JANUARY 2022 • Vol. 7 • Issue 10
MONTHLY • Pages 64
₹ 200

RNI No.: DELENG/2015/67140; Published on: Every month; Posted at Lodi Road HPO, New Delhi on 9-10th of every month

THE AWARE CONSUMER

www.theawareconsumer.in

OUT OF THE BOX
Danger of Imminent Risks in Diagnostic Testing

RESEARCH FEATURE
Striving to Reduce Overpricing and Make Testing Accessible

DIAGNOSTIC DEVICES
– Pressing Need for Regulation

INTERVIEW

Mr. Jatin Mahajan
Managing Director
J Mitra & Co. Pvt. Ltd.

The AWARE CONSUMER wishes all our readers a happy and prosperous New Year 2022!

PLUS ROUND UP • MY MARKET • THE PRESCRIPTION

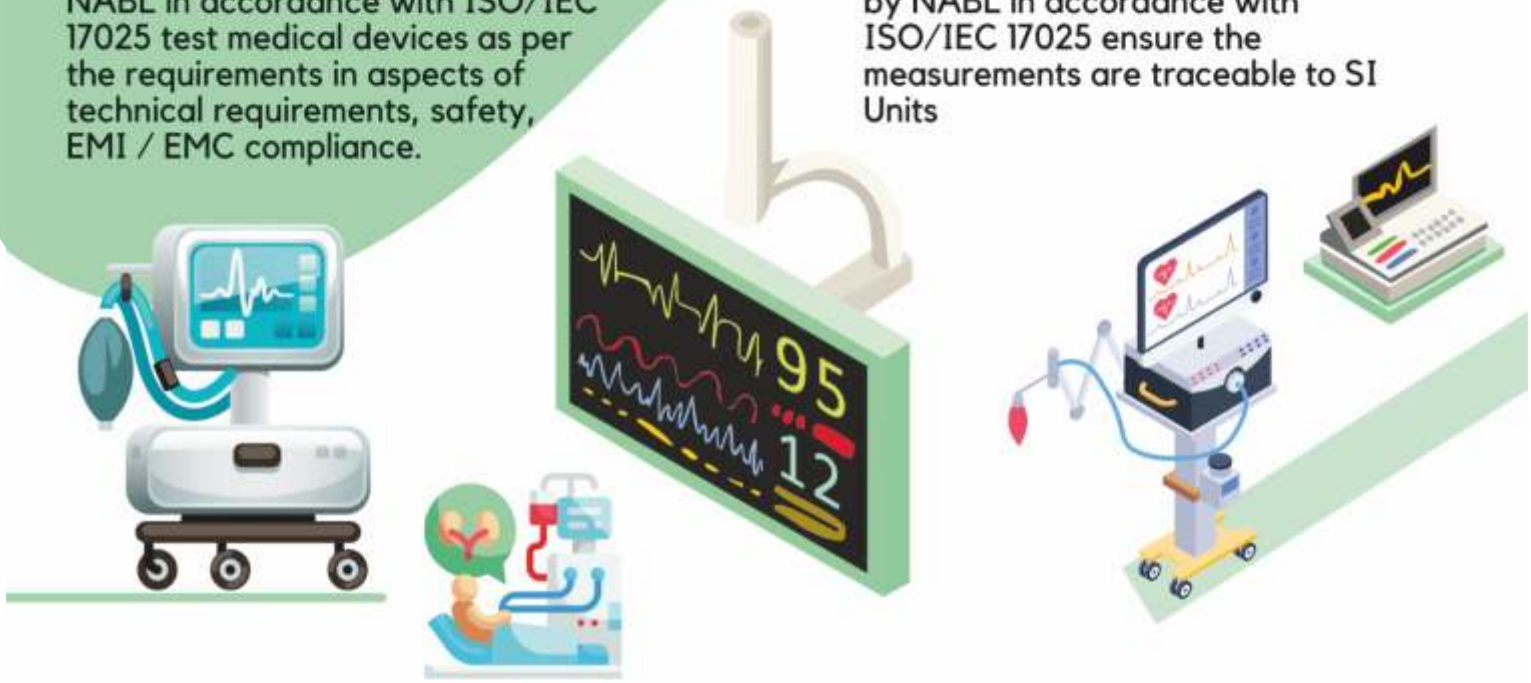
NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES

Medical devices form a critical part in medical diagnosis, patient safety and support as life saving systems in patient recovery.

It is crucial that medical devices meet the requirements of safety, functionality and compliance to specifications.

Testing Laboratories accredited by NABL in accordance with ISO/IEC 17025 test medical devices as per the requirements in aspects of technical requirements, safety, EMI / EMC compliance.

Calibration Laboratories accredited by NABL in accordance with ISO/IEC 17025 ensure the measurements are traceable to SI Units



Details of accredited laboratories are available on NABL website (www.nabl-india.org) under Laboratory Search -> Accredited Laboratories
Select Country: India, Field: Testing, Discipline: Electronics, Group: Medical Electrical Equipment
Select Country: India, Field: Calibration, Discipline: Medical Devices

NABL complies to ISO/IEC 17011 and is a full member and signatory to ILAC and APAC MRA

National Accreditation Board for Testing and Calibration Laboratories (NABL)
NABL House
Plot No. 45, Sector 44
Gurugram, Haryana - 122003
Email: info@nabl.qcin.org | Ph: 0124 4679700

VIEW  POINT

MESSAGE FROM PUBLISHER & EDITOR

Increasing Value of Diagnostics in Delivering Healthcare

HEALTHCARE HAS BECOME considerably complex riding on phenomenal advancements in medical technology. Yet, modern healthcare can be divided into two broad facets – diagnosis and therapy. Medical devices play a starring role in both these aspects as they are used in varied ways for the investigation, prognosis, treatment, monitoring, prevention and alleviation of different medical conditions.

Diagnostic devices, especially, have evolved enormously in the last few decades with laboratory parameters and other biomarkers guiding the clinical analysis and medical interventions. These medical equipment – from simple thermometers and stethoscopes to blood, urine and gene analyses to x-ray, ultrasound, ECG, CT scan and MRI machines - enable clinicians to observe and measure various aspects of a patient's health before forming a clear diagnosis.

Indeed, diagnostic information clarifies the nature, cause and extent of a disease, which is then used to decide on the best course of action for a patient – be it medical treatment, further testing or even no action – thus leading to improved patient management and maintaining continuity of healthcare. Early diagnosis is known to avert or at least diminish health issues on many occasions.

The COVID-19 pandemic has placed effective diagnostics front and centre for rapidly and accurately detecting the deadly SARS-CoV-2 virus. Testing has become a buzzword; nobody can deny the critical contribution of large-scale testing and novel testing innovations in controlling the spread of this global health threat.

However, a few pertinent questions are staring us in the face. How sure can we be that the data emerging from the diagnostic equipment is in fact reliable? Who is paying the price for the inadvertent errors that lead to incorrect diagnosis – be it emanating from man or machine? Come to think of it, are the investigations always necessary? And what about the obscene amounts of money that patients are forced to shell out for finding out what could be wrong with their body?

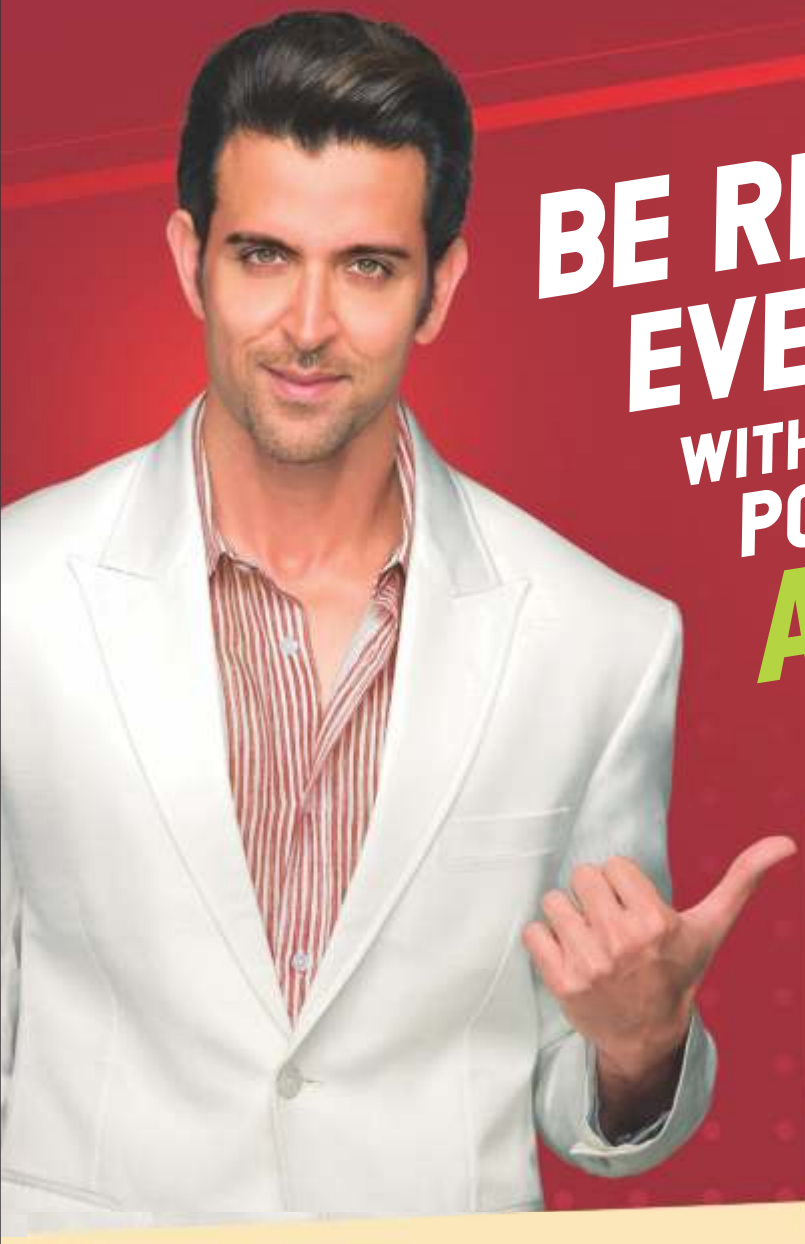
Food for thought for sure!

Prof. Bejon Kumar Misra
Publisher & Editor
bejonmisra@theawareconsumer.in

LUPIN

LUPIN LIFE BE ONE®

BE READY EVERY DAY WITH THE POWER OF AYURVEDA



Be One has the **power of 8 natural actives** with adaptogen formula. In today's hectic lifestyle it provides energy, helps build immunity and enables you to stay active every day. It is a scientifically tested complete supplement for a healthy body and mind.

- ENERGY*
- IMMUNITY*
- HEALTHY BODY AND MIND*
- DEVELOPED AND TESTED WITH DRDO#

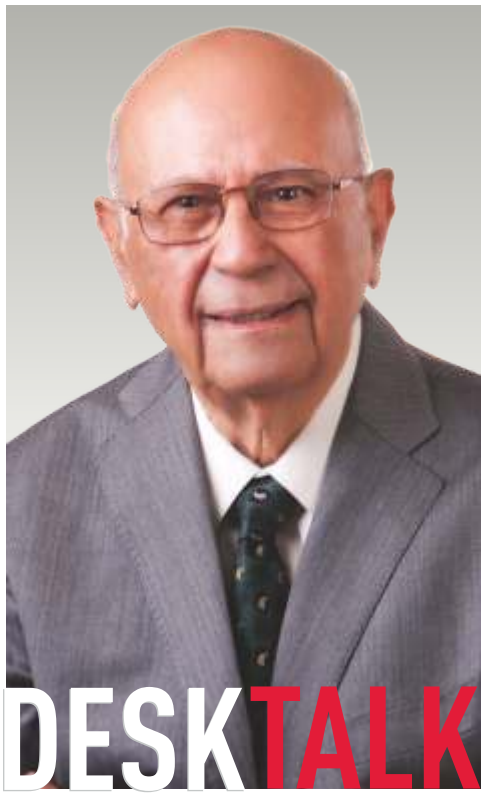
ASHWAGANDHA | SHATAVARI | SHILAJIT | PIPPALI

AVAILABLE AT YOUR NEAREST CHEMIST STORES & LEADING ECOMMERCE WEBSITES

A QUALITY PRODUCT FROM LUPIN | TOLL FREE : 1800 266 7440 | EMAIL : CUSTOMERCAREOTC@LUPIN.COM

*Data in files available for all above claims #Developed and tested with DIPAS of DRDO | Gopinathan PM, Grover SK, Gupta AK, Srivastava KK. Effects of a composite Indian herbal preparation on combat effectiveness in low-intensity-conflict operations. Mil Med. 1999 Nov;164(11):814-9. PMID: 10578595

PRAFULL D. SHETH
Editorial Board Member



DESKTALK

AREN'T WE LEANING TOWARDS OVERRELIANCE ON LABORATORY DIAGNOSTICS?

THIS IS THE era of evidence-based medicine! Diagnostic-driven decision making is ruling healthcare to the extent that healthcare professionals seem to be overly obsessed with investigative tests, x-rays and scans.

Walk into the consulting room of even the best doctor in town and he is bound to hand you a slip marked with a battery of tests. You will be asked to come back with the reports before he will prescribe any further treatment – be it a simple stomach complaint or a more complicated health scare like heart trouble.

Time was when the best doctors were those who had exceptional clinical skills and could use their medical instincts - based on patient history and physical examination - to diagnose the illness or ailment. Cut to today when we are witnessing an over-medicalisation of clinical practice characterised by an excessive dependence on pathology and radiology reports.

We surely cannot deny that medical tests play an important role in making fool-proof judgements. However, the medical fraternity is often well aware that many of the tests are not really needed or the results won't actually help them decide how to treat the patients. This becomes a sheer waste of time and money for the patient, not to mention having to go through an unpleasant or painful experience that will not even benefit their health. The associated risks are another matter altogether.

What we need is a more rational use of diagnostics in medical practice. Doctors should be able to sense when to employ their intuitive reasoning and when analytic testing is required. Why not go back to spending more time with the patients and actually listen to their complaints rather than prescribing tests on autopilot? Why not trust your knowledge and experience to make the correct prognosis?

Let diagnostics be a means and not an end! Instead of holding on to testing as a crutch, go back to holding the patient's hand to make a presumptive diagnosis and then order laboratory tests in a judicious manner!

INSIDE

THE AWARE CONSUMER JANUARY 2022

THE AWARE CONSUMER
UNLOCKING CONSUMER POTENTIAL
www.theawareconsumer.in

JANUARY 2022 • Vol. 7 • Issue 10

Owner, Printer, Publisher & Editor:
Prof. Bejon Kumar Misra

EDITORIAL CONSULTANTS
Prafull D. Sheth
Bina Jain
Suman Misra
Prakash Rao
Dr. A. Raj
Dr. Manisha Kukreja Batla
Dr. Alka Mukne
Pyush Misra
Shashank D. Sudhi
Payal Agarwal

DESIGNER: Galaxy; Yellow Palette
DESIGN CONSULTANT: Maanav Khaitan

WEB DESIGNER:
Manish Mohan
Ebrahim Bhanpurawala

MANAGER CIRCULATION
S. K. Venkatraman

Published at:
B - 306, 1st Floor,
C.R. Park, New Delhi-110019

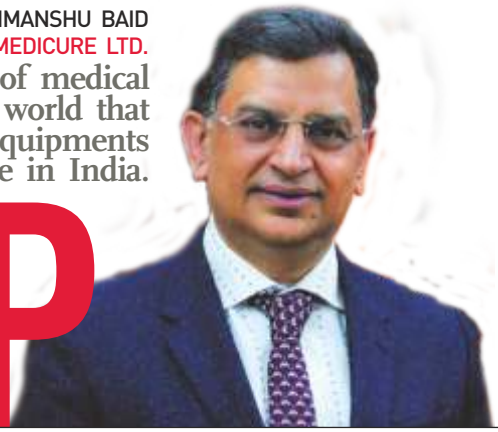
Printed at:
M/s. Swastika Creation
19, D.S.I.D.C. Shed, Scheme 3,
Okhla Phase II, New Delhi - 110020

For any queries, please contact us at
bejonmisra@theawareconsumer.in
Phone: 9311044424

Total number of pages - 64, Including Covers

HIMANSHU BAID
MANAGING DIRECTOR, POLY MEDICURE LTD.

India has the potential to become a leading exporter of medical equipments and devices. We have shown to the world that PPE Kits, N95 masks, ventilators and many other critical equipments which we imported a year back are now being made in India.



ROUNDUP

Controlling the Pricing of COVID-19 Testing

India needs a model of consolidated and pooled procurement to drive down testing costs, improve the quality of testing, and increase test kit availability

DATA BRIEFING

The cumulative doses administered in the country so far under the nationwide COVID-19 vaccination drive has exceeded 133.17 crore.

AFFORDABILITY AND ACCESSIBILITY of testing are the cornerstones of an effective response to the unprecedented COVID-19 pandemic. After all, it is testing data that provides real-time information on a new virus that is mutating regularly.Ceiling prices imposed by the government reflect the efforts to keep testing accessible and affordable.

At the beginning of the pandemic, testing was restricted to government hospitals and labs where it was offered free of charge to the patients. When it was expanded to NABL-accredited private laboratories, the Supreme Court initially ordered all tests to be carried out for free. However, this was not considered feasible, and the free testing was soon restricted to citizens covered by the Ayushman Bharat public health insurance scheme. The rest had to pay a whopping Rs. 4500 for the RT-PCR tests. Following this, the government reduced the charges to Rs. 3,500 rupees in a hospital and Rs. 4500 for home testing.

