

# **Acknowledgements**

#### **Contributors**

#### **Sattva Knowledge Institute**

- · Ritika Ramasuri
- Anushka Anand
- · Granthika Chatterjee
- Harsh Bhatt
- · Lakshmi Sethuraman
- · Anantha Narayan
- Rathish Balakrishnan

#### **Jhpiego**

- Dr. Suhela Kapoor
- · Dr. Parag Bhamare
- Dr. Anunaya Jain
- Dr. Yashpal Jain

#### **Innovators**

Name	Organisation
Arun Agarwal	Janitri
Ambar Srivastava	TrueHB
Amit Vernekar	Chemioptic
Aditya Kulkarni	CareNx
Anand Madanagopal	Cardiac Design Labs
Amrita Sukrity	SpotSense
Arvind Badrinarayan	Muse Diagnostics
Arvind Pachhapur	Strand
Dr. Gayatri Mandada	Fides Medtech
Komal Agarwal	EzeRx
Mohit Saxena	Dimagi
Rajat Jain	Sunfox Technologies
Rahul Pathri	Docturnal
Rohan Aggarwal	Vidcare
Sumona Karjee Mishra	Prantae
Dr. Vaishnavi Kulkarni	Intignus Biotech
Vibhav Joshi & Shaunak Patel	InnAccel

## **Diagnostics Ecosystem Stakeholders**

Name	Organisation
Dr. Kavita Aneja	Samrakshan Program, Indian Radiological & Imaging Association
Krisha Mathur	ACT Grants
Dr. Kshama Kothari	Social Alpha
Dr. Niranjan Joshi	C-CAMP
Parvathy Ramanathan	GH Labs
Dr. Prashant Nag	Tata 1mg
Raghu Dharmaraju	ARTPARK, IISc
Sapna Behar & George Mathews	Icarus Design
Dr. Sarabjit S Chadha	FIND
Srinivas Ramanujam	Villgro
Sushmita Sundar	Research & Innovation Circle of Hyderabad
Dr. Vijender Jeph	Samridh Healthcare Blended Finance Facility



#### **Disclaimer**

This report has been produced by a team from Sattva Consulting as a product for the Sattva Knowledge Institute (SKI). The authors take full responsibility for the contents and conclusions. Any participation of industry experts and affiliates who were consulted and acknowledged here does not necessarily imply endorsement of the report's contents or conclusions.

This report only provides the findings of our limited search and is based on information acquired through conducting interviews of the organisations named/featured/attributed in the report, publicly available information on such organisations, and publicly accessible documents/information that may have been submitted/filed/reported by these organisations. SKI has not conducted any independent searches of any information or data presented in the report or on the organisations named/featured/attributed in the report, nor have we conducted searches using any specialised diligence software/tools/vendors/ third parties/regulators. SKI does not comment on, nor has it reviewed the compliance status of the organisations mentioned in this report, which remains the sole responsibility of the users of the report.

This report is provided for information purposes only. No advice or services are being offered or provided by Sattva Media and Consulting Private Limited ("Sattva") or SKI in or under this publication. This report is not a substitute for professional advice or availing services. Users of this document should seek advice or other relevant assessments regarding the appropriateness of recommendations referred to in this report and should consult their advisors before making any decisions. Sattva and SKI accept no liability and will not be liable for any loss or damage arising from any use of this report, howsoever arising. To quote this report, please mention: Sattva Knowledge Institute and Jhpiego, *Making Antenatal Diagnostics Work*, February 2025. Use of the report's figures, tables or diagrams, must fully credit the respective copyright owner where indicated. Reproduction must be in original form with no adaptions or derivatives. For use of any images in the report please contact the respective copyright holders directly for permission.

This work is licensed under the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License:

**Attribution** - You may give appropriate credit, provide a link to the licence, indicate if any changes were made. **Non-Commercial** - You may not use the material for commercial purposes.

Share A Like - If you remix, transform, or build upon the material, you must distribute your contributions under the same licence as the original.



To view a copy of this license, visit http://creativecommons.org/licenses/by-nc-sa/4.0/



#### **About Sattva Knowledge Institute**

Sattva Knowledge Institute (SKI), established in 2022, is our official knowledge platform at Sattva. The SKI platform aims to guide investment decisions for impact, shedding light on urgent problems and high potential solutions, so that stakeholders can build greater awareness and a bias towards concerted action. Our focus is on offering solutions over symptoms, carefully curating strong evidence-based research, and engaging decision-makers actively with our insights. Overall, SKI aims to shift intent and action toward greater impact by influencing leaders with knowledge. All of our content proactively leverages the capabilities, experience and proprietary data from across Sattva.

