Sattva Knowledge Institute SKI primer

ACCELERATING HEALTHCARE: LANDSCAPE OF DIAGNOSTICS IN INDIA

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Acknowledgements

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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.

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CONTENTS

ABBREVIATIONS

AI	:	Artificial Intelligence
CAGR	:	Compound Annual Growth Rate
COPD	:	Chronic Obstructive Pulmonary Disease
CEA	:	Clinical Establishments Act
HER	:	Electronic Health Record
FDI	:	Foreign Direct Investment
FLW	:	Front Line Workers
HWC	:	Health and Wellness Centre
IVRS	:	Interactive Voice Response System
ML	:	Machine Learning
MoHFW	:	Ministry of Health and Family Welfare
NABL	:	National Accreditation Board for Testing and Calibration Laboratories
NCD	:	Non-communicable Diseases
NEDL	:	National Essential Drug List
PHC	:	Primary Health Centre
PHR	:	Personal Health Record
PPP	:	Public Private Partnership
RMNCH+A	:	Reproductive, Maternal, New-born, Child and Adolescent health
SC	:	Sub Centre
SDG	:	Sustainable Development Goals
TB	:	Tuberculosis
VIA	:	Visual Inspection with Acetic acid
WHO	:	World Health Organization

EXECUTIVE SUMMARY

Diagnostics is critical **for timely detection, guiding treatment decisions, preventing diseases, and improving overall healthcare quality and outcomes.** It also plays a vital role in reducing treatment costs and advancing medical research. Recent developments in policy, volume of investments, and innovation are gradually affecting change in India's diagnostics sector.

A significant portion of India's diagnostic landscape is comprised of **private laboratories** - operating independently and collaborating with Indian states and philanthropic organisations **- and the emergence of healthcare startups** in this sector. Investments in the sector are steadily on the rise, and are projected to reach **$28 billion by 2028.** The rise of healthcare startups has led to a surge in tech-enabled diagnostic solutions in the market. These solutions concentrate on various aspects, including **point-of-care testing, real-time diagnostics, clinical decision support systems, data-driven lab optimisation solutions, and AI in medical imaging.**

Portable and low-cost digital health solutions can reduce over-dependence on the physical presence of specialists, and can be deployed in remote areas. Emerging technological innovations, such as handheld ultrasound devices and AI-enabled imaging solutions hold the potential of bringing precision to diagnosis. Recognising the need for diagnostics, the government has set various guidelines and standards, such as the **Indian Public Health Standards** to offer services at various touchpoints. The **National Essential Diagnostic List** specifies a set of tests that should be available at various facilities for diagnosis of diseases.

Despite the combined efforts of the government and the private sector to provide sufficient diagnostic services, challenges such as **insufficient healthcare infrastructure, a shortage of trained professionals, financial constraints, governance and regulatory challenges,** and **innovation challenges** still persist in the realm of screening and timely detection. Other systemic challenges collectively impact the awareness, agency, and access to these services among the population. Stakeholders also need to be cognisant of critical risks such as overdiagnosis, uncoordinated processes, poor follow-ups, and technological redundancies within the diagnostic ecosystem.

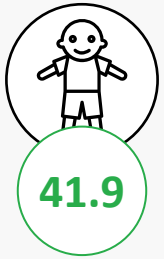
THE IMPORTANCE OF DIAGNOSTICS

India has a long road ahead to achieve its SDG 3 targets.

24.9

Neonatal Mortality Rate[1]

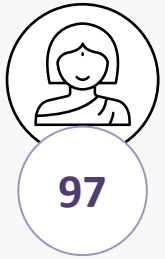
[deaths per 100,000 live births]



41.9

Under-five Mortality Rate[2]

[deaths per 100,000 live births]



97

Maternal Mortality Rate[3]

[deaths per 100,000 live births]

TOP CAUSES OF DEATH

Children	Women	Men
374 deaths from **neonatal disorders** [4]	90 deaths from **ischemic heart disease** [7]	127 deaths from **ischemic heart disease** [10]
110 deaths from **respiratory infections** [5]	60 deaths from **COPD** [8]	69 deaths from **COPD** [11]
57 deaths from **congenital defects** [6]	59 deaths from **diarrheal diseases** [9]	51 deaths from **diarrheal diseases** [12]

[deaths per 100,000 annually in 2019]

Why is it important to focus on diagnostics?

> ***"The diagnostic process is a complex, iterative, collaborative activity with the goal of narrowing down the diagnostic possibilities and developing a more precise and complete understanding of a patient's health problem."***
>
> - The Lancet Commission on Diagnostics

These global health priorities necessitate a strong diagnostics system.[13]

Universal Health Coverage (UHC)

Improved management and the rational use of medicines and health technologies are some of the major goals of UHC. The launch of the WHO's first Essential Diagnostics List in 2018 affirmed the importance of diagnostics in achieving healthcare coverage for all.

Antimicrobial Resistance Mitigation

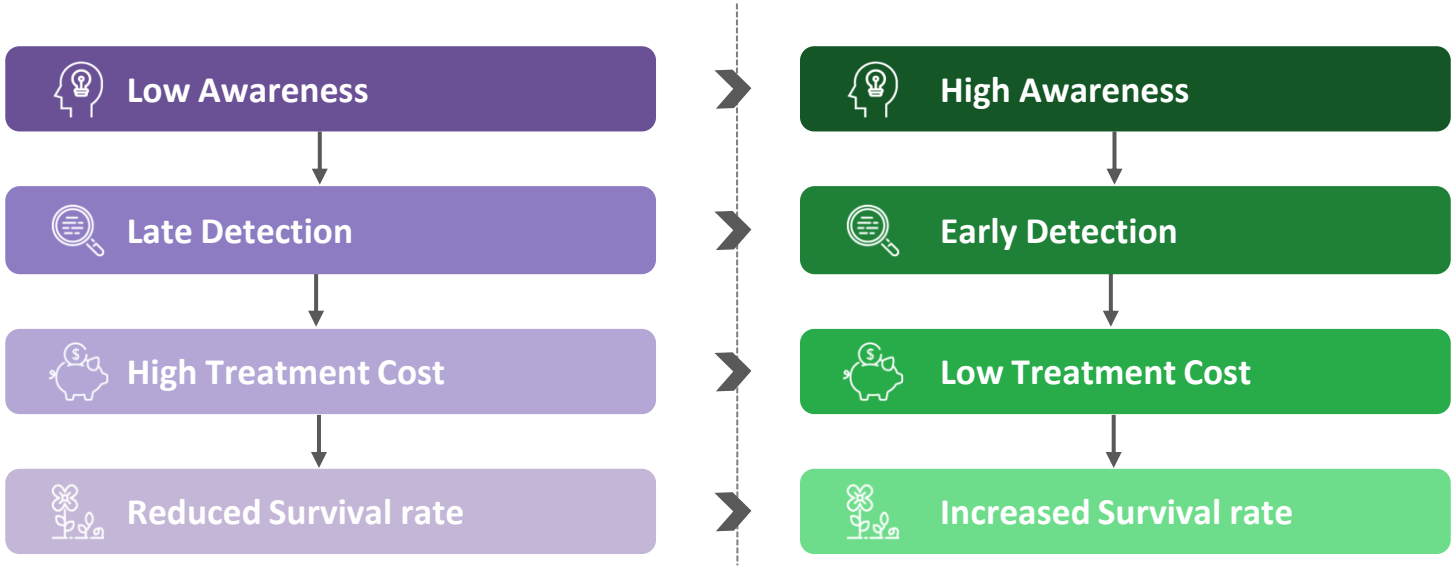
Two important developments in 2019 - a new AMR indicator was added to the SDG monitoring framework, and the WHO declared AMR as one of the top ten global public threats to humanity - underscored the centrality of diagnostics to mitigating the overuse of antibiotics.

