Sattva Knowledge Institute

jhpiego
Saving lives. Improving health. Transforming futures.

BUILDING KNOWLEDGE INFRASTRUCTURE TO IMPROVE SCREENING & DIAGNOSTICS FOR WOMEN'S HEALTH OUTCOMES

April 2024

Acknowledgements

Content Contributors and Reviewers

Sattva Knowledge Institute

Anantha Narayan, Advisor

Anushka Anand, Knowledge Analyst, Health Practice

Granthika Chatterjee, Practice Manager, Health Practice

Lakshmi Sethuraman, Partner, Health Practice

Rathish Balakrishnan, Co-founder and Managing Partner

Ritika Ramasuri, Knowledge Associate, Health Practice

Yashasvi Murali, Practice Manager, Health Practice

Jhpiego

Dr. Anunaya Jain, Country lead Digital Health, India: Technical Director, Digital Health and Data Analytics Hub (DIGIT)

Dr. Parag Bhamare, Country Lead Maternal Newborn Health, India

Dr. Shailendra Hegde, Program Director - UP and Bihar, Non Communicable Diseases, India

Dr. Somesh Kumar, Country Director/Jhpiego-India: Senior Director - Office of Global Program & Technical Excellence, Jhpiego - MD, US

Dr. Yashpal Jain, Associate Director Maternal Newborn Health, India

Expert Contributors at the Workshop

Organisation	Name	Position
Roche Diagnostics	**Abinash Chaudhary**	Head of Governance Affairs & Policy
Wadhwani AI	**Aditya Nayan**	Associate Director Partnerships and Fundraising
Bill & Melinda Gates Foundation	**Amrita Shekhar**	Senior Program Officer
Rockefeller Foundation	**Anna Rego**	Lead-Policy & Strategy (Independent Consultant)
Bill & Melinda Gates Foundation	**Dr. Anshul Chaudhary**	Program Manager, Digital Health
The Blended Finance Company	**Aparna Dua**	Director
Biocon	**Dr. Anupama Shetty**	Mission Director
Jhpiego	**Dr. Anupama Rao**	Advisor, Clinical Services and Training
Jhpiego	**Dr. Bharti Kachhwya**	Program Officer
Children's Investment Fund Foundation	**Dr. Hemang Shah**	Director, Child Health and Development
FOGSI	**Dr. Jaydeep Tank**	President
PHC Bhowapur, Ghaziabad	**Dr. Prachi Pal**	Medical Officer
FIND	**Dr. Sarabjit Chadha**	Technical Director
Embebo	**Dr. Shiv Kumar**	Director & Co-Founder
USAID	**Kachina Chawla**	Division Chief, Health Systems Strengthening
FIND	**Krithika Raghavan**	Senior Manager, Advocacy & Communications
Vital Strategies	**LM Singh**	Managing Director & Global Head
Novartis	**Lokesh Manikonda**	Global Health Lead

India Health Fund	**Madhav Joshi**	CEO
Lupin Human Welfare & Research Foundation	**Dr. Nachiket Sule**	Head of Health Program
Tata 1mg	**Prashant Nag**	Vice President, E-diagnostics
HSTP	**Rajeev Sadanandan**	Director
AAM Sikroda, Ghaziabad	**Rehan Rana**	CHO
CCDC	**Sailesh Mohan**	Consultant
Jhpiego	**Dr. Smita Padhi**	Senior Advisor, Telehealth
Villgro	**Srinivas Ramanujam**	CEO
Lupin	**Tushara Shankar**	Head of CSR
AAM Sikroda, Ghaziabad	**Vandana**	ANM
Piramal Foundation	**Vanshika Gupta**	Program Manager
Apollo Hospitals	**Vinita Sethi**	Senior VP & Chief Public Affairs Officer
HT Parekh Foundation	**Ziaa Lalkaka**	CEO

Pre-Workshop Expert Discussants

Organisation	Name	Position
GIZ	**Amit Paliwal**	Program Director
Bill & Melinda Gates Foundation	**Dr. Anantha Krishnan**	Senior Program Officer
Koita Centre for Digital Oncology	**Dr. Nikesh Shah**	CEO
Banyan Academy of Leadership in Mental Health	**Nachiket Mor**	Visiting Scientist
FIND	**Sanjay Sarin**	VP, Access
Bill & Melinda Gates Foundation	**Suneeta Krishnan**	Deputy Director - India Country Office

Disclaimer

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*

CONTENTS

EXECUTIVE SUMMARY 06

CONTEXTUAL OVERVIEW 07

BARRIERS AFFECTING SERVICE DELIVERY 13

SOLUTION PATHWAYS 17

NEXT STEPS AND WAY FORWARD 31

REFERENCES 34

Executive Summary

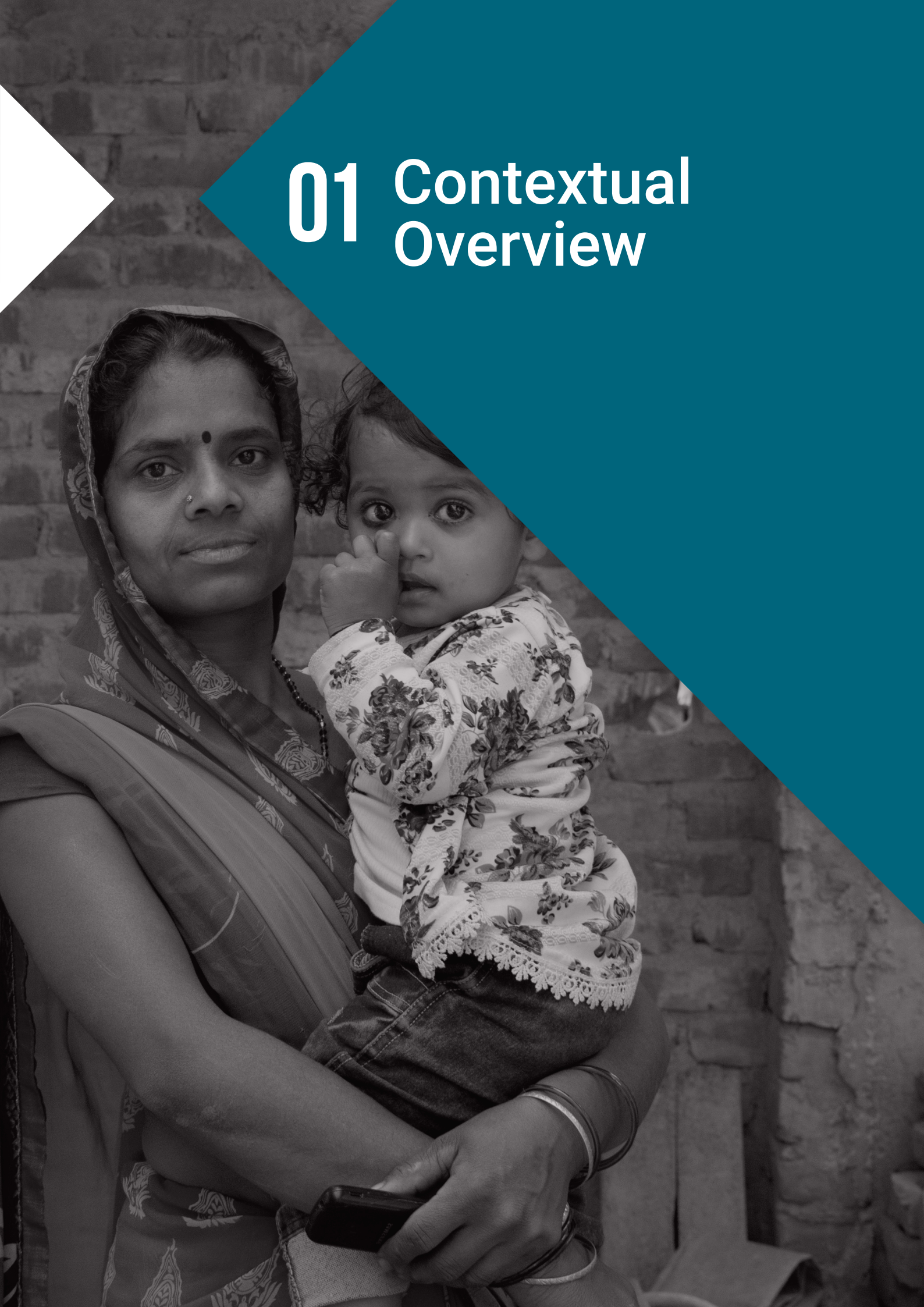
The dual burden of communicable and non-communicable diseases (NCDs), along with poor RMNCH+A outcomes afflict the health systems in India. Therefore, screening and diagnostic products and services are crucial for managing high-burden conditions such as cardiovascular diseases, common cancers, and diabetes. A cross-sectional study also revealed a greater prevalence of NCDs among women.[1] Existing gender inequalities also affect the demand and supply of diagnostic products and services in India. Delayed detection of critical conditions reduces survival rates and increases the out-of-pocket expenditure on treatment. Therefore, there is a dire need to orient efforts to bring about a gender-responsive change in the field of screening and diagnostics in India.