After rumbling protests started emerging from laboratory managements - they argued that the price caps were not adequate to cover the input costs along with the data entry, manpower, quality control and logistics expenses - in May 2020, the ICMR said that it would not regulate the prices anymore and the standardisation was left to the states.

State governments have been capping the costs ever since which ranged between Rs. 900 and Rs. 3000. Maharashtra, Rajasthan, Tamil Nadu and Andhra Pradesh have been at the forefront of price caps on COVID-19 tests. The Delhi government drastically slashed the rates, first to Rs. 800 and then to Rs. 500 in August 2021.

Yet, the affordability constraints in most states lock out the marginalised population from accessing testing and care in the private sector. While the testing continues to be free in state-run primary health centres and hospitals, it is the price caps that have been blamed for the slow ramp up in testing rates in the country. And still price discrepancy has been rampant in the private sector all along.

CDSCO Postpones Registration for New Licensing Regime

THE TRANSITION INTO the new licensing regime under the Medical Device Rules (MDR) 2017 is pushed forward by almost two years! The Central Drugs Standard Control Organisation (CDSCO) released a draft Medical Devices Amendment Rules, 2021 notification extending

Delhi Government Pulled Up for Unauthorised Pathological Laboratories

IN THE LATEST development on a PIL filed by Prof. Bejon Kumar Misra stating that unauthorised laboratories and diagnostic centres are being managed by unqualified technicians, on 22nd November, 2021, the Delhi High Court directed the Delhi government to file an affidavit on how pathological laboratories are being regulated in the city. The bench further inquired if the state has taken any action against those running in violation of the framework.

Lawyer Shashank Deo Sudhi argued on behalf of the petitioner that medical diagnostic laboratories in Delhi are unregulated which poses a threat to the lives of the citizens. A submission was made that the 'wrong reports' signed by 'unqualified technicians' robbed the public of proper treatment. He further implored for the framing of a robust health policy to govern path labs along with stern action against those running in violation of the ICMR and WHO guidelines.

The authorities have to submit a one page affidavit on how the Delhi government is complying with the Clinical Establishment Rules, 2018 and also inform the court about the number of complaints received.

It is noteworthy that the government got the judicial rap in the hearing despite the counsel arguing that path labs in Delhi are regulated under the said rules, all medical reports have to be signed by a registered medical practitioner having post-graduate education and action is being taken on complaints against erring labs. The lawyer further propounded that the Delhi Health Bill is at an 'advanced stage'.

The plea filed with the court reads, "'Such illegal labs continue to mushroom in and around Delhi-NCT and it can be easily estimated that the total number of such illegal pathological and diagnostic labs can be anywhere between 20,000 and 25,000, and every street in the capital has such illegal pathological labs. The National Accreditation Board for Testing and Calibration Laboratories (NABL) under the Quality Council of India (QCI) is optional and not mandatory before the opening of a pathological or diagnostic lab in Delhi". The bench also asked Prof. Misra to show 'instances' of false medical reports from path labs.

It will be interesting to see what the government has to say in its affidavit as the fact remains that the government has not yet adopted the Clinical Establishment Act. The authorities just keep saying they are bringing a better law since the last three years!

the submission of ISO 13485 certificate for registering medical devices from 30th September, 2021 to 31st May, 2022. The regulations are not in place as yet and are likely to come into being only by 1st October, 2023.

Product quality becomes the victim again due to the continuing delay in regulations. Unauthentic product certificates will continue to flood the medical devices market in the meanwhile. As Mr. Anil Jauhri, former CEO, National Accreditation Board for Certification Bodies (NABCB), underlines, "Until the time regulations are not in place, the manufacturers will show certificates most of which are unauthentic to impress the buyers who generally are ignorant. The risk of unauthentic certificates remains very high as medical devices are not yet regulated. Once regulated and licensing regime is in place, there will be some quality assurance. In the absence of regulations, the buyers or customers will not be assured of any quality. Voluntary unauthentic, even fake, certificates will continue to rule the Indian market."

ICMR Laying the Road for 'Make in India' Medical and Diagnostic Devices

INDIAN COUNCIL OF Medical Research (ICMR) has joined hands with Indian Institute of Technology (IITs) to establish 'ICMR at IITs' under the ambitious Medical Device and Diagnostics Mission. Accordingly, Centres of Excellence (CoE) will be set up for 'Make in India' product development and their commercialisation in medical devices and diagnostics space. The philosophy is to develop 'more for less for more' to ensure wider product outreach with a mandate to promote 'Global Affordable Need-Driven Healthcare Innovation' (GANDHI).

The ICMR-DHR Centres of Excellence have initially been set up at 6 IITs in Bombay, Guwahati, Hyderabad, Kanpur, Kharagpur and Madras. They will collaborate with the medical institutes to develop need-driven, affordable and inclusive healthcare solutions for their wider adoption.

The thematic areas under the COE have been strategically designed to ensure that the newly-developed products and technologies synergise with the requirements of the National Health Mission, Ayushman Bharat and other public health programmes. 'ICMR at IITs' are primed to bridge the gap in technology development and commercialisation cycle for a larger public health impact. The strategic indigenous development will slowly reduce the country's dependence on imports by fostering the development of robust state-of-the-art medical devices and diagnostic equipment. The import substitution will pave the way for both Atmanirbhar Bharat and vigorous economic growth.

Director General, Dr. Balram Bharagava upholds that this initiative will have a significant impact on improving access to affordable quality healthcare, particularly for middle and lower-income segments of India. ICMR will ensure large scale implementation of the programme while taking forward the newly-developed technologies for scale-up and commercialisation in public-private partnership through involvement of industries.

Consumers, Beware

Overprescribing of tests is becoming a regular phenomenon

Do You Really Need That Medical Test?

Is the carte blanche use of commonly ordered tests and investigations required or even warranted? Aren't the unnecessary tests just increasing costs and anxiety in patients without yielding any benefits?

VISIT A DOCTOR for a persistent or recurring headache and it is very likely that he will order a CT scan or even an MRI along with certain other 'routine' blood and urine tests. You are happy that the good physician is leaving no stone unturned to find the cause of your ailment.

But is it really needed?

A basic neurological examination with questions about the symptoms and prior injuries can suffice most of the times for ordaining an effective line of treatment. Medical experts themselves opine that a brain imaging CT scan is warranted only after a car crash or other serious accident or in the case of symptoms like confusion, tingling on one side of the body or loss of hearing.

In a similar vein, doctors have become prone to ordering a stress test to measure heart health during routine wellness check-ups even for patients who are at low risk for heart disease. What if the test yields misleading results leading to extensive downstream testing and invasive treatments, not to mention overriding worry and stress?

Even during the ongoing COVID-19 pandemic, we are seeing that doctors are recommending an entire battery of special tests like chest x-ray, CT scan, coagulation test, CRP test and others as a blanket standard of care, even in asymptomatic patients. It is obvious that while these tests are extremely helpful, not every patient needs all of them!

This kind of over-testing, where doctors prescribe more tests than actually needed, leads to unnecessary treatments and expenses. And does anyone ever consider the physical burden on the patients? Imagine an old man having to go through the hassle of drinking multiple glasses of water and waiting to get an ultrasound done with a bladder that is ready to burst. Then there is the agony of being poked again and again with needles to draw blood or having weird instruments inserted in unimaginable places!

Key Role of Diagnostics

Getting the right diagnosis is a key aspect of health care. Medical tests are crucial for detecting a condition, determining the diagnosis and planning the treatment. Doctors also rely on the test results to check if a treatment is working or to monitor the condition over time. In general, around 70% of medical decisions are guided by diagnostic information. What's more, timely tests often save lives too.

Regular health screening is considered essential for the early detection of a health disorder or disease in people who otherwise look and feel absolutely fine. For instance, there may be no outward signs or symptoms, but a routine blood test can reveal diabetes, high cholesterol or hyperthyroidism. The screening can also bring a high-risk condition to light which can be managed with lifestyle changes or medication before it becomes a serious malady. This is exactly why people are advised to get their blood pressure checked at least once a year and women over 25 should get a mammogram and pap smear every two to three years. Specific tests can also be required based on the age, gender and health history of the patient.

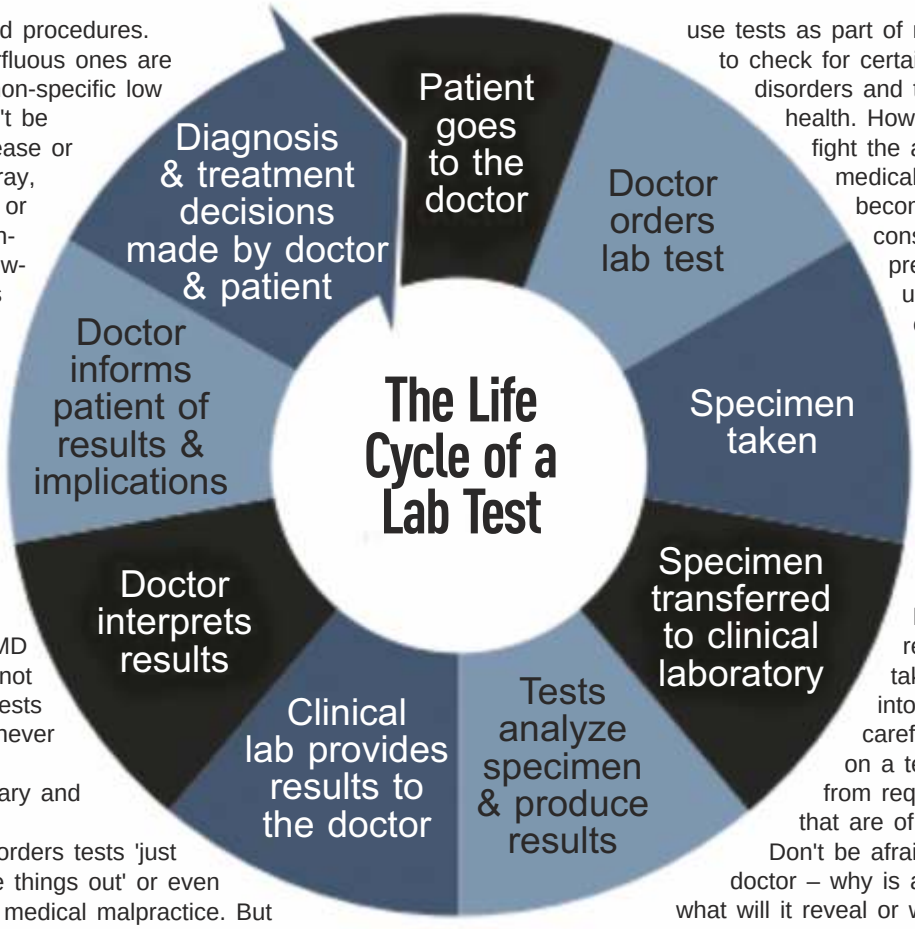
Medical experts themselves opine that a brain imaging CT scan is warranted only after a car crash or other serious accident or in the case of symptoms like confusion, tingling on one side of the body or loss of hearing.

Creating a Mess

Many consumer and medical groups are questioning the need for

different testing and procedures. Some of the superfluous ones are imaging tests for non-specific low back pain that can't be attributed to a disease or condition; chest x-ray, cardiac stress test or imaging before non-heart surgery; follow-up imaging studies for ovarian cysts that are not causing a problem and so on.

President and CEO of American Board of Internal Medicine (ABIM) Foundation, Christine Cassel, MD suggests, “This is not to say that these tests or treatments are never needed. They are sometimes necessary and often overused.”



Many a doctor orders tests 'just to be sure', to 'rule things out' or even as protection from medical malpractice. But this is not just about erring on the side of caution or the fear of missing something. Some of them are going overboard with a runaway system that has no brakes, guardrails or other controls. The over-diagnosing and over-treating can have unethical connotations too in the form of kickbacks or 'commissions' paid by the diagnostic facilities for referrals. The lucrative financial rewards goad the medical professionals to order way too many unnecessary tests.

Not just that, many 'overcautious' patients are worried about their health to the extent that they go to their doctor wanting tests that the latter wouldn't have ordered otherwise. While a few doctors may take the time to explain why the tests are unnecessary, others simply go ahead and prescribe them just to satisfy the patient.

While going overboard with testing is becoming common; the excessive reliance on the reports is also a matter of concern. For instance, when a patient has a rattling chest and is coughing green phlegm, but the thermometer and x-ray of lungs reads fine, the doctor may pronounce that everything is fine and decline the need for treatment/investigation. This may just end up inviting an imminent health disaster.

The Way Forward

It is not like patients should skip the screening or refuse to get the testing altogether. Doctors obviously need to use tests as part of routine check-ups, to check for certain diseases and disorders and to monitor patient health. However, they should fight the approach that more medical care is better and become more conscientious about prescribing unnecessary and expensive tests. There are some conditions when diagnosis and treatment can be done even without ordering a test!

We, as consumers, also have to become responsible and take our health back into our hands. Think carefully before insisting on a test and refrain from requesting treatments that are of little or no value. Don't be afraid to question the doctor – why is a test required and what will it reveal or why a procedure is being scheduled. Like:

- What does he expect to learn from the test?
- How will the test results impact diagnosis and treatment?
- What are the risk factors of the test?
- In case of high risk, are there any alternative ways to get a diagnosis?
- What would happen if you do NOT get the test done?

Discuss your concerns or symptoms with the doctor and make sure that they are taken seriously. Be an active participant in the treatment and make it clear that you wish to avoid unnecessary investigations. Do not hesitate to get a second opinion if needed. Most importantly, if something doesn't seem right, speak up!

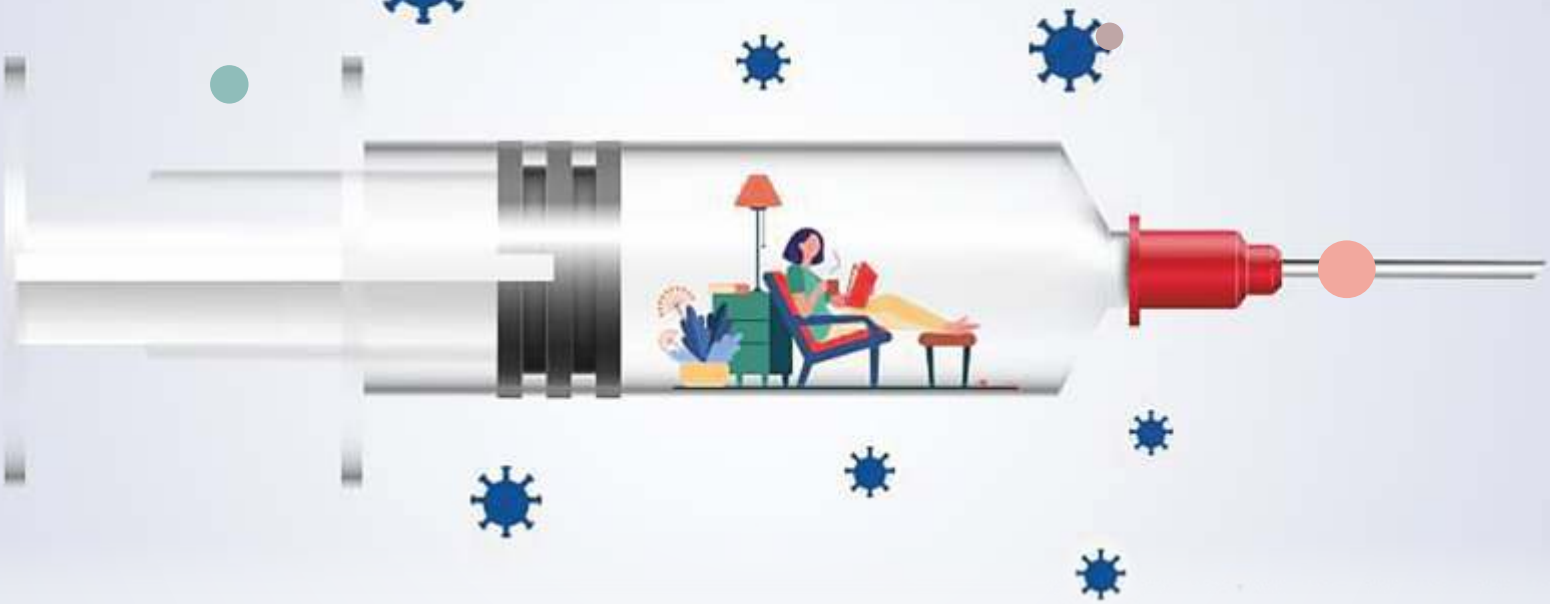
Conclusion

Diagnostic tests have their place and are essential on many counts. It is the lack of ethics and unnecessary difficulty to the patients which is driving the push for 'less is more'! It is easier for doctors to order a blood test than conducting a thorough physical; but testing cannot and should not be considered a substitute for physical examination. Practicing sound medicine by making patient wellbeing the number one priority is the need of the hour….

#LetsBeatCorona

DISPO VAN

THE TRUSTED BRAND PROMOTING PATIENT SAFETY



STAY IN, STAY SAFE!

www.hmdhealthcare.com • info@hmdhealthcare.com

Rajiv Nath

- Mg.Director@ HMD
- Forum Coordinator@ AIMED

"Not every war is won on a battlefield. Some wars can also be won sitting at home."

#Stay**Home**Stay**Safe**

Striving to Reduce Overpricing and Make Testing Accessible

Affordable and accessible diagnostics are central to effective health care. However, Indian healthcare is defined by both inaccessibility and unaffordability of medical testing. The government is attempting to establish cost-effectivity as well as achieve universal health coverage through the National List of Essential Diagnostics and other measures!