Global Health Security

Pandemics, political conflict and war threaten people's well-being, and further complicate the dynamics of healthcare provision. The fragmented and under-researched nature of diagnostics in humanitarian medicine imperils global health security.

The Lancet Commission on Diagnostics estimates that 1.1 million premature deaths in LMICs could be averted through timely diagnostics.

Diagnostics plays a pivotal role within the healthcare system, offering essential information to healthcare service providers for arriving at a diagnosis and make **well-informed decisions regarding the delivery of care, encompassing aspects such as prevention, screening, detection, treatment, and management.**[14]



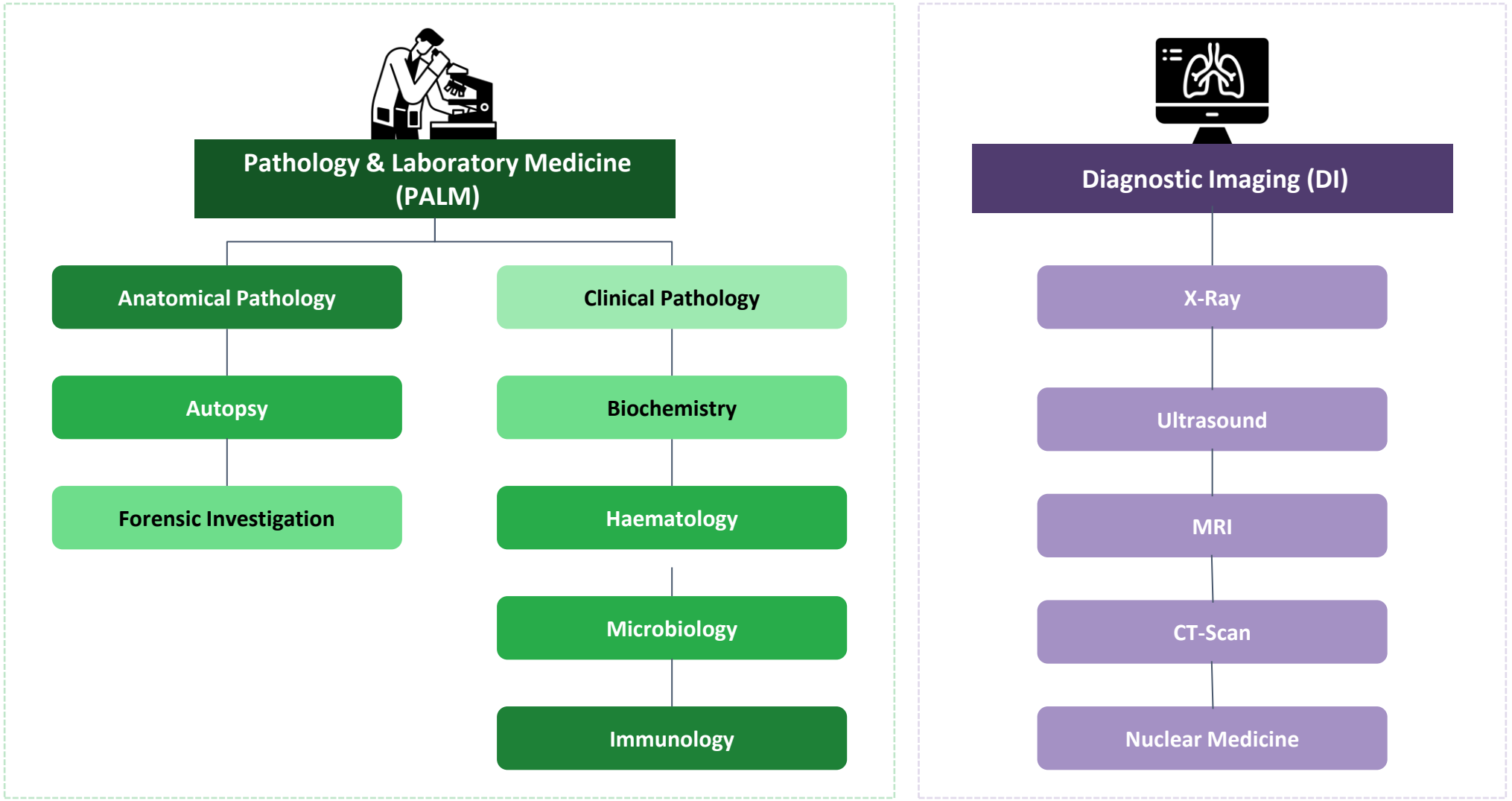
For instance, by offering early diagnosis for cancer, healthcare professionals can ensure prompt treatment, especially for breast, cervical, and colorectal cancers. This would lead to increased cancer survival rates and reduced costs associated with the treatment and cure of cancer patients.[17]

