ADVANCING FETAL HEALTH

Emerging Technologies in Fetal Monitoring

Adhuna
Advancing Delivery of (Quality) Healthcare through Upgraded Newborn (and Intrapartum Care) Approaches

Global Health Strategies

FOGSI

ADVANCING FETAL HEALTH:
EMERGING TECHNOLOGIES IN FETAL MONITORING

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01 Objectives / Purpose and Methodology

This white paper highlights the importance of modern fetal monitoring in reducing neonatal deaths and complications. It provides evidence-based recommendations to improve access to these technologies and to shape policies that support innovation. By outlining key research priorities and actionable steps, this document serves as a practical guide for clinicians[1], policymakers[2], public health professionals[3], researchers, medical scientists[4], and the medical device industry[5] dedicated to improving health outcomes related to fetal well-being in India.

The key objectives of the paper are as follows:

- Enhance stakeholders' understanding of the critical role of fetal health monitoring in reducing neonatal mortality and morbidity by highlighting current monitoring methods, technologies, and emerging innovations, and their potential advantages over existing solutions.
- Provide evidence to support policy changes to incorporate the latest fetal monitoring innovations by presenting data on both existing and emerging technologies across the public and private sectors.
- Identify potential pathways to expand access to emerging fetal monitoring technologies, ensuring that these innovations are accessible across healthcare settings.
- Shape future research priorities by highlighting key areas of improvement in fetal health monitoring that, if addressed, could lead to more effective and equitable care.

The paper was developed using a mixed-methods approach to collect, triangulate, and present relevant data from primary sources (stakeholder convening, in-depth interviews, and case-study informants) and detailed secondary desk research. It builds on insights from the National Convening on Fetal Well-being, organized by FOGSI and held in August 2024. It brought together clinicians across specialties (gynaecology, radiology, paediatrics, neonatology), public health experts, and researchers from institutions such as All India Institute of Medical Sciences (AIIMS), St. Johns Research Institute (SJRI), Jawaharlal Nehru Medical College (JNMC), and Translational Health Science and Technology Institute (THSTI) to identify opportunities and challenges in fetal surveillance. Recommendations are based on insights from the multi-stakeholder group. Further, in-depth interviews were conducted with two leading obstetricians and gynaecologists, Dr Seetha Ramamurthy Pal, Consultant Fetal Medicine & Obstetrics, Ankuran Clinic, and Dr Meenakshi Ahuja, Senior Director Obstetrics & Gynaecology, Fortis La Femme, whose valuable insights have been included in the paper.

The paper also includes four case studies from institutions innovating in fetal health technology: THSTI (biomarker-based risk stratification), THSTI (AI powered gestational age assessment), JNMC (low-cost Doppler monitoring), and Jhpiego (AI-enabled maternal care in underserved areas). Each institution provided data and inputs with formal consent.

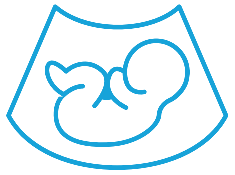
02 Introduction

Importance of Fetal Monitoring

Each year, nearly 300,000 women and 5 million fetuses or neonates die during childbirth or shortly thereafter, a burden concentrated disproportionately in low- and middle-income countries.[6] India witnesses 32,000[7] maternal and 640,000[8] newborn deaths every year. Fetal monitoring is a crucial aspect of obstetric care that assesses fetal health throughout pregnancy and childbirth. Identifying women and their fetuses at risk for intrapartum-related morbidity and mortality could facilitate early intervention.[9] Recent technological advancements have improved the precision of fetal assessments, leading to better outcomes in obstetric practice.

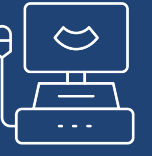
India is striving to achieve Sustainable Development Goal (SDG) 3.2, which targets reducing under-five mortality rates to 25 per 1,000 live births and neonatal mortality rates to 12 per 1,000 live births by 2030.[10] India faces considerable challenges in maternal and fetal health, especially in rural areas. The National Family Health Survey (NFHS-5) reports that approximately 30%[11] of pregnant women attend their first antenatal visit after the first trimester.[12] This inadequacy leads to preterm births, low birth weight, and neonatal complications, ultimately impacting health outcomes. To improve neonatal and maternal outcomes, a comprehensive understanding of the current intrapartum care landscape, particularly fetal health, is crucial to accelerating progress toward these goals.

Intrapartum care is essential for positive maternal and child health (MCH) outcomes. The health of a fetus depends on multiple interacting factors, underscoring the importance of healthcare professionals' attention throughout gestation, including growth and development, and the absence of abnormalities or complications. Fetal monitoring is routinely offered to patients in labour to reduce the risk of adverse neonatal outcomes. Continuous monitoring of fetal growth indicators such as fundal height, clinical estimation of growth, appropriate dating of pregnancy, fetal movements, as well as imaging indicators such as fetal biometry, biophysical profile, and colour Doppler, along with fetal heart monitoring, plays a crucial role in achieving better neonatal outcomes. Additionally, correlations between maternal and fetal health are evident, such as the association between a shortened cervix and increased risk of preterm birth, as well as preeclampsia and fetal growth retardation.



While assessing maternal health is relatively easy, assessing fetal well-being has always been tricky. This has led to significant technological advances in fetal well-being assessment, thereby bridging the gap between biotechnology and antenatal medicine. It is broadly divided into early pregnancy, late pregnancy, and assessment during labour. While the early assessment involves genetic check-ups and malformations, the late pregnancy check-ups aim at delivering a healthy fetus at term by standard vaginal delivery.[13]

Medical technologies, particularly devices for intrapartum care, are crucial in detecting fetal distress and high-risk pregnancies. They reduce stillbirth risk and enhance the management of conditions like diabetes and hypertension. Early interventions are vital for mitigating obstetric complications, optimizing delivery timing, and improving overall birth outcomes. With early neonatal deaths—accounting for 73% of all postnatal deaths globally—stemming mainly from preventable conditions like neonatal infections, preterm birth, low birth weight, and birth asphyxia– such advancements are particularly vital in addressing neonatal morbidity and mortality. Technological advancements[14] in maternal-fetal medicine, including telemedicine, AI-driven gestational assessments, and advanced fetal monitors, are revolutionizing care for pregnant women by providing critical insights into fetal health, identifying risks, and enabling timely interventions to improve outcomes.



In this vein, this white paper aims to provide an overview of critical gaps and areas for improvement in the landscape of fetal health monitoring technologies. By presenting an overview of existing methods and assessing the strengths and limitations of emerging innovations for fetal monitoring, the paper demonstrates their transformative potential across diverse clinical settings.

03 Fetal Monitoring within Indian Policy landscape

Fetal monitoring is a critical component of MCH services in a diverse and populous country like India. Despite progress, significant interstate disparities persist in birth rates and infant mortality rates across the country. States like Madhya Pradesh, Uttar Pradesh, and Odisha continue to report high infant mortality rates, with figures exceeding 35 per 1,000 live births, highlighting the urgent need for targeted interventions. With disparities in healthcare access and quality among rural and economically disadvantaged people, the effective monitoring of fetal health plays an essential role in safeguarding maternal-fetal outcomes. Expanding the reach of fetal health monitoring technologies can help bridge these gaps, ensuring early risk identification and timely medical intervention, particularly in high-burden regions.

Current Guidelines and New Interventions

The government of India has in place several guidelines and interventions, including new ones. They are Surakshit Matritva Aashwasan (SUMAN), the Midwifery Initiative, Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA), Janani Suraksha Yojana (JSY), and LaQshya, to further improve key maternal and newborn health indicators. These initiatives focus on improving the Quality of Care during the antepartum, intrapartum & postpartum periods.[15] The various guidelines outline essential practices for intrapartum care, emphasizing skilled attendance at birth, regular fetal monitoring, respectful maternity care, access to emergency interventions, and encouraging the use of evidence-based practices to manage complications effectively.