This report is a joint effort by JHPIEGO and Sattva Knowledge Institute to document insights from the national-level stakeholder convening on improving women's health outcomes through effective screening and diagnostics, with technology as an enabler. It identifies challenges of demand and supply and ecosystem-level issues in making screening and diagnostics accessible and available to women. On the demand side, work needs to be done to improve women's health-seeking behaviour by promoting awareness and encouraging women's agency. On the supply side, access to screening and diagnostic services needs to be improved by ensuring that the product solutions are fit-for-user; the women's life course approach is at the crux of programmatic approaches to screening and diagnostics; and programmatic interventions must be integrated within the public health system, as opposed to being rolled out in silos.

The report proposes solutions to enable upstream system-level problem-solving, such as an assessment framework to influence capital flow into products, blended finance instruments, community-validation infrastructure for products within low-resource settings, a learning network for women innovators in diagnostics, and policy change to transform the role of frontline workers.

The future of screening and diagnosis across disease areas will be technology-led. The design of these solutions must consider the local, social and cultural contexts of their deployment. Innovators need more financing mechanisms to help them reach these underserved markets better. Blended financing solutions like returnable grants and volume guarantees can be deployed to support innovators in this space. The suggested action items are geared towards making each of the solution ideas tangible and effective for all stakeholders in the ecosystem.

01 Contextual Overview



Women's health needs are disproportionately unaddressed, with low levels of screening and diagnosis across disease areas.

Almost four billion women, slightly less than half of the world's population, face health and safety issues unique to their gender. These include pregnancy-related conditions, menopausal symptoms, cancers of the breasts and ovaries, as well as health problems that strike women proportionately higher than men – such as respiratory distress.

In India as well, the health burden on women is consistently high across various disease areas. Approximately 50 million women in the country grapple with reproductive health issues. Anaemia is particularly prevalent, affecting approximately 50% of women of reproductive age, and leading to complications during pregnancy and childbirth.[2]

75% of perinatal morbidity and mortality occurs due to high-risk pregnancies, which represent roughly **20-30%** of all pregnancies nationwide.

Despite these statistics, data indicates that **30%** of women **do not avail themselves of antenatal check-ups during the first trimester**, and **42%** fail to complete the recommended **four antenatal visits throughout their pregnancy**.[3,4]

More than **1.9 lakh** women were diagnosed with breast cancer in India in 2022 resulting in **98,337** deaths.

Yet, only **0.9%** of women aged 30-49 years **have undergone a breast examination for breast cancer**.[5,6]

39.1% of the total tuberculosis cases in 2021 were women. Despite this, research indicates that a substantial proportion of TB cases, estimated at **one-third**, remain undiagnosed each year, with a **notably low rate of microbiological detection among women**.[7,8]

Social and cultural barriers play a significant role in shaping treatment-seeking behaviour, particularly among women. Factors such as limited access to healthcare facilities, insufficient awareness and education about health issues, and a lack of autonomy to make health-related choices and decisions contribute to these barriers.

AGENCY

89.9% of women in the country can not make independent decisions about their healthcare.[9]

AWARENESS

Only **56.7%** of women knew where to get an HIV test, as opposed to **70.4%** of men.[10]

ACCESS

59.5% of women faced at least one problem accessing healthcare services.[11]

As a result, women may face challenges in seeking timely and appropriate healthcare services, thereby exacerbating health disparities and hindering efforts to improve overall health outcomes.

Innovative, non-invasive screening and diagnostic products with the ability to function effectively in low-resource healthcare settings are trying to bridge the gap in access and availability. However, even when advancements in diagnostic technologies occur, the capacity of healthcare systems in LMICs to adopt and utilize these innovations can be a significant barrier. This deficit manifests in several ways. Firstly, limitations in healthcare provider training and expertise can hinder the effective implementation of new diagnostic tools. Secondly, infrastructure and budgetary constraints may impede the acquisition and maintenance of sophisticated equipment. Finally, fragile healthcare delivery systems may struggle to integrate novel diagnostics into existing workflows, limiting their reach and impact. These capacity limitations exacerbate existing social and cultural barriers, further marginalizing women in LMICs, and hampering their access to potentially life-saving diagnostic tools.

Timely screening, early detection, and awareness can lead to effective treatment for a disease.

Early detection allows early medical intervention, which may slow the progression of the disease, and reduce both morbidity and mortality.[12] The WHO has been promoting early screening and diagnosis to ensure chances for successful treatment.

Late detection of diseases can lead to higher treatment costs and reduced survival rates. Research suggests that about 20% of Indian households are afflicted by catastrophic health expenditure and about 2.4 million Indians die of treatable conditions annually.[13,14] In 2021, the Lancet Commission on Diagnostics estimated that 1.1 million premature annual deaths

and 38.5 million Disability Adjusted Life Year (DALY) losses could be averted in LMICs if the diagnostic gap is reduced from 35-62% to 10%, for six priority conditions, namely diabetes, hypertension, HIV, tuberculosis in the overall population, and hepatitis B virus infection and syphilis among pregnant women.[15]

The emphasis on reducing the gap in diagnostics should be in tandem with reducing the treatment gap since health outcomes post-detection are highly dependent on the availability of, and access to quality treatment services. While we recognize the importance of every stage within the care continuum, the joint stakeholder discussion by Sattva Knowledge Institute and JHPIEGO focused on upstream, supply-side gaps and necessary interventions for improving women's health outcomes by making early screening and timely detection available and accessible to women in low-resource settings.

Policy reforms, private investments, impetus on improving health system capacity and the surge in domestic innovation are providing tailwinds to improve the landscape of screening and diagnostic products.

POLICY

The policy landscape for screening and diagnostics comprises

- national-level legislations,
- legislations by states,
- executive rules for the implementation of statutory components,
- schemes and programmes under the National Health Mission,
- a national list prescribing the list of essential diagnostic equipment and services to be made available at public health facilities at all levels, and
- schemes by intersecting ministries for encouraging domestic innovation.

The Drugs & Cosmetics Act (1940) is the foremost national-level legislation that regulates the import, manufacture, distribution, and sale of drugs, biosimilars, and medical devices in India.[16] The Clinical Establishment Act (2010) was enacted by the union government under Article 252 of the Indian Constitution (power to legislate for states with consent) for adoption in Assam, Bihar, Haryana, Jharkhand, Rajasthan, Uttarakhand, Uttar Pradesh, and later adopted by Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim.[17] The Medical Devices Rules (2017), overseen by the Central Drug Standard Control Organisation (CDSCO), enables the regulation of all medical devices based on risk classifications.[18] The National Medical Devices Policy of 2023 was launched to encourage the development and manufacturing of medical devices in India.[19]

The National Essential Diagnostics List was published by the ICMR in 2019 for the standardisation of diagnostics and screening at all levels of care within public health facilities. It was inspired by the WHO Essential Diagnostics List first released in 2018.[20] It was also inspired by the Free Diagnostics Services Initiative under NHM, which is a national-level programme to ensure the access to, and availability of diagnostic services in public health settings.