IMPACT

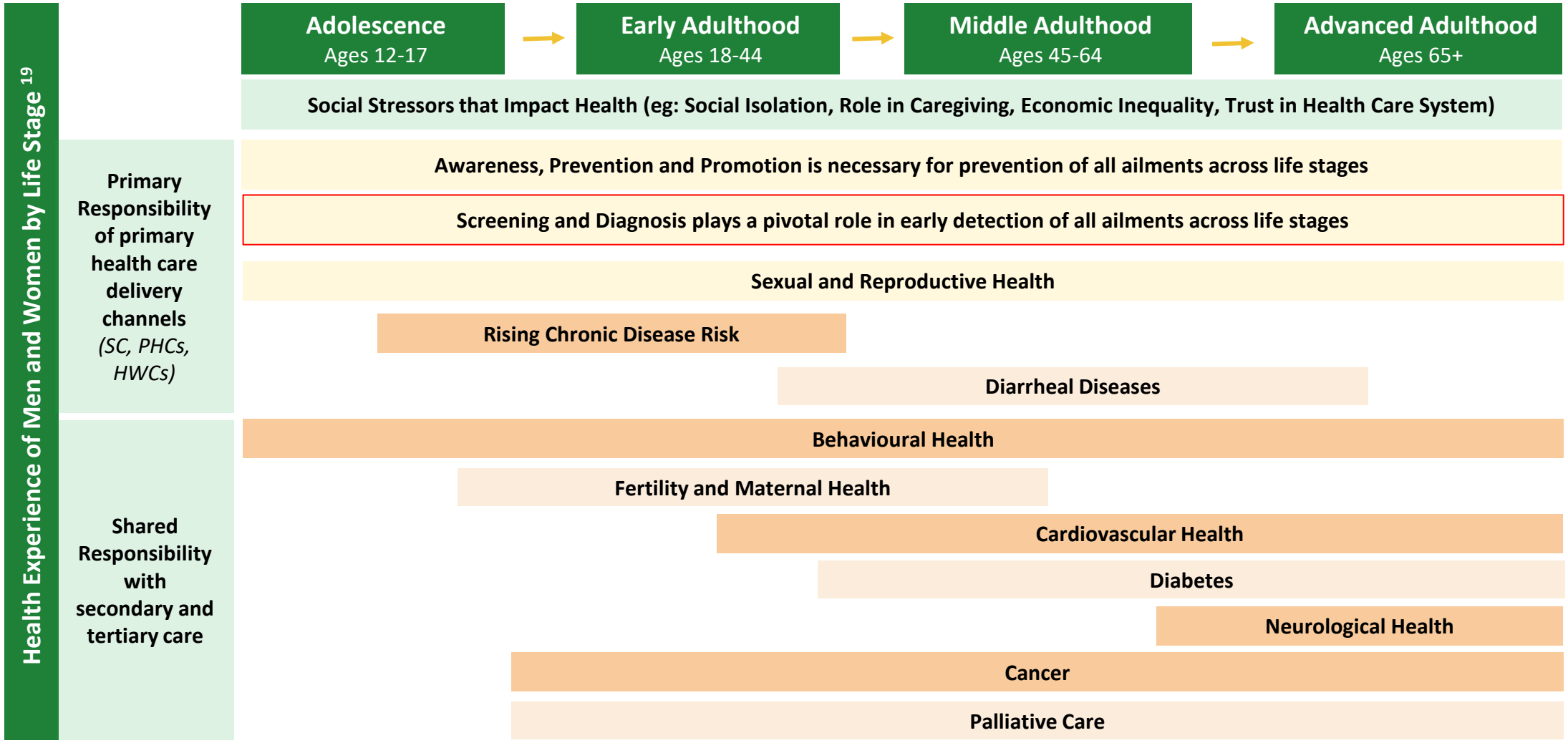
VIA screenings for cervical cancer at primary care level can prevent **22,000** deaths in India, and **76,000** deaths in other resource-poor countries.[15]

Among women aged 30-49 years, over **95%** of cervical cancer cases are avoidable, and over **80%** of cervical cancer mortality can be reduced by good quality screenings.[16]

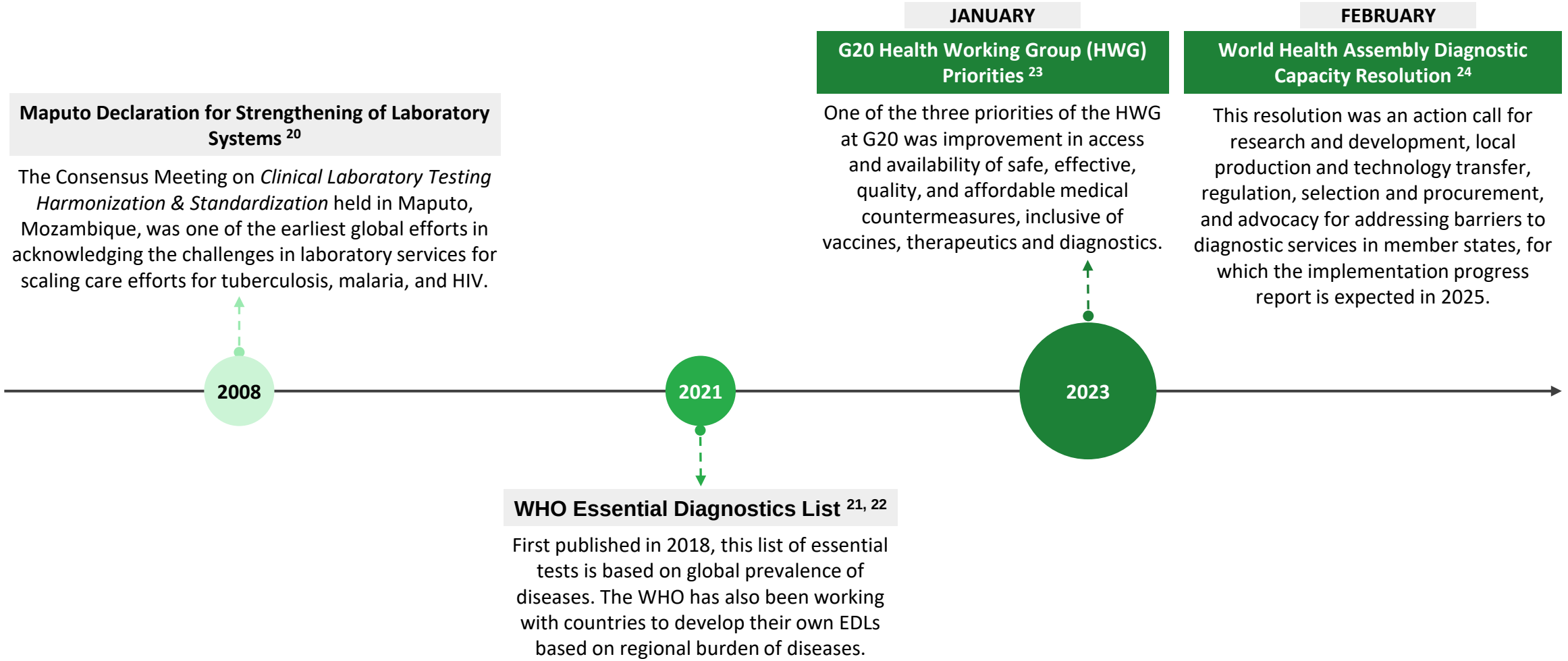
The field of diagnostics can be understood through two important disciplines - PALM and DI.



For all ailments across life stages, screening and diagnosis play a pivotal role in the disease progression.