India also incorporates the WHO[16] guidelines on intrapartum care, which help improve the quality of care, including the active management of the third stage of labour. The Indian Public Health Standards (IPHS) are a set of specifications for the planning and maintenance of public healthcare infrastructure in the country. It includes the expected standard of care for maternal and child health and the specific equipment required for fetal monitoring (e.g., fetal Doppler, CTG). The revised edition was published in 2022 by MoHFW.[17] In 2017, the Indian Council of Medical Research (ICMR) published the revised National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, which included trials of devices for the detection of fetal abnormalities.[18] The Materiovigilance Programme of India (MvPI) was launched by the Drug Controller General of India (DCGI) in 2015 to enhance the protection of the health and safety of patients, healthcare professionals, and others by reducing the likelihood of adverse event recurrence associated with medical device use.[19]

Among these, the PMSMA, launched in 2016, seeks to improve the quality and coverage of antenatal care (ANC), including diagnostics and counselling services as part of the Reproductive Maternal Neonatal Child and Adolescent Health (RMNCH+A) Strategy. It provides a monthly check-up scheme to ensure comprehensive maternal care during pregnancy. For Individual High-Risk Pregnancy (HRP) tracking, MoHFW launched e-PMSMA (Extended -Pradhan Mantri Surakshit Matritva Abhiyan) in January 2022. Key focus areas include the provision of essential investigations, such as a second-trimester ultrasound, and medications to all pregnant women. Special efforts target unregistered women and high-risk pregnancies, while private sector specialists are encouraged to offer voluntary services at under-resourced public facilities.[20]

The Government's guidelines on the appropriate use of ultrasonography (USG) during pregnancy aim to reduce maternal and perinatal mortality. Key objectives include determining the number of USGs required, early detection of fetal anomalies and high-risk pregnancies, and enhancing healthcare providers' skills in interpreting obstetric USG to improve care. These standards emphasize quality, documentation, informed consent, understanding limitations, and patient rights.[21]

JSY[22] (launched in 2005 & revised periodically) is a government scheme that aims to reduce maternal and neonatal morbidity and mortality by promoting institutional deliveries, particularly among economically disadvantaged groups, through cash incentives for women giving birth in government healthcare facilities. It also enhances healthcare providers' ability to implement effective fetal monitoring practices. While JSY itself does not exclusively focus on fetal monitoring, various aspects of the program include promoting safe delivery practices that involve fetal tracking as part of maternal health care. Recent interventions include enhanced training for healthcare providers in emergency obstetric care and the adoption of technologies such as mobile applications (mHealth) for real-time monitoring and communication, which further aid in managing intrapartum emergencies.

SUMAN Initiative[23] aims to eliminate preventable maternal and newborn deaths and morbidities at public health facilities. All complications during delivery, such as PPH and eclampsia, will be stabilized before referring patients to appropriate facilities. In settings where SHC-HWC serves as a delivery point, the Community Health Officer (CHO), trained as a Skilled Birth Attendant (SBA), will manage regular deliveries. High-risk pregnant women will be referred to higher centers. The labour room will be equipped in accordance with maternal health guidelines, ensuring the availability of essential logistics and medications. Under the SUMAN initiative, pregnant women and newborns at public health facilities are entitled to a range of free services categorized into Basic, BEmONC, and CEmONC packages.

JSSK (Janani Shishu Suraksha Karyakaram)[24] entitlements include free drugs and consumables, free diet during hospitalization, free diagnostics, and free blood transfusion if required. This initiative also provides free transport from home to the institution, between facilities during referrals, and back home. The scheme was expanded to cover complications during the antenatal and postnatal periods, as well as sick infants up to 1 year of age.

State-of-the-art Maternal and Child Health Wings (MCH wings)[25] have been sanctioned at District Hospitals/District Women's Hospitals and other high-caseload sub-district facilities as integrated facilities for providing high-quality obstetric and neonatal care.

Dakshataa[26] national training program, launched in 2015, is a strategic 3-day training capsule aimed at upskilling health care providers, including doctors, staff nurses, and ANMs, to improve the quality of intrapartum care.

The Government of India has taken a historic and landmark policy decision to roll out midwifery services in the country through the 'Midwifery Services Initiative which aims to create a cadre of Nurse Practitioners in Midwifery who are skilled in accordance with competencies prescribed by the International Confederation of Midwives (ICM)[27]:

Limitations of the Public Healthcare System

Despite the comprehensive network of government-funded healthcare facilities, several limitations persist within India's public healthcare system. Resource constraints, inadequate infrastructure, and variability in the quality of care often hinder the effective management of fetal health during childbirth. Many public institutions face shortages of trained personnel, particularly obstetricians and neonatologists, which can severely impact the monitoring and management of high-risk pregnancies (World Health Organization, 2018).

The sheer volume of patients in the public sector, often with three patients per bed, makes individualized fetal monitoring difficult, and progress in scaling up these technologies has remained stagnant for decades. The current public sector infrastructure does not support a 1:1 ratio of fetal monitoring, underscoring the urgent need for greater availability and accessibility of monitoring machines, particularly for high-risk pregnancies. A structured approach to intrapartum monitoring (IPM) is essential to ensure that CTG data is not only captured but also promptly interpreted and acted upon.[28]

While there are policies regulating ultrasound usage and recommendations from medical societies, structured government-backed guidelines for fetal monitoring remain largely absent in India, limiting the ability to standardize care, leading to significant urban-rural disparities. While conferences and academic discussions on fetal monitoring are held at higher levels, grassroots awareness among healthcare providers remains limited, reducing the potential impact of emerging technologies and best practices.[29]

The Role of the Private Healthcare Sector

The private healthcare sector in India plays a vital role in advancing fetal health and enhancing intrapartum outcomes. Private hospitals and clinics are often equipped with advanced medical technologies and specialized care that may not be available in public facilities. Many of these institutions are at the forefront of adopting new technologies, such as fetal heart rate monitoring systems, biomarkers, and algorithms that provide ongoing assessments of fetal well-being during pregnancy and labour. Additionally, private healthcare providers often offer more personalized care and shorter wait times, making them attractive options for pregnant women, particularly in urban areas.

04 Fetal Monitoring Technologies

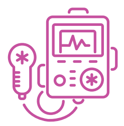
An Overview

Fetal monitoring has evolved significantly over the decades, transitioning from basic manual techniques, such as a fetal stethoscope or a Pinard horn, to sophisticated technological solutions that enable continuous, non-invasive monitoring of the fetus.

Modern fetal monitoring includes various advanced technologies, such as wireless, waterproof electrode patches that provide greater mobility and freedom for expectant mothers. There is also an increasing focus on integrating cloud storage and electronic health records with remote monitoring capabilities, enabling healthcare providers to access real-time data about fetal health.

Recent advancements in sensor technologies include fetal electrocardiography utilizing abdominal electrodes, photoplethysmography using near-infrared light, fetal magnetocardiography, and fetal pulse oximetry. These non-invasive methods are expected not only to enhance the accuracy of fetal assessments but also to improve the overall birthing experience for mothers, who can remain more active and less constrained during labour. Other advancements and emerging technology with potential in fetal monitoring technology include: Electronic fetal monitoring (EFM), Fetal pulse oximetry[30] (FPO), Fetal electroencephalography[31] (fEEG) [is still in the early stages of development and has not yet been widely adopted in clinical practice],[32] Near-infrared spectroscopy (NIRS) involves the use of light to measure the oxygen saturation of the fetal blood-it can be used to monitor the fetal brain, liver, and kidney function and is particularly useful in cases of fetal hypoxia and acidosis, which can lead to brain damage and other complications.[33] UC Irvine engineering researchers have developed a novel method of monitoring fetal heart rate through a compact abdominal patch embedded with an algorithm called Lullaby. To improve prenatal care, the innovative wearable device will enable expectant mothers to monitor fetal and maternal health at home—users will only need a smartphone.[34]

Details of various categories of technologies, indicators monitored, and expected health outcomes are as follows:[35]



Fetal Sensors:

Historically, two primary methods have been employed in hospital settings: intermittent auscultation (IA) and continuous electronic fetal monitoring (CEFM). CTG has become the standard for continuous fetal monitoring in high-risk pregnancies. Typical indicators monitored include fetal heart rate (FHR), uterine activity (contractions), heart rate and frequency variability, and the duration of accelerations and decelerations. The continuous monitoring allows for real-time identification of fetal distress, which is crucial in preventing adverse outcomes like hypoxia and potential brain injury. The development of additional methods, such as fetal pH monitoring, fetal lactate measurement, and fetal pulse oximetry, has further enhanced the ability to assess fetal well-being during labour.

When women in labor visit a health facility, it is important to monitor the wellbeing of the mother and the fetus. The fetal heart rate informs us about the oxygenation. When it goes out of a defined range, it indicates potential fetal distress/ hypoxia or reduced oxygenation and thus, action needs to be taken. Fetal heart is normally heard using a fetoscope or stethoscope and the beats counted. Similarly, the frequency, duration and intensity of maternal uterine contractions helps us understand the progress of labour. These measurements need to be done every 30 minutes. In busy labour rooms with limited human resources this is tough to do, thus delaying the identification of a potential complication and the required intervention.

Advanced fetoscopes have emerged as a wireless device that can be attached to the mother's abdomen while she is in labor. It captures the fetal heart rate, uterine contractions, and maternal heart rate, too. Readings from multiple such devices can be monitored at a central location or remotely. Continuous readings address the need for frequency and reduce workload. Remote monitoring allows skilled human resources, even outside the health facility where the woman is admitted, to monitor maternal and fetal well-being and take needed action promptly. Furthermore, wearable textile-based monitoring systems have also emerged as practical tools for early detection of complications and evaluating interventions. These flexible sensors, created through weaving, knitting, and embroidery, integrate seamlessly into garments, enabling practical, non-invasive fetal heart rate monitoring using bio-potential electrodes used in ECG, EMG, and EEG applications.

Imaging Technologies:

These play a vital role in assessing fetal anatomy and health. Ultrasound has become the primary imaging modality in prenatal care, enabling healthcare providers to visualize fetal development and detect congenital anomalies. Recent advancements in USG technologies focus on incorporating sophisticated algorithms for critical tasks, such as assessing gestational age, identifying small for gestational age (SGA) fetuses, evaluating amniotic fluid levels, and detecting congenital anomalies.