Provision of appropriate diagnostics at affordable prices is necessary for ensuring comprehensive healthcare services

THE ECONOMIC SURVEY 2017-18 focussed on the accessibility and affordability of medical diagnostics in India stating that, "Diagnostics are an important part of the healthcare system that provide the information needed by service providers to make informed decisions about healthcare provision related to treatment and management". It further noted that, "Limited affordability and access to quality medical services are among the major challenges contributing to delayed or inappropriate responses to disease control and patient management".

The survey analysed prices of diagnostic tests across various cities in India and revealed that there are wide differences in average prices, that too without any rationale. For example, a lipid profile test costs just Rs. 90 in some cities to a steep Rs. 7,110 in others. An albumin test can be as cheap as Rs. 20 in some cities or as expensive as Rs. 1,810 in others. In a similar vein, 2D echo tests range between a minimum Rs. 500 to a steep Rs. 5200 while liver function tests can cost anywhere between Rs. 100 to Rs. 2500.

It is not just about price disparities and overcharging for the tests. It was also deduced that these hospitals were charging more than private diagnostic centres with profit margins ranging from 100% to 1737% on drugs, consumables and diagnostics. Not only is it common for hospital-based centres to price the tests higher than standalone diagnostic centres, but many of them insist that they will accept in-house reports only!

However, NPPA's hands are tied when it comes to taking action against the errant hospitals. Regulating the cost of diagnostics is also outside the scope of both the NPPA and the central government as only individual states are authorised to take such initiatives. Affordability in healthcare can become achievable if the states adopt the Clinical Establishments Act, 2010 which prescribes transparency in costing.

Accessibility: Another Looming Issue

A 2018 survey on 'Availability of Essential Diagnostics in Primary Care in India' reported gaps in the availability of essential tests for malaria, HIV, hepatitis and other diseases in three states. Other studies also reveal critical lulls in the availability of key diagnostic equipment and supplies – like glucometer, blood glucose estimation strips, needles, urinary protein strips and electrocardiogram machines - at primary health centres and community health centres.

This is leading to serious public health challenges, such as antibiotic overuse and the resultant antimicrobial resistance. Therefore, lack of accessibility to quality diagnosis is another grave obstacle to delivering healthcare to the masses. On the other hand, proper availability can prove valuable for both disease diagnosis and surveillance.

Range In Prices/Average Costs Of Diagnostic Tests Across Cities In India, 2017

Name of Diagnostic Test	Costs of Diagnostics (in ₹)		Average Costs of Diagnostics (in ₹)	
	Minimum (of all cities)	Maximum (of all cities)	Minimum (of average price of cities)	Maximum (of average price of cities
Lipid Profile Test (125)	90	7110	217	759
ANC test (74)	110	6500	389	2396
Albumin test (120)	20	1810	100	203
2d echo test (51)	500	5200	856	2412
Electrolyte test (121)	30	3000	245	627
Liver Function test (117)	100	2500	210	1186
Thyroid test (123)	100	3100	300	721
ESR test (103)	10	1100	35	116
Dengue IgG test (114)	100	3600	315	1312

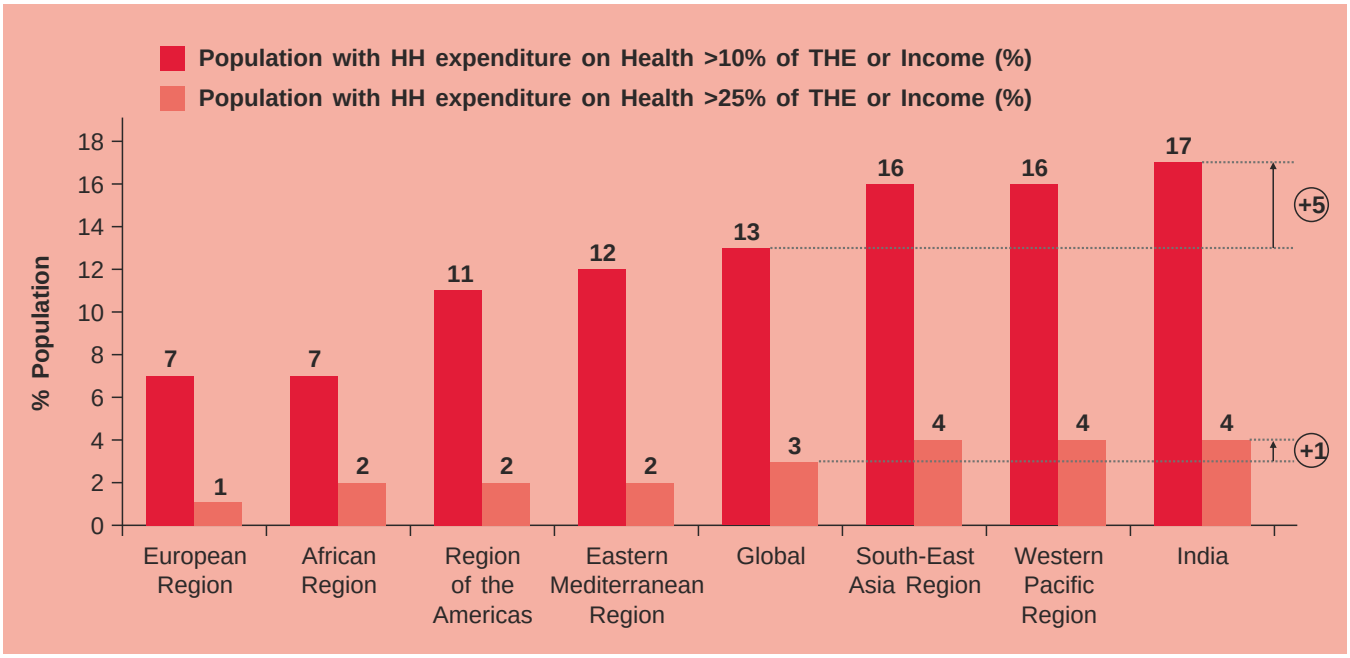
The difference in medical test prices across cities is more than 1000%

Source: Economic Survey 2018

The Economic Survey further observed that the out of pocket expenditure (OoPE) on health services stands at a whopping 62% (NHA 2014-15) which adversely impacts the poorer sections and widens inequalities. With diagnostic tests estimated to attribute around 10% of the OoPE on healthcare, it was concluded that the government needs to standardise prices of medical diagnostic tests to reduce the hefty financial burden on the consumers.

Following the release of the Economic Survey report, the National Pharmaceutical Pricing Agency (NPPA) analysed bills from four major private hospitals in the Delhi-NCR region and found that diagnostic services constitute 15.56% (second largest component) of a patient's bill.

Comparison of Health Expenditure Across Regions



India has one of the world's highest out of pocket expenditure, of which nearly 60% are spent on drugs and diagnostics.

Source: World Health Statistics 2020

Making Reliable and High Quality Diagnostic Testing Affordable and Accessible

Poor investment in diagnostics is responsible for high out-of-pocket expenses on medical testing. The government did attempt to reduce the excessive financial strain by launching the Free Drugs Initiative and Free Diagnostic Service Initiative under the National Health Mission (NHM) in 2015. The latter is geared towards providing essential diagnostics – laboratory and radiology - at all levels of public health care, free of cost. It is being implemented in 24 states through different models like in-house testing, public–private partnership and private providers; the actual number of free tests varies from state to state.

Under this initiative, the central government and the states together make annual investments of about US$175 million to meet the costs of conducting tests, maintaining equipment and consumables (Source: NHM 2020). A guidance document - on how to analyse gaps in existing equipment availability, procurement, management of supply chain, human resource hiring and training, quality control and data management and analysis – was recently provided to the states to assist them in strengthening health-care systems to deliver diagnostics services.

With absence of quality diagnosis forming a crucial gap in the healthcare system around the world, the World Health Organization (WHO) published the first WHO Model List Of Essential In Vitro Diagnostics in 2018to improve diagnosis and treatment outcomes around the world. Comprising of 58 tests (for detection and diagnosis of a wide range of common conditions) to be carried out at primary healthcare centres and 55 tests (for detection, diagnosis and monitoring of priority diseases such as HIV, tuberculosis, malaria, hepatitis) at reference laboratories, this list is designed as an evidence-based reference point for individual countries to formulate their own lists of essential diagnostics.

Since then, the list is being updated every year and the 2021 version includes WHO-recommended COVID-19 tests (PCR and Antigen) and also expands the suite of tests for vaccine-preventable and infectious diseases and non-communicable diseases (such as cancer and diabetes). It has introduced a section on endocrinology that is considered crucial for women's health. For the first time, it has also incorporated tests that should not be supplied - because they are not cost-effective, are unreliable or have been surpassed by newer, easier to use technologies.

> "Access to quality tests and laboratory services is like having a good radar system that gets you where you need to go. Without it, you're flying blind. All countries should pay particular attention to the diagnostics space and use the essential list to promote better health, keep their populations safe, and serve the vulnerable."
>
> *- WHO Director-General, Dr Tedros Adhanom Ghebreyesus.*

India has had a National List of Essential Medicines - a catalogue of medicines whose ceiling prices are fixed by NPPA in accordance with a government order - for the past 25 years; however, diagnostics remained a neglected area. The Indian Council of Medical Research (under the Ministry of Health and Family Welfare) followed the WHO's footsteps to create a similar National List of Essential Diagnostics (NLED) to ensure that the cost of basic diagnostics is within the reach of the common man.

ICMR spearheaded a consultative process with WHO officials, microbiologists, pathologists, radiologists, clinicians, industry representatives, government officials, representatives of civil society and other technical experts. Five meetings were organised over a period of 15 months to deliberate on the latest available evidence of disease burden and the changing healthcare needs so as to reach a consensus on the criteria for which diagnostics are essential as well as how the list will be operated and updated. In the process, glaring gaps where diagnostic solutions for priority health-care conditions are needed were also identified.

The various stakeholders even worked on defining how the list of essential drugs and diagnostics can work in harmony, whether devices and diagnostics should be taken together and how the diagnostics list can be used for price control. However, domestic manufacturers opposed regulating the cost of diagnostics and called for a transparent mechanism that will promote competition in diagnostics.

The National Essential Diagnostics List was released in 2019 for all levels of healthcare – village level, primary, secondary and tertiary care. With this, India became the first country in the world to compile and release such a list. It is noteworthy that the diagnostics list has been customised to suit the landscape of our country's healthcare priorities.

The NEDL is comprehensive and ambitious. It incorporates:

- 117 general laboratory tests for routine common conditions and for the diagnosis of communicable and noncommunicable diseases. These are grouped in categories like haematology, clinical pathology, biochemistry, microbiology and serology.
- 29 disease-specific tests for HIV, hepatitis, tuberculosis, dengue, malaria and area-endemic diseases.
- 24 imaging tests such as x-rays, computerised tomography scans, magnetic resonance imaging scans and ultrasound sonography.
- Point-of-care diagnostics like rapid blood glucose, digital haemoglobinometer and cardiac biomarkers have been listed.
- Certain tests are classified as desirable tests and should be included in regions or states with high disease burden of that disease.
- Medical tests relevant to new programmes such as Health and Wellness Centres (HWCs) under the Pradhan Mantri Jan Arogya Yojana have been included.
- In Vitro Diagnostics products corresponding to the tests done on blood and tissue samples are also recommended.
- A list of human resources - ASHA workers, lab technicians and pathologists for different levels of health care – are specified based on the list of diagnostics.
- Guidance document on 'Regulatory Framework for Diagnostics: National and International' is available.

Moreover, separate lists have been prepared for each type of facility – subcentre/HWC, primary health centre/HWC, community health centre, sub-district hospital and district hospital based on the utility and requirement of tests at that level, infrastructure, training available or proposed to be made available through other initiatives. The list specifies the:

- **Test category:** Category/discipline to which the test belongs
- **Specimen type:** Types of specimen(s) that can be used for the test
- **Product/equipment:** Product/equipment on which the test is best conducted

The National List has been strategically harmonised with the Free Diagnostics Service Initiative, the Indian Public Health Standards and various disease-control programmes undertaken by the Ministry of Health to provide an expanded basket of tests in the public health system while seeking to deliver improved patient outcomes.

It is hoped that the list will not remain a sterile document and will be optimally implemented at the ground level in a way that it improves evidence-based patient care, increases affordability of tests, promotes effective utilisation of public health facilities, helps detect outbreaks, reduces antibiotic abuse, addresses the antimicrobial resistance crisis, improves regulation and quality of diagnostic tests, strengthens accreditation and quality of laboratories, improves the supply chain and inspires new research. The government should periodically revise the list of essential diagnostics and also regulate their prices.

The list is primed to homogenise availability of diagnostics is the country.

"A list will help manufacturers like us, to know exactly where to focus our research and development time and resources. Moreover, a list will help us build an economy of scale where we can make profits by selling diagnostics in bulk to the government"

- Chandrashekhar Nair, Molbio Diagnostics

National Essential Diagnostics List (NEDL)

- **India has got its first National Essential Diagnostics List (NEDL).**
- **It is finalised by the Indian Council of Medical Research (ICMR).**
- **It aims to bridge the current regulatory system's gap that do not cover all the medical devices and in-vitro diagnostic device (IVD).**

Existing Challenges and Loopholes

The ICMR identified the following challenges in the implementation of the NEDL:

- Adoption by states and harmonisation with local standard diagnostic protocols and treatment guidelines.
- Provision of requisite infrastructure, processes and human resources.
- Ensuring quality of tests including External Quality Assurance Scheme and quality control.
- Adequate utilisation of NEDL tests for making informed decisions for treatment protocols.

Moreover, the list seems to have overlooked point-of-care rapid tests for the detection of typhoid and other infectious diseases. In their article on 'Introducing a National Essential Diagnostics List in India', authors Sonam Vijay, Raman R Gangakhedkar, Chander Shekhar and Kamini Walia point out that, "To harness the full potential of the evolving diagnostics landscape, a separate Diagnostics Working Group should develop a national strategic plan focusing on research and policy on diagnostics. Such a working group could facilitate the creation of regulatory frameworks for diagnostics and laboratories; provide a pathway for the evaluation of available diagnostics for their uptake in the health-care system; and formulate a process for periodic updating of the list. These three tasks would ensure an optimal use of existing diagnostics as well as timely uptake and use of innovations in diagnostics."

Conclusion

The prices of common diagnostic tests are not only steep, but also tend to vary significantly from one hospital/diagnostic centre to another based on factors like utilisation levels, source of financing, etc. What the healthcare sector needs is a price range based on acceptable methodology to promote rational use of diagnostics. The focus has to be on keeping rampant profiteering in check while increasing access to affordable healthcare.

Assessing the Laboratory Diagnostic Industry in India

A Healthcare Federation of India – NATHEALTH study highlights the crucial role played by laboratory diagnostics in improving accessibility, affordability and accountability in Indian healthcare while reporting that the industry suffers from limited focus on quality standards.

DIAGNOSTICS FORM A central pivot in responding to the challenges of both communicable and non-communicable diseases. The growing importance of evidence-based medicine has given a major impetus to the industry – it has evolved from being just an investigation provider to a solution provider and offers a wide array of up to 4500 tests (as per industry discussions) and counting. A majority of medical tests done globally today are also offered in India. With the focus shifting from curative care to preventive care, diagnostics are taking centre stage and are increasingly performed in prevention and wellness!

The NATHEALTH 'An Assessment of India's Laboratory Diagnostic Industry' study - released by Dr. Vinod Paul, Member (Health), NITI Aayog during the 6th Annual Summit of the Federation in December 2019 – stresses on the undeniable fact that a robust and vibrant medical diagnostics industry is a fundamental requirement to achieve the vision of universal health coverage (UHC) and the Sustainable Development Goals (SDGs).

Importance of a Robust Diagnostics Industry

The study states in unequivocal terms that diagnostics have a conclusive impact on both early detection of ailments and the care continuum; they provide the rationale for screening and detection of diseases at an early stage, prognosis, determination of treatment regime and monitoring of patients. Diagnostic tests form the basis of medical decision making, thus reducing the spend on trial-error treatment, hospital stay and over-prescription of medicines.