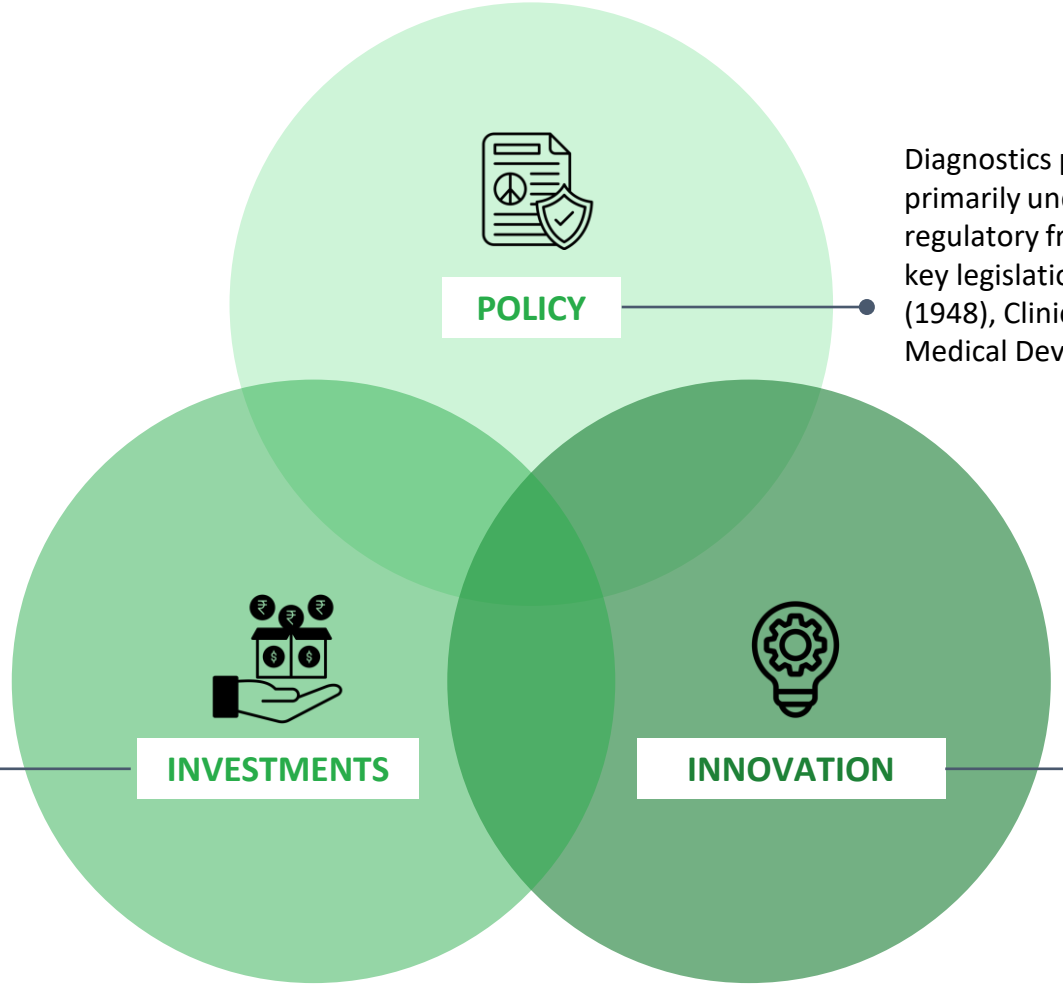
Over two decades, global public health initiatives have asserted the importance of diagnostics in healthcare services.



THE CURRENT STATE OF DIAGNOSTICS IN INDIA

India is experiencing an upward inflection point in diagnostics.

Advances in policy reforms, substantial investments, and a surge of innovation are collectively transforming the diagnostics sector in India.



Diagnostics policy and governance in India are primarily under the purview of the CDSCO. The regulatory framework for diagnostics is defined by key legislations, such as the Drugs & Cosmetics Act (1948), Clinical Establishment Act (2010), and the Medical Devices Rules (2017).

India is witnessing major investments from private healthcare firms, venture capital, and global investors. Public-private partnerships, government funding for better infrastructure, rural access, and technology upgrades are also on the rise.

Healthcare innovation is on the rise, with government support and numerous startups focusing on point-of-care testing, real-time diagnostics, and AI/ML in medical imaging.

The Indian diagnostics sector is projected to grow significantly, amounting to $28 billion by 2028 doubling its 2022 value of $14.7 billion.

Overview of the Sector

- The Indian diagnostics sector is experiencing robust growth, characterised by **an annual CAGR of 11-12 percent.**[25]
- Hospitals and diagnostics centres have received **Foreign Direct Investment (FDI) of $6.8 billion** between April 2000 and June 2020.[26]
- In 2021, the medtech sector secured an impressive **$2.2 billion** in funding through 131 deals.[27]

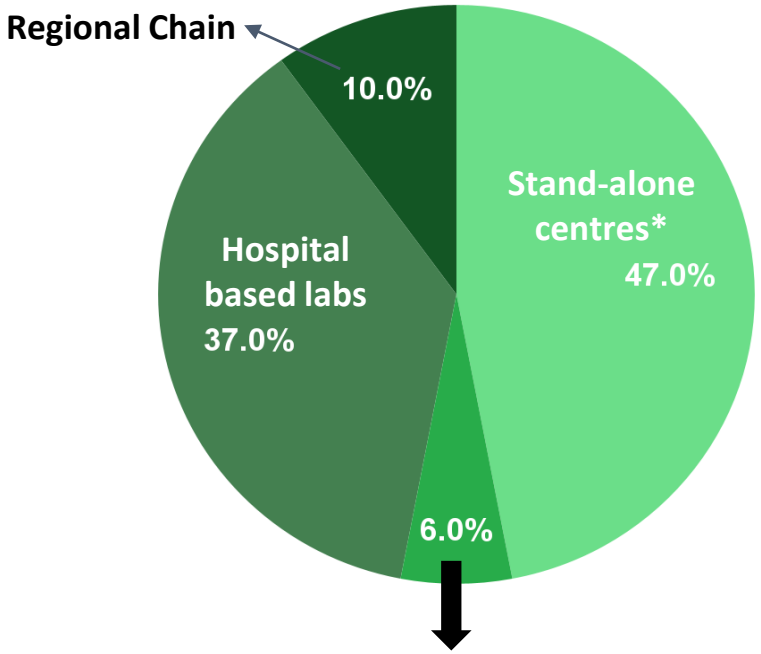
Landscape of the Diagnostic Industry

PROVIDERS	ENABLERS	PAYERS
Healthcare Facilities	Government Initiatives	Government Partnerships with Private Labs
Private Sector Labs	Emerging Healthcare Startups	Philanthropic Organisations

- Point-of-Care Testing
- Real-time Diagnostics
- Clinical Decision Support System
- Data-driven Lab Optimisation Solutions
- Artificial Intelligence in Medical Imaging

Private labs and public-private partnerships account for a major share in the diagnostics sector.

Private Sector Share in the Market [28]



(*Single-unit centres operating on a small scale providing either pathology, basic radiology, or advanced radiology services)

Government Partnerships with the Private Sector [29]

In 2022, **Maharashtra** entered into partnership with **Apollo Hospitals** to establish diagnostic centres throughout the state, encompassing a wide range of services.

In 2021, the state of **Rajasthan** collaborated with **SRL Diagnostics** to introduce telemedicine and teleradiology services in district hospitals across the region.