Among schemes by intersecting state agencies to encourage innovation, the Performance-Led Incentive Scheme was launched in 2020 by the Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers) to provide financial incentives encouraging domestic manufacturing and attracting investments into the medical devices sector.[21] Medtech Mitra – an initiative by NITI Aayog, Indian Council of Medical Research and CDSCO – is designed to promote the development of affordable and accessible indigenous medical devices/in-vitro diagnostics. This initiative provides strategic support to MedTech innovators for clinical evaluation, regulatory facilitation, and uptake of new products.[22]

Health Technology Assessments (HTA) are encouraged by WHO as a policy practice for interventions and products. They play a crucial role in optimising resource allocation within the healthcare sector. In India, HTA is overseen by the Health Technology Assessment in India (HTAIn), operating under the Department of Health Research (DHR) within the Ministry of Health & Family Welfare (MoHFW). By providing evidence-based evaluations of health technologies, HTAIn helps inform policy decisions that facilitate access to quality healthcare while reducing out-of-pocket expenditures (OOPs) for individuals.[23]

INVESTMENTS

India is also receiving investments from private healthcare firms, venture capital, and global investors. The medtech segment is projected to grow to $54 billion in 2025, capturing 32% of the preventive healthcare market by 2025.[24] Hospitals and diagnostics centres industry also received around $697.5 million in FDI, witnessing a 39% growth in 2020-21.[25]

HEALTH SYSTEM CAPACITY

Deficiencies in health system capacity have historically constituted a significant barrier to effective delivery, particularly for women in LMICs. This lack of capacity manifests in several ways.

- Geographically limited access to well-equipped healthcare facilities creates a significant hurdle, especially for women in remote areas.

- A shortage of qualified healthcare providers, particularly female professionals, further restricts access to essential services.

- The absence of advanced diagnostic tools and equipment specific to local contexts hinders the ability to detect and diagnose diseases accurately and efficiently, especially for women's health. This, in turn, delays access to appropriate treatment and can have negative consequences for morbidity and mortality rates.

To address this challenge, governments and international organizations are increasingly prioritizing investments to strengthen health system capacity. A prime example is India's Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM). PM-ABHIM is a large-scale initiative dedicated to bolstering health system capacity across the country. The mission specifically targets areas with limited infrastructure by allocating resources for the establishment of critical care blocks in district hospitals. Furthermore, PM-ABHIM emphasizes the upgrading of public health laboratories with advanced diagnostic equipment, enabling a wider range of accurate testing procedures. It bolsters block-level health units, which serve as the primary point of contact for many women in rural areas. By improving the physical infrastructure, staffing levels, and diagnostic capabilities of these local facilities, PM-ABHIM presents a strong opportunity to strengthen healthcare delivery for women in India.

INNOVATION

The landscape of healthcare innovation in India is experiencing a surge, with 3,548 active startups in 2021 contributing to the country's digital healthcare ecosystem.[26] These startups typically fall into five distinct archetypes, encompassing point-of-care testing, real-time diagnostics, clinical decision support systems, data-driven lab optimisation solutions, and artificial intelligence applications in medical imaging. Moreover, technological advancements, particularly in mobile health (mHealth) and wearable health technologies, as well as the introduction of mobile medical units, are fostering further product innovation within the sector. Government initiatives such as Make in India, Made for India, Ayushman Bharat, and The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices are also playing crucial roles as enablers for encouraging innovation in the medtech sector. The convergence of private sector entrepreneurship and governmental support is driving advancements in healthcare delivery and accessibility across India.

02 Barriers Affecting Service Delivery

The discussion highlighted several challenges on demand and supply that affect service delivery of screening and diagnostics for women.

On the demand side, frontline workers contend with poor health-seeking behaviour among women, as well as their distrust towards the health system.

Stigma and misconceptions pose significant obstacles to early healthcare-seeking behaviour among women. Even after diagnosis and referral, women are reluctant to seek further medical attention, unless they perceive the situation as life-threatening. This pattern of severe **neglect in health-seeking behaviour** underscores a critical issue.

In the context of pregnancy, women typically only engage with Accredited Social Health Activists (ASHAs) and Auxiliary Nurse Midwives (ANMs) during their fourth-month check-up, coinciding with the timing of vaccination. This delayed engagement reflects a **missed opportunity for early intervention and care**.

Efforts to educate women on self-screening for breast cancer, such as through Swasthya Melas organised by frontline workers, have encountered setbacks, with low attendance rates. This highlights **resistance among women** to proactively seek early care.

Additionally, **cultural norms and gender dynamics** contribute to women's reluctance to discuss reproductive and maternal health issues with male Community Health Officers, particularly in rural areas. This further hinders access to essential healthcare services and information.

On the supply side, the lack of contextual validation significantly hampers the adoption of innovations.

An example is the utilisation of a pressure sensor-based device in breast cancer screening in a rural setting, which unfortunately yielded a high rate of false positives. Consequently, women were referred for mammograms, the gold standard in breast cancer detection. However, this workaround may not always be feasible or accessible, particularly in resource-constrained and rural settings.

Similarly, while thermal imaging holds promise as a technology for breast cancer screening, it faces practical challenges, such as requiring the body to be at a specific temperature for accurate readings. Environmental factors, such as high temperatures in summer or open settings, can also undermine its efficacy.

The high implementation cost of a validated cervical screening and diagnostics device, endorsed by the ICMR and state governments posed a significant obstacle to widespread adoption, particularly in resource-limited healthcare settings. Additionally, Community Health

Officers (CHOs), who play a crucial role in facilitating screenings, often need more equipment and training to carry out these interventions effectively.

There is a **dearth of operational research** to understand how solutions can be effectively integrated into existing healthcare workflows, highlighting the need for experimentation and collaboration.

Poor funding pathways for domestic innovation along with limited concessional financing and fiscal incentives for developers and manufacturers, low import duty for foreign companies, and high taxes imposed on domestic manufacturers also pose challenges.

There are various systemic barriers both at the health facility level and the health provider level.

Women encounter numerous challenges in accessing healthcare services after being diagnosed with diseases, including **unclear or non-existent care pathways**. Public health facilities often lack respectful care, leading to **judgmental or dismissive attitudes towards rural women**.

The ability for experimentation has been limited within the public sector. Additionally, there is a **lack of collaboration** between the public and private sectors, as well as with the community, hindering the effective delivery of healthcare services.

Reliability issues plague screening tests, with the distinction between screening and confirmatory tests often needing clarification. It is essential to establish clear outcome measures, assess the reliability of solutions, and implement effective risk stratification strategies.

The current diagnostics landscape is characterised by separate, verticalised programmes rather than integrated service delivery by community health workers, leading to a **lack of intersectionality** and emphasising the need for a more holistic approach.

Moreover, **success metrics vary widely among ecosystem players**, with the government often focusing on patient/provider perspectives, while innovators prioritise disease perspectives. Bridging this gap and aligning success metrics is crucial for improving healthcare outcomes and fostering innovation in the sector.

The challenge also lies in determining the scale of screening based on prevalence, and addressing **ethical considerations**, particularly when treatment is unaffordable and/or inaccessible. With the treatment gaps plaguing the healthcare service delivery and uptake in India, it is imperative to weigh with ethical consideration the consequences of merely enabling screening, early detection, and awareness without making treatment available for marginalized women.

Siloed digital health innovations are creating inefficiencies, delayed feedback loops, and weak investment outcomes.

The proliferation of innovation in healthcare presents a challenge due to the absence of a common standard and a clear definition of problems to solve for scalable impact towards achieving the SDGs, especially with women and their families in focus. **Innovators often work in silos**, focusing on developing end-to-end solutions without considering opportunities for integrated solutions or collaborating to address gaps.