Editor: Anagha Wankhede Design: Usha Sondhi Kundu; cognitive.designs@gmail.com	
Photos: Jhpiego & Pixabay	•
	,



# CONTENTS

<b>Executive Summary</b>	
Despite Overall Improvements, Many Indian States Underperform in Healthcare Delivery for Women	07
The Ecosystem Encourages Incubation and Development, but Early Adoption and Commercialisation Remain a Challenge	11
Research Methodology	14
Insights	16
References	23



# **Executive Summary**

#### Effective antenatal care is required to reduce India's MMR

In October 2024, the Executive Director of the United Nations Population Fund, Dr. Natalia Kanem, lauded India's efforts in reducing the MMR (maternal mortality rate) by 70% between 2000 and 2020, to 97 per 100,000 live births. However, this is still above the 2030 SDG 3 (Sustainable Development Goal) target of 70 per 100,000 live births. The MMR in states such as Assam, Madhya Pradesh, and Uttar Pradesh are well above 150. Poor health infrastructure is one factor that holds back an improvement in our MMR. However, socio-economic factors and the lack of women's agency create low utilisation of available antenatal care services. Diagnostic tools become important in this context – the Lancet Commission on Diagnostics has stated that premature deaths (across multiple areas) can be reduced by 1.1 million annually by reducing the diagnostics gap in low and middle-income countries from 35-62% to 10%.

Adoption and commercialisation are challenges for India's diagnostics ecosystem India has a significant ecosystem for screening and diagnostic devices, with state-led as well as private incubation programmes. However, early adoption and commercialisation remain issues. The Sattva Knowledge Institute & Jhpiego held an expert consultation at the SKI Annual Summit in February 2024, which led to three key root-cause hypotheses: (1) limited understanding of the social context among investors, (2) lack of gender sensitivity and understanding of on-the-ground realities among innovators, and (3) limited capacity of states to integrate innovations in their health systems. We interviewed 17 diagnostic product developers and 12 ecosystem stakeholders to understand the complexities involved.

#### **Insights from our study**

Our recommendations to mitigate the above challenges, based on our study, fall into three broad buckets: (1) diagnostic tool design, (2) workflows of frontline staff and their constraints, and (3) the role of investors. Some of the important considerations include non-invasiveness and privacy, the need for more women technicians, enabling investors and innovators to understand social determinants of health inequities at the last mile, thoughtful integration of the devices in on-the-ground workflows, focus on device durability, portability, and functioning in low-resource settings and the move from a grantled approach by philanthropy to a more holistic one that covers every stage from product ideation to commercialisation.





rom the aspirations of the Millennium Development Goals (MDGs), to the continued pursuit of the Sustainable Development Goals (SDGs), maternal mortality has been a longstanding global health challenge. The first target under SDG 3 – Good Health & Wellbeing – is "to reduce the global maternal mortality ratio (MMR) to less than 70 per 100,000 live births" by 2030.¹ However, the World Health Organisation (WHO) deems the current maternal mortality statistics "unacceptably high".²

Figure 1: MMR trends around the world<sup>2,3</sup>

**95%** of preventable maternal deaths in 2020 occurred in Low & Middle-Income Countries (LMICs).

Countries in Sub-Saharan Africa (70%) and Southern Asia (16%) account for **87%** of global maternal deaths.

MMR in Southern Asian countries declined by **67%** between 2000 and 2020.

In the same period, India witnessed a **70%** decline, with MMR at **97** per **100,000** live births.

However, the MMR in Assam, Madhya Pradesh, and Uttar Pradesh are higher than **150** per **100,000** live births.



While the reduction in national MMR average reflects significant progress, there remain sharp disparities across Indian states, with some of the Empowered Action Group (EAG) states and others still reporting alarmingly high levels of maternal mortality. As seen in *Figure 2*, at least 11 states have MMR documented as being greater than the national average of 97. The Empowered Action Group (EAG) states (Bihar, Madhya Pradesh, Chhattisgarh, Odisha, Rajasthan, Uttar Pradesh, and Uttarakhand) – except Jharkhand – and other states such as Assam, Haryana, Punjab, and West Bengal report higher MMR compared to the national average.<sup>4</sup>