Increasingly, magnetic resonance imaging (MRI) is used for more detailed, high-resolution imaging of fetal anatomy, particularly to evaluate brain development and detect abnormalities. MRI allows healthcare providers to visualize the fetus in utero and to detect abnormalities early on. MRI can also be used to monitor the fetal brain and to assess fetal growth and development. By providing detailed visualization, these imaging modalities enhance the capacity for early diagnosis and intervention. It is a non-invasive imaging test that provides detailed information about the fetus's anatomic structures, yielding clear, high-resolution images. Fetal MRI can supplement the information obtained from a high-resolution fetal ultrasound and can provide additional information regarding the baby's diagnosis. It is performed in the 2nd or 3rd trimester of pregnancy. The typical indicators monitored are fetal growth and development, anatomy, and structural abnormalities (brain, spine, body). Accurate imaging aids the timely diagnosis of congenital conditions, thereby supporting informed clinical decision-making regarding interventions during pregnancy or delivery.

Risk Stratification Tools and Biomarkers:

Essential for assessing various risk factors that may predispose pregnancies to complications, these tools integrate multiple data points, including maternal health history and existing conditions, to identify pregnancies that require closer monitoring. Biomarkers, often derived from maternal blood tests, serve as biological indicators for assessing fetal health and determining the risk of complications. Emerging research emphasizes the importance of these objective measurements in personalizing care.

Advances in biomarker technology and risk stratification have been paramount in earlier assessment of conditions such as preeclampsia and gestational diabetes compared with traditional methods. The evolving landscape includes genetic screening (e.g., non-invasive prenatal testing using cell-free fetal DNA), comprehensive metabolic panels, proteomic and genomic assays for personalized risk assessment, placental biomarkers, etc.

AI and Machine Learning Tools:

The potential for artificial intelligence (AI) and machine learning to complement existing technologies is now increasingly recognized. AI algorithms can analyse fetal heart rate patterns, providing predictive insights that help clinicians make timely and informed decisions regarding fetal distress. The integration of AI into existing monitoring systems promises to refine diagnostic capabilities, leading to better outcomes through improved interpretation of complex datasets, reduced reliance on manual assessments, and support for clinical decision-making by predicting outcomes and identifying risks.

Key applications of AI in fetal monitoring include noise suppression to improve data accuracy, feature detection from complex fetal heart rate patterns, fetal state classification, and enhanced risk stratification. By rapidly processing information, AI and ML facilitate timely diagnoses, enabling proactive interventions that enhance fetal health outcomes during labour.

Strengths and Limitations of Existing Technological Innovations[36]

Strengths of Technological Innovations in Fetal Monitoring

The strengths of current technological innovations in fetal monitoring are multifaceted, offering enhanced accuracy, accessibility, and individualized care.

- **Ultrasound imaging** remains the gold standard for fetal assessment worldwide and in India, due to its non-invasive nature, cost-effectiveness, and portability. It serves numerous clinical purposes, from confirming pregnancy viability to detecting congenital anomalies and monitoring fetal growth throughout gestation.
- **Magnetic resonance imaging (MRI),** though less commonly used due to its higher cost, can image the fetus in any plane, providing a large field of view of the fetus and placenta with excellent soft tissue resolution of the brain, airway, lungs, and abdomen; particularly in complex cases where ultrasound may be inadequate. It provides superior soft-tissue contrast and detailed multi-planar imaging, which is beneficial for evaluating abnormalities.
- **Cardiotocography (CTG)** is the standard method for continuous fetal heart rate (FHR) monitoring during labor, allowing for rapid detection of fetal distress. The emergence of **fetoscopes and textile-based wearable devices** has further enhanced FHR monitoring by enabling continuous, non-invasive tracking of fetal well-being, with the potential to transform intrapartum care. These wearables, still in development, hold promise for individualized monitoring and improved maternal comfort by allowing greater mobility during labor.
- **Risk Stratification Tools** can effectively identify pregnancies at heightened risk for complications, facilitating targeted care interventions and resource distribution for high-risk patients. Biomarkers from maternal blood tests can provide insights into fetal well-being and help identify conditions such as preeclampsia or gestational diabetes before presenting symptoms. They provide quantifiable data that can enhance the safety and effectiveness of prenatal screening and better address individual patient needs. Identification of high-risk pregnancies at an early stage facilitates timely interventions and reduces adverse maternal and neonatal outcomes.

A significant breakthrough in fetal monitoring is the integration of **artificial intelligence (AI) and machine learning (ML)** tools. These technologies assist in processing large datasets, identifying subtle patterns, and predicting fetal health outcomes that traditional methods may overlook. AI-driven analytics can support clinicians by providing real-time risk stratification and aiding decision-making.

A key strength discussed at the **National Convening on Technologies for Monitoring Fetal Well-being (FOGSI, August 2024)** was the **development of wireless fetal monitoring devices** that enhance patient mobility, allowing continuous monitoring while enabling expectant mothers to move freely. This improvement is crucial during labor, fostering a more natural birthing experience. Furthermore, non-invasive monitoring techniques, such as abdominal fetal ECG and photoplethysmography, address limitations of Doppler-based monitoring, including maternal heart sound interference. The application of automated algorithms has the potential to reduce human error in fetal monitoring, minimizing false positives and decreasing unnecessary interventions, including cesarean sections.

Standardized clinical guidelines tailored to India's healthcare infrastructure will further strengthen fetal monitoring outcomes. While international frameworks from FIGO and WHO provide valuable references, they must be adapted to local conditions to ensure feasible implementation across public and private healthcare settings. Capacity-building efforts, including continuous medical education (CME) on fetal monitoring techniques, labor profiling, and interpretation of partograms and CTG readings, will enhance the competency of clinicians, nurses, and auxiliary nurse midwives (ANMs). Bundled approaches that integrate multiple fetal monitoring technologies rather than relying on a siloed approach will optimize perinatal outcomes.

While technological advancements in fetal monitoring show great promise, their success hinges on seamless integration into existing maternal healthcare frameworks, ensuring accessibility, usability, and clinical efficacy.

Limitations and Challenges of Technological Innovations in Fetal Monitoring

Despite their numerous advantages, technological innovations in fetal monitoring present several challenges that must be addressed to maximize their clinical impact. A key limitation of **ultrasound imaging** is its dependence on operator expertise. Inadequate training can lead to misdiagnoses or missed fetal abnormalities. Additionally, image quality may be compromised by maternal obesity, low amniotic fluid, or suboptimal fetal positioning. Early first-trimester detection of anomalies remains challenging due to the embryo's small size, which limits visualization accuracy. **MRI**, while offering superior imaging, is cost-prohibitive and largely inaccessible in low-resource settings.

FHR monitoring, including CTG, has not consistently demonstrated reductions in perinatal mortality and morbidity in randomized controlled trials. A significant concern is the **high intra- and interobserver variability** in interpretation, leading to inconsistencies in clinical decision-making and an increased rate of cesarean sections. While **textile-based wearable monitors** have the potential to revolutionize fetal surveillance, their technical capabilities need further refinement to ensure **accurate and reliable signal acquisition**, particularly in home-based and low-resource settings.

The integration of **AI and ML in fetal monitoring** also poses several challenges. AI models are only as effective as the datasets they are trained on, and biased or incomplete data can lead to skewed algorithms that ultimately result in misleading predictions and affect patient safety. Concerns have been raised about AI's **"hallucination" phenomenon**, where algorithms may generate inaccurate outcomes that could result in erroneous clinical decisions. The regulatory landscape for AI-driven fetal monitoring solutions remains unclear, and **data privacy regulations** present additional hurdles to widespread adoption. The clarity regarding AI-driven solutions and the necessary regulatory approvals is lacking. The Data Protection Act is also a hurdle. Moreover, **overreliance on AI** may overshadow healthcare professionals' clinical judgment, raising ethical concerns about the balance between human expertise and automated decision-making.

At the **FOGSI National Convening**, gynaecologists highlighted difficulties in interpreting fetal monitoring data, particularly in cases of ambiguous CTG readings. There is a pressing need for structured guidelines to support fetal surveillance in both antenatal and intrapartum care. Currently, antenatal monitoring provides only a "snapshot" view of fetal well-being at fixed time points, failing to capture dynamic fetal conditions comprehensively.

One limitation of traditional fetal monitoring technologies is that they provide only information on fetal heart rate and uterine contractions, not on fetal oxygenation status or neurological function. This limitation has led to the development of new technologies, such as near-infrared spectroscopy (NIRS) and magnetic resonance imaging (MRI), that allow for more comprehensive fetal monitoring.[37]

Financial and infrastructural constraints also limit the adoption of advanced fetal monitoring technologies. **High costs** associated with MRI, AI-integrated ultrasound, and wearable fetal monitors make them inaccessible to many public healthcare facilities in India. The successful implementation of these technologies requires **significant investment** in training for healthcare providers, as variability in skill levels can impact the accuracy of monitoring. Additionally, specific fetal monitoring techniques, such as **biomarker-based screening**, are not universally available, and their reliability can fluctuate, leading to potential false positives or negatives that complicate clinical decision-making.