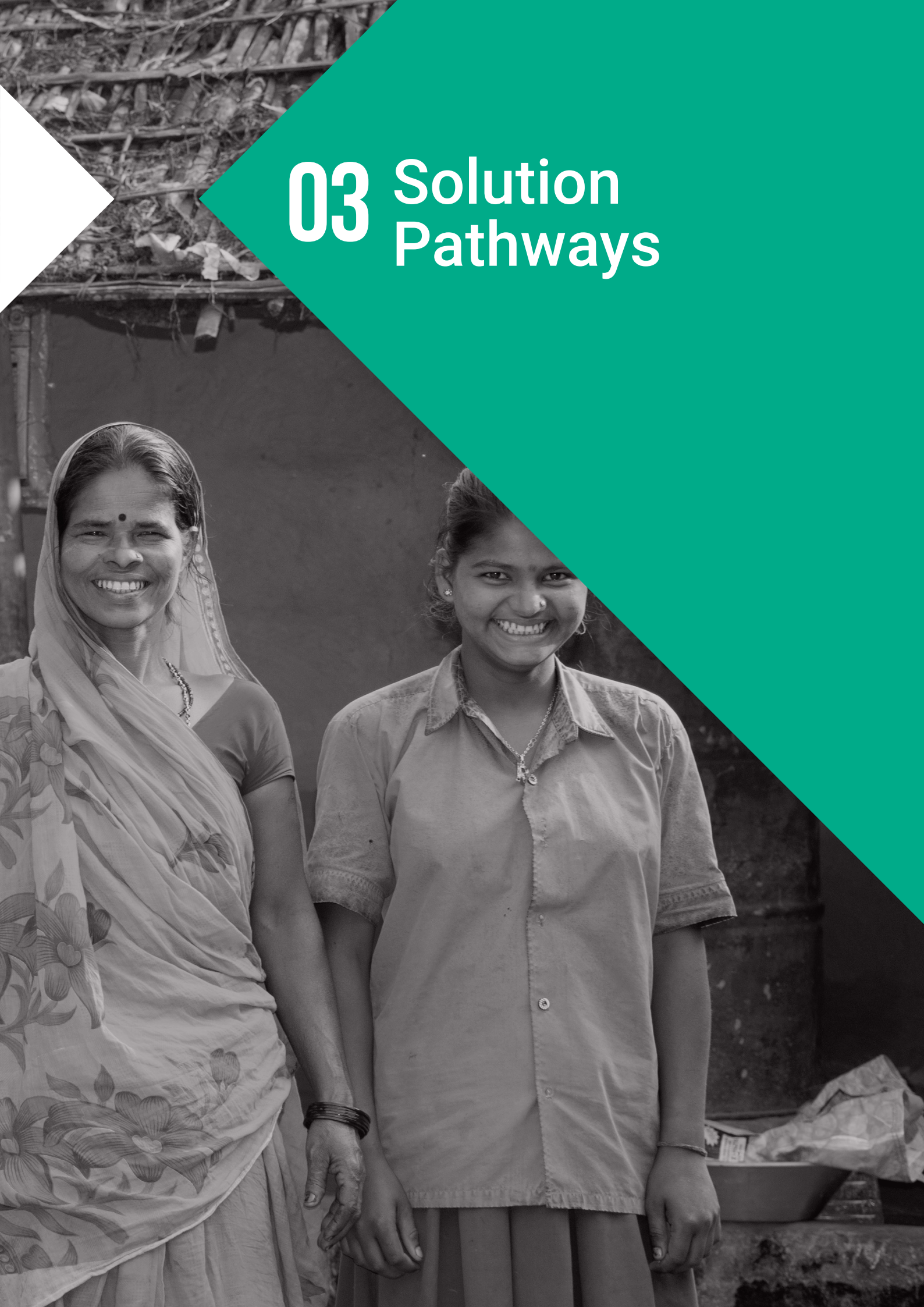
The siloed approach can exacerbate existing health disparities. Solutions designed for specific demographics or requiring high-tech infrastructure might neglect the needs of marginalized communities or those in LMICs with limited internet access. This creates a digital divide and hinders progress towards equitable health outcomes as envisioned in the SDGs.

Moreover, the fragmented nature of innovation leads to **inefficient resource allocation**, as funding and expertise are spread thinly across numerous projects. This **limits opportunities for integration and scalability**.

In the context of women's health, engaging a diverse range of stakeholders – including healthcare providers, NGOs, community leaders, and policymakers – is essential. Effective feedback loops are crucial for continuous improvement. Innovators today may **lack mechanisms for exchanging information and best practices**, leading to **ineffective feedback loops**. This hampers the identification of areas in need of improvement and limits the effectiveness of interventions.

It is crucial to engage health providers across cadres in defining the problem from their perspective and establishing boundary conditions. The solution must be fit-for-user, and stakeholder engagement throughout the design process is essential, especially considering the public health system's limited technology adaptability. Consistent evidence-sharing becomes imperative in this context.

03 Solution Pathways



We are committed to building and developing knowledge infrastructure for the diagnostics ecosystem to improve women's health outcomes.

Today, the market is saturated with end-to-end solutions that promise to transform the landscape. However, these end-to-end solutions are not made for systems as they exist at the last mile. Our existing systems need plug-in solutions to close the gaps in addressing the needs and challenges of the healthcare ecosystem for underserved women at scale. These plug-in solutions will be the building blocks that can be leveraged and adopted by the ecosystem actors in their work for bettering women's health outcomes. Quite like open source software, open data, and open content repositories are the building blocks used by professionals of all sectors and fields to improve the efficiency of their work. The knowledge-led public good solutions proposed by SKI aim to improve efficiency, integrate the social equity lens, and provide for underserved women whose needs and challenges remain unaddressed due to market failures and the state's limited capabilities.

To enable effective screening and diagnosis for women, there is a need to focus on four key levers and address underlying social determinants.

The discussion yielded that addressing social determinants is crucial when designing solutions for effective screening and diagnosis of women's health. Understanding cultural sensitivity and socioeconomic factors is paramount, as these factors significantly influence healthcare-seeking behaviours and access to services. Incorporating gender-responsive data and evidence into decision-making processes is essential for understanding the unique health needs and challenges faced by women. Collaboration with women's health experts and stakeholders is also critical for ensuring the effectiveness and relevance of interventions. Engaging women's

Figure 1: Key levers to enable effective screening and diagnosis for women

health advocates, researchers, community leaders, and grassroots organisations allows for the co-creation of solutions that are informed by lived experiences and local knowledge.

Fit-for-user solutions

The solutions should be designed with a focus on user-centric design principles for user-friendly, accessible, and culturally appropriate interfaces for women with an ability to function in, and service low-resourced settings.

Life-stages approach

Focused on diseases and conditions affecting women across all life stages.
Identify specific diagnostic gaps across these conditions concerning mortality and disease burden.

Health systems integration

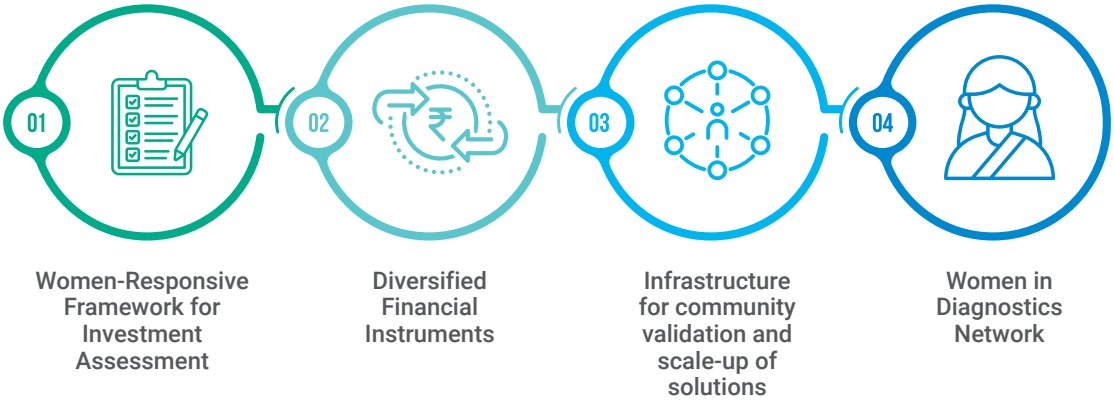
Integration of selected and proven solutions with the health systems - public and private - to demonstrate long-term impact.