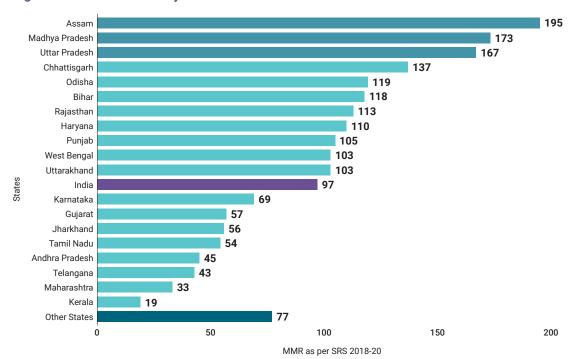


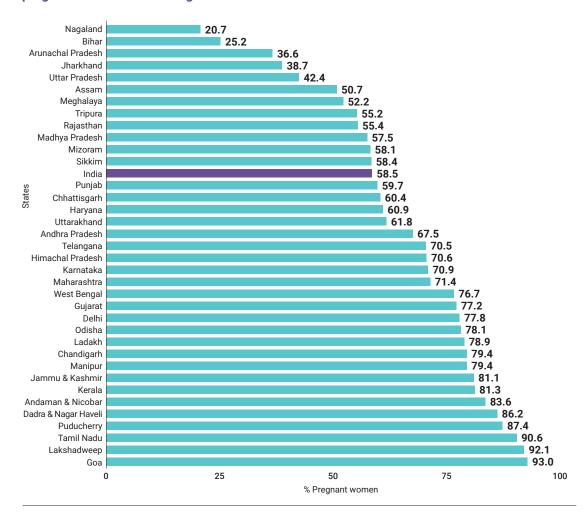
Figure 2: Maternal Mortality Ratio in Indian States<sup>4</sup>

Notably, several of these states also show a lower-than-average percentage of pregnant women having four or more antenatal care (ANC) visits. It is estimated that 74% of global maternal deaths arising from severe bleeding, infections, eclampsia, hypertensive disorders, unsafe abortions, and other complications during delivery are potentially preventable by implementing the WHO's Mother-Baby Package – a set of evidence-based guidelines for health promotion, early detection, and management of complications up until the postpartum period. ANC is a vital framework for essential healthcare functions such as health promotion, screening for issues, diagnosing conditions, and preventing diseases. This approach is essential for ensuring the well-being of women, unborn foetuses, newborns, and by extension, their communities. ANC is also provided via the Village Health Sanitation and Nutrition Days (VHSNDs) which are expected to be conducted once a month in every village. The VHSNDs are an important platform, not only for enabling ANC services but also for health promotion activities and counselling services. Several states are doing poorly in the uptake of the required number of ANC visits. In states like Nagaland, Bihar,



Arunachal Pradesh, Jharkhand, Uttar Pradesh, Assam, Meghalaya, Tripura, Rajasthan, Madhya Pradesh, Mizoram, and Sikkim, greater efforts have to be made to improve the uptake of at least four ANC visits by pregnant women.<sup>9</sup>

Figure 3: As per the National Family Health Survey 2019-21, a national average of 58.5% of pregnant women had undergone four or more ANC visits.<sup>9</sup>



While the WHO recommends that a pregnant woman receive 8 ANC contacts, the National Health Mission (NHM) recommends at least 4 ANC visits. <sup>7,8</sup> In every ANC check-up, the essential routine tests include measuring weight, blood pressure, and respiratory rate. The frontline health worker is also expected to check for pallor and oedema, along with performing abdominal palpation, where they gently press on the abdominal area with their hands to identify abnormalities. Routine laboratory tests include blood and urine samples for haemoglobin and sugar + protein respectively. <sup>8</sup>

#### Challenges in antenatal care

Lack of utilisation of ANC services and poor health infrastructure are two major challenges to improving maternal health outcomes. The utilisation of ANC services by pregnant women in India is determined by socio-economic factors, such as wealth or standard of living, caste, educational status of the woman and her husband, rural-urban location, and women's agency in making household decisions. An analysis of the National Family Health Survey – 4 (NFHS) data from the EAG states revealed that the proportion of women not utilising the ANC services was higher in the poorer and poorest wealth quintiles, Scheduled Caste and Scheduled Tribe groups, Muslims, and among those with no education. The proportion of women receiving antenatal care services as well as prior information on pregnancy complications increased in line with higher income and education levels.

When it comes to health infrastructure, only about 20% of the assessed public health facilities in India score 80% or more on service and infrastructural requirements of the Indian Public Health Standards (IPHS). Social determinants of health influence demand or health-seeking behaviour on the one hand, and supply-side challenges in delivering comprehensive ANC services at the last mile on the other. Consequently, women from marginalised communities are more likely to bear the brunt of poor health outcomes.