In 2019, **Delhi** partnered with **Dr. Lal Pathlabs,** and initiated a PPP with a budget allocation of $6 million to facilitate affordable diagnostics services for Delhi's economically backward population.

The **Tamil Nadu** government partnered with **Metropolis Healthcare** to establish comprehensive diagnostic facilities across government hospitals throughout the state.

Collaborative efforts between healthcare providers, development practitioners and philanthropists to improve the adoption of diagnostic solutions in India are growing.

ACT Grants and Transform Rural India have collaborated to deploy Niramai's **thermal imaging technology** within mobile screening units to **detect early stage breast cancer** in **Maharashtra**.[30]

Qure.ai has partnered with PATH to implement **AI-enabled TB screening** at four hospitals in **Maharashtra**. It has enabled the screening of 90,000+ patients at seven public hospitals in Mumbai.[31]

India Health Fund, an initiative by Tata Trusts, is supporting Medprime Technologies' **microscope-agnostic AI-enabled diagnosis** software to detect **mosquito-borne diseases.**[32]

FIND and CIPLA collaborated to improve **Hepatitis C virus** diagnosis by supporting the improvement of the sensitivity of new HCV diagnostic tests, and building diagnostic capacity in India.[33]

USAID has increased diagnostic capabilities and strengthened community engagement for **Tuberculosis**. It is also scaling up high-impact interventions for **HIV Diagnosis** in India.[34]

With 3548 active healthcare startups, healthcare innovation is supporting the healthcare technology and device manufacturing ecosystem in India.

Technological advancements are increasing product innovation in the sector.

mHealth and wearable health technologies

such as the mDiabetes initiative to enhance health-seeking behaviour among individuals dealing with diabetes.[35]

Point-of-care testing (PoCT) services

reduce diagnostic expenses, enhance accessibility, and alleviate the workload of healthcare professionals.[36]

Deploying medical mobile units

helps enhance accessibility to healthcare services in rural areas.[37]

Government initiatives are also trying to enable innovation.

Initiatives like Make in India and Made for India

have significantly encouraged innovation in the med-tech sector, especially in light of the pandemic.[38]

The Ayushman Bharat initiative and the National Health Protection Scheme

are encouraging the innovative potential in India's healthcare ecosystem. [39, 40]

The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices

intends to boost domestic manufacturing and investments in medical devices.

STRENGTHENING SCREENING AND DIAGNOSIS WITH TECHNOLOGY

Digital health solutions are portable, cost-effective, reduce dependency on the physical presence of a specialist, and can be deployed in remote locations.

Digital health solutions, if implemented correctly, could increase awareness, enable early screening and effective diagnosis of diseases, and potentially improve life expectancy by increasing patients' ability to seek care before symptoms worsen.

Awareness

- **Improved health awareness and health-seeking behaviour,** adherence to check-up through IVRS, WhatsApp, and targeted messaging

Access and Affordability

- **Access to diagnostic services irrespective of location:** Urban-to-rural doctor density ratio is 3.8:1 in India. Digital screening services can connect all regions to the healthcare network irrespective of the location.
- **Increased affordability in accessing care**: Teleconsultations, home diagnostics, point-of-care diagnosis can reduce travel time and cost of higher health facilities.

Diagnosis

- **Early detection of risks** through longitudinal view of patient health records (through EHR, PHRs)
- **Point-of-care digital tools improve screening and diagnosis rate** by providing:
  - Real-time diagnostics
  - Clinical Decision Support System for FLWs
  - Data-driven solutions

Early Detection

- Data collected at various levels can **help analyse disease patterns and predict future outbreaks.**

(Adapted from WHO [41])

Digital technologies can streamline workflows, thereby enhancing efficiency and improving the accuracy and quality of results.

Streamlining Workflows and Enhancing Efficiency of Labs [42]

- Electronic Health Records and Laboratory Information Management Systems facilitate the **smooth integration of patient data, test requisitions, and outcomes** – enhancing efficiency, accuracy, and time management for laboratory technicians.
- Digital health solutions automate tasks like sample labelling, tracking, result reporting, and **enhancing operational efficiency.**

Improving Accuracy and Quality of Results [43]

- AI and ML technologies process vast datasets to **detect patterns and offer valuable insights,** enhancing diagnostic precision.
- By examining historical data and patient patterns, predictive analytics can identify **potential health risks and early disease indicators** enabling healthcare professionals to intervene early, deliver timely treatment and improve health outcomes.

Enhancing Collaboration and Communication [44]

- Digital health solutions enable **real-time data sharing and remote access to laboratory findings,** fostering swift consultations and collaborative efforts.
- Telemedicine and telepathology platforms empower clinicians to **remotely review lab results and offer timely guidance,** breaking down geographical barriers.

Cutting-edge digital innovations, like **handheld ultrasound devices and pulse oximeters,** have the potential to offer accurate diagnoses at the primary healthcare level. **Rapid point-of-care diagnostic tests,** used for conditions such as diabetes, HIV, and malaria can provide essential treatment guidance through their quick analyses. [45]

Archetypes of tech-enabled diagnostic solutions

Point-of-Care Testing

Screening and diagnostic testing conducted at the site of patient care.

- Niramai
- Janitri
- AINDRA
- Piiko.in

Real-time Diagnostics

Continuous monitoring and instant feedback for decision making.

- Care mother AnandiMaa
- Janitri

Clinical Decision Support Systems

Subsequent treatment steps provided to a health professional after analysing clinical data.

- medic
- dimagi
- SPOTSENSE Making Healthcare Simple

Data-driven Lab Optimisation Solutions

Business intelligence and analytics to improve operational efficiency of the lab.

- Labsmart
- PerkinElmer For the Better
- ONWARDASSIST

Artificial Intelligence in Medical Imaging

Shifting the workload of reading medical images to artificial intelligence.

- ARTELUS
- MobileODT Mobile Optical Detection Technologies
- qure.ai
- SIGTUPLE
- JOHARI medtech

Illustrative Solution: The NIRAMAI breast cancer screening test, Thermalytix, is an AI-powered computer-aided diagnostic engine.

Niramai Thermalytix utilises a high-resolution thermal sensing device and a cloud-hosted analytics system to analyse thermal images, ensuring dependable, early, and precise breast cancer screening.[47]

Increased Efficiency and Access

Thermalytix is radiation-free and non-invasive, provides high accuracy (automated scoring and image annotations for malignancy), and it performed well in mammography in women with dense breasts.

Value, Time, and Scale of Success

Thermalytix has regulatory clearance in India, Europe, UAE and Kenya. It has been used by 1,00,000+ women in 150+ hospitals/diagnostic centres and 5000+ screening camps in India.

Results from clinical trials

- A study on **258** symptomatic women, both under and above the age of 45, shows the potential of Thermalytix to be a supplemental diagnostic modality for all ages.[48]
- Another study on **470** women demonstrated the efficacy of Thermalytix for breast cancer screening in women of all age groups.[49]

Thermalytix, with its automated scoring and image annotations of potential malignancies and vascularity, can assist the clinician in better decision making, and improve quality of care in an affordable and radiation-free manner.