Innovation financing

Availability of adequate financing instruments to test implementation and financial viability of the tech solutions.

The discussion brought forward ideas in the form of public goods that can propel collaborative action for solving complex social problems.

Figure 2: Solution Ideas for Ecosystem-Level Public Goods



A. Women-Responsive Framework For Innovation Assessment

Integrating a gender lens and looking at women at every stage of product development and commercialisation is imperative.

The need and opportunity

Femtech encompasses a wide array of solutions to improve healthcare for women across several female-specific conditions, including maternal health, menstrual health, sexual health, fertility, menopause, and contraception, as well as several general health conditions that disproportionately affect women.[27]

It currently only accounts for 1.4% of capital invested in healthcare, highlighting a significant gap in funding for women's health, with merely 4% of healthcare R&D funding directed towards it.[28] While this gap affects women at large, women experiencing varying levels of marginalisation suffer grave effects. Additionally, the product-market fit is missing at the last mile, with a dwindling number of innovations becoming successful. The solutions available also lack the ability to scale within public health systems.

These challenges are rooted in information asymmetry. There is often a limited understanding of the context of the solutions among investors during solution assessment and validation. Additionally, innovators may lack a comprehensive understanding of on-the-ground realities during the ideation and validation phases of their products.

There is a pressing need to augment financial resources directed towards the development of solutions that prioritize the unique experiences and requirements of women. This strategic imperative transcends mere ethical considerations. Research suggests that centering women in the design process fosters the creation of interventions with broader applicability. Women navigate a multitude of sociocultural contexts, and effectively addressing the challenges they face within these diverse environments necessitates the development of adaptable and universally relevant solutions. Such an inclusive approach demonstrably enhances user adoption, ultimately maximizing the impact and efficacy of the implemented solutions. By strategically investing in women-responsive design, we not only ensure equitable access and participation but also cultivate a more robust and far-reaching positive influence.

At the same time, it is important to acknowledge the complexities of doing this. Focusing on women's needs must also include the interconnectedness of gender with other social identities (race, class, sexual orientation). A solution designed for working mothers might not address the needs of stay-at-home mothers or single women without childcare options. Generalizing "women's needs" can further complicate solution adoption. Women in rural areas might have vastly different needs and priorities than urban women. Culturally specific factors also play a role and must be factored into solution design and implementation.

By prioritising women-responsive solutions, there is potential to drive better application and adoption across diverse contexts. There exists an opportunity to incorporate women-centric solution design for low-resource settings as a crucial aspect in investment decisions within the diagnostic solutions ecosystem.

Description of the tool

This evaluation framework in the form of a tool will include socio-cultural, economic, and other key gendered factors that influence access, use, adoption, and acceptance of digital screening and diagnostic solutions to enable effective solution design, and evaluate solution effectiveness to guide investment decisions.

Outcomes

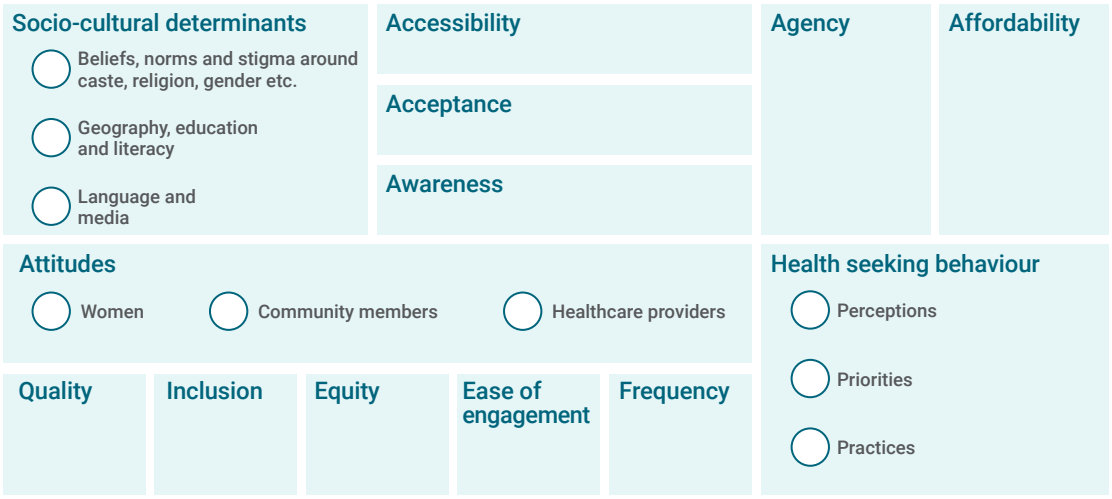
The expected outcome is that enabling investors, including philanthropic entities, to evaluate and invest in women-responsive solutions and innovations in digital screening and diagnostics will lead to increased solution inclusiveness and relevance. This, in turn, will enhance adoption and uptake among intended users, ultimately driving improved business outcomes.

Core characteristics of the framework

1. **Design principles:** The product will be a public good to go beyond individual pilots, supporting multiple contexts with a focus on public health systems.
2. **Framework Creation:** The framework will be codesigned with funders, medtech professionals, investors, gender experts, public health experts, and medical professionals.
3. **Testing the framework:** A series of pilots will be conducted to test the usefulness of the framework for specific diseases across age groups in specific geographical settings.
4. **Outputs:** Outputs would include knowledge products, the framework, and convenings to encourage adoption.

Indicative Parameters for the framework

Figure 3: Indicative Parameters



USE CASES

Using the framework to inform capital flow by assessing innovations

Use Case: Cardiovascular Diseases

A new screening/diagnostic device with high sensitivity to check for cardiovascular diseases requires the patient to disrobe to be administered the test by a paramedic/ technician. In such a situation, depending on the various socio-cultural contexts women may not be comfortable and avoid getting tested.

Applying the framework

On applying the framework (by feeding in parameters on the interactive online tool), the tool will highlight these barriers that innovations should address -

- **Acceptability:** Low willingness to undergo the test which requires women to disrobe in the presence of a male technician/paramedic.

Informing Capital Flow

For strong business outcomes and high uptake by women, the tool will inform investors to:

- To evaluate the product for investment based on social acceptance.
- Facilitate technical assistance to the innovators to modify the product whereby it does not require women patients to disrobe.

Using the framework to inform capital flow by expanding portfolio categories

Use Case 1: Cancer

DNA HPV screening is still not considered the first line for screening of cervical cancers. The test can be conducted through both physical, facility-based methods administered by healthcare providers, and self sampling techniques.

Applying the framework

It highlights these barriers that innovations should address:

- **Accessibility:** Inability of women to come to facilities
- **Impact and collaborating for interoperability:** Low impact of just innovating on screening for HPV but not enough focus on what happens thereafter – screen and treat is the answer, not just screen!

Informing Capital Flow

For strong business outcomes and high uptake by women, the tool will inform investors to:

- Design comprehensive screen and test solutions that are highly sensitive (ensuring high efficacy of tests and eliminating acceptability barriers).
- Focus on improving the cost efficiency of solutions and on innovative models of financing to make these affordable.
- Focus on integrating innovations into workflows that ensure women have the most efficient, continuous and comprehensive care experience.

Use Case 2: Maternal Health

Antenatal care guidelines typically recommend a minimum of four check-ups during pregnancy. However, according to NFHS-5 data, 42% of women fail to complete this recommended number of check-ups. Among the challenges faced, there is significant resistance to physical screenings, particularly due to invasive procedures like vaginal ultrasounds, compounded by the unavailability of female doctors. Consequently, there is a notable risk of overlooking high-risk pregnancies (HRP) in these circumstances.