#### Importance of diagnostic tools and services

In 2021, the Lancet Commission on Diagnostics underscored the importance of diagnostics to quality healthcare, and how its absence particularly affects poor, rural, and marginalised populations. Poor accessibility to diagnostics afflicts close to 47% of the global population. The existing diagnostics gap in LMICs (for diabetes, hypertension, HIV and TB for the overall population; hepatitis B virus infection and syphilis for pregnant women) is between 35-62%. The Commission estimated that bringing this to 10% can reduce premature deaths by over 1 million, and Disability Adjusted Life Year (DALY) losses by 38.5 million, i.e. 2.5% of total annual deaths and 1.8% of total annual DALY losses in LMICs.<sup>13</sup> However, user-friendly diagnostic tools that are suitable to underresourced settings are not easily available. Therefore, efforts towards improving last-mile availability and accessibility of screening and diagnostic tools could be one of the pathways for bridging the diagnostics gap.





t is important to understand the innovation ecosystem for screening and diagnostic tools in India. India has nearly 80% import dependency in the medical device sector due to a lack of high-end technology and poor availability of raw materials. 14 Offering in-vitro testing services can be challenging when there are insufficient laboratory networks. Issues with device design make radiodiagnosis difficult to deliver to remote areas. Environmental factors – such as ambient temperature, availability of the required reagents and consumables, and operational capability of providers – affect the quality and performance of tests. Making gold standard tools for confirmatory tests widely available at the last mile is neither desirable nor an efficient strategy for solving the diagnostics gap. However, innovations that can help overcome design and performance-related limitations in existing tools are pressingly required.

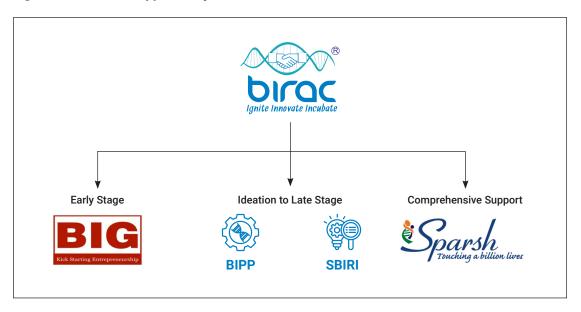
Recognising the importance of strengthening India's innovation and manufacturing capabilities in the med-tech sector, the Biotechnology Industry Research Assistance Council (BIRAC) was started in 2012 as a non-profit enterprise to support innovation and research in



biotechnology through grants, mentoring, and partnerships.<sup>15</sup> Some important initiatives by BIRAC for providing grants and mentoring support to innovators include:

- The Biotechnology Innovation Grant (BIG) in the ideation to early stage category,
- The Biotechnology Industry Partnership Programme (BIPP) and Small Business Innovation Research Initiative (SBIRI) in the ideation to late stage category,
- The Social Innovation Programme for Products Affordable & Relevant to Societal Health (SPARSH) to provide comprehensive support for social innovation, and
- · The equity funding programmes.

Figure 4: Initiatives supported by BIRAC



The MedTech Mitra Scheme launched in December 2023 – under the partnership of the NITI Aayog, Indian Council of Medical Research (ICMR), and Central Drug Standard Control Organisation (CDSCO) – aims to provide end-to-end hand-holding to innovators, including scaling efforts in the public sector.<sup>16</sup>

In addition to these public sector initiatives, the Stanford-India Biodesign programme was started in 2008, in partnership with the Department of Biotechnology (DBT) and All India Institute of Medical Sciences (AIIMS), for training fellows towards creating healthcare technologies for underserved communities in India.<sup>17</sup> The Gates Foundation also provides grants through their Grand Challenges initiative in partnership with BIRAC. Incubation support is also being provided by organisations like India Health Fund, Villgro, C-Camp, Social Alpha, and Research & Innovation Circle of Hyderabad. International non-profit organisations, such as PATH and Jhpiego have contributed to establishing the need for innovation that can respond to women's healthcare needs at the last mile, the needs of frontline health workers, and infrastructural issues in remote areas.



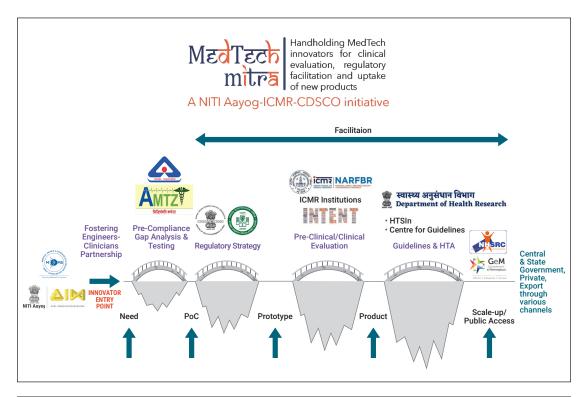


Figure 5: MedTech Mitra - Empowering innovators to face challenges in the development pathway

Source: ICMR

Despite these promising initiatives and efforts by the public sector and the non-profit sector, the adoption of high-potential and frugal technologies remains chequered. To understand the roadblocks in the lab to the health-facility pathway, Sattva Knowledge Institute partnered with Jhpiego India to conduct an exploratory study. Based on prior interactions with ecosystem stakeholders, the root-cause hypotheses were articulated, and this study attempted to test these hypotheses.

