crucial signs such as pulse rate (PR), breathing rate (RR), and oxygen levels (SPO2) during hospital visits.

Also, a June 2021 piece in the Indian Journal of Paediatrics mentioned that breathing problems are usual in both early and term babies. The right use of breathing help tools can save lives. Often non-invasive breathing help is enough, but sometimes intrusive breathing help might be needed.

So, the benefits that breathing help and tracking tools provide should push this part to grow during the predicted time.

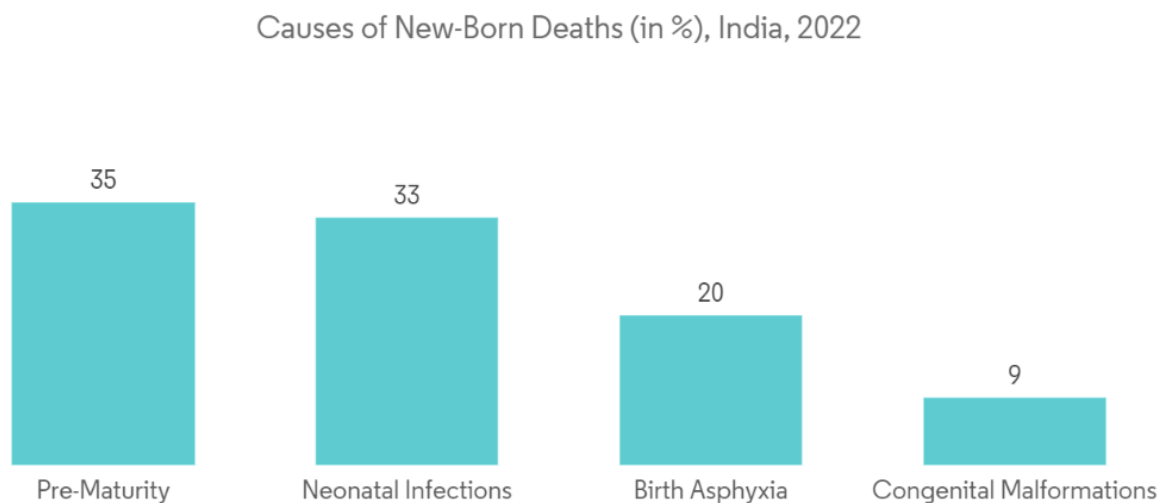


Figure-3

India's Neonatal and Prenatal Devices Market Segmentation:

One of the most important devices in gynecology and obstetrics has to be fetal monitoring devices, which are utilized for assessing fetal health during labor and delivery. They help health personnel monitor vital signs and recognize complications early enough to institute timely interventions that will benefit mother and baby.

Neonatal devices form the most important function in the neonatal ICU since they provide specific care to newborns who require intensive medical attention. This category comprises incubators, which maintain the optimum temperature, devices for monitoring vital signs, phototherapy equipment for treating jaundice, as well as respiratory assistive devices to support breathing.

Care equipment in India for the fetal and neonatal segment is categorized into two chief categories: Prenatal & Fetal Equipment and Neonatal Care Equipment. The first has offerings such as Fetal Dopplers, Monitors, and Pulse Oximeters, and the latter comprises many devices like Neonate Incubators, Monitoring Devices, Phototherapy Units, and Respiratory Assistance equipment. These segments, therefore, show the diversity of the healthcare settings within the country, with the market value being in USD million, thereby showing the amount of investment and priority given to the improvisation of maternal and infant health outcomes in the country as a whole.

By Product Type	Prenatal & Fetal Equipment	Fetal Dopplers
		Fetal Monitors
		Fetal Pulse Oximeters
		Other Prenatal and Fetal Equipment
	Neonatal Care Equipment	Incubators
		Neonatal Monitoring Devices
		Phototherapy Equipment
		Respiratory Assistance and Monitoring Devices
		Other Neonatal Care Equipment

Figure-4

Global FMD Market:

The global fetal monitoring market amounted to US\$3.4 billion in 2022; it is expected to prominently reach US\$6.2 billion by 2032 at a CAGR of 6.2% during the forecast period from 2023 to 2032. Fetal monitoring is definitely one of the most crucial diagnostic tools utilized at the time of labor for monitoring fetal movement, heart rate, and the frequency of maternal contractions. Basically, it is going to monitor the well-being of the fetus and the progress of labor in order to ensure safe childbirth. Medically, fetal monitoring is a way to check the health of an unborn baby by providing relevant information to health care providers so that they might timely intervene and optimize maternal and infant outcomes.

Market Dynamics of FMD:

The increasing cases of gestational diabetes, hypertension, and preterm labour have made the practice of monitoring the foetus a matter of routine to monitor foetal well-being and detect any fits before time. Thus, ensuring timely interventions and effective management of complex pregnancies. Underdeveloped and developing countries are increasingly adopting new fetal monitoring solutions like software-based telemetry systems. In the coming years, the markets shall be driven because the healthcare spending in countries such as India and China shall be surging due to the growing economies.