Applying the framework

It highlights these barriers that innovations should address:

- **Accessibility:** Inability of women to come to facilities
- **Awareness:** Limited awareness about the importance of health-seeking behaviour during pregnancy
- **Acceptability:** Low willingness to undergo invasive screenings by male doctors, in lack of private spaces

Informing Capital Flow

For strong business outcomes and high uptake by women, the tool will inform investors to:

- Design portable imaging and digital solutions that can be used and managed by community health workers to reach pregnant women in their homes (addressing low awareness and access barriers).
- Recognise the opportunity to develop non-invasive AI-based screening for HRPs (enabling higher uptake).

B. Diversified Financial Instruments

Crafting financial instruments requires centring around the problem of diagnostics with the identification of users, source of concessional capital as well as measurement metrics for outcomes.

The need and opportunity

Today, there is a lack of growth stage-specific financial support for fem-tech innovators to sustain implementation and adoption within low-resource settings. As health-tech innovations take a longer time to demonstrate success and reach financial viability, appropriate financial instruments can help with capital support for innovators to address women-centric solutions. This becomes applicable, especially in low-resource settings where the probability of failure is higher.

Description of the tool

A stage-by-stage (along the lab-to-market pathway) demonstration of financing instruments to inform funders on specific impact funding instruments that can be leveraged for supporting diagnostic innovation

Outcomes

Investors will be able to maximise their ROI for women's health by deploying the right financial instruments according to funding requirements of product development and commercialisation.

Eg: Funders and impact investors could take a gradual approach to funding product development from grants at the early stage (for demonstration of success), to mixing and matching with instruments such as returnable grants and volume guarantees for sustained scale-up.

Process

1. **Research and Landscaping:** Conduct extensive research on existing blended finance pathways showing positive results for health or similar use cases in other sectors.
2. **Expert consultations:** Engage experts (innovative finance specialists, health economists, incubators, investors) to identify white spaces in health-tech innovative financing.
3. **Identify funding needs** at each stage and across short-term and long-term timelines of product development and commercialisation.
4. **Integrate with pilots in progress:** Shortlist pilots showcasing the success of tech innovations to test different types of blended finance models.

Framework for Investment

		Grant	Results based financing	Development Impact Bonds	Volume Guarantees	Credit Guarantees	Returnable Grants	Concessional Debts	Debt / Equity
SUPPLY (increasing digital health solution availability for the underserved market)	Product ideation								
	Product development and pilot								
	Manufacturing and deployment								
	Scale up								
DEMAND (increasing citizen and healthcare provider uptake)	Driving citizen demand								
	Increasing healthcare facility uptake								
	Capability building of healthcare providers								

Usability of different types of financing — Low — Medium — High

USE CASES

Use Case Example 1

Solving cash flow-related challenges for emerging digital health solution providers by **leveraging returnable grants**

Returnable grants can bridge the capital gap by providing upfront capital at zero interest. Innovative digital health solutions require longer gestation periods in the underserved market. A steady cash flow during the initial years which can be enabled by returnable grants that are structured in the form of zero-interest loans with only a moral obligation to repay.

A health-tech company with AI/ML capability for detecting breast cancer and TB was in need of funds to expand to other geographies and fulfil orders by several state governments.

- The sales cycle in the public sector was long and they needed upfront capital.
- They were able to secure a loan from a leading NBFC but needed additional collateral to avail of loans.
- **An impact funder agreed to fund at this stage with returnable grants and combine them with a commercial loan from an NBFC**.
- This allowed the startup to scale up faster and achieve financial sustainability without the burden of equity funds.

Use Case Example 2

Driving adoption of digital health solutions by increasing citizens' and healthcare providers' ability to pay, and reducing unit manufacturing cost and capex using **volume guarantee as a financial instrument**

Newer solutions with the potential to bridge the gap in healthcare delivery often face challenges to lower their production costs or capex because of lower volumes. This can be solved by increasing the production volume of products, supplying them at lower unit costs, and capturing a larger market. A volume guarantee can provide the necessary price and volume commitment to the manufacturing company and serve as a shock absorber in case of market failures.

A point-of-care diagnostic device with the capability to test for 10+ parameters has seen an uptake in low-resource settings, especially from small private hospitals and pharmacies.

- To achieve the goal of reaching out to more low-resource hospitals and nursing homes, a leading philanthropic funder partnered with the organisation to provide a long-term sales guarantee to reduce prices and enable scale-up.
- Through innovative partnerships and volume guarantees, the cost of the diagnostic device could be reduced by 30%.
- It saw an increase in adoption across 20+ Indian states.

C. Infrastructure for community validation and scale-up of solutions

Creating ecosystem enablers for innovation is necessary to design a unified, standardised open platform and infrastructure to support an end-to-end loop.

The need and opportunity

Plenty of innovation happening without a common standard. Innovators are working in silos and creating end-to-end solutions that have limited uptake in the existing health systems instead of developing solutions that could plug the gaps within the existing system. Siloed pilots lead to delays in feedback loops, affecting learning and adaptation, policy development, and weak investment outcomes in the ecosystem. Currently, solutions need to improve on scalability and targeting limitations, inadequate accountability within systems, limited community agency, insufficient research depth to foster innovation, absence of programmatic integration, cultural acceptability challenges, and a gap between development efforts and on-the-ground implementation.

A platform that enables the pooling of resources and testing of solutions in real-life low-resource scenarios is important for not only the success of innovation but also the better functioning of healthcare facilities, and ultimately providing access to screening and diagnostic services for women.

Description of the solution

Infrastructure with appropriate partnerships and resources that can enable clinically tested solutions to be community-validated and scaled up across multiple low-resource contexts.

This infrastructure would bring together stakeholders such as epidemiologists, women's health experts, physicians, paramedical staff, incubators, med-tech investors, experienced biomedical engineers, public health researchers, bioethics experts, and economists to advise on the scale-up. The infrastructure resources would include partnerships with non-profits managing low-cost private and public hospitals where these solutions can be tested and scaled.

Outcomes

The platform will enable diagnostics and screening using an integrated approach.

Figure 4: Infrastructure for Community Validation

Inclusions in the platform

- Higher TRL cut-offs for screening and diagnostic products with clinical validation and regulatory certifications to ensure quality benchmarks for community validation.
- Validation trial opportunities in varied settings, inclusive of diverse weather conditions, demographic subgroups, infrastructural and logistical dependencies, and diverse personnel capabilities and capacities.
- Conducting a Health Technology Assessment to determine direct and indirect consequences of adopting concerned products, such as cost-effectiveness for bringing down the out-of-pocket expenditure for screening and diagnostics, and check for any potential social and ethical externalities that may negatively affect the health outcomes for women.
- Enable linkages with state governments for adoption, especially wherever primary care infrastructure and personnel capabilities are appropriate and well-suited for the successful implementation of the products within existing workflows.
- Technical support to refine product enhancements, such that they can demonstrate high functional value and performance within low-resource public health settings, with minimal support enablements.

Process

The platform will test and validate the solutions in low-resource settings.

1. Conduct small-scale testing of the solutions in real-world settings within the target communities.
2. Have an appropriate feedback loop built in on usability, acceptability, and effectiveness.
3. Once the digital health solution has undergone iterative refinement based on pilot testing, conduct formal validation studies to assess its impact on health outcomes.
4. Leverage infrastructure partnerships to support the scale-up of the validated solutions.

VALUE FOR THE PLATFORM

- A community that owns a coordination and convening platform
- A secretariat from the platform that engages with the key stakeholders
- Regular conversations and events for the ecosystem to formalise engagements and dissemination
- Engage with both products and software that are medical devices
- A test-bed available to all with a library of needs
- Challenges for the platform

CHALLENGES FOR THE PLATFORM

- Funding for the platform
- Securing government alignment from the outside
- Ability to influence procurement mechanisms in the public sector
- Priorities of the public sector may not necessarily be just value-driven
- Scale-up challenges may remain
- Disincentives to align with needs may be difficult to enforce

D. Women in Diagnostics Network

This is a forum that can offer trained women biomedical engineers and innovators on-ground learning to understand nuances of health-seeking behaviours, social determinants of health, and healthcare systems in underserved settings.