Cultural and logistical barriers also pose challenges. Tracking pregnant women across healthcare facilities is difficult due to **migration patterns and the cultural norm of women traveling to their maternal homes for delivery**. During the study discussed at the FOGSI National Convening, researchers addressed this challenge by establishing robust field-staff networks to improve tracking and follow-up. However, referral compliance remained a significant issue, particularly when **asymptomatic pregnant women and their families resisted transfer to tertiary centers**, even when abnormal Doppler findings indicated potential complications.

Ultimately, while technological innovations offer transformative potential for fetal monitoring, a **balanced approach** is essential. Advanced tools must be integrated into **comprehensive, evidence-based clinical protocols** to ensure accessibility, affordability, and alignment with healthcare realities. Further research should prioritize **geographic diversity in validation studies** and efforts to refine fetal monitoring technologies for diverse healthcare settings. Addressing these limitations through **collaboration among clinicians, researchers, and policymakers** will be crucial to ensuring that these innovations translate into tangible improvements in maternal and fetal health outcomes.

Balancing traditional diagnostic tools with emerging innovations in fetal monitoring requires a pragmatic approach that integrates clinical expertise with technological advancements. Conventional tools such as the stethoscope remain essential, particularly as an initial screening modality for detecting fetal growth restriction. However, for high-risk pregnancies requiring continuous monitoring, reliance on more advanced technologies, such as cardiotocography (CTG) machines, becomes crucial. While CTG has been associated with an increased number of cesarean deliveries, its value in identifying fetal distress in high-risk cases is undeniable. In practice, clinicians still rely on fundamental clinical judgment, supplementing it with newer technologies such as ultrasound, which is now as routinely used as a stethoscope in many settings. The challenge lies in ensuring that technology enhances decision-making rather than replacing essential diagnostic skills, preserving the clinician's role in interpreting and contextualizing findings.[38]

Promising Practice: Training and Protocol

Monitoring of FHR (Intrapartum Fetal Heart Monitoring Practices) is not performed at the desired frequency in accordance with standard guidelines. This may lead to poor neonatal outcomes, necessitating an intervention to improve compliance. Providers in the study reported challenges with Doppler use, which may be attributable to the use of non-standardized equipment. Providers also reported difficulties with stethoscope use. The introduction of a globally recognized and approved standard Doppler could improve use and compliance with the protocol. Simultaneously, it needs to be tested to generate learning. The introduction of such a device is feasible within the given environment of focused intrapartum care. In addition, a brief refresher training or orientation on the WHO and SBA protocols for FHR monitoring would help reorient labour room staff to the importance and necessity of frequent FHR monitoring.[39]

05 Spotlighting Case Studies

GARBH-INi cohort- Risk Stratification and Biomarker Discovery by THSTI

Abstract

Preterm birth (PTB) remains a significant maternal and neonatal health challenge. The cohort, the most extensive longitudinal study of pregnant women in low- and middle-income countries (LMICs), offers a well-phenotyped biorepository with ultrasonographic parameters (N=12,000) to enhance PTB risk stratification. The study employs a multi-omics approach, including epidemiological and clinical risk factor analysis, ultrasound-based predictors, biomarker identification, and pathway analysis, to develop risk-stratification algorithms. Identified innovations include a dipstick test for PTB-associated bacterial infections, the use of Lactobacillus consortia as a therapeutic probiotic candidate, and genomic variants linked to PTB risk. By combining proteomic and metabolomic approaches, this initiative aims to refine diagnostic and therapeutic interventions for PTB. Findings from this study will provide a national and global resource that supports evidence-based policymaking and healthcare innovation.

Results so far

A multi-omics approach has enhanced preterm birth (PTB) risk stratification, with biomarker-based screening emerging as a promising tool for early maternal health interventions. The study successfully identified genetic, proteomic, and metabolomic biomarkers for PTB, and a dipstick bacterial test for PTB-associated infections proved cost-effective. Ongoing efforts focus on validating these biomarkers and expanding dipstick test trials in external cohorts. Currently, proteomic and metabolomic markers are undergoing validation, and the dipstick test is advancing toward large-scale trials. With strong potential for integration into public and private healthcare systems, biomarker-based screening significantly improves PTB risk prediction, offering a scalable and affordable approach to preterm birth detection.

GARBH-INi cohort-AI powered gestational age assessment by THSTI

Abstract

Accurate pregnancy dating is critical for optimal maternal and neonatal care, yet traditional methods struggle with precision in later trimesters. This study leverages artificial intelligence (AI) to enhance gestational age estimation using ultrasound data from the GARBH-INi cohort in India. The GARBH-INi Ultrasound-image-based Gestational age Estimator (GAUGE) employs deep learning to extract fetal characteristics beyond conventional biometry, significantly improving accuracy in the second and third trimesters. GAUGE is more accurate than Hadlock (44% difference) and Intergrowth-21st (35% difference). Additionally, a novel postnatal GA assessment tool integrates metabolic markers from neonatal heel prick and umbilical cord blood, achieving an error margin of ±7 days. By incorporating AI-driven models into portable ultrasound devices, this study aims to transform prenatal screening, particularly in resource-limited settings, thereby improving pregnancy management and neonatal outcomes.

Results so far

AI-based GA estimation has demonstrated superior accuracy, particularly in later trimesters, enhancing preterm birth prediction and outperforming traditional biometric dating methods. AI-powered models, including the GAUGE model, showed improved performance relative to Hadlock and Intergrowth-21st estimates, with a Streamlit-based web app increasing accessibility. However, challenges such as limited validation across diverse populations and the complexity of AI interpretation persist. Solutions included expanding study sites, training clinicians, and developing offline-compatible models to address rural technical constraints. The GAUGE model is undergoing advanced validation, with ongoing efforts to embed AI-based GA estimation into ultrasound systems to improve scalability. AI-driven GA estimation has improved accuracy by 35-44% over standard methods, strengthening preterm birth prediction and neonatal care, with strong potential for large-scale implementation in hospital settings.

AI-assisted risk stratification models in underserved areas by Jhpiego

Abstract

Jhpiego, in collaboration with the Government of Madhya Pradesh and supported by Takeda Global CSR, has developed a digital, data-driven maternity care continuum. This system ensures comprehensive tracking of maternal health from preconception through the postpartum period, integrating critical service-delivery points. The initiative comprises four key components: 1) Bluetooth-enabled biomedical devices for real-time vital sign monitoring during antenatal care (ANC), 2) Digital Mother-Child Protection (MCP) cards for longitudinal data capture, 3) Digitization of intrapartum care to enhance labor management, and 4) Analytical dashboards for health system administrators. These components are integrated into existing digital platforms across intervention districts. Currently, efforts focus on using these datasets to develop AI-driven predictive models for maternal (e.g., pregnancy-induced hypertension, obstructed labor) and neonatal (e.g., preterm birth, stillbirth) outcomes, thereby facilitating risk stratification and personalized care interventions.

Results so far

The implementation of a digitized maternity care continuum in Madhya Pradesh has significantly improved fetal and maternal health monitoring by integrating real-time data across service delivery points. Bluetooth-enabled biomedical devices facilitate continuous fetal monitoring during antenatal care, while digital MCP cards and analytical dashboards streamline data flow for early risk detection and timely interventions. Despite initial resistance to technology and infrastructure challenges in remote areas, the system has enhanced decision-making and labor management. Moving forward, AI-powered predictive analytics will be leveraged to identify high-risk pregnancies and neonatal complications, enabling proactive and personalized care to improve maternal and newborn outcomes.

UMBIFLOW study: a low-cost Doppler ultrasound tool for abnormal fetal umbilical artery resistance indices (RI) among women by JNMC

Abstract

Few interventions exist to address the high burden of stillbirths among healthy pregnant women in low- and middle-income countries (LMICs). This study aimed to determine the prevalence of abnormal fetal umbilical artery resistance indices among low-risk pregnant women using a low-cost Doppler device (Umbiflow) in five LMICs. A multicentre, prospective cohort study was conducted in Ghana, India, Kenya, Rwanda, and South Africa. Trained nurses or midwives performed a single, continuous-wave Doppler screening using Umbiflow for low-risk pregnant women between 28 and 34 weeks of gestation. Of 7,151 women screened, 495 (6.9%) had an abnormal resistance index (RI), including 14 (0.2%) with absent end-diastolic flow (AEDF). Women with abnormal RI had higher rates of section (40.8% vs. 28.1%), labor induction (20.5% vs. 9.0%), and low birth weight (<2500 g) (15.0% vs. 6.8%). Findings suggest that a single Doppler screening can detect fetuses at risk of growth restriction and adverse perinatal outcomes.