Source: ICMR





### **Research hypothesis**

hroughout our engagement on this subject, several problem statements related to systemic barriers, infrastructural gaps, and social determinants were discussed.

Based on an expert consultation held with public health stakeholders by Sattva Knowledge Institute's Health Practice Team and Jhpiego India, three root causes were articulated as the hypothesis to explain the adoption failure of promising med-tech devices with use cases for women's health. They are as follows:

- Information asymmetry results in a limited understanding of the context for investors during solution assessment and validation.
- Innovators may also lack comprehensive insight into on-the-ground realities during
  the ideation and product validation stages. Additionally, there may be a lack of gender
  sensitivity among innovators, affecting their ability to develop solutions that effectively
  address gender-specific needs and challenges.
- · States exhibit limited capacity to assess and integrate innovations adequately.



#### **Research question**

To test the hypothesis, the research exercise attempts to answer the following question:

What does it take for screening and diagnostics innovations to respond not only to the healthcare needs and constraints of marginalised women but also to be compatible with the workflow and skill levels of frontline health workers operating within low-resource settings?

This exploratory study attempted to uncover the challenges in developing products that can account for social determinants of women's health, and also the lived realities of frontline health workers in low-resource healthcare facilities at the last mile. Additionally, this study also attempted to understand the challenges in the adoption of screening and diagnostic tools in both public and private healthcare systems.

#### **Data collection**

The research design primarily relies on the qualitative method of key informant interviews with relevant stakeholders. The convenience sampling method was used to identify 51 innovative screening and diagnostics products for antenatal care. These products were identified from databases such as Inc42, Traxcn, and Crunchbase; and product portfolios of incubating organisations such as C-CAMP, Villgro, Centre for Healthcare Entrepreneurship, Samridh Healthcare Blended Finance Facility, Health Quad, Social Alpha, and the Research and Innovation Circle of Hyderabad. Technology Readiness Level (TRL) as framed by BIRAC was an important criterion for exclusion, as only products at TRL 4-5 and above (with the exception of Jananya) were selected.<sup>18</sup> The interview guide meant for innovators broadly covered questions related to needs assessment, centring on:

- Women patients, frontline health workers, and low-resource settings in product development
- The journey through clinical trials, regulatory validation, quality assurance certifications, and pilots
- · Challenges faced in early adoption and sustaining further growth

Interviews were conducted with innovation incubation support professionals to understand their landscape view of antenatal care and challenges to innovation concerning product development and adoption. 17 innovators and 12 ecosystem stakeholders (incubators and funders) were interviewed (the complete list is available in the acknowledgements).





To the best extent possible, innovators should consider noninvasiveness in tool design, privacy in the operational design, and social determinants related to health-seeking behaviours.

#### Non-invasiveness in the design of diagnostic tools and services

Considering the socio-economic barriers to healthcare faced by women, point-of-care (PoC) screening tools must be as non-invasive as possible. For example, during the deployment of the AnandiMaa ANC PoC suite, male members in women's families expressed reservations regarding the pricking and collection of blood samples as they feared misuse. In such situations, the frontline health worker made efforts to win the community's trust through frequent visits to provide at-home healthcare services and gradually persuaded family members of the importance of blood sample collection for measuring glucose and haemoglobin (Hb). On the other hand, a device like EzeCheck is a non-invasive haemoglobin screening tool for anaemia that can detect haemoglobin in less than a minute without drawing a single drop of blood from the human body. When the subject places their left finger on the light bed, the device analyzes biomarker changes at various wavelengths of light using absorption spectroscopy. The individual pattern is then processed by an Al algorithm to generate the haemoglobin value.



"Initially, male partners resisted doorstep antenatal care, particularly the [haemoglobin] Hb and glucose tests, fearing blood samples could be misused. Health workers had to reassure families that the blood was solely for testing. Over time, as they saw the benefits, male partners became proactive, boosting trust in health workers and increasing early pregnancy disclosures and healthcare facility visits, with some facilities seeing a 3-7x rise in patient inflow."

- Aditya Kulkarni, Founder, CareNx

#### Privacy in service delivery

Honouring human-centricity in the design of tools and how they are deployed is important not only from a trust-building perspective but also to ensure better uptake of ANC services. Therefore, ensuring that the operational design is considerate of women's comfort and privacy while they undergo testing is of utmost importance, as this will also determine their willingness to seek ANC services, and trust the health system for further care and treatment.

