INDIA'S DIAGNOSTIC SECTOR - ECONOMY

NEWS: *India's diagnostics sector plays a crucial role in the healthcare industry, facilitating early disease detection and treatment planning.*

WHAT'S IN THE NEWS?

The tragic case of Shankar Dhange, whose sister lost her life due to incorrect diagnostic test results, underscores the serious risks posed by inadequate regulation and oversight.

1. Role and Contribution to Healthcare

- The **diagnostics sector** plays a **pivotal role** in India's healthcare system, contributing approximately **9%** to the overall healthcare industry.
- It is **essential for disease management**, aiding in **early detection, accurate diagnosis, and treatment planning**.
- The sector's growth is being driven by **technological advancements**, increased **awareness about preventive healthcare**, and **rising demand for high-quality diagnostic services**.

2. Market Size and Growth Projections

- The Indian **diagnostics industry is expanding rapidly**, with its market size expected to reach an estimated **₹1,275 billion by 2028**.
- This growth is fueled by factors such as:
    - **Increasing burden of chronic and infectious diseases**
    - **Greater adoption of digital health technologies and artificial intelligence (AI) in diagnostics**
    - **Rising health insurance penetration, encouraging people to undergo diagnostic tests**
    - **Government initiatives aimed at improving access to affordable diagnostic services**

3. Existing Infrastructure

- India currently has **approximately 300,000 diagnostic laboratories** spread across the country.
- However, a large proportion of these are **unregulated standalone labs**, operating without **mandatory accreditation or quality control measures**.
- **Digital health platforms** and **AI-driven diagnostic solutions** are transforming the landscape, enabling **remote testing, automated interpretations, and faster results delivery**.

Challenges Facing the Diagnostics Sector in India

1. Weak Regulatory Oversight

- A major challenge in the sector is the **lack of uniform regulations**, as **only 12 states and Union Territories** have adopted the **Clinical Establishments (Registration and Regulation) Act, 2010**.
- Many diagnostic centers **operate without mandatory accreditation**, leading to **variations in quality standards** and **patient safety concerns**.
- The **absence of standardized protocols** in sample collection, testing, and reporting affects diagnostic accuracy and reliability.

2. Shortage of Skilled Personnel
- There is a significant **deficit of trained professionals**, including **pathologists, microbiologists, radiologists, and lab technicians**.
- This shortage impacts **diagnostic accuracy, quality control, and overall efficiency** in delivering medical test results.
- Many laboratories employ **unqualified technicians**, leading to an increase in **erroneous diagnoses** and **misinterpretation of test reports**.

3. Urban-Rural Divide in Diagnostics Access
- Despite **70% of India's population residing in rural areas**, only **24% of the total diagnostics sector revenue** comes from these regions.
- Rural healthcare infrastructure remains **underdeveloped**, with **government-run diagnostic centers suffering from poor funding, inadequate staffing, and lack of advanced equipment**.
- Limited access to **high-quality diagnostics in remote areas** results in **delayed disease detection and improper treatment outcomes**.

4. High Cost of Private Diagnostic Services
- **Lack of standardized pricing** for diagnostic tests has resulted in **significant cost disparities** between different service providers.
- Many **private laboratories charge exorbitant fees**, making quality diagnostic services inaccessible to **low-income and uninsured patients**.
- **State-funded diagnostic initiatives**, such as **Telangana's 'T-Diagnostics' and Kerala's 'Aardram Mission'**, aim to offer affordable services but **face logistical and operational challenges** in scaling up.

5. Prevalence of Fraudulent Practices
- The sector is plagued by **fake pathologists and unauthorized technicians**, leading to **compromised patient safety and diagnostic errors**.

- Many small labs **purchase the signatures of pathologists**, issuing reports **without proper medical review**.
- The lack of **a centralized monitoring system** allows **unqualified personnel** to operate without accountability.

Regulatory Framework Governing the Diagnostics Sector
1. Clinical Establishments (Registration and Regulation) Act, 2010
- Aims to **regulate diagnostic centers** by setting **minimum service standards** for infrastructure, quality, and staffing.
- However, this law has been **adopted by only 12 states and Union Territories**, leading to **poor implementation** across the country.

2. NABL Accreditation (National Accreditation Board for Testing and Calibration Laboratories)
- NABL provides **voluntary accreditation** to diagnostic labs, ensuring compliance with **quality and reliability benchmarks**.
- While large **diagnostic chains adhere to NABL guidelines**, a **majority of small and standalone laboratories operate without accreditation**.

3. State-Specific Regulations
- Some states have introduced **individual regulatory frameworks** to oversee diagnostics, such as:
    - **Karnataka and Kerala:** Have separate regulations, but **enforcement remains weak**.
    - **Tamil Nadu (Clinical Establishments Regulations Rules, 2018):** Mandates **minimum space requirements for laboratories**, ensuring that **labs maintain proper operational standards**.

Way Forward: Reforming India's Diagnostics Sector
1. Strengthening Regulations and Compliance
- Make **NABL accreditation mandatory** for **all diagnostic centers**, ensuring uniform quality standards.
- Implement **nationwide enforcement** of the **Clinical Establishments Act** across all states and Union Territories.
- Establish a **centralized regulatory body** to oversee compliance, monitor fraudulent practices, and improve accountability.

2. Expanding Workforce and Training Programs
- Increase **medical education seats** and introduce **specialized training programs** for:
    - **Pathologists**
    - **Microbiologists**
    - **Radiologists**
    - **Medical lab technicians**
- Mandate **regular upskilling and certification** for lab personnel to maintain diagnostic accuracy and **keep up with technological advancements**.
- Set a **limit on the number of laboratories** a single pathologist can be associated with, reducing the practice of **ghost pathologists**.

3. Eliminating Fraudulent Practices
- Introduce **digital tracking systems** for lab reports to **prevent misuse of pathologists' credentials**.
- Enforce **strict penalties** for ghost pathologists, unqualified technicians, and laboratories issuing reports **without medical supervision**.

- Conduct **regular audits, inspections, and surprise visits** to ensure compliance with accreditation and quality control measures.

4. Bridging the Urban-Rural Divide
- Increase **government investment in rural healthcare infrastructure**, setting up **state-of-the-art diagnostic centers** in underserved areas.
- Expand **public-private partnerships (PPPs)** to improve **availability and affordability** of diagnostic services in **remote locations**.
- Scale up **successful state-funded initiatives** like **T-Diagnostics and Aardram Mission** to ensure **nationwide access to affordable diagnostics**.

5. Standardizing Pricing and Quality Control
- Introduce **price caps for essential diagnostic tests**, preventing **overcharging by private labs**.
- Establish **Standard Operating Procedures (SOPs)** for:
  - **Sample collection**
  - **Testing methodologies**
  - **Reporting formats**
- Mandate **internal and external quality control** measures to maintain **consistency and reliability** in diagnostic outcomes.

Conclusion

India's diagnostics sector is a **critical pillar of healthcare**, playing a key role in **disease detection, prevention, and management**. However, **regulatory gaps, skill shortages, cost disparities, and fraudulent practices** continue to hinder its growth and accessibility. Addressing these challenges through **stronger regulations, capacity-building, and public-private collaborations** will ensure **affordable, high-quality diagnostics for all**, bridging the gap between **urban and rural healthcare infrastructure**.

Source: https://www.thehindu.com/sci-tech/health/how-the-diagnosis-sector-in-india-became-a-runaway-juggernaut/article69175702.ece