Illustrative Solution: Artelus's Diabetic Retinopathy Screening (DRISTi) is an AI product designed to detect the early presence of diabetic retinopathy (DR).

ARTELUS

DRISTi, driven by deep learning-based AI algorithms, examines digital images to detect and identify early signs of diabetic retinopathy (DR) during a routine eye check-up.[50]

Increased Efficiency and Access

The AI-powered solution empowers non-specialists to utilise DRISTi for screening various eye conditions, including diabetic retinopathy (DR), glaucoma, choroidal neovascularisation (CNV), and diabetic macular edema (DME). It achieves this by analysing retinal and OCT images.

Value, Time, and Scale of Success

The solution has been commercially available since 2016, and is presently deployed in 50 centres throughout the country. It received the CE mark in India in June 2018, making it available for sale not only in Europe, but also in Asian markets.

Results from tests

At a test with the **Dubai Health Authority** at the Dubai Diabetes Hospital, **DRISTi** demonstrated a **96 percent** sensitivity when compared to the assessments of a retinal specialist.[51]

Illustrative Solution: Qure.ai is using AI to make healthcare more affordable and accessible.

qure.ai

qXR, Qure.ai's AI-powered chest X-ray screening tool was used in the Purnia district of Bihar to enable healthcare workers in the dual screening of COVID-19 and lung diseases such as TB.[52]

Increased Efficiency and Access

Qure's qXR reduced the frequency of errors in detection and side-labelling of radiographic findings.

Value, Time, and Scale of Success

Around 2500 chest X-rays were processed and 299 TB-presumptive patients were identified using qXR, facilitating crucial early detection.

Results from clinical trials for qXR

The qXR AI algorithm exhibited impressive performance metrics, with a sensitivity of 96%, specificity of 100%, and an accuracy rate of 96% in identifying overlooked and incorrectly labelled chest X-ray findings. It effectively detected both mislabelled and missed anomalies.[53]

Qure.ai also harnesses deep learning technology to offer automated interpretation of radiology exams, including CT scans and ultrasound scans.

The pandemic has expedited the adoption of diagnostic technology, and this trend is expected to continue in the upcoming years.

Investments in the diagnostics sector are currently on the rise, and are anticipated to continue increasing in the future.

The medtech segment, consisting of diagnostics and therapeutics, is projected to grow to **$54 billion in 2025,** capturing **32%** of the entire preventive healthcare market by 2025.[54]

The domestic diagnostic market is anticipated to experience a CAGR of about **12% to 13%** in the next five years.[55]

Rapid ICT penetration and government efforts have led to technological advancements in diagnostics and care delivery.

Encouraging the move from manual to automated processing through cloud-based robotics and AI will significantly **reduce the need for human interventions** in tasks like sample handling, analysis, and diagnosis.[56]

Approximately **3,548** active health tech startups with technologies such as AI/ML enabled point-of-care diagnostic devices, telemedicine platforms, clinical decision support solutions, and various others are currently in operation.[57]

GLOBAL AND DOMESTIC POLICY LANDSCAPE FOR DIAGNOSTICS

The policy landscape for diagnostics in India consists of legislations, guidelines for standards, basic minimum requirements, and enforceable rules for regulation.

The Drug and Cosmetics Act, 1940

The Act regulates the import, manufacture, distribution, and sale of drugs, biosimilars, and medical devices. All medical devices, including diagnostic imaging machines are classified as "drugs" under the Act.

Clinical Establishments Act, 2010

Establishes consistent minimum quality standards for diagnosis and treatment while making it mandatory for all types of healthcare facilities to register. The Act is in effect in 12 states and 6 union territories through the invocation of Article 252 of the Indian Constitution.

Free Diagnostics Service Initiative, 2015

Launched under the National Health Mission by MoHFW, the initiative supports all states in providing free essential diagnostic services, including laboratory and radiology services, through public health facilities.

Indian Medical Devices Rules, 2017

Overseen by the Central Drug Standard Control Organisation (CDSCO), the rules offer risk-based categorisation, set product standards, and define timelines for obtaining licenses.

National Essential Diagnostics List, 2019

Developed by ICMR, this is a list of essential tests based on utility and requirements at all levels of care within the public health system. The basket of essential tests was built upon the Free Diagnostic Service Initiative, IPHS guidelines, and NHM programmes.

Indian Public Health Standards, 2022

Formulated under the National Rural Health Mission, IPHS and revised in 2022, it provides guidelines to ensure that optimal specialised care is delivered to the community while upholding and sustaining an acceptable standard of quality of care.

The Drugs, Medical Devices and Cosmetics Bill, 2022

The bill – intended to replace the Drugs and Cosmetics Act of 1940 – proposes to amend and consolidate regulations for quality, safety, and clinical trials of drugs, medical devices, and cosmetics.

National Medical Device Policy, 2023

The policy charts a path for boosting the growth of the medical device sector, emphasising safety and quality to ensure access to patient-focused, innovative, high-quality and affordable healthcare products for improved healthcare outcomes.

The Indian Medical Device Rules 2017 took the first step toward improving patient safety concerning medical devices in India.

With a primary focus on manufacturing, import, sale, distribution, and ensuring quality and safety control, the Indian Medical Device Rules aim to enhance regulations in the medical device sector.[58]

DEVICE CLASSIFICATION

Based on the intended use, associated risks, invasiveness, and duration of contact, India's Central Licensing Authority (CLA) classifies medical devices and IVD into four risk classes:

Class A Low risk	Class B Low-moderate risk	Class C Moderate-high risk	Class D High risk
Absorbent cotton wools, surgical dressing, alcohol swabs, etc.	Thermometer, BP monitoring device, etc.	Diabetic retinopathy detection device, etc.	Ventricular bypass device, etc.

The National Essential Diagnostics List has established the sets of diagnostic requirements to be made available at public healthcare facilities.

- MoHFW launched the Free Diagnostics Service Initiative in 2015 to improve the availability of accessible and quality diagnostics in public health facilities.
- The NEDL extends the efforts of the Free Diagnostics Service Initiative and other diagnostic programmes by the MoHFW to offer a broader range of tests at various tiers within the public health system.