In regard to the device technology, there may be products such as the ultrasound systems whereas portable foetal monitors have improved the monitoring sensitivity and productivity thus increasing the sales. More data analysis in real time coupled with wireless connectivity and the portability feature creates convenience in the monitoring process for healthcare providers and expectant mothers; hence, making these low-cost devices present significant opportunities in these regions. Government initiatives in support of maternal and child health care, such as Healthy People 2030 by the United States Department of Health and Human Services, have increased the adoption of fetal monitoring in prenatal care to enable equality in the levels of healthcare, hence addressing health disparity.

Market growth will further be fueled by the fact that demand for fetal monitoring during pregnancy has increased with technological advancements and increases in preterm and birth rates. Moreover, the potential demand in fetal monitoring devices is growing outside developed markets, such as China, Brazil, and India, mainly triggered by technology advancement and rising awareness among masses on various aspects of perinatal health.

Despite such developments, acquiring high-order fetal monitoring equipment and the subsequent maintenance have remained a big hindrance to healthcare facilities using the technology, especially those in low-resource settings. A large initial investment and further costs incurred in the purchase, maintenance, and calibration of the equipment are sometimes too high and therefore act as a deterrent measure for diffusion across health providers.

Governments, Academic research institution, and Pharmaceutical companies face a financial crunch, and they might cut down the funding for research and technology development projects

significantly. This, in parallel, will lead to delayed or abandoned projects. It will keep a check on the demand for fetal monitoring devices during such times. It will also have to, most likely, cut down the processes and bring down the costs for various regulating bodies. This further will add a negative effect on the dynamics of the market.

Segmental Overview:

The analysis of the fetal monitoring market informs in detail regarding different segments of the market. Here is what this means in human terms.

The market is categorized based on products and their numerous types, including ultrasound machines, electronic fetal monitoring (EFM) devices and accessories, and consumables of these devices. Ultrasound machines are also sub-categorized into 2D, 3D, and 4D ultrasound machines, and other devices that provide Doppler imaging. EFM machines are also sub-categorized into external and internal EFM monitoring machines, according to the way or situation that these machines operate on or in before delivery.

Monitoring methods can be said to be either invasive or non-invasive, and this reflects the different ways in which healthcare professionals could obtain key information regarding fetal well-being.

In portability, the devices are either portable or non-portable, and this indicates the flexibility that the devices could take in different healthcare settings.

Applications of fetal monitoring include intrapartum and antepartum monitoring. The first is labor; the second occurred before the onset of labor and the two have different goals and objectives with regard to medical care to the mother and safe delivery processes of a baby.

End users for these technologies are hospitals and maternity hospitals, clinics, and other healthcare settings, which showcases diversity in the user settings where fetal monitoring becomes a must.

Geographically, the analysis of the market includes the crucial regions of North America, Europe, Asia-Pacific, and LAMEA (Latin America, the Middle East, and Africa) and covers the regional diversity of healthcare practices and market dynamism.

This detailed segmentation helps stakeholders learn how in the various contexts of the globe fetal monitoring technologies are used so as to frame strategies of improving maternal and fetal health outcomes.

By the product:

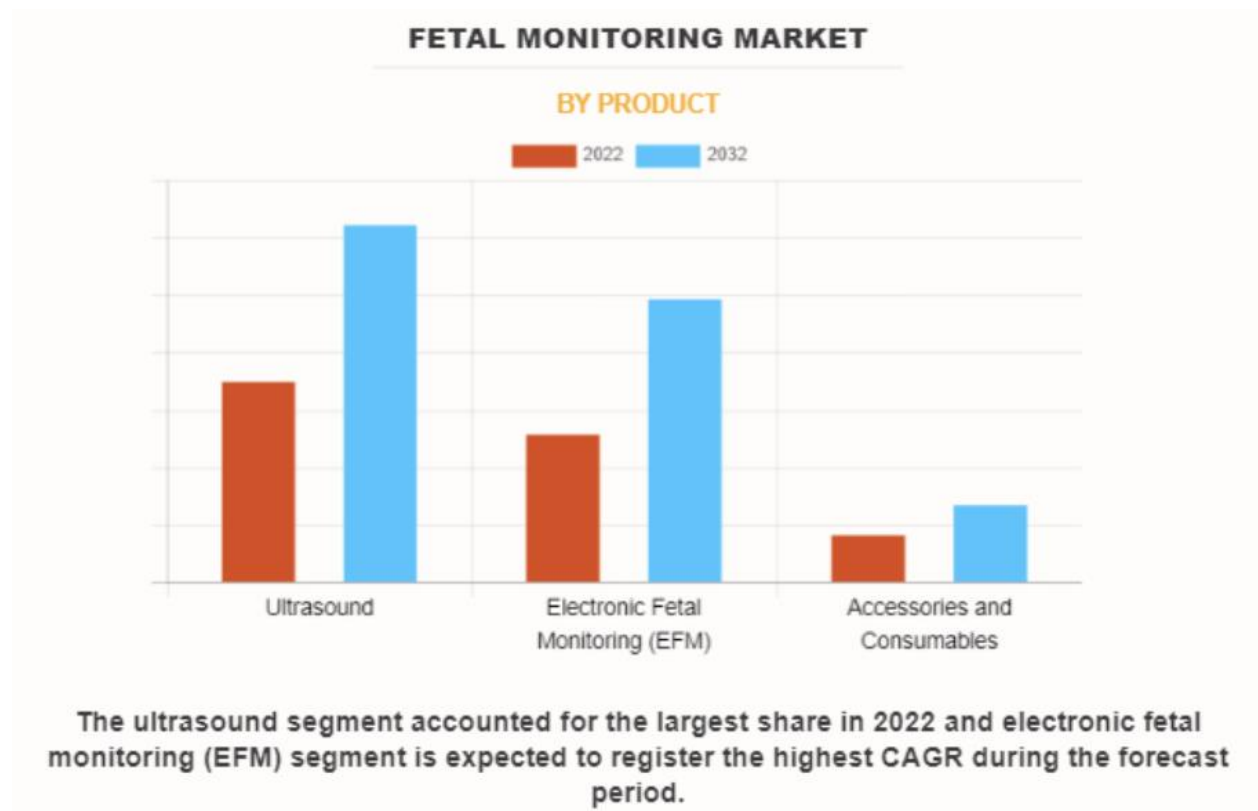


Figure-5

By the method:

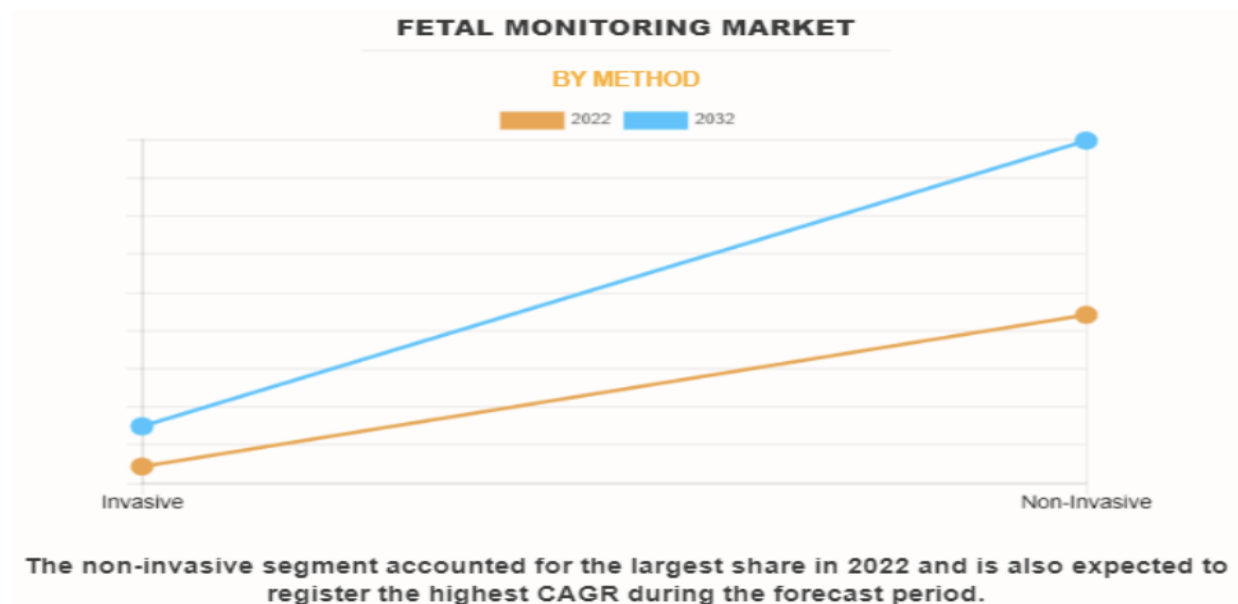


Figure-6

By the Portability:

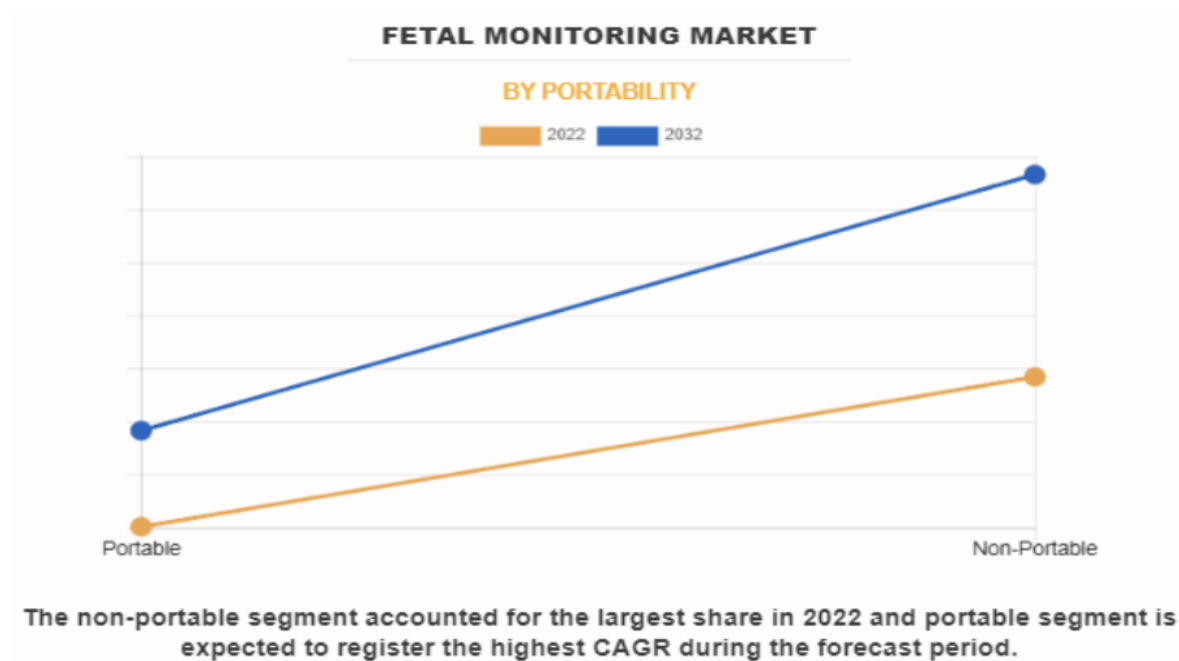


Figure-7

By an application:

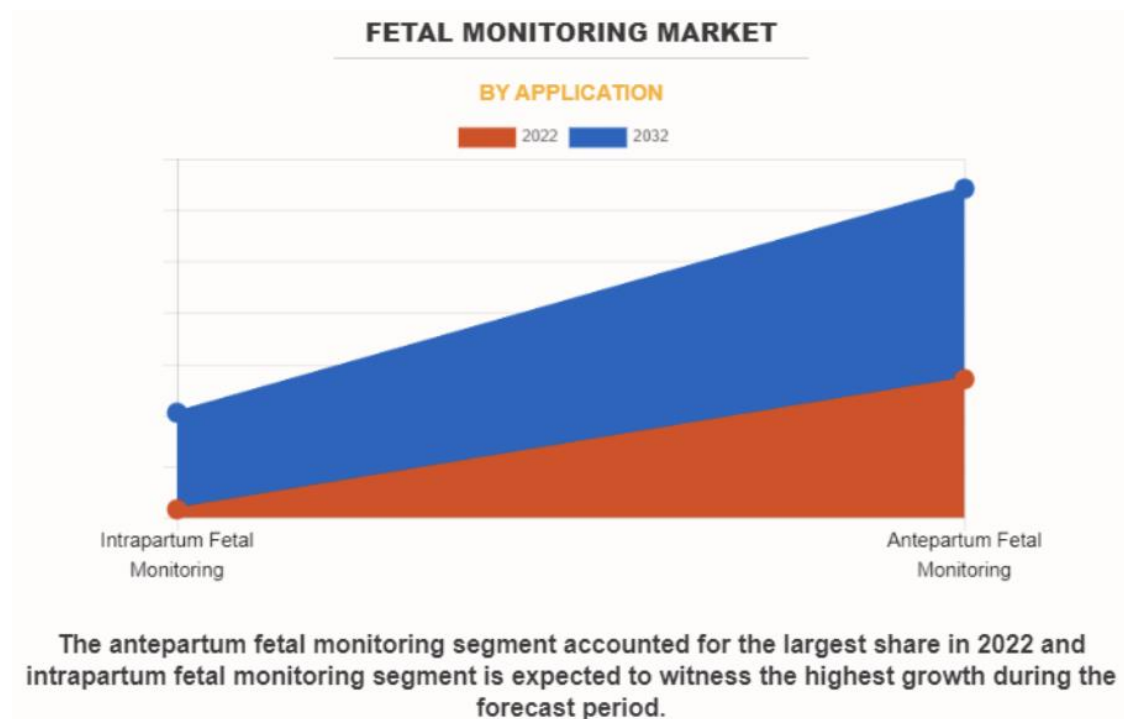


Figure-8

By an end User:

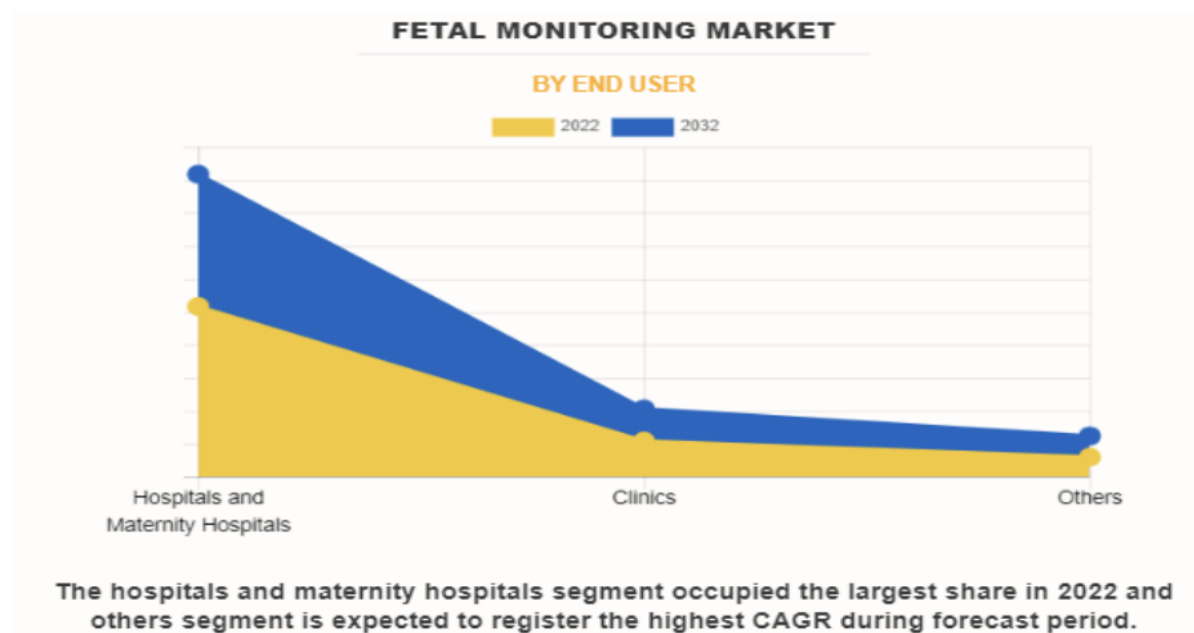


Figure-9

Chapter 3 - Methodology

Objective: To critically critically assesses the current status of fetal monitoring devices in India, relates challenges and innovations in this area, and evaluates the consequences for improving maternal and neonatal health outcomes.

Specific Objectives:

Evaluate the Efficacy and Adoption:

- Assess the clinical efficacy of different fetal monitoring devices used in India.
- Analyze the adoption rates and barriers to the utilization of these devices across various healthcare settings, including urban and rural areas.

1. Identify Challenges:

- Investigate the primary challenges faced in the implementation and widespread adoption of fetal monitoring devices, including cost, accessibility, training, and regulatory hurdles.
- Examine the disparities in access to advanced fetal monitoring technologies between different socio-economic groups and geographic regions.

2. Analyse Innovations:

- Review the latest technological advancements in fetal monitoring, including wearable devices, telemedicine integration, and AI-enhanced monitoring.
- Evaluate the potential of these innovations to address existing challenges and improve maternal and neonatal health outcomes.

3. Assess Implications for Health Outcomes:

- Study the impact of fetal monitoring devices on mother and neonates' health outcomes, including early detection of complications, reduction in perinatal mortality and morbidity, and overall health improvements.

- Investigate the long-term developmental outcomes for neonates monitored with advanced fetal monitoring technologies.

4. Policy and Regulatory Recommendations:

- Provide recommendations for policymakers and healthcare providers on enhancing the implementation and effectiveness of fetal monitoring devices.
- Suggest strategies for improving training and education of healthcare professionals in the use of these technologies.

5. Future Directions and Research:

- Identify areas for future research and innovation in fetal monitoring to further improve maternal and neonatal health outcomes.
- Propose frameworks for integrating fetal monitoring devices with broader maternal and child health programs in India.

Literature Review

- Conducted a comprehensive review of relevant literature on advanced fetal monitoring devices and future trends.
- Identified key concepts, theories, and frameworks related to advanced fetal monitoring devices.
- Gathered information by searching academic journals, industry reports, conference proceedings, primary research via questionnaires, and other reliable sources.
- Visited some websites with government-released data about the market size and future aspects of fetal monitoring devices

Material and Methods:

Study Design: Exploratory with Descriptive Type

Setting: This study will involve primary research aimed at gathering data from surveys, legal documents, regulatory documents, and existing reports.

Study Population: Individuals working in healthcare-related domains.

Sampling Technique: Non-Probability Convenient Sampling

Sample Source: Primary and Secondary research sources

Data Analysis Plan:

Surveys and reports will be analyzed using MS Excel, if necessary.

Chapter 4 - Results & Discussions

I have done primary research with **175 respondents (gynecologists)** and asked them some questions that helped me in my dissertation.