Results so far

A study on handheld Doppler use among low-risk pregnant women in India found a low incidence (6.9%) of abnormal resistance index (RI), though those with abnormalities had higher rates of obstetric interventions, including C-sections and NICU admissions. Visual and auditory enhancements improved usability, and nearly all pregnant women accepted the screening. However, referral compliance was a significant challenge, as asymptomatic women and their families often refused transfer to tertiary centers. Periodic training of ANMs and nurses at the primary care level was crucial for implementation. Tracking enrolled women was difficult due to migration and cultural norms, but this challenge was addressed through robust field-staff networks. Future research should expand geographic representation and introduce repeat Doppler screening in the third trimester for improved validity. Although no upgraded device is currently available, early detection of abnormal RI via Doppler screening shows promise in preventing perinatal mortality. However, further follow-up is needed to assess the long-term impact on mortality rates.

In conclusion, all these case studies have been categorised according to the product/technology innovation cycle, and, as depicted in Figure 1, all four innovations are currently in the early stages of learning and generating evidence on potential impact, and will move towards production/innovation development.

Figure SEQ Figure 1: Categorisation of emerging technologies (case studies) as per product innovation cycle

1 Learning / Generating evidence on potential impact

Work Closely with any registered medical body recognized by the Government of India (E.g: ICMR) for learning + R&D to generate efficacy data.

2 Product/ Innovation Development

Work with local Indian manufacturers for Product Development + Localization + Evidence generation on performance and quality

3 Regulatory Approvals& Product Introduction

Product introduction processes with partnerships for launch and approvals Health Technology Assessments (HTA), navigating regulatory processes for all innovations

4 Policy Advocacy

Introduction of products in relevant policy spaces and as public health guidelines: for USG, CTGs and other imaging and sensor technologies in question. Inclusion in the EDL portal/ EML portal/ GeM

5 Health System

Complex Adaptive System - Federal < State Dynamic.

Health system include focus on the different building blocks - Financing, Supply Chain Management, Facility Readiness and community linkages with Health System, Capacity building. This also includes learnings from system wide implementation

6 Impact to Scale

Sustainable scale and Volume Guarantee, Large scale adoption through procurement through Tenders/ GEM portal

GARBH-INi cohort- Early Risk Stratification using biomarkers (THSTi)

The identified biomarkers from respective omics domains will be validated on external cohorts. The confirmed validated biomarkers will be tested in clinical settings to determine their ability to accurately predict PTB and assess their utility in routine clinical care.

GARBH-INi cohort-AI powered gestational age assessment (THSTi)

The GAUGE model was patented and the research team is in conversation with relevant stakeholders to develop a PC based software which can be easily used by clinicians.

Antenatal Doppler screening for fetuses at risk of adverse outcomes (JNMC)

A larger multicentric study is needed to strengthen evidence, and support integration into routine low-risk antenatal care at the primary level to reach a diverse population.

AI assisted risk stratification models in underserved areas (Jhpiego)

Further research and validation of predictive models using diverse population datasets will be required to enhance their accuracy and clinical applicability.

Product Innovation Lifecycle

(as reported until February 2025)

06 Call To Action / Strategic Pathways

Improving fetal monitoring in India requires coordinated action from key stakeholders, including clinicians, researchers, policymakers, public health professionals, and medical device manufacturers. Each group plays a crucial role in enhancing the innovation, quality, accessibility, and effectiveness of fetal surveillance. This section outlines targeted recommendations for each stakeholder group, highlighting their unique contributions and responsibilities in strengthening fetal monitoring practices across the healthcare system.

Clinicians

- **Integrate fetal monitoring into standard routine protocols:**
  Improving fetal monitoring in India requires a proactive approach from clinicians to enhance prenatal and intrapartum care. Integrating routine fetal monitoring into standard prenatal protocols is essential to detecting complications early and reducing maternal and neonatal mortality. Going forward, clinicians can promote a blended approach that integrates basic tools (e.g., stethoscopes) and advanced technologies (e.g., ultrasound, CTG) to strengthen clinical judgment and diagnosis, particularly in high-risk pregnancies.
- **Focus on Capacity Building:**
  Clinicians must prioritize regular training and continuing medical education (CME) in fetal monitoring and evaluation, with emphasis on labor profiling, partogram interpretation, CTG interpretation, and improved clinical decision-making. These skills should be integrated into MBBS curricula, while refresher training programs for nurses, auxiliary nurse midwives (ANMs), and support staff will ensure competency across all levels of care.[40]
  In addition to personal skill development, training support staff—including nurses and ANMs—will ensure consistency in monitoring and decision-making throughout all levels of care. Collaborating with local and international experts can further refine best practices and cross learning.
- **Strengthen communication with patients:**
  Educate expectant mothers and their partners/spouses/families about the value of fetal monitoring and ensure informed, shared decision-making, particularly in referrals and high-risk cases.
- **Advocate for structured clinical protocols:**
  Clinicians to proactively advocate with policy and decision makers for the development and adoption of standardized, India-specific guidelines for antenatal and intrapartum fetal monitoring.

Policymakers

- **Develop India-specific national guidelines for fetal monitoring:**
  A critical step is to establish structured guidelines for antenatal and intrapartum fetal monitoring. While frameworks from FIGO and WHO provide valuable reference points, these must be adapted to India's healthcare infrastructure and resource availability. Standardized protocols, co-developed with practicing clinicians, will improve accessibility and ensure practical implementation in both public and private healthcare settings.[41]
- **Strengthen regulatory frameworks:**
  The integration of AI-driven technologies in fetal monitoring raises critical privacy and confidentiality concerns that must be addressed through robust policy frameworks. While clinicians and their teams may have controlled access to patient history through designated keywords or secure systems, broader hospital access to such sensitive data introduces potential vulnerabilities. The way hospitals manage, store, and protect patient information remains a key consideration, particularly in the absence of standardized data security protocols. Without clear data governance guidelines, there is a risk of unauthorized access, data breaches, or misuse of patient records. Strengthening policies to ensure encryption, role-based access controls, and strict consent mechanisms will be essential to maintaining trust in AI-enabled fetal monitoring while safeguarding patient confidentiality. The clarity regarding AI-driven solutions and the necessary regulatory approvals is lacking. The Data Protection Act also poses a hurdle and requires strengthening.[42]
- **Invest in public sector capacity:**
  Policymakers also play a critical role in expanding equitable access by fostering public-private partnerships, integrating telemedicine solutions, and ensuring that infrastructure is available across diverse healthcare settings.[43] Creating an enabling environment for better fetal care requires increasing accessibility to fetal monitoring tools, ensuring affordability, and establishing standardized norms for proper utilization. Mandatory documentation and compliance measures can also significantly enhance the quality of fetal monitoring practices.[44]

Researchers and Medical Scientists

- **Identify and address knowledge gaps through contextual research:**
  Researchers play a crucial role in advancing fetal monitoring technologies by identifying gaps in current knowledge, particularly in diverse socio-economic and geographical settings. Conduct large-scale, multi-centric trials across myriad geographies and socio-economic groups to validate emerging technologies (AI/ML, NIRS, wearables).
- **Generate evidence to inform and guide programmatic design:**
  By framing research questions that address these gaps, they can generate evidence on the effectiveness of existing fetal monitoring techniques across different Indian populations, with a specific focus on overcoming rural access challenges. Their contributions extend beyond research, informing the formulation, design, and implementation of programmatic efforts to improve neonatal outcomes.
  Furthermore, curate diverse, high-quality datasets to improve the accuracy and fairness of AI-based fetal monitoring models, and study the ethical implications of AI-driven decisions and the impact of new technologies on clinical workflows and provider autonomy.

- **Facilitate cross-sector collaborations to expand access and innovation:**
  Researchers must work with technologists, public health experts, and clinicians to co-develop fetal monitoring tools adapted to local needs.

Public Health Professionals

- **Translate research into policy and support evidence-based policymaking:**
  Translating research findings into actionable recommendations for national guidelines is essential to ensuring the widespread adoption of effective monitoring techniques. Additionally, close collaboration with policymakers is vital to enabling evidence-based decision-making and reinforcing maternal and fetal health policies. Furthermore, collaborate with the government and other partners to incorporate fetal monitoring indicators into routine public health monitoring to identify systemic gaps.
- **Build and facilitate partnerships:**
  Public health professionals must work alongside government agencies and NGOs to secure funding for public health campaigns that enhance prenatal care and fetal monitoring. They should explore opportunities for collaboration with the private sector to integrate cutting-edge technologies into India's healthcare system.
- **Design community-level education:**
  Create awareness campaigns on the importance of regular monitoring, referral compliance, and the use of new diagnostic tools.