It further reveals that while operating at only 4% to 5% of the total healthcare expenditure, the medical diagnostics industry influences the remaining 95% of the cost. Around 70% of medical decisions regarding early disease diagnosis, patient prognosis and treatment selection are based on laboratory diagnostic results. Along with treatment regime selection, diagnostic test results help in monitoring the patient condition during

5% Spend on diagnostics as a percentage of total current healthcare expenditure

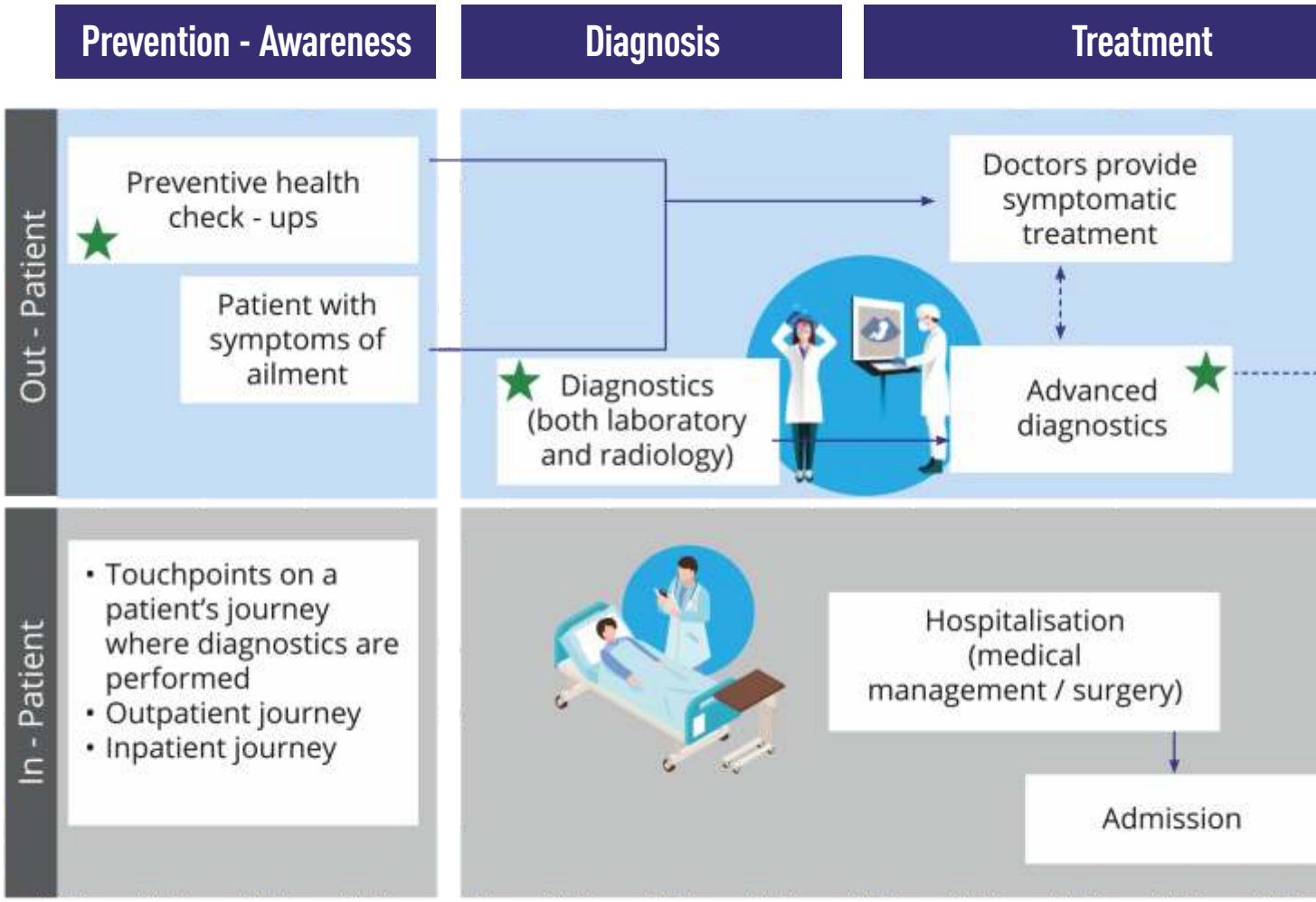
70% of medical decisions are based on lab results

25% Ratio of average revenue per customer in a diagnostics lab and average hospitalisation cost

Laboratory tests contribute 80% of the objective data in clinical records

Accounting for a minor share of total healthcare expenditure, diagnostics help limit overall healthcare expenditure

Diagnostics are a crucial part of a patient's journey as 70% of medical decisions are based on laboratory results



★ Touchpoints on a patient's journey where diagnostics are performed

recovery and follow-up. With these multiple touchpoints, laboratory tests contribute 80% of the objective data in clinical records. In modern medicine, with data analytics and artificial intelligence taking centre stage, these clinical records will help in predictive analysis and disease prevention as well.

Industry Dynamics

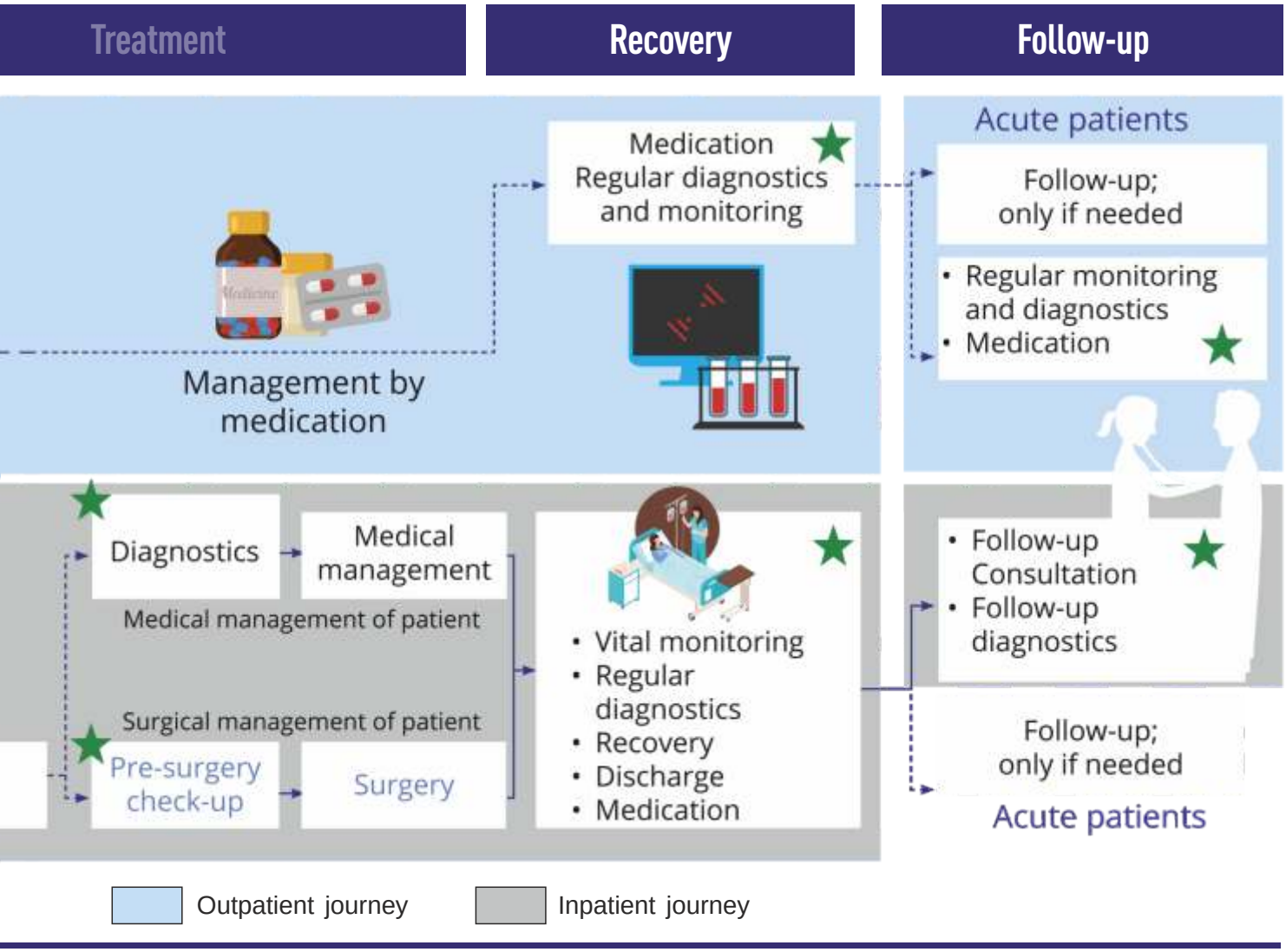
The Indian laboratory diagnostics industry was estimated at USD 5 to 6 billion with more than one lakh labs in operation just before the beginning of the pandemic and expected to grow at a CAGR of 13% to 14%, which is higher than the overall growth rate of the healthcare industry.

However, it is clear that the industry is highly fragmented and non-standardised - there are multiple delivery formats, with no single market leader or monopoly in the system. The largest of the organised players has a market share of less than 5%.

Furthermore, patient centricity is taking a front seat in medical diagnostics with innovative measures like collection centres and home sample collection, reduced turnaround time for report generation and rapid alerts to customers.

Affordability

The Indian diagnostic industry operates at one of the lowest price points in the world. The uninsured rates for lab tests in the USA and New Zealand are around eight times and two times the test prices in India respectively. Even when



compared with under-developed countries, lab test prices in Kenya and Rwanda are around four times and two-and-a-half-times those in India respectively (refer image 1).

Availability

Almost all the tests of modern medicine are available in India. With their focus on high-end tests and advanced diagnostics, the national diagnostic chains have even been able to limit the number of samples going out of the country. The latest medical technologies, skilled doctors and availability of specialised diagnostics have helped India consolidate its position as a preferred destination for high-end medical tourism, including oncology, transplants and cardiology (refer image 2).

Accessibility

Diagnostics chains are making healthcare geographically accessible by enabling access to modern diagnostics facilities even to people living in remote areas. An analysis of the geographical presence of labs and sample collection centres of three of the largest organised chain players in the private sector reveals that more than 50% of the districts identified by NITI Aayog as aspirational districts and lacking most in terms of basic infrastructure are being served by one of these three players (refer image 3).

Quality

It cannot be denied that the quality of the tests has improved over the years with more automation and more

Indexed laboratory prices in India vs the USA, New Zealand, Kenya and Rwanda					
	India	USA	New Zealand	Kenya	Rwanda
Urine culture	1.0	5.7	1.9	2.6	1.6
T3 (free)	1.0	9.5	3.1	10.4	3.5
T4 (free)	1.0	9.5	3.1	10.4	3.5
HIV I and II AB screening	1.0	13.6	2.2	1.1	3.3
Prolactin	1.0	74	2.8	3.3	3.0
Quantitative HcG	1.0	9.0	1.9	2.5	2.3
PSA (total)	1.0	5.1	1.1	2.6	2.3
LFT	1.0	4.8	3.0	3.5	3.3
Lipid profile	1.0	14.9	1.5	1.5	1.2
HCV Ab	1.0	2.8	0.8	1.3	1.3

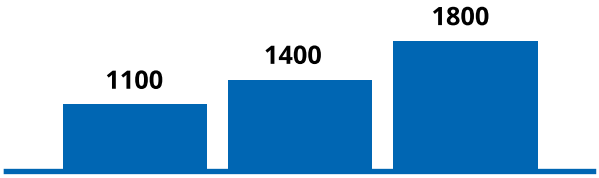
Prices of lab diagnostic tests in India are amongst the lowest in the world (Image 1)

Test menu India

~3,500–4,500 ------ **Test menu provided by top diagnostics centres in India**

The test menu has increased rapidly in the last 5 years

Increase in specialised test menu (2010–2018)

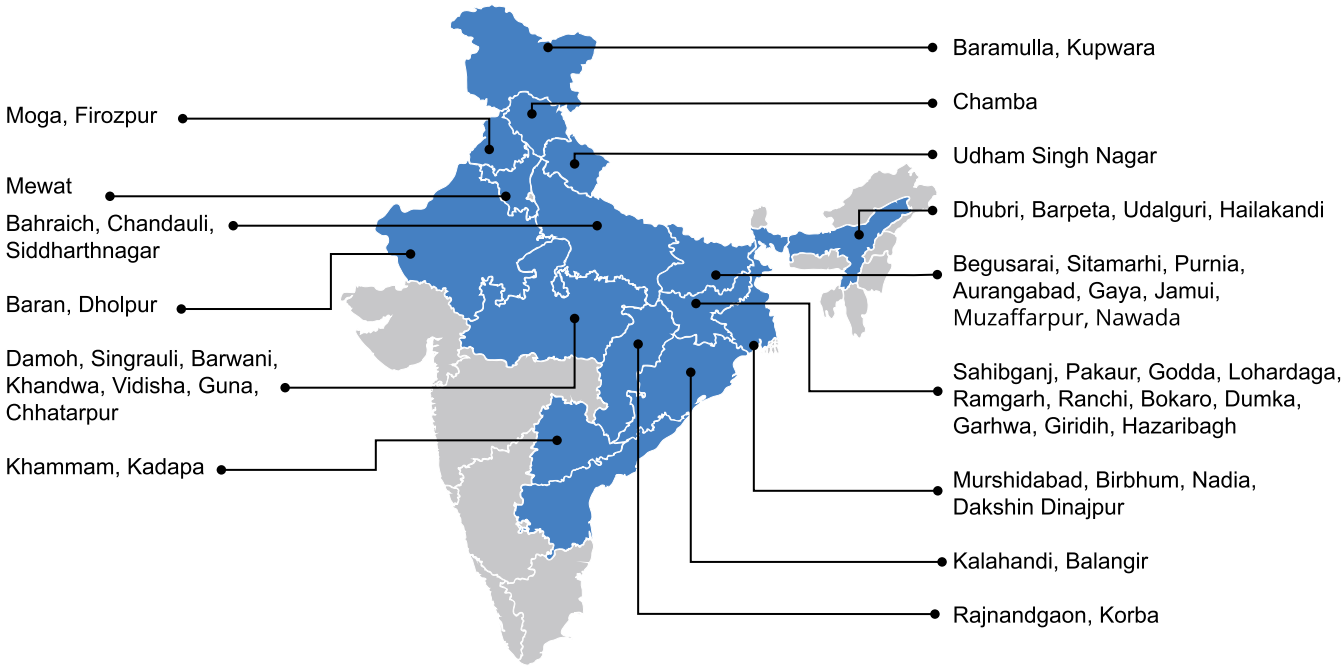


Specialised tests

Molecular diagnostics, flow cytometry, genetics/ cytogenetics and histopathology among others

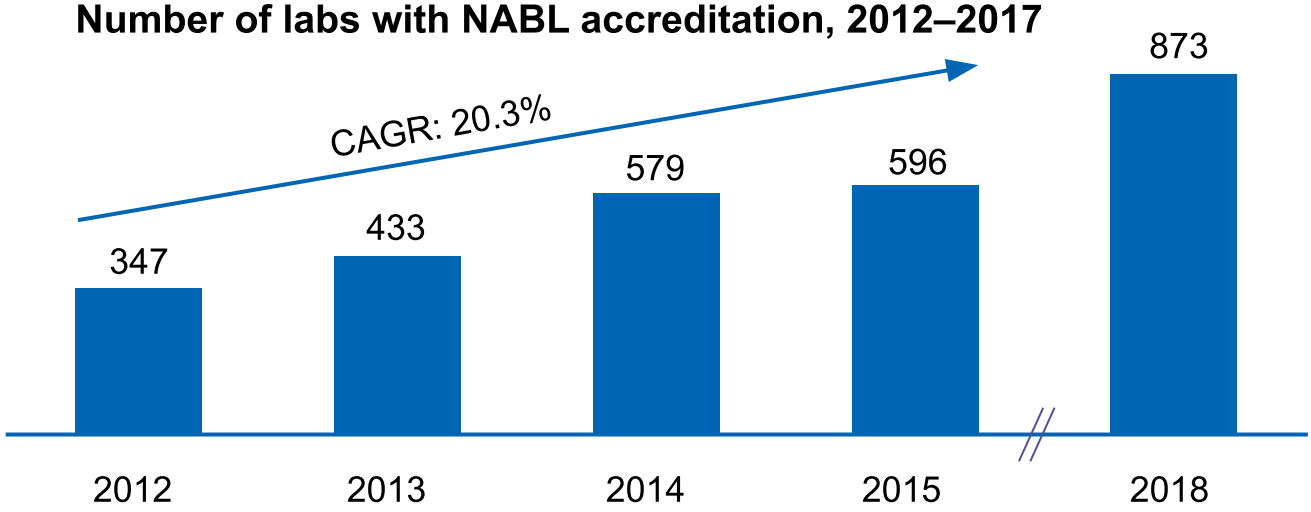
National laboratories are moving towards high-end tests and advanced diagnostics and pathology *(Image 2)*

List of the most backward districts of India where laboratory services are made available by one of the three leading laboratory chains in India



Even the most backward districts have ready access to modern diagnostics (Image 3)

Number of labs with NABL accreditation, 2012–2017



The number of labs with NABL accreditation increased at a CAGR of around 20% between 2012–2017 (Image 4)

Update

The government's move to restrict COVID-19 testing to accredited labs has given a boost to accreditation and there are more than 2240 NABL accredited medical testing labs (as on 30th November 2021) that ensure trustworthy test results. However, this still remains a drop in the humungous ocean of private laboratories in the country.

Snapshot of the Indian diagnostics market

Multiple delivery formats
- Total number of labs 100,000–110,000
- Delivery formats; Hospital labs, stand-alone labs, national chains, regional chains

High fragmentation
- Market dominated by stand-alone centres
- Low focus on accreditation, especially in the unorganised sector

High growth rate
- Market size: USD 5–6 billion
- CAGR: ~13–14% higher than overall healthcare industry growth

Key characteristics of the Indian lab diagnostics market

1. Large number of firms
2. Free and fair competition
3. Large number of buyers
4. Low entry and exit barriers
5. No proprietary knowledge no proprietary ownership of any medical tests
6. Factors of production (labour, capital, entrepreneur and land) are freely mobile
7. Market governed by forces of supply and demand

The market is governed by forces of supply and demand, with service quality and pricing driving market success.

sophisticated tests being performed. Laboratories are going for accreditation and deploying some of the best standards like CAP accreditation, NABL and ISO certification. However, less than 1% of the labs were NABL accredited before the pandemic (1039 as of 1st March, 2020), a majority of them being hospital-associated labs or labs from regional/national diagnostics chains (refer image 4).