Benefits from the implementation of NEDL [59]

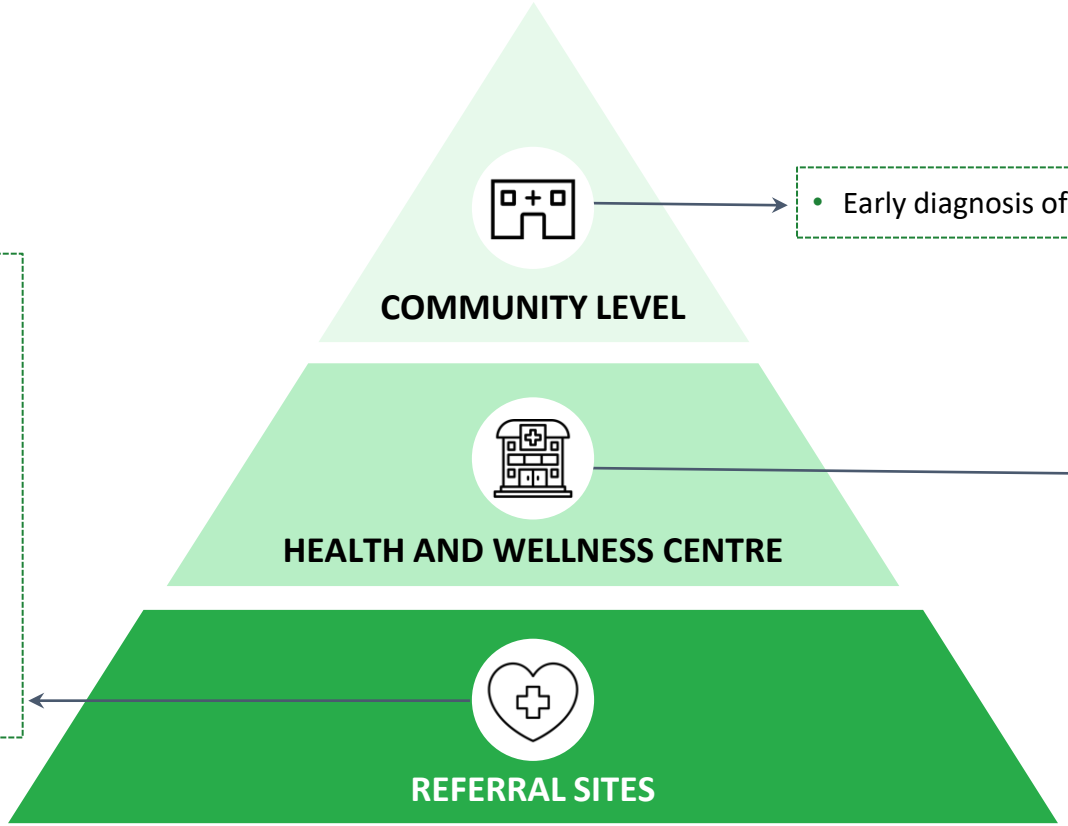
Improved health care delivery through evidence-based care	Effective assessment of disease burden
Improved patient outcomes and reduction in OOPE	Addressing the antimicrobial resistance crisis
Effective utilisation of public health facilities	Effective surveillance and outbreak identification

The NEDL contains separate tests in lists that have been prepared for each type of facility – sub centre/HWC, primary health centre/HWC, community health centre, sub-district hospital, and district hospital.

The lists contain information on the test category, the type of specimen that can be used in the test and product/equipment on which the test is best conducted.

Indian Public Health Standards, revised in 2022, establish guidelines for diagnostics at various touchpoints.

Point-of-care diagnostic services should be made accessible at Health and Wellness centres, and the availability of fourteen diagnostic tests should be ensured as essential diagnostics.[60]



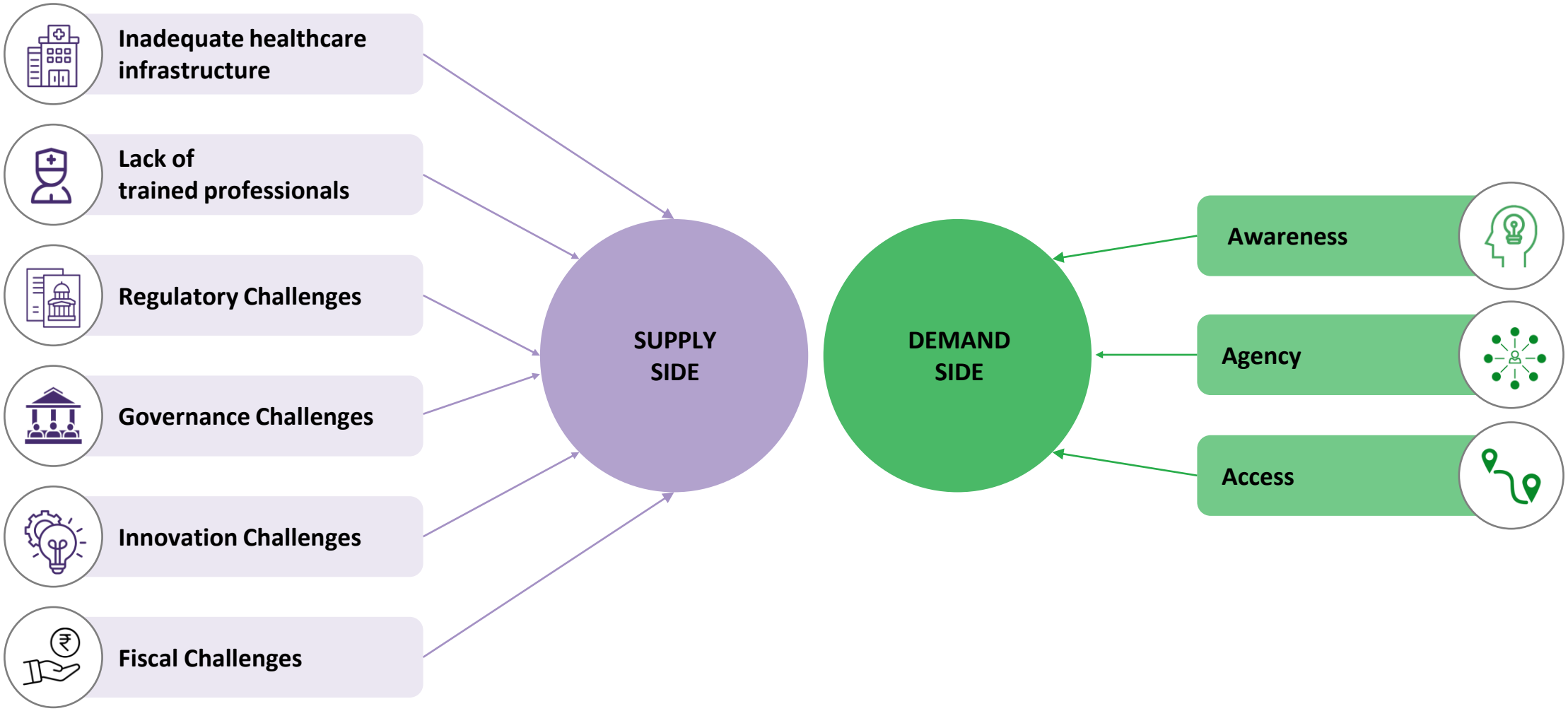
- Early diagnosis of pregnancy

- Diagnosis and treatment for disability, deficiencies and development delays in adolescents
- Diagnosis of HIV/AIDS cases
- Diagnosis of communicable diseases such as fevers, gastroenteritis, skin infections, typhoid, rabies, helminthiasis
- Diagnosis of NCDs such as diabetes, cancer
- Diagnosis of blindness, hearing and speech impairment

- Diagnosis for vector borne diseases such as malaria, dengue, chikungunya, filaria, kala-azar, Japanese encephalitis, TB and leprosy
- Diagnosis for blindness and refractive errors
- Diagnosis and treatment services for common ophthalmic diseases
- Screening for oral, breast and cervical cancers

CHALLENGES IN SCREENING AND DIAGNOSTICS

While efforts have been made to streamline the adoption of diagnostics, challenges within the sector persist.