> "The next steps for scaling the digitized maternity care continuum include expanding AI-powered predictive analytics to improve risk stratification for maternal and fetal complications. Strengthening interoperability with state or national health information systems will ensure seamless data flow across care levels. Capacity building for healthcare providers on digital tools and AI-driven decision-making will be critical for sustained adoption. Further research and validation of predictive models using diverse population datasets will be required to enhance their accuracy and clinical applicability."
>
> **- Jhpiego**

Medical device industry

- **Drive innovation through emerging technologies and validate them through clinical trials and pilot programs:**
  The medical device industry plays a pivotal role in advancing fetal monitoring technologies by driving innovation and refining devices. Investing in clinical trials and pilot programs is essential to validating new solutions, while collaboration with academic and research institutions helps tailor devices to specific healthcare needs. It is also crucial that manufacturers prioritise usability and affordability, thereby designing cost-effective, intuitive devices (e.g., wearable or handheld monitors) for low-resource settings.
- **Facilitate cross-sector collaborations to expand innovation and its adoption**
  To facilitate widespread adoption, industry leaders must forge partnerships with governments, NGOs, and healthcare organizations, ensuring accessibility across diverse settings. Engaging with regulatory bodies to streamline approval processes is critical for accelerating market entry. Additionally, by developing scalable and cost-effective technologies that uphold high standards of quality, safety, and reliability, the industry can ensure that these innovations are seamlessly integrated into healthcare systems.
- **Enhance manufacturing, distribution, and sustainability:**
  Strengthening manufacturing processes, optimizing distribution networks, and prioritizing sustainability will enhance supply chain resilience and cost efficiency. Standardizing and simplifying technology—similar to the simplicity of ECG—can encourage wider adoption among healthcare providers. Additionally, ensuring that facilities conduct regular stock checks of essential monitoring devices, including addressing common issues such as battery replacements, is crucial for sustaining operational efficiency. Encouraging local manufacturing will not only lower costs but also facilitate the adoption of advanced technologies in smaller nursing homes and lower-tier healthcare facilities.[45]

  Given India's high population density and diverse socioeconomic conditions, the integration of innovations in fetal well-being is critical to improving maternal and neonatal health outcomes in India. By embracing technological advancements, fostering community engagement, and addressing systemic challenges, stakeholders can create a healthier future for mothers and their children. The commitment of governments, healthcare providers, researchers/innovators, and communities is essential to drive these changes and ensure that the benefits of innovation reach the last mile in India.

Case Study 1 — Risk Stratification and Biomarker Discovery for Preterm Birth: GARBH-INi Cohort by THSTI

Abstract

Preterm birth (PTB) remains a significant maternal and neonatal health challenge. The cohort, the largest longitudinal study of pregnant women in low- and middle-income countries (LMICs), offers a well-phenotyped biorepository with ultrasonographic parameters and longitudinal diverse type of samples collected from N=12,000 across trimesters to enhance PTB risk stratification. The study employs a multi-omics approach, including epidemiological and clinical risk factor analysis, ultrasound-based predictors, biomarker identification, and pathway analysis to develop risk stratification algorithms. Identified innovations include a dipstick test for PTB-associated bacterial infections, the use of Lactobacillus consortia as a therapeutic probiotic candidate, and genomic variants linked to PTB risk. By combining proteomic and metabolomic approaches, this initiative aims to refine diagnostic and therapeutic interventions for PTB. Findings from this study will provide a national and global resource, supporting evidence-based policymaking and healthcare innovations.

Key Words

Preterm birth, biomarkers, risk stratification, multi-omics, proteomics

Innovation

- **Technological Innovation and Medical Problem:** Preterm birth (PTB) is a leading cause of neonatal mortality, yet current screening methods often miss high-risk cases. This study introduced a multi-omics approach using genomic, proteomic, metabolomic and microbial markers for early PTB prediction. A low-cost dipstick test has been developed for rapid identification of PTB-associated microbiota in high vaginal swab samples enabling timely intervention, especially in low-resource settings.
- **Gap in Existing Solutions and Need for Innovation:** Current PTB detection relies on clinical assessments and ultrasound, which are limited in accuracy and accessibility. No biomarker-based screening exists for PTB identification early in pregnancy.
- **Target Audience and Beneficiaries:** This innovation benefits pregnant women in LMICs, where access to advanced maternal healthcare is limited. Public hospitals, private clinics, researchers, and biotech companies can integrate biomarker-based screening for early intervention and precision maternal care.
- **Innovations:**

  1. SNP panel for screening high-risk women using DNA
  2. Dipstick assay for rapid identification of PTB-associated microbiota for screening high risk women for early interventions
  3. Proteo-metabolic markers as a screening tool to stratify pregnant women at a high risk of PTB.

- **Implementation steps:** Industry engagement for GMP production of Lactobacillus consortia, validation of dipstick assays in external cohorts, and development of SNP panels.

Research Design

- **Demographic Scope:** Conducted in India, using data from the GARBH-INi cohort. Included 12,000 pregnant women with detailed biorepository and ultrasound parameters. Focused on preterm birth risk factors in Indian women.
- **Study Design:** Longitudinal Cohort study with multi-omics analysis (proteomics, metabolomics, genomic and microbial signatures). Also included nested case-control studies for investigating placental derived markers circulating in maternal blood associated with adverse pregnancy outcomes.

Data and Analysis

- **Present Data, Outcomes, and Statistical Analyses:** The multi-omics approach to identify biomarkers of adverse pregnancy outcomes leveraged the presence of stored well phenotyped high quality biospecimen collected from the enrolled women of the **cohort** and archived at an ISO-20387 accredited biorepository. Nested case control studies as a discovery phase had been planned under the respective omics domains. Verification and validation of the results are underway, using a case cohort design.
- **Measured Outcomes, Rationale, and Data Collection:** The study measured genetic, proteomic, and metabolic biomarkers, as well as microbial signatures of PTB. Longitudinal biospecimen sampling was conducted from first-trimester enrollment to delivery. Maternal vaginal microbiome samples were analyzed to identify PTB-associated bacteria, while placental tissue and serum proteomics provided insights into molecular changes linked to PTB risk.
- **Outcome Measures - What Has Changed:** The case control studies nested within the cohort have identified biological markers that can predict or are associated with adverse pregnancy outcome, in our case PTB. Genetic, proteomic, and metabolic biomarkers, as well as microbial signatures have been identified some of which are novel and have not been reported associated with PTB. State of the art technology to isolate placental enriched extracellular vesicles from maternal blood have been established to study the placenta, an unobtainable tissue across the trimesters.
- **Current Timeframe & Future Timelines:** The study is in the clinical validation phase, with ongoing efforts to refine biomarker-based PTB risk models.

  – Future Timeline: By 2024-2026, researchers aim to validate the dipstick test in external cohorts, develop genomic risk prediction tools, and collaborate with industry partners for large-scale integration of biomarker-based diagnostics into maternal healthcare.

Results (thus far)

- **Lessons Learned:** Multi-omics approach enhances PTB risk stratification, and biomarker-based screening offers a new frontier in preterm birth prediction, enabling earlier maternal health interventions.
- **What Worked Well & What Didn't:** The study successfully identified genetic, proteomic, and metabolomic biomarkers for PTB, and the dipstick bacterial test for screening of high-risk women for PTB-as a cost-effective screening tool.
- **Future Directions for Research:** Further validation of identified biomarkers and expansion of dipstick test and SNP panel in external cohorts is ongoing.

- **Obstacles and Solutions:** High-throughput omics technologies generate vast amounts of data, with the challenge of analyzing and integrating the data acquired on different platforms. Leveraging power of computational tools, and cloud computing with better visualization techniques is the way forward. Implementation of the validated biomarkers identified using these complex techniques would need to be translated to cost-effective, easy to use lab-based tests for usage in routine clinical practice.
- **Advice for Others Doing Similar Work:** Studies carried out using human samples often have a small sample size due significant challenges in omics-based research for resources and funding. Results from small sample size studies may generate variability that makes it difficult to draw robust conclusions or generalize findings across different populations. Strategic collaborations with similar cohorts and robust validation protocols would lead to development of universal screening markers that would be easier to deploy at a national level or even global scale.
- **Current Status of Technology:** Proteomic and metabolomic markers for PTB are undergoing validation, while the dipstick bacterial test has shown strong potential and is moving toward large-scale trials.
- **Key Findings & Public Health Impact:** Biomarker-based screening can significantly improve PTB risk prediction, and the dipstick test offers a scalable, affordable alternative for preterm birth detection, making it ideal for integration into public and private healthcare systems.

Next Steps/ Way Forward

- The identified biomarkers from respective omics domains will be validated on external cohorts. The confirmed validated biomarkers will be tested in clinical settings to determine their ability to accurately predict PTB and assess their utility in routine clinical care.
- A robust risk prediction model with a high AUC (Area Under the Curve), will be developed combining the clinical, ultrasound, and biological risk factors identified in the study population.
- A thorough understanding of the mechanism of these risk factor/s associated with PTB will be crucial for developing therapeutic interventions.
- Role of placenta is being explored in pregnancy complications and adverse pregnancy complications, as it plays a pivotal role in maintaining pregnancy and regulating fetal development.