The need and opportunity

A majority of the medtech innovators and biomedical engineers from urban backgrounds may not have exposure to the needs and challenges of underserved populations, and underserved women in particular. Therefore, rural women's perspective is largely missing in the solution design and development processes.

Description of the solution

A learning and knowledge-exchange network for entrepreneurs, and industry actors committed to underserved women's healthcare needs at the grassroots.

Outcomes

Under the guidance of mentors, community practitioners, and local medical providers, the biomedical engineers and innovators will create a technology solution plan for screening and diagnostics. The developed solution will be tested and piloted in the given setting and evaluated for overall impact on health-seeking behaviour.

STEM offers a lot of opportunities for women to participate and actively contribute towards innovations. The network will have a stratified approach to cater to the needs regarding research, opportunities, and access to certain resources.

Process

1. **Identify partner nonprofits** that work on promoting indigenous innovations, and technical expert organisations.
2. **Co-create programme plan** with nonprofit partners, experienced biomedical engineers, medical providers, and social epidemiologists/medical sociologists.
3. **Continuous monitoring** of process weaknesses and successes through a routine feedback mechanism for all stakeholders involved.
4. **Evaluate outcomes** by measuring the improvement in health-seeking behaviour after implementation of the product pilot.

These solutions cannot succeed without the re-imagined role of a cadre of frontline health workers equipped and empowered to strengthen screening, diagnostics, and treatment uptake at the last mile.

The frontline health staff recounted a range of difficulties related to implementing early screening and diagnosis. Poor health-seeking behaviour in communities and the lack of trust in the healthcare system are persistent hurdles in improving the uptake of screening and diagnostics for women. Participation in health camps conducted to bring services to the communities is low. Additionally, the inconsistencies in the regular functioning of devices and equipment procured for public health facilities and infrastructural challenges regarding consistent power supply affect the service provision of affordable screening and diagnostics for women's health. The daily workflows of frontline health staff are highly demanding. A considerable volume of patients and expectations are placed upon them without a strong enabling ecosystem.

We had invited women during Swasthya Mela to learn about self-screening for breast cancer, but nobody turned up. Non-invasive screening and diagnostic devices will be helpful in light of poor health-seeking behaviour among rural women.

— **Dr. Prachi Pal**, Dasna (Ghaziabad)

Women are often uncomfortable speaking to a male CHO, therefore teleconsultation sessions are organized for RMH issues.

— **Rehan Rana**, CHO, Rasulpur Sikroda (Ghaziabad)

This further emphasizes that while breakthrough med-tech solutions can help care providers in low-resource settings, health outcomes are largely dependent on treatment uptake and follow-up by patients.

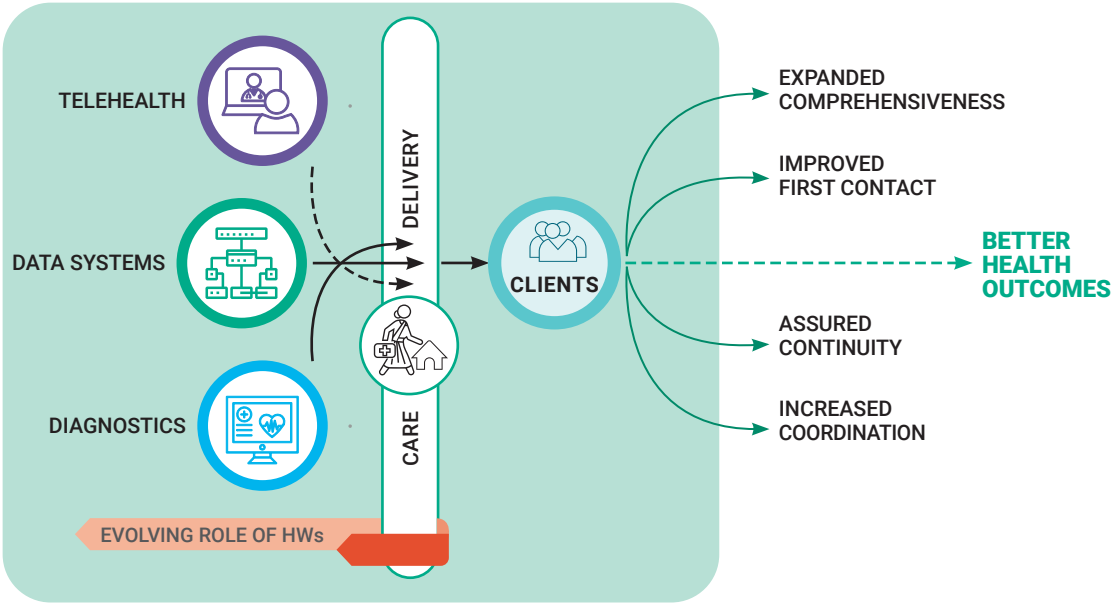
Weak treatment uptake and non-adherence to treatment are crucial challenges that lead to poor health outcomes. The influx of new health devices and diagnostics is ushering in a transformed healthcare landscape, demanding a three-pronged shift in the role of providers.

- **Reskilling will be paramount**. Health professionals will need to become adept at interpreting data from devices and learn to use AI-powered diagnostics, seamlessly integrating technology into their practices to deliver differentiated care models.

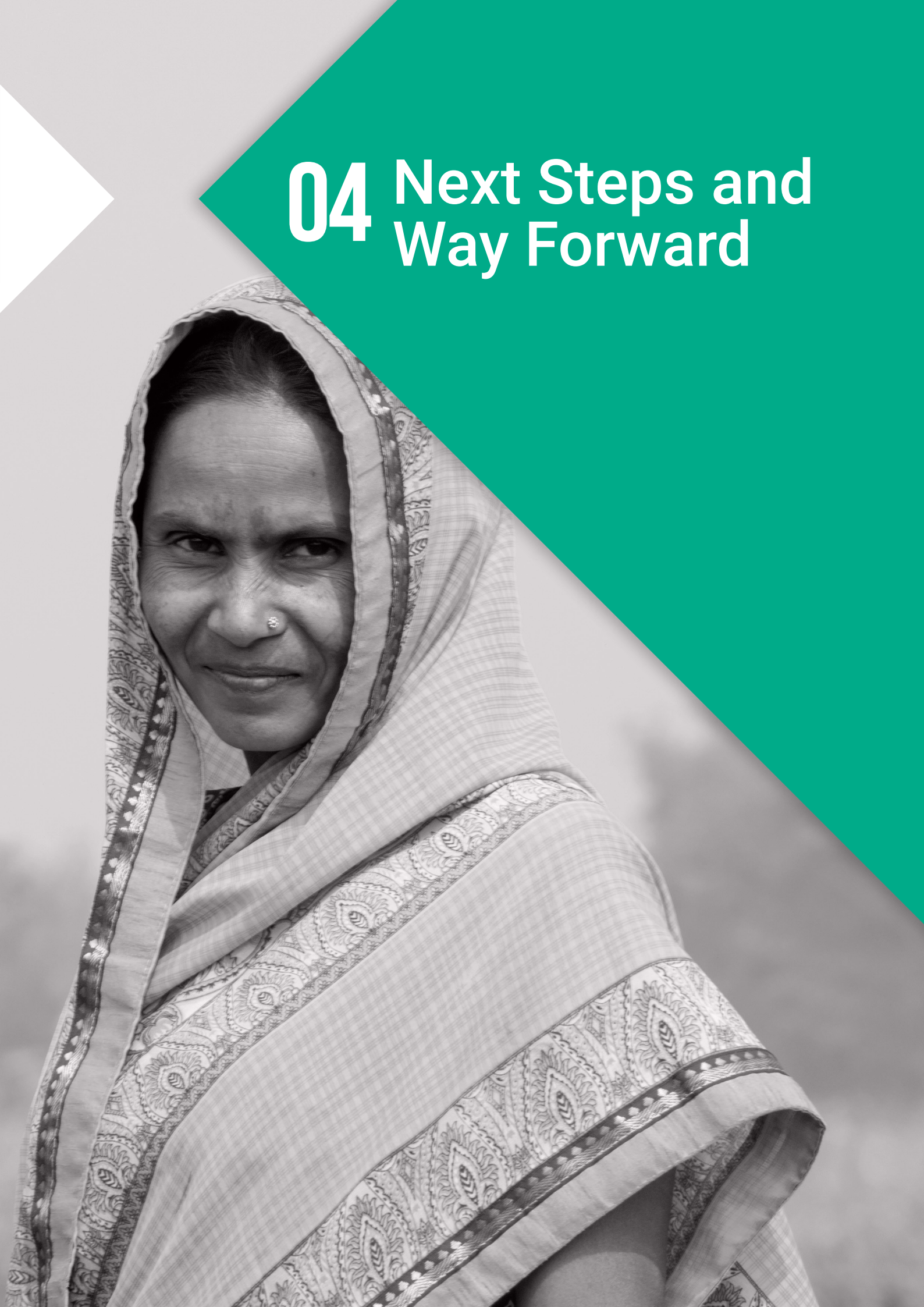
- **The focus will move from individual reactive care to group-based proactive prevention**. By leveraging real-time health data, providers will need upskilling to identify potential issues early and personalize treatment plans in care teams, collaborating and coordinating across domains and roles.