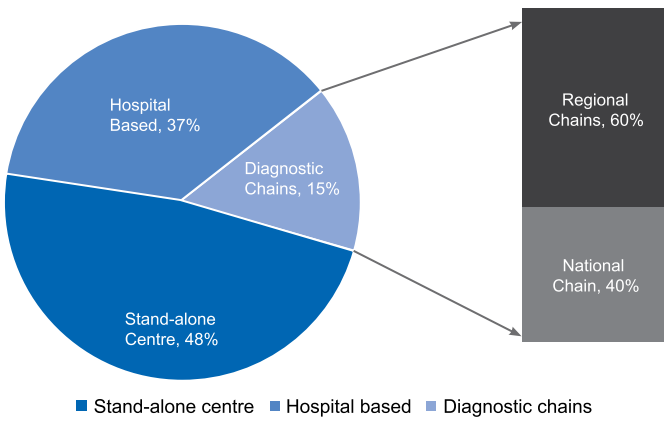
The landmark study concludes that given the right impetus, the industry can play an important role in the health and economic well-being of the country by:

- Creating job opportunities
- Increasing access to diagnostics
- Becoming a diagnostics centre of excellence in the region
- Providing entrepreneurship opportunities
- Offering advanced personalised test menu
- Increasing trained and highly skilled manpower
- Ensuring the success of Ayushman Bharat

Interpretations

Ayushman Bharat is a significant step towards achieving the goal of UHC. The medical diagnostic industry can play a key role in the realisation of this goal. However, the study construes that the industry suffers from cost

Break-up of the Indian diagnostics laboratory market by provider type



Source: Industry discussions

pressures driven by high custom duty and the Goods and Services Tax (GST) structure.

Commenting on the findings of the study, Dr Sudarshan Ballal, President, NATHEALTH observed, “A robust diagnostic ecosystem is critical for the success of schemes like Ayushman Bharat”. Highlighting how making efforts to establish minimum quality requirements, ease

Partnering together for a Healthy India

Industry Ask	Rationale	Call to Action By Govt.	Projected Impact
Minimum quality standards	• Undefined standards leads to varying levels of quality and clinical standards compliance. Defining the minimum norm will help patients avail quality diagnostic services.	• The government should push for the minimum quality standards, thus ensuring the availability of quality diagnostics facilities.	• Improved quality of diagnostics
Reduction in Customs Duty	• High customers duty leads to higher equipment cost which in turn results in higher price to patients.	• High custom duty on the import of diagnostic equipment has to be borne by providers. The government should collaborate with the industry to lower custom duty so that this benefit can be passed on to patients.	• Opening of more number of labs • Reduction in prices • Large employment opportunity
GST Benefit	• Healthcare industry including diagnostics is today unable to claim the benefit of input tax credit under GST.	• The government and industry should collaborate to ensure that the industry benefits from GST while easing the cost burden on providers.	• Lower cost burden on providers which in turn will facilitate reduction in prices for patients.
Partnership for Ayushman Bharat – Health & Wellness Centres	• Govt. has announced 1.5 lakh health & wellness centres which will offer diagnostic services. The expertise of the private sector could be leveraged to provide quality diagnostics at an appropriate cost to the exchequer.	• Evaluate models for partnering with the diagnostic companies w.r.t. the Ayushman Bharat – Health & Wellness Centres.	• Access to quality diagnostics for a large segment of population from certified labs • Could lead to lower costs for the Govt.

custom duty and extend input tax credits for GST can expedite the journey, he further emphasised that, “Such policy measures would support the diagnostic segment to ensure that the benefits of quality diagnostics and wellness can be delivered to the country as a whole.”

In sum, there are hardly any rules or regulation governing the laboratory diagnostic industry. This coupled with the lack of strict entry barriers to the industry has led to the mushrooming of diagnostic labs of questionable quality in every nook and corner of the country. Unfortunately, this unorganised sector – which fails to follow protocols and lacks accreditations – is dominating the industry. There is also a lack of price standardisation causing high level of discrepancies between diagnostic test prices.

Furthermore, the Ken Research report on 'India Diagnostic Laboratories Market Outlook to FY - 2025' also draws attention to the highly fragmented structure of the industry while stressing on the dire need for strict regulations to bring about uniformity along with high quality testing standards.

Dr. Navin Dang, owner of a leading NABL-accredited laboratory chain in New Delhi said, “The medical laboratory industry in the country is a jungle without any rules where every Tom, Dick and Harry can open a shop and play with the trust and lives of vulnerable patients. This is essentially due to a complete lack of enforcement anywhere. Things won't change unless accreditation is made mandatory rather than voluntary.”

> “There is no stratification of labs and there is lack of awareness. People don't know the difference between an accredited lab and any other lab. That is because there is no legislation around it. We are competing with the mom and pop shops, hospital-based labs, as well as larger players and the only comparison people have is on cost.” - Sanjay Arora, Founder and Managing Director of Suburban Diagnostics which spends more than Rs. 1 crore per year to maintain its accreditation.

Conclusion

The Clinical Establishment (Registration and Regulation) Act did seek to regulate the pathology and imaging laboratories, but it seems to be left in cold storage. Going forward, the government and industry should join hands to work towards a healthy India!

Smart DIAGNOSTICS

– Kickstarting a Healthcare Revolution

Diagnostics is becoming more intelligent by the day with technological enablement, digitisation and automation becoming the defining factors. Digital technologies will become the potential game-changer that will drive the next generation of patient-centric personalised medicine.

DIAGNOSTICS ARE THE backbone of delivering effective health care and the invaluable role of technology in laboratory medicine cannot be denied. New-age technologies are driving innovative advances in medical testing with Artificial Intelligence (AI), Machine Learning (ML), Internet of Things (IoT), big data and cloud computing being incorporated into laboratory products and concepts, thus making diagnostics more efficient, convenient and personalised. Additionally, portable devices, point-of-care testing and telemedicine are revolutionising both access to diagnosis and healthcare. Smartphone-based detection technology is further pushing a paradigm shift towards smart and connected health monitoring.

Almost every mobile user today has downloaded at least one of the thousands of healthcare apps!

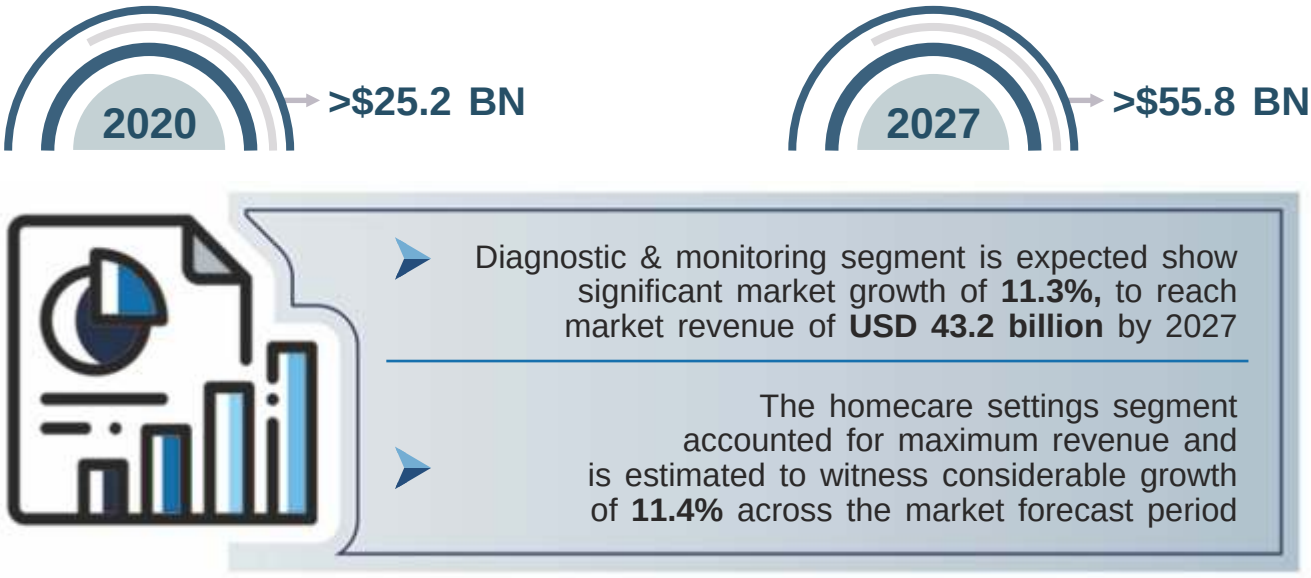
The advancements range from ease of use and improved sensitivity to rapid results to higher accuracy in interpreting the outcomes. Indeed, tests which used to take hours of a pathologist's time can now be done in minutes. It is now possible to investigate hitherto unknown pathogens and even track new disease outbreaks.

A revolution of digital technologies is on the horizon with smart devices poised to transform diagnostics

In fact, the COVID-19 pandemic has given a further fillip to diagnostic technologies with innovative testing solutions for detecting the SARS-CoV-2 virus being developed at exceptional speed. Home rapid test kits are already becoming the norm now and point-of-care RT-PCR tests are in development. Worldwide, scientists are working on developing smart biosensors to quickly and instantly detect the infection - promising solutions like breath fingerprinting, plasmonic-based biosensor and touchless remote monitoring sensor are being reported every day. Digital technology is also supplementing laboratory notification by way of symptom-based online case identification, self-assessment mobile phone apps and more.

Let us take a look at some of the digital diagnostic trends that are transforming the future of healthcare:

- **Point-of-care testing solutions –** At-home diagnostics are simplifying testing and analysis procedures even while facilitating better disease diagnosis, monitoring and management. It reduces travel time for both samples and results. Moreover, the results are stored in a secure digital environment which can be accessed by healthcare providers. What started with pregnancy kits and handheld blood glucose level, blood pressure and cholesterol measurement devices has expanded into innovative digital devices for monitoring heart diseases and providing ECG reports via phone adaptors.Pulse oximeters have become common in every household in the pandemic era!
- **Real-time diagnostics -** Wearable biosensors are all about collecting physical health information in 'real-time' for continuous monitoring as opposed to the 'snapshot' view of traditional tests, setting the stage for integrated care. The devices range from watches, glasses, contact lenses, rings, clothing and bandages to implantable and even ingestible devices (smart pills) that are designed to constantly track the heart rate, blood pressure, skin temperature, respiratory rate, body motion and other physiological indicators in an intelligent manner. The robust data can instantly flag any irregularities and provide feedback leading to quick and better clinical decisions. In fact, there is an increasing preference for wearable devices like fitness trackers for monitoring vital health parameters. Some can even provide basic dietary and exercise activity guidance to users.
- **Personal genetic analysis –** The blood, hair, skin or other tissue samples of a person can be used in predictive genetic tests to identify the risks of developing genetic disorders in the future. Predicting future risks before the symptoms appear can even prove to be lifesaving.
- **Artificial intelligence diagnosis –** Artificial intelligence and even machine learning-based systems are being used to drive laboratory automation. The technology can interpret imaging and pathology results with a far greater accuracy than human experts, thus accelerating reading time and automatic prioritising of urgent cases.



Computer algorithms have been designed to analyse pictures of skin rashes and send diagnosis and treatment options to patients via e-mail or SMS. However, acceptance remains low in the medical community with both radiologists and doctors being sceptical and distrusting about the algorithmic advice. Better integration of the AI tools with human decisionmakers is imperative.

- **Clinical decision support solutions –** These tools are designed to sift through enormous amounts of digital data to work out the context and meaning of the test output. They also support in suggesting next steps for patient treatment, provide helpful alerts about available information and can even identify potential problems like dangerous drug interactions, thus paving the way for expert advice and informed actions based on algorithms. This improves diagnosis accuracy, reduces incidence of missed diagnosis/misdiagnosis, and enables timely medical treatment leading to better patient outcomes.
- **Telemedicine –** Smart devices are also supporting telemedicine by enabling remote monitoring of vitals in patients, something which became paramount during the COVID-19 waves and lockdowns.

The medical fraternity is embracing new-age technologies across streams – from monitoring gastrointestinal disorders to psychiatric analysis to neurodegenerative disease management. The primary transformational changes across the emerging technologies is the immediate access to health data for the patients and timely sharing of vital information for the healthcare providers. The patients become empowered and can be actively involved in their treatment decisions. At the same time, it can even relieve some of the capacity pressures on the laboratories, especially the shortage of qualified and trained pathologists.

The Future is Beckoning

The use of digital technology is still in the infancy stage and new advancements hold the promise of more cutting-edge diagnostic tools to assist and improve diagnosis.

As per estimates from a recent report by Global Market Insights, the global smart medical devices market – comprising of connected biosensors, wearables and implantables, smartphone-enabled diagnostics - is expected to grow at the rate of 11.3% between 2021 and 2027 and will surpass $55.8 billion by 2027.

Indian diagnostics labs provide employment to around 0.8 million people and have the potential to create a similar number of jobs in the next 10 years given the right stimulus

Conclusion

The growing assimilation of digital technology in diagnostic testing is catalysing both improved patient experience and outcomes by enhancing the speed and efficiency of the testing process. The challenge now is to make healthcare more accessible and affordable so that technology can truly deliver benefits to the consumers. But a note of caution is also essential as blindly trusting the technology can lead to medical errors.

CONSTANT DEVELOPMENT OF REGULATIONS FOR DIAGNOSTIC AND MEDICAL DEVICES

India has a streamlined and integrated regulation for medical devices (including diagnostics) under the umbrella of drugs

Over the years, the Government of India has inculcated a series of rules and regulations for the medical devices, diagnostics and equipment in the country. With various other measures to support the manufacture and use of diagnostics, the stage is set for a quality-driven, safety-led, performance-oriented, transparency-focused and self-sufficient diagnostic sector!

MEDICAL DEVICES PLAY a critical role in ensuring a holistic and properly functioning healthcare system – they protect public health by diagnosing, preventing, monitoring, predicting, treating and alleviating various illnesses apart from assisting people with physical impairments to improve their quality of life. The range of medical devices is very broad - including diagnostics and equipment - and is constantly evolving as new devices emerge. It follows that the quality and efficacy of these medical devices should be regulated at all levels of the supply chain to ensure safety to the patients.

The import, manufacture, sale and distribution of medical devices are governed by the provisions of the Drugs & Cosmetic Act 1940 and Rules 1945 in India. The scope of this law is restricted only to the specific medical devices which are notified by the Government from time to time as 'drugs' (commonly referred to as 'notified medical devices').

While only disposable syringes, needles and perfusion sets had been notified in 1989, some more were identified for regulation akin to a drug through periodic notifications. Yet, no clear medical device regulations existed in India prior to 2005 when 10 more sterile devices were notified under the Act. It was in 2007 when the Drug Controller General of India (DCGI) formulated a new set of guidelines for the manufacture and import of medical devices in the country.

The year 2017 marked a new era in the regulation of medical devices when the Ministry of Health & Family Welfare (MOHFW) overhauled the medical device regulatory process by notifying the Medical Device Rules, 2017 under the Drugs & Cosmetics Act, 1940. Coming into force on 1st January, 2018, medical devices are regulated by the Central Drugs Standard Control Organisation (CDSCO), the apex drug regulator under the MOHFW.

The Rules are framed in alignment with the WHO Global Model Regulatory Framework for Medical Devices (including IVDs) and adhere to the stepwise approach to regulating medical devices based on guidance documents developed by the Global Harmonization Task Force (GHTF) and the International Medical Device Regulators Forum (IMDRF). They lay out comprehensive quality requirements and other special regulations to be followed by manufacturers, marketers, sellers and importers of notified medical devices.

At the same time, the medical devices were also classified based on their intended use, risk profile and other parameters:

Class A – Devices with low risk

Class B - Devices with low to moderate risk

> "The Medical Device rules are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices, which will foster 'Make in India' also. Any Medical Device which is being marketed in India should comply with the Bureau of Indian Standards (BIS) or as notified by the central government. If both of them are unavailable, then International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and ASTM International are there for standardisation of medical devices." - *O S Sadhwani, Former Joint Commissioner & Drugs Controller, FDA – Maharashtra*

Class C - Devices with moderate to high risk

Class D – Devices with high risk

This classification system dictates how the device is regulated - Class C and D devices subject to more stringent regulations than Class A and B devices. This gave manufacturers some much-needed clarity on the design and material-related risk assessment and management.

On 8th February, 2021, the health ministry further notified eight medical devices – including implantable medical devices, CT scan equipment, MRI equipment, defibrillators, dialysis machines, PET equipment, x-ray machines and bone marrow cell separators as 'drugs'– and brought them under the purview of the Drugs and Cosmetics Act, effective from April 1, 2020

There were rising concerns about the safety, quality and performance of the majority of medical devices that were largely unregulated and outside the purview of the law. Various stakeholders kept pushing for regulating all non-notified medical devices.

On 11th February, 2020, the Drugs Technical Advisory Board (DTAB) - India's highest advisory body on drugs – decided to finally bring all medical devices under the fold of quality and safety regulation. The Ministry released two notifications:

- A new comprehensive and all-inclusive definition of medical devices which brings all medical devices (including both imported and locally manufactured implantable and diagnostic devices) under the ambit of the regulatory framework for quality control and price monitoring.
- The Medical Devices (Amendment) Rules, 2020 (to come into effect from 1st April, 2020) requiring the initial registration (and subsequent licensing) of the medical devices.

NATIONAL CONSUMER DAY

This year the Department of Consumer Affairs celebrated National Consumer Day in hybrid mode on 24th December with the theme 'Consumer – Know Your Rights'. Minister of Consumer Affairs, Mr. Piyush Goyal released e-books on Mediation, E-Filing before Consumer Redressal Commission, Landmark Judgments on Consumer Law and Practice, etc. The day-long event witnessed informative and interesting panel discussions on misleading advertisements, new initiatives in Legal Metrology Act, 2009 and recent initiatives in hallmarking among others.