Case Study 2 — Applications of AI in Antenatal Ultrasound – Using Data from GARBH-INi cohort by THSTI

AI-Powered Gestational Age Estimation for Improved Maternal Care – Advancing accurate and scalable gestational age assessment using AI-driven tools for better pregnancy outcomes

Abstract

Accurate pregnancy dating is critical for optimal maternal and neonatal care, yet traditional methods struggle with precision in later trimesters. This study leverages artificial intelligence (AI) to enhance gestational age estimation using ultrasound data from the GARBH-INi cohort in India. The GARBH-INi Ultrasound-image based Gestational age Estimator (GAUGE) employs deep learning to extract fetal characteristics beyond conventional biometry, significantly improving accuracy in the second and third trimesters. GAUGE is more accurate by 44% compared to Hadlock and 35% compared to Intergrowth-21st. Additionally, a novel postnatal GA assessment tool integrates metabolic markers from neonatal heel prick and umbilical cord blood, achieving an error margin of ±7 days. By incorporating AI-driven models into portable ultrasound devices, this study aims to revolutionize prenatal screening, particularly in resource-limited settings, ensuring better pregnancy management and neonatal outcomes.

Key Words

AI in pregnancy care, gestational age estimation, fetal monitoring, cohort, SGA fetuses, antenatal ultrasound, GAUGE

Innovation

- **Medical Problem:** Accurate estimation of gestational age (GA) remains challenging. Traditional methods, such as clinical estimates and standard biometric ultrasound models, often yield inaccurate GA predictions, especially for fetuses with abnormal growth. The study presents AI and biomarker-based innovations for prenatal care: the GAUGE model for accurate gestational age estimation.
- **Gap Addressed:** Existing GA models (Hadlock, Intergrowth-21st) have high error rates, especially for SGA fetuses. Many regions lack affordable ultrasound tools and trained sonographers. The AI-powered GAUGE model and biomarker-based PTB risk stratification provides a better alternative, addressing these gaps.
- **Target Audience and Beneficiaries:** Pregnant women seeking antenatal care.
- **Key innovations:**
  - GAUGE model for GA prediction using ultrasound images.
  - Prediction of post-natal gestational age using metabolomics & machine learning .
- **Implementation Steps:** The GAUGE model was patented and the team is in conversation with all stakeholders to develop a PC based software which can be easily used by clinicians.

Research Design

- **Demographic Scope:** Conducted in India, using data from the GARBH-INi cohort. Included 4,000 pregnant women, and over 5,323 ultrasound scans. External validation data collected retrospectively from 311 cases in an ultrasound lab in New Delhi.

Study Design: AI-driven cohort study

Data and Analysis

- **Present Data, Outcomes, and Statistical Analyses:** This study leveraged data from the GARBH-INi cohort to develop an AI-powered gestational age estimation model, improving pregnancy dating accuracy. A dataset of 5,323 ultrasound scans was used to train and validate GAUGE model, with additional validation on 311 cases from an independent ultrasound lab in New Delhi. The AI model demonstrated a 44% improvement over Hadlock and a 35% improvement over Intergrowth-21st methods for second- and third-trimester pregnancy dating. Post natal GA estimation model showed that GAUGE reduced errors to ±7 days.
- **Rationale, and Data Collection:** The study measured gestational age (GA) accuracy, as incorrect dating can lead to misclassification of preterm and growth-restricted fetuses, impacting maternal and neonatal care. Ultrasound images were collected longitudinally from the GARBH-INi cohort, capturing fetal biometric parameters such as head circumference, femur length, and abdominal circumference. AI models were trained using these features, along with deep-learning-extracted characteristics, improving GA estimation beyond traditional methods.
- **Outcome Measures - What Has Changed:** AI integration has improved pregnancy dating accuracy, particularly for small-for-gestational-age (SGA) fetuses, which are often misclassified using standard biometry. The GAUGE model demonstrated superior performance in later trimesters, reducing reliance on first-trimester dating. Additionally, a postnatal GA assessment tool was developed using metabolic markers from neonatal heel prick and umbilical cord blood.
  - **Current Timeframe & Future Timelines:** The study is currently in the external validation phase, with efforts to evaluate real world performance of the model in 7 prospective cohorts across India.
  - **Future Timeline:** The GAUGE model was patented and the team is in conversation with all stake holders to develop a PC based software which can be easily used by clinicians .

Results (thus far)

- **Lessons Learned:** AI-based gestational age (GA) estimation improves accuracy in later trimesters and outperform traditional biometric dating methods.
- **What Worked Well & What Didn't:** AI-powered GA models outperformed Hadlock and Intergrowth-21st estimations, and the Streamlit-based web app improved accessibility, but limited validation across diverse populations and complexity of AI interpretation remain challenges.
- **Future Directions for Research:** External validation using data from 7 prospective cohorts across India is on the way.
- **Obstacles and Solutions:** Limited dataset diversity, clinician skepticism, and rural technical constraints were tackled by expanding study sites, providing AI training, and developing offline-compatible AI models.
- **Advice for Others Doing Similar Work:** Prioritizing user-friendly AI models, ensuring widespread validation before deployment, and combining AI tools with existing fetal monitoring technologies will improve adoption.
- **Current Status of Technology:** The GAUGE model is in advanced validation, with ongoing efforts to integrate AI-based GA estimation into ultrasound machines for scalability in public and private maternal healthcare.
- **Key Findings & Public Health Impact:** AI improves GA estimation by 35-44% over standard methods, enhancing preterm birth prediction and neonatal care, with high scale-up potential across hospital settings.

Case Study 3 AI-assisted risk stratification models in underserved areas by Jhpiego

Quality assured care continuum: a step towards AI powered risk stratification to improve fetal wellbeing

Abstract

India has made significant strides in improving institutional birth rates and enhancing the quality of maternal and newborn healthcare. However, fragmentation in the continuum of care persists, limiting real-time decision-making. To address this, Jhpiego, in collaboration with the Government of Madhya Pradesh and supported by Takeda Global CSR, has developed a digital, data-driven maternity care continuum. This system ensures comprehensive tracking of maternal health from preconception to postpartum, integrating critical service delivery points.

The initiative comprises four key components: 1) Bluetooth-enabled biomedical devices for real- time vital sign monitoring during antenatal care (ANC), 2) Digital Mother-Child Protection (MCP) cards for longitudinal data capture, 3) Digitization of intrapartum care to enhance labor management, and 4) Analytical dashboards for health system administrators. These components are integrated into existing digital platforms across intervention districts.

Currently, efforts are focused on utilizing these datasets to develop AI-driven predictive models for maternal (e.g., pregnancy-induced hypertension, obstructed labor) and neonatal (e.g., preterm birth, stillbirth) outcomes, facilitating risk stratification and personalized care interventions.

Key Words

Continuum of care, AI powered risk stratification

Innovation

- Existing digital health systems operate in silos, with community and facility-level data not integrated, leading to delays in critical interventions. Current solutions do not provide real- time decision-making support for healthcare workers, limiting predictive insights for maternal and newborn health outcomes.
- The innovation in this project is a digitized maternity care continuum integrating Bluetooth- enabled biomedical devices, digital Mother-Child Protection (MCP) cards, intrapartum care digitization, and analytical dashboards. This system enables real-time tracking of maternal and newborn health data, ensuring timely decision-making across different service delivery points.

- Example: An ANM in a rural district uses Bluetooth connected devices to detect high risk conditions during an ANC visit ensuring seamless transfer of findings automatically on the ANMOL MP application. The data, later gets automatically uploaded to the digital MCP card and flags the risk on the digitized platform whenever such digital version is fetched as subsequent service delivery point, such as labor rooms providing complete history for each identified case. This enables early referral, timely decision and supports management of complications. The deidentified aggregated information is also available on the district and state level dashboards for administrative decisions and resources allocation.

Research Design

- This is a being implemented as demonstration project in existing public health settings.

Data and Analysis

In 20 months of implementation in the demonstration district, 150 ANMs successfully utilized Bluetooth-enabled connected devices during 67999 ANC visits, resulting in approximately 37% reduction in transcription errors. This improvement minimized data inconsistencies and reduced heaping around average values for critical vital indicators such as blood pressure (32%), hemoglobin levels (50%), fetal heart rate (24%), and maternal weight (49%), ensuring more precise clinical assessments. The enhanced data accuracy directly contributed to improved detection of high-risk pregnancies, increasing risk identification rates from 8% to 13% for key vitals, enabling timely referrals and interventions.

Currently, 48 facilities actively use digital MCP cards and digitized labor rooms, ensuring seamless data continuity across maternal care phases. Additionally, officials across all 51 districts and state health departments utilize real-time dashboards for routine reviews and data-driven decision- making. The established continuum of care has facilitated end-to-end tracking of 141763 pregnancies across 931 provider contact points, ensuring comprehensive maternal health monitoring and timely interventions within 31 months of implementation.