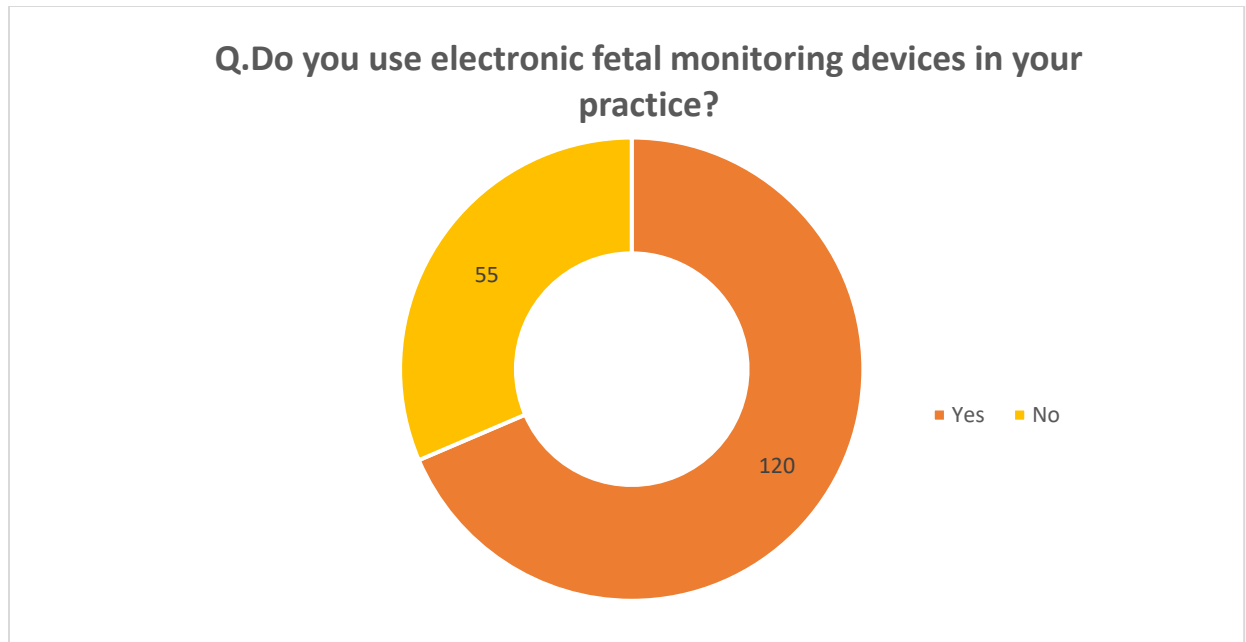


Figure-10

As per the survey, out of 175 doctors, 120 are using fetal monitoring devices and 55 are not. Traditional methods or practices might be the reasons for not using them.

Q.How frequently do you use fetal monitoring devices during routine check-ups? (Rate 1-5, where 1 is 'Very less' and 5 is 'Always')

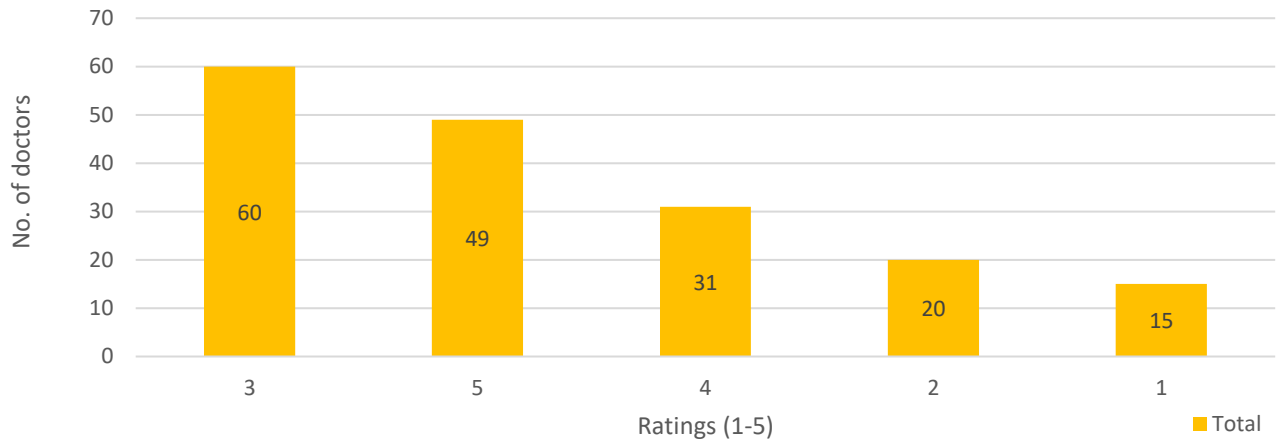


Figure-11

Per the survey, out of 175 gynecologists, 60 have rated the 3, 49 have rated the 5, 31 have rated the 4, 20 have rated the 2, and 15 have rated the 1. Most doctors frequently use FMD.

Q.How frequently do you use fetal monitoring devices during high-risk pregnancies? (Rate 1-5, where 1 is 'Very less' and 5 is 'Always')