The team at Aware Consumer would like to suggest that the government release the theme well in advance so that consumer protection organisations can work on it accordingly!

Till February, 2020, only 37 categories of medical devices were regulated or were notified to be regulated in the near future

1. Disposable Hypodermic Syringes;
2. Disposable Hypodermic Needles;
3. Disposable Perfusion Sets;
4. Substances used for in vitro diagnosis including Blood Grouping Sera;
5. Cardiac Stents;
6. Drug Eluting Stents;
7. Catheters;
8. Intra Ocular Lenses;
9. I.V. Cannulae;
10. Bone Cements;
11. Heart Valves;
12. Scalp Vein Set;
13. Orthopedic Implants;
14. Internal Prosthetic Replacements;
15. Ablation Devices;
16. Ligatures, Sutures and Staplers;
17. Intra Uterine Devices (Cu-T)
18. Condoms;
19. Tubal Rings;
20. Surgical Dressings;
21. Umbilical tapes;
22. Blood/Blood Component Bags;
23. Organ Preservative Solution;
24. Nebulizer (effective from 1 Jan. 2021);
25. Blood Pressure Monitoring Device (effective from 1 Jan. 2021);
26. Glucometer (effective from 1 Jan. 2021);
27. Digital Thermometer (effective from 1 Jan. 2021);
28. All implantable medical devices Equipment (effective from 1, April, 2021);
29. CT Scan Equipment (effective from 1, April, 2021);
30. MRI Equipment (effective from 1, April, 2021);
31. Defibrillators (effective from 1, April, 2021);
32. PET Equipment (effective from 1, April, 2021);
33. X-Ray Machine (effective from 1, April, 2021);
34. Dialysis Machine (effective from 1, April, 2021);
35. Bone marrow cell separator (effective from 1, April, 2021);
36. Disinfectants and insecticide specified in Medical Devices Rules, 2017;
37. Ultrasound equipment (effective from 1, November, 2020).

This Amendment introduced two changes:

- Registration of Newly Notified Medical Devices by their respective manufacturers and importers.
- Exemption for the 37 categories of already regulated or notified medical devices from the requirement of registration. They can carry on business based on the license issued by the appropriate licensing authority.

This move will finally bring quality, certification and pricing of medical devices under the purview of the government, thus ensuring that they are safe and conform to quality standards and will be subject to an annual price increase of 10%.

The prime feature is the mandatory registration and licensing requirement (from the appropriate licensing authority) before undertaking any business in notified medical devices. A dedicated online registration portal - Online System for Medical Devices – has been established by the CDSCO while license application is streamlined through another online electronic platform.

The registration process entails submitting the name and address of the company, the address of the manufacturing sites, device details, ISO 13485 certificate accredited by the National Accreditation Board for Certification Bodies or International Accreditation Forum. Once the device is registered, a registration number is generated which has to be mentioned on the label of the device. Registered importers and manufacturers have to strictly conform to their documented quality management system.

A license is issued after third-party quality checks and the license holder's business premise is subject to periodic inspection. Licensees are mandated to maintain detailed records of the sale-purchase of notified medical devices and ensure traceability in the event of a quality/safety-related failure or complaint. The licensing authority can also verify the documents any time and investigate failures or complaints. The CDSCO is authorised to even suspend registration or cancel licences.

The registration of the newly notified medical devices was kept voluntary for an 18 month period (till 1st October, 2021). Post registration, manufacturers and importers have a window of 36 months for Class A and B devices and 42 months for Class C & D devices for acquiring the requisite license. All compliance provisions of the Medical Devices Rules 2017 will apply to the respective devices on the expiry of these time periods. This period between registration and licensing can be used to iron out existing manufacturing issues in quality, capacity, logistics and supply chain to ensure full compliance for getting the license.

Medical devices that are not registered by the due date cannot be marketed or sold in India until a registration is obtained. Failure to obtain a license within the prescribed period can lead to criminal prosecution resulting in imprisonment and monetary fines. Any stock of medical devices that are sold without registration or license can be confiscated.

This kind of double verification – registration followed by license - will bring a robust verification regime into

Class of medical device	Licensing Authority	Stipulated timeline for processing application	Deadline for obtaining license
Class A and B (import)	DCGI	Up to 9 months from the date of application	August 11, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	August 11, 2023
Class A (manufacture)	State-level Licensing Authority	Up to 45 days from the date of application	August 11, 2022
Class B (manufacture)	State-level Licensing Authority	Up to 140 days from the date of application	August 11, 2022
Class C and D (manufacture)	DCGI	120 - 180 days (estimated)	August 11, 2023

It is not mandatory to have a registration number in order to obtain a license

play while incentivising new players. ISO 13485 being the standard for quality management system for designing and manufacturing a medical device, this certification requirement further equips indigenous manufacturers to access and compete in the world market where they will be treated on par with leading global companies.

The CDSCO released a new classification of non-notified medical devices and in-vitro diagnostic devices (IVDs)on 3rdSeptember, 2020 which provides new risk-based classification lists to manage India's clear regulatory pathways and requirements.

Classifying almost 1866 medical devices and 80 IVDs, the CDSCO has established 24 categories based on subdivisions applied at internationally acceptable classification and on the First Schedule of Medical Device Rules, 2017. There are 24 categories of medical devices and 3 categories of non- notified IVDsincluding:

- IVD analysers (53 individual IVD types)
- IVD instruments (18 device types)
- IVD software (nine device types)

Software has been included as a category for the first time in the regulation encompassing 60 device types such as data analysis software, secondary displays for glucose monitoring, insulin pump and other devices, and orthodontic and dental software.

The CDSCO eased various compliance requirements that can cause disruptions in the supply chain on account of the extenuating demands imposed by the unprecedented COVID-19 pandemic:

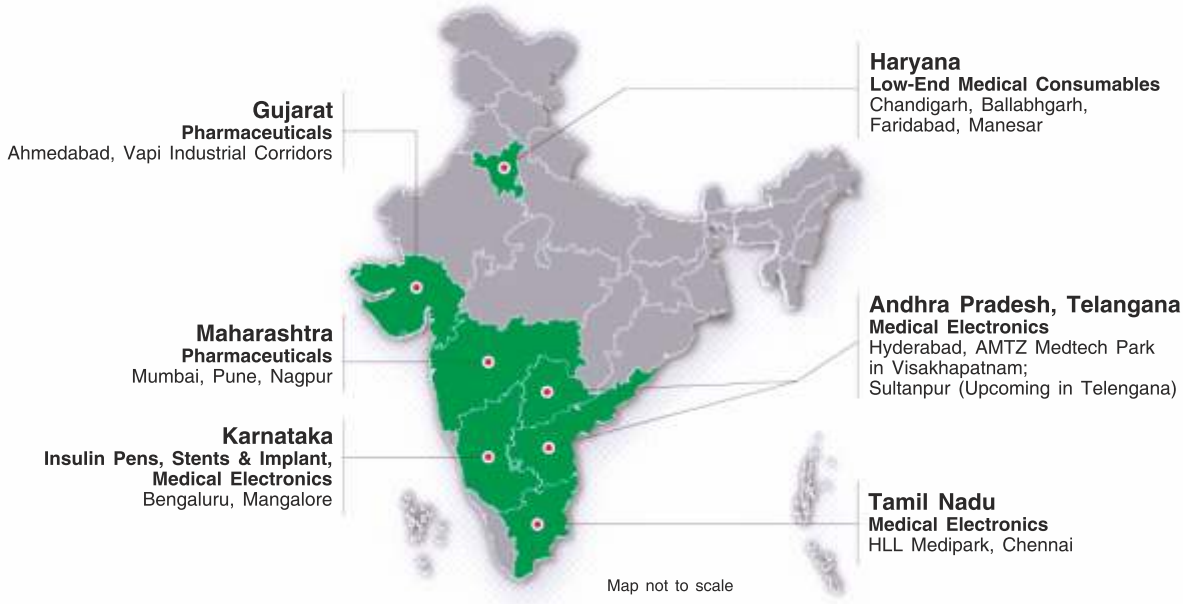
- **Import Relaxation** – Applicants for medical device import license exempted from submitting notarised/apostilled documents
- **GMP Relaxation –** Extension of the validity of the Good Manufacturing Practice Certificate expiring between March 2020 and August 2020
- **RC Notification** – Extension of the validity of the registration certificate granted to foreign drug manufacturers seeking to export drugs into India for the purposes of sale
- **Drug Import Notification –** Extension of the validity of the import license granted to importers of drugs for the purposes of sale
- **License Application Extension –** Submission of application for license for manufacture or import of CT scan equipment, MRI equipment and all implantable devices is extended to 30th June, 2022.
- **Certificate Submission Extension –** Submission of ISO 13485 for registration of medical devices is extended to 31st May, 2022.

In September 2021, the government constituted a Medical Device Technical Advisory Group (MDTAG) under the aegis of MOHFW and led by the DCGI to draft a new Drugs, Cosmetics and Medical Devices Bill. The high-level committee undertook pre-legislative consultations, examined the present Act and is working towards framing the new Drugs, Cosmetics and Medical Devices Act.

Other Measures

- The National Accreditation Board for Testing and Calibration Laboratories (NABL) is the nodal agency for accreditation of laboratories but accreditation is not mandatory.
- Free Diagnostic Service Initiative is providing essential diagnostics at all levels of public health care.
- National Essential Diagnostics List was formulated to improve the availability of quality diagnostics across health facilities in India.
- A cess of 5% on import of certain medical goods was announced so as to increase the cost of importing medical devices thereby supporting domestic manufacturers.
- Under the 'Manufacturing Ecosystem Cluster Development' approach to boost indigenous

Manufacturing Clusters for Medical Devices



Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of medical devices	
Overview	INR 3,420 Crore
Incentive	5% of incremental sales over base year 2019-20 will be provided on the segments of medical devices identified under the scheme.
Total financial outlay	INR 121 Crore
Tenure	FY 2020-2021 to FY 2027-2028
Promotion of Medical Devices Parks	
Overview	A one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected medical device parks proposed by a State Government
Incentive	100 Crore per park
Total financial outlay	INR 400 Crore
Tenure	FY 2020-2021 to FY 2024-2025

manufacturing of medical devices, medical device parks that provide all the essential infrastructure (allowing companies to 'plug and play') are being developed around six clusters in the country with an outlay of Rs. 400 crore. This will reduce cost of production by 40% to 50% along with delivering varied other benefits.

- A Production Linked Incentive (PLI) Scheme was announced in 2020 to augment and strengthen indigenous manufacturing of medical devices and equipment in four identified categories under Atmanirbhar Bharat. With an outlay of Rs. 3,420 crore, it extends an incentive of 5% of incremental sales to eligible applicants.
- In October last year, the government removed export curbs on all diagnostic kits and reagents including instruments used in detection of COVID-19 infections.
- There is some discussion on enacting a new legislation specifically for medical devices.

Conclusion

The government recognises the importance of diagnostics as an indispensable component of the healthcare system. It is instituting a proper regulatory and monitoring framework to ensure safe and tested medical and diagnostic devices reach the end user.

"Think of diagnostics as the foundation of a building. Without a strong foundation, you can never have a strong, stable or safe structure!"

J. Mitra & Co. Pvt. Ltd.
.....a vision to serve mankind

MR. JATIN MAHAJAN

Managing Director of J. Mitra & Co. Pvt. Ltd., India's leading IVD (in-vitro diagnostics) manufacturer and Joint Coordinator, AiMeD (Association of Indian Manufacturers of Medical Devices) speaks to The Aware Consumer about the ground-breaking developments in diagnostics and how they are revolutionising healthcare in the country.

Dedicated towards the cause of preserving human life through technology and innovation, Mr. Mahajan has over 16 years of experience in the field of medical diagnostics. At the helm of J Mitra for the past 18 years, he has steered the company to its present glory – regional leader, exporter to over 40 countries, and more than 55 patents with the title of 'India's Patent King' by Wall Street Journal..

Jatin Mahajan is a well-established name in the medical fraternity as a promoter of excellent quality medical diagnostic test solutions for the detection of various infectious diseases. His cost-effective, safe and international-standards compliant products are used by most of the big names, and his clientele reads like a who's who of the medical diagnostic fraternity. He is a regular speaker at industry forums and has been bestowed with various awards and recognitions including India's Greatest Leaders 2018-19 Award (AsiaOne's Pride of Nation Awards).

MR. JATIN MAHAJAN

Q What is the role of diagnostics in healthcare? How are the new advancements in technology benefitting the patients?

Diagnostics is the first line of defence and ensures better health and fitness. Diagnostic services play a vital role in spotting health problems and catalysing informed medical interventions with higher integrity due to evidence-backed decisions. It is the foundation for establishing the health disorder and deciding on the appropriate therapeutic, surgical, or medical solution. Seventy percent of all critical medical choices are based on diagnostics. The average life expectancy of an Indian has increased from 52.5 years (1980) to 61.5 years (2000) to 69.3 years (2020), thanks to accurate diagnostics and cutting-edge medical treatments.

Improvements and innovations in diagnostics are focused on developing new diagnostic procedures, medical devices like stents; precise diagnostic scanners; and surgical robots. Screening & Diagnostics have improved remarkably. Advancements in technology have ensured that the machines are less complex, smaller in size, and portable. Technological advances have resulted in the usage of many of these devices in patient homes and point-of-care, even in remote regions, enabling the treatment of patients away from medical facilities. Advancement in diagnostics has catalysed:

- Accurate diagnostics and targeted treatment
- Reduced the duration of hospital stay
- Better healthcare outcomes
- Increased access to patient care
- Reduced burden on existing medical resources
- Cost reductions
- Higher peace of mind
- Lessor discomfort
- A broader spectrum of coverage of healthcare available to the masses

Q Do you think diagnostic testing is being overused with needless over-testing?

Not at all. Accurate diagnostics form the basis of all therapeutical decisions. It is an absolute must to get this correct. Think of diagnostics as the foundation of a building. Without a strong foundation, you can never have a strong, stable or safe structure. Similarly, without the correct diagnostics, all therapeutical decisions are a mere shot in the dark with no possibility of treating the patient.

Q Do you find any concerns about the quality of medical testing based on the errors and failures in diagnostics?

Over the years, the diagnostics industry, nationally and globally, has become very robust. Accuracy of testing now ensures almost 100 percent error-free diagnostics. In addition, constant research & development and technological advancements continue to crease out all testing anomalies.

AIMED, QCI and NABL have joined hands to voluntarily develop the ICMED certification, which is at par with international ISO quality standards. All diagnostic tests adhere to various stringent international quality norms and certifications. This is not an issue with reputed brands. Indian diagnostics solutions are one of the best in the world in terms of quality, precision and affordability.

Q What are the key challenges arising around the application of diagnostic regulations during the COVID-19 pandemic?

The ICMED certification needs to be adopted by the Indian government and strengthened to garner the stature equivalent to its international counterparts.

During the pandemic, the curb on the export of diagnostics to other countries was not thought through properly. As a result, most Indian manufacturers had surplus Covid-19 test kit stocks not utilized in the domestic market. The export curb resulted in these stocks losing their shelf life, catalysing massive losses for the manufacturers.

Q Different stakeholders have been clamouring for a separate law for medical devices for quite some now. What are your expectations from the government?

We need to ensure that the ICMED certification attains the stature of other globally recognized certifications. The certification will ensure that our products are readily accepted in the international markets and there are no delays due to red-tape or seeking additional locally-relevant benchmarks. We should adopt the Global Harmonization Task Force's (GHTF) definition and rules-based classification of medical devices. We expect this significant issue to be sorted quickly.

Q How can the diagnostics sector build resilience and prepare for future threats?

Diagnostics manufacturers are addressing all the challenges they had encountered during the pandemic – raw material shortage, supply chain, automation to counter possible workforce shortage. In addition, there is a renewed focus on hygiene, quality, and safety standards (which are already relatively high for the industry) in line with the need for risk mitigation possibly arising due to corona or any other infection.

Localization is a key focus area. We will strive for the creation of more vendors for raw materials in India. Dependence on foreign supplies must be reduced.

The government-industry interface is being strengthened to ensure that we have a voice within the government and all policy and governance aspects of the industry are legitimately and promptly addressed. We felt that the foreign players had a better interface with the government while domestic players did most of the credible work during the pandemic.

Innovation and R&D will be a vital focus area to create newer and better diagnostics solutions. The industry will also focus on the international markets for driving revenues and growth.

AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Registration of Diagnostic Centres Remains a Pipe Dream

"The Clinical Establishment Act 2010 aims to organise the health sector so as to make medical facilities available, accessible and affordable to the consumers. So why is it stalling and delayed even after over a decade?"

– questions *Pyush Misra*

Implementing the Clinical Establishment Act in letter and spirit can streamline healthcare services in India, including diagnostic testing

THE CENTRAL GOVERNMENT enacted the Clinical Establishments (Registration and Regulation) Act, 2010 to provide for the registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services. The Act makes it mandatory for all clinical establishments - across all recognised systems of medicine both in the public and private sector, including diagnostic centres – to register themselves and provide standard treatment/testing to the consumers.

A clinical establishment can apply for a permanent or provisional (valid for a year) registration. Registration will be granted only if it adheres to the following conditions:

- Minimum standards of facilities and services
- Minimum requirement of personnel
- Provision and maintenance of records and reports

Additionally, the rates for procedures and services charged by the clinical establishments should be within the range determined by the Central Government from time to time in consultation with the state governments. They are also required to prominently display the details of rates charged and facilities available in both English and the local language.