Results (thus far)

- The implementation of a digitized maternity care continuum in Madhya Pradesh has demonstrated significant improvements in maternal and newborn health monitoring. One of the key lessons learned is that real-time data integration enhances decision-making, enabling early risk detection and timely interventions. However, successful adoption requires sustained capacity building and support for healthcare providers to ensure efficient use of digital tools. While the integration of Bluetooth-enabled devices, digital MCP cards, and analytical dashboards worked well in streamlining data flow across different levels of care, challenges such as initial resistance to technology, infrastructure limitations in remote areas, and the need for stronger data governance were observed.
- Moving forward, the focus will be on developing AI-powered predictive analytics to identify high-risk pregnancies and neonatal complications allowing for proactive and personalized care. These models will help in stratifying risks, enabling healthcare providers to prioritize cases and improve maternal and newborn outcomes. The status of this technology sees its active use across select districts, with ANMs, healthcare facilities, and administrative officials utilizing digital tools for real-time decision-making.

Next Steps/ Way Forward

- The next steps for scaling the digitized maternity care continuum include expanding AI- powered predictive analytics to improve risk stratification for maternal and fetal complications. Strengthening interoperability with state or national health information systems will ensure seamless data flow across care levels. Capacity building for healthcare providers on digital tools and AI-driven decision-making will be critical for sustained adoption. Further research and validation of predictive models using diverse population datasets will be required to enhance their accuracy and clinical applicability.

Case Study 4

Antenatal Doppler screening for fetuses at risk of adverse outcomes: a multicountry cohort study of the prevalence of abnormal resistance index in low-risk pregnant women (UMBIFLOW) by JNMC

Antenatal Doppler screening for fetuses at risk of adverse outcomes: a multicountry cohort study of the prevalence of abnormal resistance index in low-risk pregnant women

Abstract

Few interventions exist to address the high burden of stillbirths among healthy pregnant women in low- and middle-income countries (LMICs). This study aimed to determine the prevalence of abnormal fetal umbilical artery resistance indices among low-risk pregnant women using a low-cost Doppler device (Umbiflow) in five LMICs. A multicenter, prospective cohort study was conducted in Ghana, India, Kenya, Rwanda, and South Africa. Trained nurses or midwives performed a single, continuous-wave Doppler screening using Umbiflow for low-risk pregnant women between 28 and 34 weeks of gestation. Of 7,151 women screened, 495 (6.9%) had an abnormal resistance index (RI), including 14 (0.2%) with absent end-diastolic flow (AEDF). Women with abnormal RI had higher rates of cesarean section (40.8% vs. 28.1%), labor induction (20.5% vs. 9.0%), and low birth weight (<2500 g) (15.0% vs. 6.8%). Findings suggest that a single Doppler screening can detect fetuses at risk of growth restriction and adverse perinatal outcomes.

Key Words

Umbiflow, antenatal Doppler, resistance index, low-risk pregnancies, LMICs, placental insufficiency

Innovation

- **Medical Problem and Innovation:** The study assessed the feasibility of Umbiflow, a low-cost, portable Doppler device for fetal umbilical artery resistance screening in low-risk pregnant women. The goal was to determine whether large-scale implementation of Doppler screening could reduce perinatal mortality and morbidity in low- and middle-income countries (LMICs).
- **Gap Addressed:** Detection of fetal growth restriction (FGR) is limited in LMICs, where clinical assessments like fundal height measurement and history-taking are often inadequate. Routine ultrasound is not universally available. Umbiflow offers an alternative to detect abnormalities earlier, improving chances of timely intervention.

- **Target Audience and Beneficiaries:** The primary beneficiaries include pregnant women in LMICs, particularly in rural and peri-urban areas, where access to advanced fetal monitoring is limited. Healthcare providers, including midwives and primary care clinicians, benefit from training programs, while policymakers can integrate Umbiflow into national maternal health strategies to improve fetal health outcomes.
- **Detailed Account:** The study used Umbiflow to screen fetal umbilical artery blood flow, identifying cases with abnormal resistance index (RI). Nurses and midwives conducted Doppler assessments, ensuring accessibility in low-resource settings.
- **Implementation steps:**
  - Pregnant women between 28–34 weeks were screened using the Umbiflow Doppler device.
  - Cases with abnormal RI were referred to higher-level facilities for further assessment.
  - A pilot study in Kraaifontein, South Africa assessed whether Doppler screening reduced unnecessary referrals to specialized care.

Research Design

- **Demographic Scope:** 7,151 low-risk pregnant women (gestational age 28-34 weeks) across Ghana, India, Kenya, Rwanda, and South Africa.
- **Study Design:** The study was a multi-country, prospective cohort study conducted in Ghana, India, Kenya, Rwanda, and South Africa.

Data and Analysis

- **Present Data, Outcomes, and Statistical Analyses:** The study screened 7,151 low-risk pregnant women across five LMICs (Ghana, India, Kenya, Rwanda, and South Africa). Among them, 6.9% (495 cases) had an abnormal resistance index (RI), indicating fetal growth restriction, while 0.2% (14 cases) showed absent end-diastolic flow (AEDF), signaling severe fetal risk. Pregnancies with abnormal RI had higher cesarean (40.8% vs. 28.1%) and labor induction rates (20.5% vs. 9.0%). The prevalence of low birth weight doubled (15.0% vs. 6.8%) in these cases. However, stillbirth rates remained unchanged, suggesting that additional interventions may be needed.
- **Measured Outcomes, Rationale, and Data Collection:** Key outcomes measured included umbilical artery RI, birth weight, mode of delivery, stillbirths, perinatal mortality, and antenatal care usage. These were chosen because RI is a critical marker of placental insufficiency and fetal risk, guiding timely medical interventions. Data collection involved a single Doppler scan between 28–34 weeks of gestation using the Umbiflow device, conducted by trained midwives. Pregnancy outcomes and medical interventions were tracked through structured follow-ups.
- **Outcomes Measured – What has changed:**
  - Of the 7151 women screened, 6.9% (493) had an abnormal RI, and 0.2% (16) had absent end diastolic flow. Women with abnormal RI had higher rates of obstetric interventions, including caesarean delivery (40.8% vs. 28.1%) and labor induction (20.5% vs. 9.0%). Neonatal outcomes, including low birth weight (15.0% vs. 6.8%) and NICU admission, were more frequent in the abnormal RI group.
- **Current Timeframe & Future Timelines:** The study has been completed across all five LMICs, with ongoing data analysis.

Results (thus far)

- **Lessons Learned:**
  - Incidence of abnormal Doppler among low-risk pregnant women from India was low (6.9%)
  - Periodic Training of the Health worker (ANMs, Staff Nurse at Primary Care Level) is a crucial element.
- **What Worked Well & What Didn't:**
  - Visual display of the umbilical artery wave pattern and auditory effects enhanced the ease of use of this handheld Doppler device efficiently.
  - ANMs/ Staff Nurse implemented the study at the Primary Health Centre.
  - Pregnant women acceptance was nearly 100%
  - Referral of all women with abnormal Doppler to the designated hospital was a significant issue identified.
  - Refusal of the pregnant women and family members for referral to tertiary center as they were asymptomatic (low risk)
- **Future Directions for Research:**
  - Diverse geographic representation is needed for improving the validity and generalizability
  - Doppler screening to be performed twice in the third trimester with 4–6-week interval.
- **Obstacles and Solutions:**
  - Due to migration and cultural norm of traveling to mother's place for delivery, tracking the enrolled women was a challenge. But we could achieve this by establishing good network of tracking with all the field staff.
- **Current Status of Technology:**
  - Currently no upgraded version of the device is available so far. Thus, we do not have additional information regarding this.
- **Key Findings & Public Health Implications:** Abnormal RI detected in 6.9% of screened women. Higher rates of obstetric interventions (caesarean, NICU admission) among abnormal RI group were noted. Early detection of abnormal RI though Doppler screening may help prevent perinatal deaths. More follow-up is needed to determine the full impact on mortality rates.

Next Steps/ Way Forward

The study was conducted in 2018 and since then, there has been no documented work on upgradation in the software or the Doppler device. No additional trials have been planned or conducted to move forward in this regard. Thus, a larger, multicentric study is needed to provide more evidence on its effectiveness which can influence the policy makers and can later be incorporated into the use in routine low risk antenatal care practices at primary care level.

This Doppler device has definite role in primary care level, especially for high-risk women which can be effectively implemented by peripheral field staff as noted in our study. In resource limited settings (remote and rural area) and non-availability of experts, this device could avert perinatal morbidity and mortality by early identification and appropriate risk stratification and referral. However, we need critical evidence in diverse population setting to support this hypothesis.

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[1] Will provide a comprehensive matrix of current and emerging fetal surveillance technologies that will aid in clinicals to enhance patient care.

[2] Will help inform guidelines that ensure equitable access to advanced fetal monitoring technologies.

community level. These include stakeholders from implementing organisations, NGOs, civil society organisations, etc

[3] Public health professionals include stakeholders that are responsible for implementing policy and health programmes/schemes at the

[4] Will synthesize existing literature and trends to motivate further studies and provide insights and help refine strategies for improving maternal and fetal health outcomes

[5] Overview of trends will guide potential product enhancements and new device development.

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ADVANCING FETAL HEALTH

EMERGING TECHNOLOGIES IN FETAL MONITORING

Adhuna
Advancing Delivery of (Quality) Healthcare through Upgraded Newborn (and Intrapartum Care) Approaches

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