#### Training innovators to understand social determinants of health

Due to their social position, cis-male engineers and innovators from urban backgrounds may not be ideally equipped to fully grasp the gender dynamics and socio-economic factors that influence women's health and health-seeking behaviours. Economic and environmental factors, social stratification based on caste, class, gender, sexuality, level of education, pre-existing deficiencies or diseases could influence health-seeking behaviours. Although grant-led fellowship programmes expose innovators to the realities of health service delivery at the last mile through immersion, it is important that incubators also emphasise and encourage innovators to understand the challenges of health service delivery and social determinants.

#### Training more women phlebotomists and technicians

The presence of male technicians/phlebotomists/care providers can be a barrier to women's uptake of ANC tests. For instance, in the case of ECG devices, the electrodes have to be placed on the chest and women are required to undress. In such instances, it becomes all the more necessary for women care providers to be trained in administering the tests, and such a consideration should be a part of the operational design. Alternatively, this could also be addressed by developing ECG monitors that do not require patients to undress. Cardiac Design Labs is developing a vitals and ECG monitoring device that can be placed on the shoulder without requiring the patient to undress.

For successful adoption of the devices, innovators must be encouraged to understand the workflows of frontline workers, routine constraints faced by them, and infrastructural challenges that can impede adoption.

"Designing for impact means simplicity and usability for frontline workers while giving patients something tangible to drive behaviour change. From Sunfox's intuitive ECG to Biosense's product for anaemia diagnostics, effective innovations leave patients with meaningful artefacts like a receipt of their results—reminders of care that enhance trust and adherence in public health."

- Srinivas Ramanujam, CEO, Villgro

#### Understanding workflows on the frontline

ASHAs, ANMs, and Anganwadi Workers are the first line of ANC service provision. Frontline health workers are overburdened with administrative tasks and tend to the healthcare needs of the people. These workers already manage various responsibilities, from conducting health screenings to maintaining detailed records, which can detract from their ability to provide patient-centred care. Implementing innovative solutions without considering the daily challenges from the administrative burden faced by these workers can lead to resistance, frustration, and decreased efficiency. Therefore, thoughtful integration of new technologies into their workflows is critical.

#### Portability for point-of-care administration

Portability of devices is crucial for frontline health workers like ASHAs, ANMs, and Anganwadi Workers, who often travel to different sites to reach underserved populations. Lightweight tools reduce physical strain on these workers and make it feasible to carry multiple devices, thereby enhancing their capacity to deliver comprehensive care. For instance, devices that can be easily transported and operated in the field encourage regular screening and increase the likelihood of early diagnosis of health conditions, which is vital for timely interventions.

#### **Device durability for low-resource settings**

Frontline health workers frequently transport these tools to various locations, which can subject them to accidental drops, knocks, and other forms of mishandling. Devices that are not built to be robust may quickly become non-functional, leading to interruptions in healthcare services and potentially compromising patient care. Moreover, the durability of these devices contributes to cost-effectiveness in healthcare delivery. When screening tools can withstand rough handling and prolonged use, it reduces the need for frequent replacements and repairs, allowing health facilities to allocate resources more efficiently.

Prioritising rechargeability of devices to mitigate power supply issues in rural areas In rural health facilities in India, electricity supply can be inconsistent, leading to operational challenges. Therefore, innovators must prioritise developing rechargeable devices to ensure reliability and continuous usage, enabling healthcare workers to provide essential services even during power outages. This adaptability can significantly improve healthcare delivery in remote areas.



#### Prioritising field validation studies in diverse settings

When developing point-of-care screening tools for rural health facilities in India, innovators must consider the financial impact of reagents and consumables, especially if tests fail at the last mile. In many rural settings, healthcare budgets are limited, and the cost of reagents can become a significant burden. If a test fails, not only does it waste valuable resources, but it also means additional costs for repeat testing, which can strain already tight budgets. Furthermore, the reliability of these tests directly affects healthcare delivery. If health workers face frequent failures, they may become discouraged and less likely to utilise the technology, leading to lower patient engagement in necessary screenings. Therefore, it is important for the social impact funders to enable innovators to conduct field validation studies in as many different low-resource settings as possible (within funding means) to identify the failure conditions. This will help the innovator to further iterate upon the device, to improve performance under those conditions.

#### Providing implementation support at the last mile

While innovators typically provide training support to frontline staff for field deployment, ongoing monitoring is crucial to identify unforeseen challenges and refine the product or operational processes as necessary to address them effectively. This could be done by instituting a programme support unit that is responsible for monitoring the implementation. Implementation efforts must also include communitization efforts through VHSNDs to improve the uptake of ANC services.