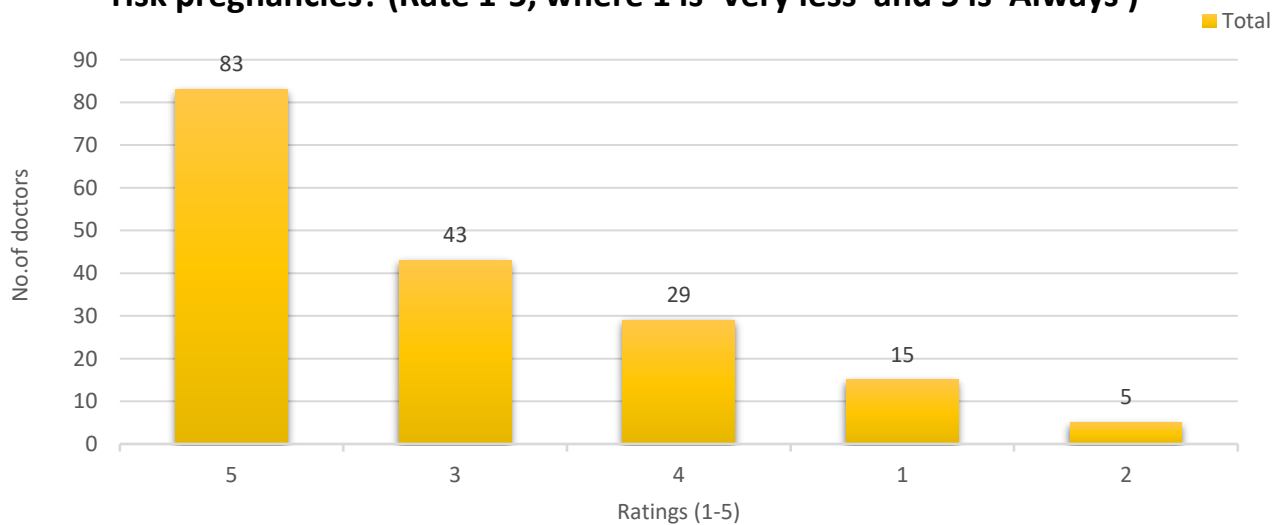


Figure-12

Per survey, out of 175 gynecologists, 83 have rated the 5, 43 have rated the 3, 29 have rated the 4, 15 have rated the 2, and 5 have rated the 1. Most doctors frequently use fetal monitoring devices in high-risk pregnancies as compared to general routine checkups.

Q. Do you face technical issues with fetal monitoring devices? (Yes/No)

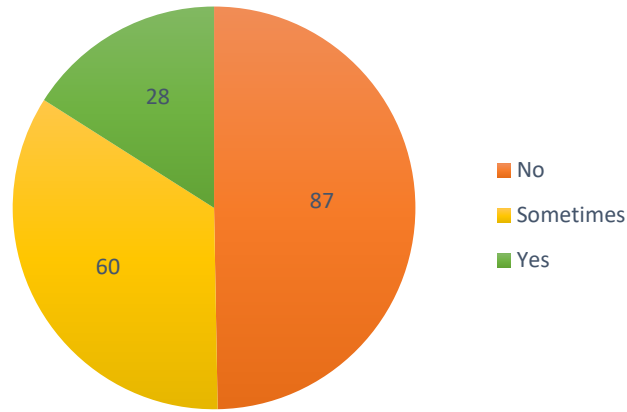


Figure-13

As per the graph, it is showing that many doctors are facing technical challenges while using fetal monitoring devices. Out of 175 gynecologists, 60 doctors say they face technical challenges while using the fetal monitoring devices.

Q.Do you believe fetal monitoring devices improve neonatal health outcomes? (Yes/No)

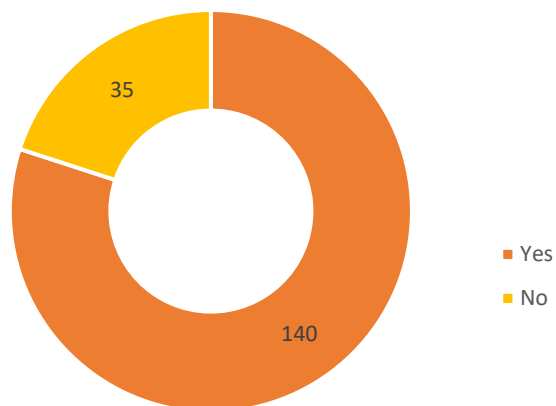


Figure-14

Out of 175 gynaecologists, 140 doctors believe that fetal monitoring devices improve neonatal health outcomes.