The district registering authority is also empowered to impose fines for non-compliance of the provisions – Rs. 50,000 for running an unregistered establishment, Rs. 25,000 for knowingly working in an unregistered establishment and Rs. 5,00,000 for obstructing investigations, withholding information or giving false information.

The Act aims to bring uniformity in the healthcare sector in terms of treatment protocols, testing methods and pricing structures. The mandatory registration and regulation will enable the government to maintain a digital registry of all the clinical establishments at the national, state and district level. This composite information will be particularly valuable for public health interventions including outbreak and disaster management.

Subsequent amendments have attempted to fill the gaps and loopholes in the Act. Especially the 2019 amendment has clarified many issues pertaining to laboratory services and ruled out some misconceptions prevailing among the diagnostic personnel. Rule 8A was inserted in the Act to establish minimum standards for pathological labs. It clearly states that, 'Every clinical establishment relating to diagnosis or treatment of diseases, where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services, are usually carried on with the aid of laboratory or other medical equipment, shall comply with the minimum standards of facilities and services as specified in the Schedule'.

The diagnostic centres have been classified into three levels – Basic Composite (Small), Medium and Advanced while listing the Essential and Desired tests that should be conducted at the said labs. Specific manpower, infrastructure, recordkeeping and legal requirements have also been defined for each type of medical laboratories.

A dedicated website (http://clinicalestablishments.gov.in/) is operational for online registration of clinical establishments.

Private hospitals and diagnostic centres are pulling the strings on the regulation of clinical establishments

Floundering in Implementation

Most states seem to be dragging their feet over implementing the Clinical Establishment Act. The major hindrance here is that health is a state subject and it is the prerogative of the state legislature to bring in the regulation. The Union Ministry of Health is repeatedly appealing to the states to adopt the same. However, a mere 11 states and 6 union territories have adopted it, that too only partially at best. Some states – like West Bengal, Telangana and Karnataka - have enacted their own laws, which is mostly a diluted version of the national legislation. Maharashtra and Madhya Pradesh have prepared drafts but not executed the Act as yet.

The National Council for Clinical Establishments, in its last meeting in July 2021, again urged the state/UT council representatives to work out the rates of common procedures and services based on the approved template of costing and list of procedures while taking the local factors and requirements into account. The National Council will prescribe the range of rates for compliance by the clinical establishments based on the suggested rates received from the states/UTs.

The harsh fact is that the private healthcare sector seems to be pressurising the state authorities as it will dent their profits. This was most obvious in Karnataka which had to water down its law in the face of stiff resistance from the private healthcare providers.

The ongoing COVID-19 pandemic has further exacerbated the need to implement the Clinical Establishment Act as it will bring in the much needed accountability in the healthcare sector – including diagnostic services.

> "We have seen during COVID second wave, how the Right to Health was compromised in the private health sector. The implementation of the Clinical Act is important but even after a decade this has not been implemented by many states so far", opines Amulya Nidhi, who is representing a PIL filed by non-profit Jan Swasthya Abhiyan, Patients' Rights Campaign and activist KM Gopakumar in February 2021 seeking affordable healthcare for all and regulation of the private health sector.
>
> Following the petition, the Supreme Court issued a notice seeking directions to operationalise all the provisions of the Clinical Establishments Act, 2010 and the accompanying rules.

Meanwhile, diagnostic centres that ignore the regulations and have inadequate or inexperienced medical staff continue to spring up all over the country. It should be noted that organised diagnostics chains make up a mere 16% of the market share, hospital-based centres have a 37% share while 47% comprises of standalone centres. *(Source: Draft Red Herring Prospectus of Metropolis)* In the absence of prescribed standards, the market has low entry barriers which further compromises the quality of services. And the sufferer is the consumer as usual, with his health and safety hanging in the balance!

Organised diagnostics chains make up a mere 16% of the market share, hospital-based centres have a 37% share while 47% comprises of standalone centres.

Defeating its Own Purpose

The one size fits all approach which clubs together all the different kinds of clinical establishments is proving to be a major drawback of the Act. Keeping the wide heterogeneity of the healthcare sector in view, a differential approach to different kinds of clinical establishments will help garner support from the various stakeholders.

The central government also needs to persevere to build consensus for the Act. The predominantly 'enforcement' approach should be replaced by an 'interventionist' approach for reshaping healthcare towards uniformity.

Moreover, political will seems to be largely missing as adequate financial and human resources are not being pressed into action for the regulatory apparatus. For instance, neither dedicated staff nor sufficient funding has been allocated for the national and state councils or the district registering authority.

Conclusion

If properly implemented, no diagnostic centre or other clinical establishment can be operated unless it has been duly registered in accordance with the provisions of the Act. The legislation will also ensure that the Indian healthcare system becomes systematised and is equipped with the basic minimum standards of medical care.

Ms. Devaki Devi Mandava
Deputy Director, QCI

The Burden of Diagnostic Errors Impedes Efficient Healthcare

"Accurate diagnosis is crucial for providing timely and effective treatment that can even prove to be lifesaving. The opposite is also true - inaccurate, delayed or missed diagnosis can lead to grievous consequences. Reducing diagnostic errors should become the focus in healthcare practice"

– says *Ms. Devaki Devi Mandava*

WHEN WE ARE ill or injured, we go to a physician to give us the right treatment which will make us well. The physician in turn relies on diagnostics to identify the nature or cause of the problem and will design a treatment plan accordingly. But what if the diagnosis gets missed, is wrong or even delayed?

Research is pinpointing that it is errors in diagnosis – and not surgical mistakes or medication overdoses - that is the most common and also causes most harm to the patients. Alas, we are not even aware that these diagnostic errors are one of the leading contributors to inefficiencies in health care.

This is not just about missing an infection due to misreading or misreporting in a laboratory test. A patient complaining of severe dizziness was diagnosed with a benign inner ear condition instead of heart trouble, only to suffer a massive stroke a few weeks later. In another case, failure to detect a splinter in a broken bone led to the splinter getting lodged in the adjacent tissue and causing internal bleeding.

The problem has intensified during the current COVID-19 global health crisis - on the one hand, patients with unusual or non-respiratory symptoms are often mislabelled as COVID negative and safe while those with any kind of respiratory issues are assumed to be COVID positive. The latter has led to missing other ailments such as bacterial sinusitis, pneumonia and even myocardial infarction.

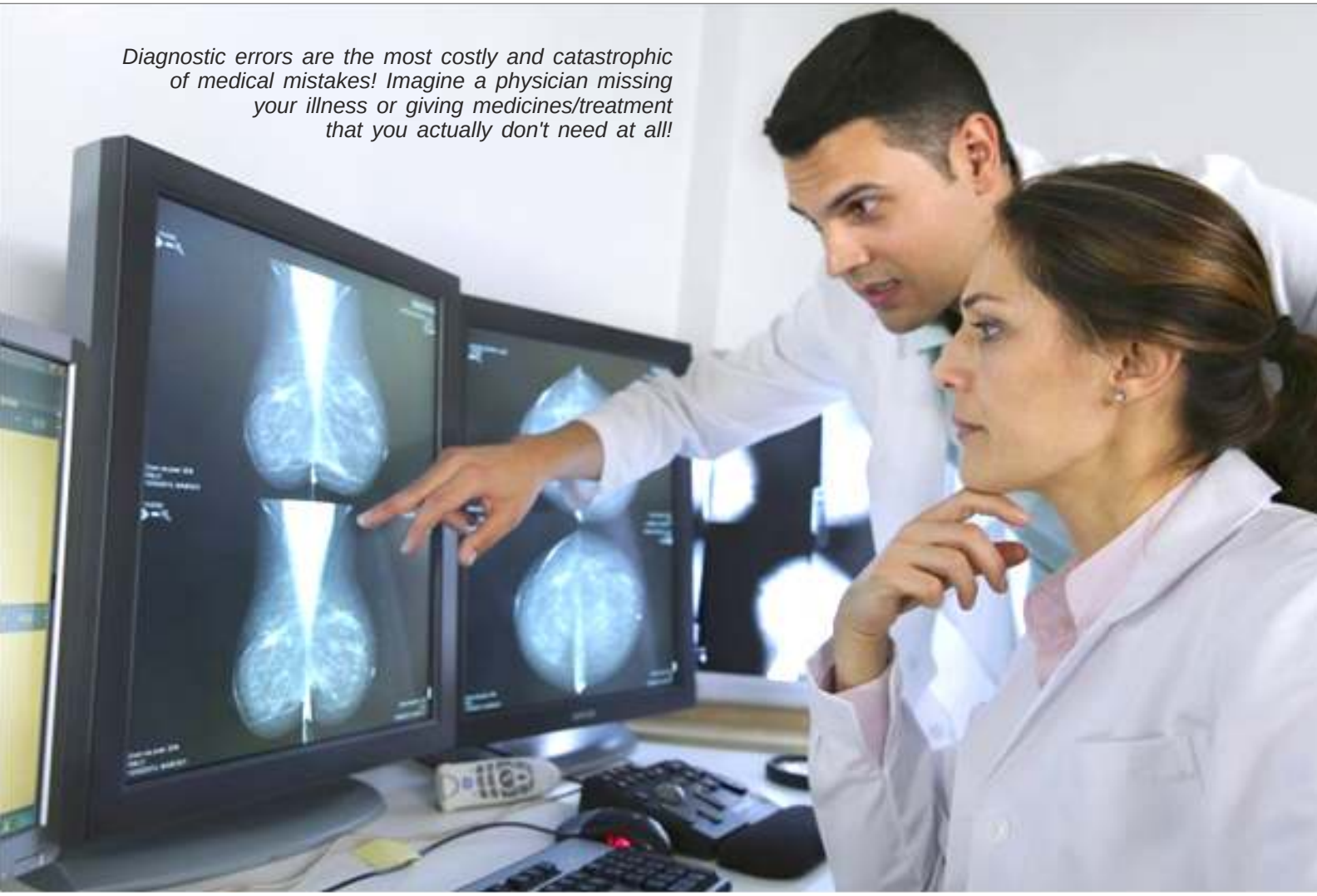
A few months ago, it was noticed that when a patient had fever, cough, cold and headaches for more than five to seven days, physicians in smaller districts put them in isolation and started COVID-19 treatment even though it is a fact that persistent high fever can be due to malaria, dengue or chikungunya too. It is only when the platelet count falls too low that dengue is considered, which might be too late at times!

Delving into the Problem

The landmark 'Improving Diagnosis in Health Care' report by the Institute of Medicine, USA defines a diagnostic error as 'the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient'.

The common types of diagnostic errors include:

- **Delayed diagnosis –** This is the most usual type of diagnostic error where the diagnosis could have and should have been made earlier. The correct malady is usually suspected only after the symptoms persist or



Diagnostic errors are the most costly and catastrophic of medical mistakes! Imagine a physician missing your illness or giving medicines/treatment that you actually don't need at all!

worsen. It is most frequently seen in cancer cases, causing the deadly disease to spread to other parts of the body.

- **Wrong Diagnosis –** This is misdiagnosis which happens when the treating Physician diagnoses the wrong illness, like heart attack being mistaken for acid indigestion.
- **Missed diagnosis –** This refers to an illness or disease that is not diagnosed at all as the treating Physician dismisses the patient's complaints or symptoms. Chronic fatigue or pain are most common here.

In addition to this, there can be other incidents like a physician accurately diagnosing one disease but failing to diagnose another related/unrelated disease or other complications which can aggravate the condition.

Here it is not just about the increased costs of incorrect testing and treatment. The fallouts are - preventing or delaying appropriate treatment, providing unnecessary or harmful treatment or even psychological repercussions, thus causing untold harm to an unacceptable number of patients. In fact, the blunders can affect everything from the patient's healing to even the very survival, with erroneous diagnosis often leading to permanently disability and even death. What is most unfortunate is that despite the enormous advances in modern medicine in the past decades, the rate of diagnostic errors has not decreased.

The glaring fact is that diagnostic errors are largely under-recognised, given that it is difficult to measure and even keep track of wrong/missed/delayed diagnosis due to the gap between the error and its detection (if at all it gets detected)!

> It is likely that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences - *Improving Diagnosis in Health Care report*

Who is to Blame?

To err is human; even the most competent and experienced medical professionals can make mistakes. In fact, most diagnostic errors cannot be attributed to lack of knowledge or even caring on the part of the physicians.

It cannot be denied that diagnostic errors are more complex and diverse than other patient safety issues. As David Newman-Toker, MD, lead author of the above report and director of the Johns Hopkins Armstrong

Institute Center for Diagnostic Excellence points out, "Diagnostic errors happen across all areas of medicine. There are over 10,000 diseases, each of which can manifest with a variety of symptoms, so it can be daunting to think about how to even begin tackling diagnostic problems." Additionally, there are a limited type of symptoms and each of them can have hundreds of possible reasons!

Diagnostic errors are likely to worsen with the increasing complexity of the diagnostic process and healthcare delivery!

Moreover, the fragmentation of modern healthcare also contributes to the growing incidence of errors. From the physicians' end, cognitive factors, subtle bias in thought process, overconfidence and lack of adequate time with the patients can waylay the diagnostic process.

Improving Accuracy and Timeliness

The cumulative burden of diagnostic errors causes a heavy human toll. Improving diagnostic outcomes is a crucial concern for both healthcare quality and safety. The chief problem here is the lack of attention to diagnostic errors. We need a greater focus on this issue with more research being devoted to understanding the causes of diagnostic errors and evaluating possible solutions. It also calls for collaboration and a widespread commitment to change across the stakeholders like healthcare professionals, healthcare organisations, researchers, policymakers and even patients and their families.

The World Health Organization (WHO) is now prioritising patient safety areas in primary care; diagnostic errors are included as a high-priority problem. It also persevered to bring the varied stakeholders on a joint platform to address the many common challenges and opportunities to reduce diagnostic errors. The Safer Primary Care Expert Working Group was set up to compile key lessons and topics for further research which led to the development of the 2016 Technical Series on Safer Primary Care.

Healthcare owes it to the patients to persevere to reduce the incidence of errors. A systematic process should be in place to assist physicians to pinpoint the exact root of particular symptoms. A few common blind spots can be overcome by using checklists and differential diagnosis with the help of various laboratory tests to ensure that all possible reasons that can cause the patient's symptoms are covered.

Physicians can take advisory services from NABL accredited laboratories for the choice of diagnostic examinations to be performed in various disciplines like Clinical Biochemistry, Clinical Pathology, Haematology, Microbiology and Infectious Disease Serology, Histopathology, Cytopathology, Molecular Testing, Cytogenetics and Medical Imaging. NABL accredited laboratories comply with the requirements of International Standard ISO 15819 Medical Laboratories – Requirements for Quality and Competence. This compliance enhances the quality of the diagnostic laboratories which gives a reliable result in a timely manner. This in turn helps the physicians in accurate diagnosis of the disease.

Indeed, accurate and timely diagnosis by pathologists is also becoming all the more crucial as any kind of error can interfere with delivering high-quality healthcare.

There is also a need for better training of laboratory staff and better education of primary care providers in varied aspects like clinical reasoning, critical thinking, cognitive heuristics and biases, test limitations, probability concepts, patient safety, managing uncertainty, etc. Practicing reflectivity and using tools will empower them to properly interpret the information and make thoughtful decisions.

Information technology can further assist in supporting diagnostic reasoning, detecting errors and enhancing follow-up and tracking.

Above all, partnering is imperative – physicians should be mindful and stop to think before pronouncing a verdict. The environment should also be more open to accepting and improving errors so as to improve patient health and safety.

Conclusion

Accurate and timely diagnosis are the two cornerstones of high-quality patient care which can be achieved with support from NABL accredited laboratories. Physicians can also make their patients aware of use of NABL accredited laboratories for timely and accurate reports. Engaging and empowering patients by educating them about the symptoms to be looked for during illness will also help to have the best outcomes.

Improving the diagnostic process is a moral, professional and public health imperative.

The Improving Diagnosis in Health Care report lays out eight major goals for effecting progress on diagnostic error:

- Facilitate more effective teamwork in the diagnostic process among healthcare professionals, patients and their families
- Enhance healthcare professional education and training in the diagnostic process
- Ensure that health information technologies support patients and healthcare professionals in the diagnostic process
- Develop and deploy approaches to identify, learn from and reduce diagnostic errors and near misses in clinical practice
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
- Develop a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses
- Design a payment and care delivery environment that supports the diagnostic process
- Provide dedicated funding for research on the diagnostic process and diagnostic errors.

Payal Agarwal
Editorial Consultant

Danger of Imminent Risks in Diagnostic Testing

"Diagnostics deliver massive benefits, but the risks cannot be ignored either. Are the risks always worth the benefits?"

– asks *Payal Agarwal*

Ever wondered if your diagnostic test is safe for you?

THE WORLD IS witnessing enormous ground-breaking advancements in medical diagnostic technologies. The potential of diagnosis is not only increasing to tackle emerging disease profiles, but also becoming quicker and more accurate.

Bacteria can be diagnosed and cultured to detect tuberculosis within 24 hours; this used to take several days and weeks earlier. A PET scan can indicate even a minute strain of cancer. A coronary CT angiogram creates a 3-D image of the heart and clots blocking the arteries.

However, the developments open up a can of worms as well. Christine Cassel, MD, President and CEO of the American Board of Internal Medicine Foundation warns, "No treatment and no test, no matter how routine, is without some risk".