- **The boundaries of the clinic will blur**. Telehealth and remote monitoring will allow providers to extend their reach, delivering advanced services directly to patients' homes, and improving accessibility and convenience. This tech-driven future of healthcare hinges on enabling providers to work with diagnostics, telehealth, and data systems simultaneously. Such a transformation hinges on a reimagined role of the community health worker from a health messenger to one of a comprehensive provider, under the remote monitoring of a general physician, working for a defined population group.[29]

Figure 5: The approach to improving outcomes through diagnostics and devices



04 Next Steps and Way Forward



To action the above solution areas, there is a need for concerted efforts in the following areas:

Design and Development Workshops

Multi-stakeholder workshops aimed at co-designing the Women-Responsive Framework, identifying growth and stage suitable innovative financial instruments, establishing the community validation infrastructure, and setting up the Women's Diagnostics Network.

The workshops will be designed to address the specific needs, opportunities, and challenges identified in each area.

Research and Landscape Analysis

Comprehensive research across all solutions to understand current gaps, best practices, and innovative models in healthcare, financing, and technology development that can be adapted for fem-tech solutions improving women's health outcomes.

Platform and Network Foundation

Technical and strategic development of the platform for community validation. This includes defining technical specifications, partnership models, and engagement strategies for community and stakeholder participation.

Pilot Programmes for Women-Responsive Investment Framework and Financial Instruments

- Implement pilot programmes to test the effectiveness of the Women-Responsive Framework and the proposed financial instruments.
- Select specific diseases, age groups, geographical settings, and existing successful pilots for these tests.
- Ensure that there are clear metrics for evaluation and mechanisms for collecting feedback.

Community Validation and Scale-up Infrastructure Development

- Build the platform to start small-scale testing of selected solutions in low-resource settings.
- Engage with partners to ensure the infrastructure supports clinical testing, regulatory compliance, and scalability of validated solutions.

Launch and Monitor Women's Diagnostics Network

- Officially launch the Women's Diagnostics Network, focusing on training, mentorship, and knowledge exchange.
- Implement continuous monitoring to assess the network's impact on technology solution development, health-seeking behaviours, and overall health outcomes in underserved populations.

Continuous Improvement and Scaling

- Based on feedback and outcomes from the pilot programs, refine and adjust the evaluation framework, financial instruments, community validation platform, and network activities.

Outcome Evaluation and Knowledge Sharing

- Develop a comprehensive outcome evaluation plan that measures the impact of each solution area on women's health diagnostics and care.
- Share findings with stakeholders through reports, knowledge products, and convenings to encourage adoption, investment, and policy support.

Strengthen Partnerships and Funding Channels

- Continuously engage with existing partners and identify new collaborators to expand the reach and impact of each solution.
- Secure funding and support for scaling successful innovations and sustaining the initiatives long-term.

Conclusion

Improving women's health outcomes requires collaboration from all stakeholders with a need for strategic investments in system-level solutions, which include products and processes. The discussion highlighted the importance of building a community to share and ideate on solutions to improve women's health outcomes.

Collaboration between funders, health system innovators, women as well as healthcare providers is crucial to ensure the delivery of outcomes. The role of funders and philanthropic organisations should extend beyond financial contributions to play a catalytic role in the development of the solutions from the beginning. Women's health experts should also be included during the product development stages to ensure that socio-cultural barriers are addressed.

References

1. Sharma S., Vishwakarma D. & Puri P., 2020, *Gender disparities in the burden of non-communicable diseases in India: Evidence from the cross-sectional study*, International Institute for Population Sciences.
2. Singh A., 2023, *Need of the hour: Enhancing women's healthcare in India*, The Times of India.
3. Prajapati, Ajay K et al., 2022, *Prevalence of high-risk pregnancy among pregnant women enrolled under Pradhan Mantri Surakshit Matritva Abhiyan in government health facilities of district Etawah, Uttar Pradesh: A cross-sectional study*, Journal of family medicine and primary care.
4. IIPS 2021, *National Family Health Survey (NFHS-5) 2019-21*.
5. International Agency for Cancer on Research, 2022, *Global Cancer Observatory*, WHO.
6. Ibid, 1
7. Ministry of Health and Family Welfare, 2022, *India TB Report 2022*.
8. Ministry of Health and Family Welfare, 2019, *National Framework for a Gender-Responsive Approach to TB in India*.
9. Ibid, 1
10. Ibid, 1
11. Ibid, 1
12. Grootendorst D.C., et al., 2009, *Screening: why, when, and how*, Elsevier.
13. Hadaye S.R. & Thampi J.S., 2018, *Catastrophic Health-care Expenditure and Willingness to Pay for Health Insurance in a Metropolitan City: A Cross-Sectional Study*, Indian Journal of Community Medicine.
14. Kruk M.E., et al., 2018, *Mortality due to low-quality health systems in the universal health coverage era: a systematic analysis of amenable deaths in 137 countries*, Lancet.
15. Fleming, Kenneth A et al., 2021, *The Lancet Commission on diagnostics: transforming access to diagnostics*, Lancet.
16. Ministry of Health and Family Welfare, *The Drugs and Cosmetics Act and Rules*.
17. Ministry of Health and Family Welfare, *The Clinical Establishments Act 2010*.
18. Ministry of Health and Family Welfare, *Medical Devices Rules, 2017*.
19. Ministry of Chemicals and Fertilizers, *National Medical Devices Policy, 2023*.
20. Indian Council of Medical Research, 2019, *National Essential Diagnostics List*.
21. Ministry of Commerce & Industry, *Status of Production-Linked Incentive Schemes*.
22. ICMR, *Medtech Mitra*.
23. Ministry of Health and Family Welfare, *HTAIn*.
24. Inc 42, n.d., *India's Healthtech Landscape In A Post-Covid-19 World*.
25. Kaswa S. & Srivastava R., 2021, *FDI in Hospitals and Diagnostic Centers and Challenges and Opportunities in Healthcare Sector*.
26. Medical Buyer, 2023, *India has 3548 active startups operating in health tech sector*.
27. Kemble E. et al., 2022, *The dawn of the FemTech revolution*, McKinsey &Company.
28. FemTech Analytics, *FemTech Industry 2021/Q2 Landscape Overview*.
29. Mor, N., Ananth, B., Ambalam, V., Edassery, A., Meher, A., Tiwari, P., Sonawane, V., Mahajani, A., Mathur, K., Parekh, A. and Dharmaraju, R., 2023. *Evolution of community health workers: the fourth stage*. Frontiers in Public Health, 11, p.1209673.