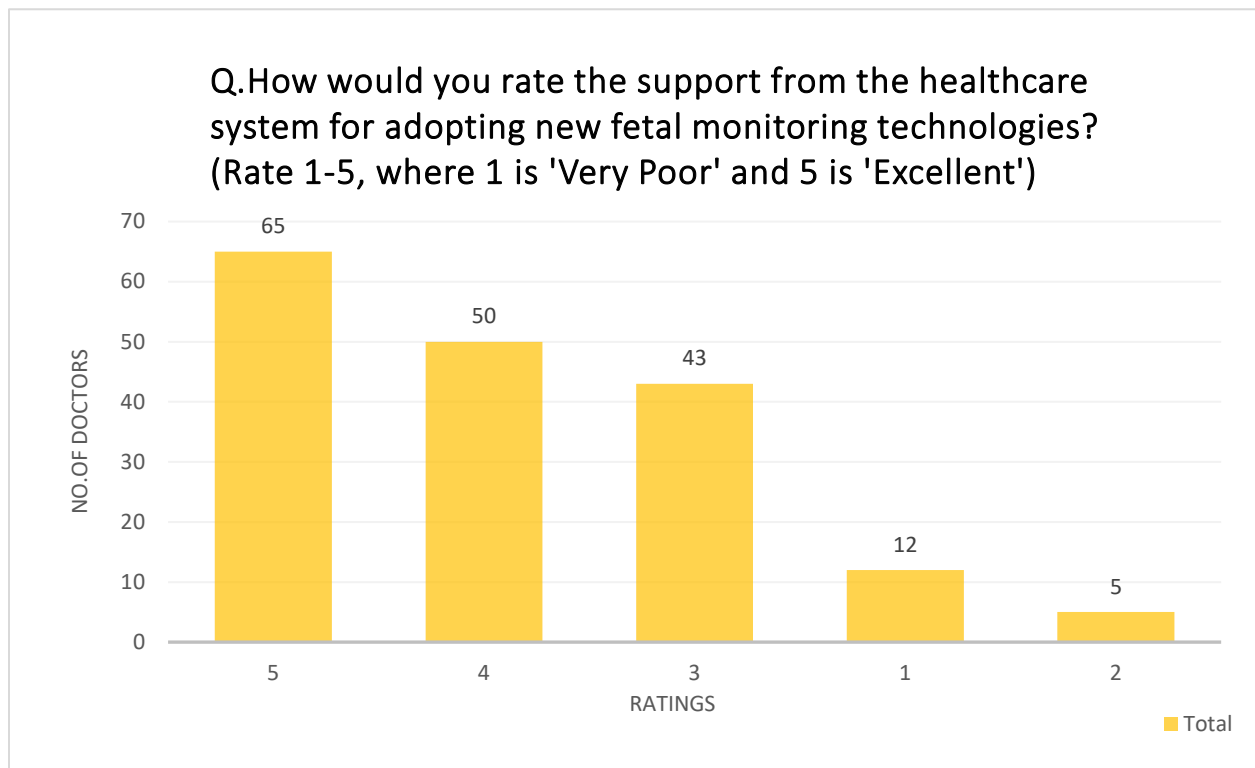


Figure-16

As per the survey, more than 150 doctors out of 175 believed that the healthcare system provides support for adopting new fetal monitoring technologies.

Chapter 5 – Conclusion

- **Adoption Rates:** Out of 175 gynecologists surveyed, 120 are using fetal monitoring devices while 55 are not. The reasons for not using these devices may be linked to traditional practices and methods.
- **Satisfaction Ratings:** When asked to rate their satisfaction with fetal monitoring devices, 60 gynecologists rated them a 3, 49 rated them a 5, 31 rated them a 4, 20 rated them a 2, and 15 rated them a 1. This indicates that most doctors find these devices satisfactory, with many frequently using them.
- **Usage in High-Risk Pregnancies:** The survey revealed that 83 gynecologists rated their use of fetal monitoring devices in high-risk pregnancies a 5, 43 rated it a 3, 29 rated it a 4, 15 rated it a 2, and 5 rated it a 1. This shows that these devices are more frequently used in high-risk pregnancies than routine checkups.
- **Technical Challenges:** Out of 175 gynecologists, 60 reported facing technical challenges while using fetal monitoring devices, indicating that technical difficulties are a significant barrier to their broader adoption.
- **Perceived Health Benefits:** A strong majority, 140 out of 175 gynecologists, believe that fetal monitoring devices improve neonatal health outcomes, underscoring their perceived importance in ensuring better health for newborns.
- **Support for Adoption:** More than 150 out of 175 doctors believe that the healthcare system supports the adoption of new fetal monitoring technologies, suggesting a favorable environment for integrating these devices into clinical practice.

In conclusion, while significant strides have been made in fetal monitoring technology in India, continuous efforts are needed to address existing challenges and leverage innovations. By enhancing accessibility, affordability, and training, and by fostering a supportive policy environment, India can further improve maternal and neonatal health, ensuring a healthier future for mothers and their babies.

By addressing the identified challenges through targeted interventions and continued innovation, India can make substantial strides in improving health outcomes for mothers and babies across the country.

Chapter 6 – Limitations

- There is a chance that the replies provided by the respondents may be biased.
- The analysis uses actual data, not projections.
- There was a limited amount of time which affected the accuracy.
- The study was conducted in Rajasthan only.

Chapter 7 –References

- **Bissonnette, B., Luginbuhl, I., & Marciniak, B.** (2014). *Fetal and Neonatal Physiology for the Advanced Practice Nurse*. Springer Publishing Company.
- **Blackburn, S.** (2017). *Maternal, Fetal, & Neonatal Physiology: A Clinical Perspective*. Elsevier Health Sciences.
- **Bhide, A., & Thilaganathan, B.** (2016). Recent Advances in Obstetric Ultrasound: Fetal Echocardiography and Fetal Cardiac Doppler. *Best Practice & Research Clinical Obstetrics & Gynaecology*, 38, 109-119.
- **Chaurasia, N., & Pandey, S.** (2019). Evaluation of Fetal Monitoring Systems: A Review. *Indian Journal of Medical Research*, 150(4), 362-369.
- **Chhabra, S., & Kakani, A.** (2007). Obstetric Morbidity and Mortality. *Indian Journal of Medical Research*, 125(4), 445-458.
- **World Health Organization.** (2018). *WHO Recommendations: Intrapartum Care for a Positive Childbirth Experience*. World Health Organization.
- **UNICEF India.** (2020). *State of the World's Children 2020: Reimagining a Future for All Children*. UNICEF.
- **Kumar, R., & Srivastava, S.** (2017). Challenges in Implementing Fetal Monitoring Devices in Rural India. In *Proceedings of the International Conference on Healthcare Informatics* (pp. 58-63).
- **Ministry of Health and Family Welfare, Government of India.** (2019). *National Health Policy 2017*. Ministry of Health and Family Welfare.
- **NITI Aayog.** (2020). *Strategy for New India @ 75*. NITI Aayog.
- **Markets and Markets.** (2020). *Fetal Monitoring Market by Product, Portability, Method, Application, End User - Global Forecast to 2025*. Markets and Markets Research Pvt. Ltd.
- **Sharma, P.** (2018). *Assessment of the Utilization of Fetal Monitoring Devices in Rural India*. Master's Thesis, All India Institute of Medical Sciences (AIIMS).