Social impact and philanthropic investors play a crucial role in engaging market investors so that innovators can go beyond grant-based funding. They must also advocate for screening and diagnostic interventions that account for underlying conditions and direct causes of maternal mortality in a given context.

Lastly, the state needs to play a bigger role for better adoption of innovations through a whole-of-government approach.

"First, ensuring early adoption engagement within the health system is crucial for start-ups to demonstrate their higher standards and value for money. Second, innovators often avoid pursuing FDA approval due to limited capital. Addressing this funding gap is essential. Enablers and ecosystem must create avenues for this. Developing a realistic technology roadmap can help align investors by showing them that innovators are not only targeting market entry but are also aiming for global best practices."

Dr. Niranjan Joshi, Programme Lead
 Digital Health and Technology Impact Programme, C-CAMP



Engaging market investors to understand the trajectory of medical grade devices

Developing medical technologies involves several capital-intensive stages, including product
development, clinical validation, regulatory clearances, and field validation. Each of these
phases requires substantial financial investment, technical expertise, and time, often leading
innovators to rely on grant funding to sustain their efforts. Unfortunately, this grant-togrant approach can create a precarious financial situation for many med-tech innovators.

Market investors may not fully understand the intricate, and often, lengthy roadmap involved
in bringing a medical product to market, leading to hesitancy in funding these ventures.

Additionally, the fragmented nature of the med-tech investment landscape can lead to a
disconnect between the innovators and the investors. Many investors may lack experience
in healthcare technologies, making it challenging for them to appreciate the potential
impact and value of innovative solutions in this space. This disconnect can result in a lack
of necessary capital at critical stages of product development, hindering the progress of
potentially life-saving technologies.

Early adoption is a major pain point for all med-tech innovators. The grants, fellowship, and incubation ecosystem cover funding for the provision of product development and validation support. However, innovators are unable to get the right support needed for commercialisation. Impact investors need to focus on creating channels that can streamline clinical validation, regulatory validation, early adoption opportunities, and in-roads for scaled adoption. They must also play a role in enabling market investors to appreciate the technology development and commercialisation roadmap for such medical-grade devices. Once their buy-in is secured, impact investors can convene a network of such market investors to facilitate better funding opportunities for product development, adoption, and health systems strengthening.

Fostering a whole-of-government approach for successful adoption of innovations BIRAC has successfully funded numerous innovations in the healthcare sector, providing essential financial support to develop new medical technologies. However, despite this funding, many of these innovations have not achieved widespread adoption within the National Health Mission (NHM) and the Ministry of Health and Family Welfare (MoHFW) programmes. One major hurdle to the adoption of new devices is the need to revise Standard Treatment Protocols (STPs). When a new medical device is introduced, it often requires adjustments to existing protocols to ensure that healthcare professionals understand how to incorporate the device effectively into their practice. These updates may involve extensive training, modifications to workflows, and even changes in the regulatory framework governing treatment practices. The process of changing STPs can be time-consuming and bureaucratic, resulting in delays that hinder the timely implementation of innovative solutions. The absence of strong advocacy for these innovations within health policy circles can also impede their acceptance. Without NHM functionaries present at the decision-making table, innovations that have been developed through BIRAC grants are unable to find buy-in within the maternal health programmes decisions of NHM. Informed by the requirements of NHM and the dynamics of rural healthcare at the last mile, innovators can work towards developing



screening and diagnostic tools that are suitable for large-scale deployments as done under NHM. This also gives the innovators an opportunity to work with the functionaries to make treatment protocols more open to innovation.

# Advocating for screening and diagnostic interventions based on major causes of maternal deaths in a given context

A study looking at 10,000 maternal deaths in India from 1997 to 2020 found that excessive bleeding, pregnancy-related infections, hypertensive disorders, and abortions have been the top direct causes of maternal deaths.<sup>19</sup> In poorer states within India, the proportion of deaths from obstetric haemorrhage had increased, and therefore it was suggested that timely identification and management of underlying conditions like severe anaemia is important to prevent maternal deaths. In richer states like Maharashtra, Tamil Nadu, and Kerala, the proportion of maternal deaths from hypertensive disorders was greater than in many of the poorer EAG states. Therefore, it becomes important for these states to not only focus on underlying conditions for haemorrhage but also prioritise hypertensive disorders among pregnant women. Philanthropic and social impact investors must accordingly advocate for the right screening and diagnostic tools for their maternal health interventions based on underlying conditions and direct causes of mortality as one of the requirements. For postpartum haemorrhage, philanthropic push for the adoption of the E-MOTIVE protocol using a calibrated blood collection drape by Jhpiego and the Federation of Obstetric and Gynaecological Societies of India (FOGSI) has been important for training paramedics in tier-2 and tier-3 cities. Based on interviews conducted with stakeholders for this report, Prantae's ProfloU, PEscreen by Intignus Biotech, and Chemioptic's solution for screening of preeclampsia are some of the emerging screening pathways vis-à-vis hypertensive disorders. While Prantae's ProfloU device was launched in 2024 and has been adopted by 25 healthcare facilities, Intignus Biotech and Chemioptic are currently developing their solutions for affordable screening of preeclampsia. On the other hand, Project Samrakshan by the Indian Radiological and Imaging Association has been implementing a three-pronged screening approach for pregnancy-induced hypertension across their intervention sites.