Supply-side challenges make the on-ground reality different. (1/2)

INADEQUATE HEALTHCARE INFRASTRUCTURE

- India's medical infrastructure faces a shortage of essential diagnostic equipment, with just 2,700 mammograms available, less than 5 percent of the equipment present in the United States.[61]
- There are only 120 PET-CT scanners in the country, primarily concentrated in major metropolitan areas.[62]
- Only 30 percent of cancer centres in India are equipped with advanced imaging technologies.[63]

LACK OF TRAINED PROFESSIONALS

- A study on facility readiness for screening of cervical cancer observed low scores for PHCs on staffing due to limited number of personnel for diagnosis.[64]
- India's health workforce density is 33.5 healthcare workers per 10,000 population, which falls below the WHO's recommended threshold of 44.5 per 10,000 individuals.[65]
- According to the Directorate of Medical Education and Research, there are around 2,200 pathologists in over 10,000 diagnostic labs in Maharashtra, with many lacking a doctor on staff.[66]

REGULATORY CHALLENGES

- The Drugs & Cosmetics Act lacks penalties for malpractices and manufacturing of sub-standard devices and fake certifications.[67]
- Manufacturing of Class A & Class B devices is regulated by State Licensing Authorities, which fragments the regulatory procedures.[68]
- There are only 18 CDSCO-certified Medical Device Testing Labs in India.[69]
- The CEA is in force in 12 states and 6 UTs but its implementation has been limited and slow.[70]
- India has around 1.1 lakh medical laboratories but only 8,633 labs are accredited by NABL.[71]

Supply-side challenges make the on-ground reality different. (2/2)

GOVERNANCE CHALLENGES

- The current pharma-centric workforce of CDSCO is lacking regulatory capacity for the medical device industry.[72]
- Component-level regulations are managed by different departments/ministries. This complicates the clearance process, and increases the time needed for approvals.[73]
- Delays in notifying Drug Testing Laboratories, and assigning device testing officers at state level adds to the delay in granting approvals.[74]
- Non-adherence of mandated timelines for audit and reporting by notified state-level bodies dilutes the implementation of Medical Device Rules 2017. [75]

INNOVATION CHALLENGES

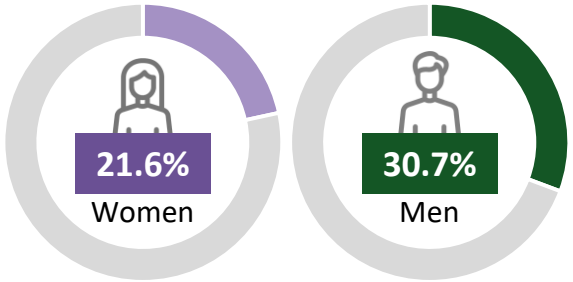
- Patient-centricity in innovation is weak, since the direct interfacing between biomedical engineers and patients is not adequately done in R&D.[76]
- There is an 80% import dependency for domestic requirements due to lack of high-end technology and scarcity of raw materials.[77]
- The lab-to-manufacturing pathway is currently underdeveloped.[78]

FISCAL CHALLENGES

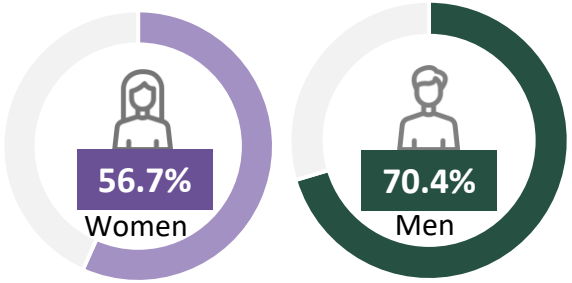
- Low import duty, 12% GST on domestically manufactured products, and 18% GST on in-vitro diagnostic equipments discourage innovation domestically.[79]
- Concessional financing and fiscal incentives for developers and manufacturers of diagnostic devices are largely unavailable.[80]
- High fees charged by notified medical device testing laboratories, such as the National Institute of Biologicals, for Class C and Class D devices can be challenging for developers without large capital.[81]

The population's awareness, agency and access to healthcare are leading to challenges in demand.

AWARENESS

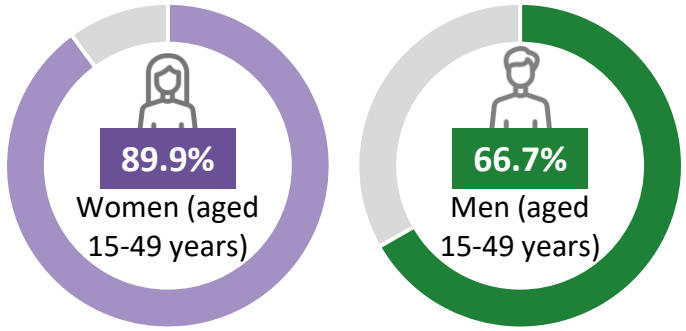


have comprehensive knowledge about HIV/AIDS.[82]

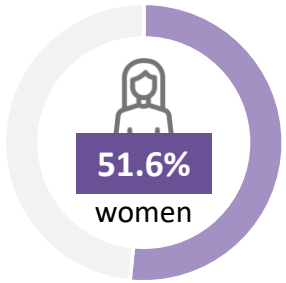


know where to get an HIV test.[83]

AGENCY



in the country could not take independent decisions about their healthcare.[85]



were allowed to go alone to a health facility.[87]

ACCESS

49.9%

households do not generally use a **government health facility.**[88]

40.2%

households do not use government health facilities as **no nearby facility** is available.[89]

59.5%

women face trouble accessing healthcare services.[90]

Notwithstanding the promise of technology, stakeholders need to be cognisant of critical risks such as overdiagnosis, uncoordinated processes, poor follow-ups, and technological redundancies within the diagnostic ecosystem.

Overdiagnosis from early screening occurs when early forms of a disease are used to give a diagnosis to patients, even if the early forms of the disease will neither present symptoms nor cause death. Consequently, unnecessary treatments are deployed.

Lack of coordination in screening processes can lead to the incorrect categorisation of individuals for testing, resulting in longer wait times for patients with more critical health conditions.

The **lack of a dedicated follow-up and treatment pathway** within the healthcare system can undermine the uptake of treatment.

Presently **emerging, yet promising, solutions may be rendered redundant** or obsolete with progress in technology and developments in medical practices over time.

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