"Project Samrakshan focuses on preventing the onset of preterm Preeclampsia (PE), early identification, and treating PE and its complications by researching new markers. However, PE has multiple causes, including issues with the placenta, heart, maternal demographics, and history. The best approach combines medical history, Doppler ultrasound, mean arterial pressure (MAP), and blood tests – known as multivariate screening – to identify risk early. This screening method has evolved over 30 years and Project Samrakshan is currently implementing it in 60-65 districts across 20 Indian states."

Dr. Kavita Aneja, National Core Committee Member of Project Samrakshan,
 Indian Radiological and Imaging Association



## **Summary Recommendations**

	Non-invasiveness in the design of diagnostic tools and services
Product and Operational Design	Privacy in service delivery
	Training innovators to understand social determinants of health
	Training more women phlebotomists & technicians
	Understanding workflows on the frontline
	Portability for point-of-care administration
	Device durability for low-resource settings
Adoption	Prioritizing rechargeability of devices to mitigate power supply issues in rural areas
	Prioritizing field validation studies in diverse settings
	Providing implementation support at the last mile
	Engaging market investors to understand the trajectory of medical- grade devices
Ecosystem Advancements	Fostering a whole-of-government approach for successful adoption of innovations
	Advocating for screening & diagnostic interventions based on major causes of maternal deaths in a given context



## References

- 1. UN, 2025, Goal 3 | Department of Economic and Social Affairs. Viewed on January 17, 2025.
- 2. WHO, 2024, Maternal mortality. Viewed on January 6, 2025.
- 3. Press Information Bureau, 2024, MMR of India declined from 384 in 2000 to 103 in 2020.
- 4. Lok Sabha reply, 2023, Case of Maternal Deaths.
- 5. Jowett, M 2000, 'Safe motherhood interventions in low-income countries: an economic justification and evidence of cost effectiveness', Health Policy, vol. 53, no. 3, pp 201-228, https://doi.org/10.1016/S0168-8510(00)00089-0.
- 6. WHO, 1996, Mother-Baby Package: Implementing safe motherhood in countries.
- 7. WHO, 2016, WHO recommendations on antenatal care for a positive pregnancy experience.
- 8. MoHFW, 2010, Guidelines for Antenatal Care and Skilled Attendance at Birth.
- 9. International Institute of Population Sciences, 2022, *National Family Health Survey* (NFHS-5) 2019-21.
- 10. Sarkar, M, Das, T, and Basu Roy, T, 2021, 'Determinants or barriers associated with specific routine check-up in antenatal care in gestational period: A study from EAG states, India', Clinical Epidemiology and Global Health, vol. 11, https://doi.org/10.1016/j.cegh.2021.100779.
- 11. Hamal, M., Dieleman, M., De Brouwere, V. et al. 2020, 'Social determinants of maternal health: a scoping review of factors influencing maternal mortality and maternal health service use in India', Public Health Review, vol. 41, no. 13. https://doi.org/10.1186/s40985-020-00125-6
- 12. MoHFW n.d., IPHS.
- 13. Fleming, Kenneth A., et al. 2021, 'The Lancet Commission on diagnostics: transforming access to diagnostics', The Lancet, vol. 398.
- 14. Rajya Sabha, "Medical Devices: Regulation & Control" Pertaining to Department of Health and Family Welfare.
- 15. BIRAC n.d., About Us.
- 16. ICMR, MedTech Mitra, accessed January 17, 2024.
- 17. Stanford Byers Center for Biodesign n.d., Stanford Biodesign in India.
- 18. BIRAC, 2018, Medical Devices and Diagnosis.
- 19. Meh, C., et al. 2022, 'Trends in maternal mortality in India over two decades in nationally representative surveys', BJOG: An International Journal of Obstetrics & Gynaecology, vol. 129, no. 4, pp. 550-561.