> "In the race to provide the best healthcare solutions to the public, the quality and safety of technology must in no way be compromised. Devices should be scrutinised and assessed for risks at all stages, both before and after they are released in the market. Nonetheless, healthcare facilities too must ensure proper training of their staff, conduct regular maintenance and create an environment that is more open to accepting and improving medical errors to reach the end goal of improving patient safety and health" *- Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry*

Basket of Risks in Diagnostics

Radiation - Imaging tests like x-rays and CT scans expose the patient to harmful radiation which is actually not considered safe. While imaging usually involves low level of radiation, the exposure can add up over the years. And excess radiation exposure is dangerous in cumulative doses – it can cause tissue damage, harm the DNA and even increase the risk of cancer years down the road. The actual risk will vary depending on the type of test done, area of the body exposed, dose of radiation and the age, gender and size of the person.

Allergens and germs – Diagnostic testing can cause adverse skin reactions in rare cases. Some people are even known to get allergies on contact with diagnostic devices – like allergic contact dermatitis caused by glucose sensors. Then there is the risk of exposure to germs in the diagnostic centre itself or from contaminated equipment. Proper disinfection and sterilisation, if possible, becomes crucial here. Obviously you don't want to become sicker because you got a diagnostic test done as you were sick in the first place!

Adverse effects – Some tests can be discomfiting or even outright painful – like a colonoscopy. Some others can lead to injuries - endoscopy of the bowel causes bleeding at times. A few can even entail a risk of morbidity or mortality — like a cerebral angiogram can lead to stroke in 0.5% of cases.

Inaccuracy – Diagnostic tests also open the door to errors and inaccuracies in the test results. In fact, the increasing complexity of the tests can cause difficulty in interpretation by the pathologist or biases can involuntarily creep in while analysing the results.

However, the inaccuracy is not always human. The testing devices itself blunder and fail many a times. In fact, it is reported that 70% of the diagnostic errors occur at the pre-analytical stage itself!

Physicians trust the diagnostic process and rely on it to identify the illness and craft a treatment plan. So, any inconsistencies in the results can end in grave outcomes – the incorrect diagnosis from a false positive test can lead to unnecessary further testing and unnecessary treatments (like biopsy or even surgery). For instance, a person who is considered a heart patient based on a false positive diagnostic test will undergo unnecessary or inappropriate therapy. This opens up another bag of risks, not to mention the needless psychological distress and financial burden.

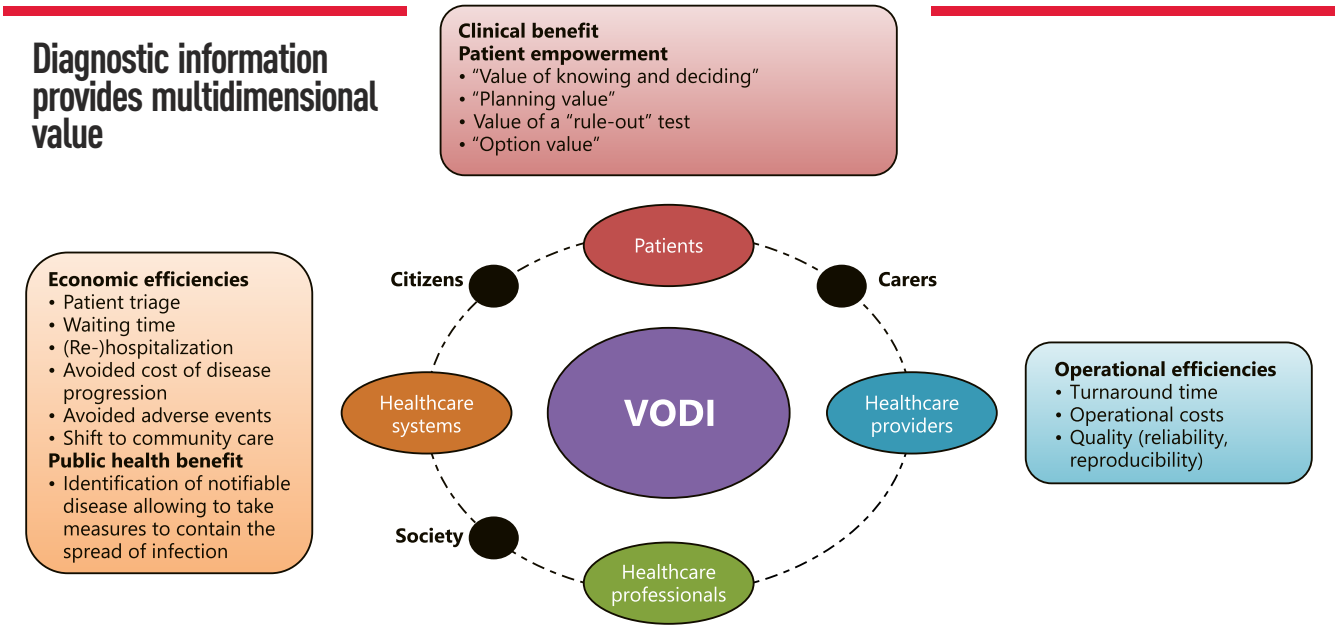
The RT-PCR test is supposed to be the gold standard for rapid and sensitive detection of the SARS CoV-2 virus, but it is not immune to incorrect results either. All of us are intimately aware of the grave fallout of both the false negative and false positive outcomes of COVID-19 testing. We have seen multiple cases of false negative results not only delaying the diagnosis of COVID-19 cases, but it is people who are handed a clear chit through inaccurate negative diagnosis who end up involuntarily spreading the deadly disease to other uninfected folks. Then again, people who are wrongly diagnosed as positive not only endure unwarranted seclusion, medication and testing, but they may actually end up contracting the disease when they are isolated along with other COVID-19 patients.

Therefore, we cannot assume that diagnostic tests are always reliable or the results will be credible at all times. Diagnostic accuracy studies are used to evaluate the ability of a test to correctly identify a target condition. However, these are also subject to variation and even bias.

Then there is the additional risk of fake reports and fabricated results. Like in the case of a nanny working in a day-care centre in Delhi who was advised a blood marker test and mammogram after developing a lump in her breast. As the test showed malignancy, she endured two excruciatingly painful, sickening and expensive rounds of chemotherapy. The next mammogram (done at another diagnostic centre) revealed that she did not have cancer at all!

Similar is the story of a 22-year-old girl who was running a persistent fever for nearly two months. Her blood samples were collected and tested by four different laboratories and yet all of them failed to detect leukaemia. It is clear that no testing was done as even a simple complete blood count would have revealed the obvious abnormality in the samples!

Sink testing is a laboratory fraud where clinical specimens are not tested; instead they are discarded in a sink drain and fabricated results are reported. This has emerged as



another common phenomenon of COVID-19 testing in unaccredited labs and home visits by shady lab personnel.

Putting the Risks into Perspective

The interplay of benefits and risks of diagnostic testing should be clearly assessed, especially in the case of screening tests. While some screenings can detect hidden abnormalities, disease probability and other issues before they intensify or turn threatening, at times they even identify health conditions that would otherwise not have affected the patient even in the long run. This is especially seen in the case of pre-operative testing and thorough health check-ups of the aged.

> The WHO concurs that detecting a disease early does not always have a benefit. It states, "If early diagnosis and treatment does not lead to an improved health outcome, detecting a disease earlier only makes people worry and have treatment for longer unnecessarily, because they do not benefit from earlier treatment."

The industry needs a multifaceted approach to understand and address the many underlying risks in diagnostic testing.

What Can Patients Do?

Discuss the test with the doctor: Talk to the doctor about whether the test is really needed, if it's the best one to use and what he or she expects to learn from it. Inquire about the risks and if they are outweighed by the benefits. In case of an imaging test, also ask what difference it will make in the clinical management of your health condition – like will it save an invasive procedure?

Ask for a lower-dose radiation test: It is a fact that different imaging tests deliver different amounts of radiation. So, if the doctor prescribes a CT scan, you can ask if another technique will be acceptable - like ultrasound (uses high-frequency sound waves) or MRI (relies on magnetic energy) or even an x-ray (has lower radiation) and therefore, lesser risks. If a CT scan is imperative, find out if there are ways to shield the body parts that don't have to be imaged.

Maintain record of diagnostic tests: Keeping a track of your entire test history and results (including pathology and radiology) can help you update the doctor and prevent him from ordering repeat tests.

Consider less frequent testing: Certain chronic health conditions can entail regular imaging tests. In such a case, you can still inquire if the doctor can extend the interval between the CT scans.There is no harm in discussing a lower-dose imaging approach or even observation without imaging.

Don't push for scans: Do you feel that a CT scan will ensure that you have had a thorough health check-up? Are you aware that the imaging rarely delivers crucial findings unless there are some relevant symptoms? And even if the scan does reveal an incidental finding, it will only cause a whirlwind of more x-rays and scans that lead to additional radiation exposure, while the potential benefit will still be up in the air. So, do not go to a physician asking for unnecessary tests.

Conclusion

All medical tests carry some degree of risk; some can even have side effects. Ensuring accuracy in diagnostics is particularly essential to cement diagnostics as a key component of healthcare.

Medical and Diagnostic Devices are Not Drugs – They Need a Separate Act!

Why do medical and diagnostic devices still follow a regulatory framework based on the drug regulations? Will Niti Aayog's Medical Devices Bill ever see the light of day? The authorities need to quickly arrive on a consensus on a separate regulatory mechanism for medical devices!

Regulation of medical devices and equipment needs a major overhaul

MEDICAL DEVICES ARE the instruments, apparatus, appliances, machines and technologies that make common medical procedures possible. They are used for bandaging a sprained wrist, implanting an artificial limb, performing heart surgery, detecting cancer and so on. The intended use varies a lot - diagnosing diseases, monitoring treatments, treating illnesses and assisting disabled people. Again, even the settings of use are pretty diverse - from clinics to inpatient/outpatient facilities and intensive care units in hospitals to specialised optical and dental facilities to palliative care to even our homes.

The medical devices can be simple, low-risk appliances like tongue depressors, thermometers and bedpans to complex, high-risk devices like stents, pacemakers and prosthetics to high-technology medical testing apparatus.

The landscape of medical devices has completely transformed over the decades driven by mind-boggling advances in technology and material science. In fact, there are about 2 million kinds of medical devices on the world market (categorised into more than 7000 generic devices groups) that can even resolve debilitating and life-threatening health conditions. Devices like masks, gloves, personal protective equipment and diagnostic tests have enabled countries to control the unprecedented COVID-19 pandemic to a great extent.

As per the Indian Medical Devices Industry report by India Brand Equity Foundation, India is among the top 20 markets for medical devices worldwide, valued at US$ 11 billion in 2020 and expected to increase at a CAGR of 35.4% to US$ 50 billion by 2025.

However, it should be noted that approximately 80% of the medical devices - including imaging equipment (CT and MRI scanners), cardiac stents, orthopaedic implants, syringes, surgical gloves, glucometers and critical care equipment - are imported into the country. The Indian medical devices industry comprises primarily of small and medium enterprises that mostly manufacture disposables and other medical supplies in the low-priced, high-volume segment while high-end and sophisticated devices are sourced from other countries.

> "We are particularly wary of the CDSCO's competence, expertise and most importantly its commitment towards patient safety, given its dismal track record. We urgently need comprehensive reforms to strengthen the regulatory mechanism in relation to patients' safety. These may include guidelines for the approval of devices including clinical investigation requirements, oversight of marketing and promotion, putting in place a robust and functioning system of adverse event reporting accessible to the public, rules for voluntary and statutory recalls, and patient compensation scheme."
> - *All India Drug Action Network co-convenor Malini Aisola was quoted as saying in The Times of India.*

Government think tank, Niti Aayog itself criticised the regulation of medical devices by CDSCO and other such bodies on the grounds that they lack the requisite expertise. It observed that, "There is a need felt for establishing a more enabling regulatory system to nurture and boost the medical devices sector….. The National Health Policy 2017 envisages strengthening the regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for medical devices in India."

To back up its stand, the think tank framed the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 to 'improve quality, enhance transparency, make it easier for the sector to do business, and formalise a regulatory framework as well as a framework for compensation'.

"The purpose of the draft Bill is to ensure that medical devices in India are safe and effective. Further, the Bill should create an enabling ecosystem for manufacturing, research and innovation", Niti Aayog said in a statement to industry stakeholders at that time. It was also primed to reduce medical device import dependency which is estimated to be around Rs. 39,000 crore.

The main provisions of the bill include:

- Penalty of Rs. 1 crore for those who import, manufacture or sell unsafe medical devices.

Approximately 80% of the medical devices - including imaging equipment (CT and MRI scanners), cardiac stents, orthopaedic implants, syringes, surgical gloves, glucometers and critical care equipment - are imported into the country.

Regulatory Apparatus for Medical Devices

More than 30 years ago, the first medical device was regulated as a drug. Today, the medical devices are governed by the Medical Devices Rule, 2017, under the Drugs and Cosmetics Act. However, till recently, a mere handful of the almost 6000 medical devices available in India were subject to regulation. The industry itself has been pushing for both regulating all devices and bringing in a separate Act for medical devices since long.

- Imprisonment of up to 3 years and a Rs. 50 lakh fine for those who fail to comply with the terms of registration or who place an improperly certified medical device on the market.
- Compensation to patients who are harmed by faulty or unsafe medical devices and implants.
- Maintaining a National Registry of Medical Devices.

Apart from the draft legislation, Niti Aayog also recommended setting up a separate regulator for medical devices – the Medical Devices Administration (MDA) - on

- **Indian medical devices market stood at Rs. 77,539 crore (US$ 11 billion) in 2020**
- **The market is expected to increase at a CAGR of 35.4% from 2020 to 2025, reaching Rs. 352,450 crore (US$ 50 billion)**
- **India has an overall 75-80% import dependency on medical devices, with export at Rs. 14,802 crore (US$ 2.1 billion) in 2019 and is expected to rise at CARG of 29.7% to reach Rs. 70,490 (US$ 10 billion) in 2025.**

the lines of the Food Safety and Standards Authority of India (FSSAI). The MDA would consist of four divisions:

- **Health and safety –** To grant permission for clinical investigation on human subjects, specify and evaluate the clinical evidence, collect and analyse results of the post-market surveillance
- **Conformity assessment –** To issue, reject, recognise, and validate conformity assessment certificates, and also conduct audits of manufacturing sites
- **Enforcement –** To inspect, investigate, carry out searches and seizures
- **Laboratory and medical devices testing –** To specify procedures for the analysis or testing of medical devices

Various stakeholders including patients who have been adversely affected by unsafe medical devices were involved in the consultation phase. "Industry experts even hailed it as a visionary and well-thought out roadmap.

Shifting Stand on Medical Device Regulation

Even while the industry was discussing the modalities of a separate Medical Devices Act with the Ministry of Health and awaiting a draft bill, in February 2020, the government decreed that all medical devices and equipment - for the purposes of diagnosis, monitoring, treatment, investigations and for supporting or sustaining life "- will be regulated as drugs under the Drugs and Cosmetics Act, 1940. The new regulatory framework of registration and licensing aims to improve the safety, quality, and efficacy of medical devices and equipment.

Accordingly, all medical devices are being moved into a licence regime in a phased manner. But the looming question is that does the regulatory body have the expanded personnel to ensure the requisite oversight over the broad range of devices that are being used today? For that matter, do the authorities even possess the necessary training to inspect and regulate these devices? Can the existing regulatory framework handle emerging products like artificial intelligence, exoskeletons or neural implants? The infamous Johnson & Johnson faulty hip implant fiasco is a case in point for the looming regulatory vacuum that essentially handicaps the authorities while letting the offenders get away scot-free. Come to think of it, will the Indian industry ever be able to cater to and compete in the global markets under the current regulation?

The Whys & Wherefores of a Separate Act

Lacking a separate legislative framework, medical devices have always been regulated as drugs under the Drugs and Cosmetics Act, 1940. This drug law is obsolete now - the usage and complexity of medical devices has changed drastically, which is not reflected in the said regulation.

For the past couple of years, medical devices are governed by the Medical Devices Rules, 2017 under the Act. However, as rules have to be in conformity with the principal legislation, they have managed to only partially improve the situation. Moreover, the quality management system adopted under the rules pertains to 2003 and not the latest one. Alas, even the dated norms of the Bureau of Indian Standards no longer conform with the revised Indian Standards Organisation/International Electro-technical Commission requirements.

Industry experts argue that medical devices pertain to the engineering genre and are inherently disparate from drugs which happen to be biomedical in nature. So, how can they be ruled by the same regulation?

Mr. Rajiv Nath, Forum Coordinator of the Association of Indian Medical Devices Industry (AiMeD) exhorts, "It's imperative to have a separate law as devices are engineering items and not medicines – an x-ray machine by no stretch of the imagination can be called a drug. Continued attempts to regulate devices under the Drugs Act without an assurance of migrating to a separate legislation will do more harm than good to the 'Make in India' campaign."

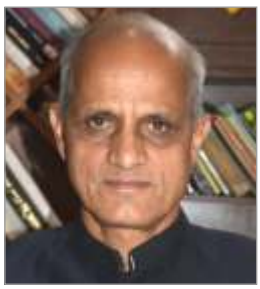
His contention holds water when he says, "'We are highly uncomfortable to be regulated under the very rigid and prescriptive Drugs Act as any non-conformity can be treated as a criminal offence by any drug inspector at his discretion and hauled before a court and there are no risk proportionate penalties. You can't have the same

The infamous Johnson & Johnson faulty hip implant fiasco is a case in point for the looming regulatory vacuum that essentially handicaps the authorities while letting the offenders get away scot-free.

penalty for a manufacturing failure of a pair of spectacles as for a contact lens or for an intraocular lens. Patient safety is more complex with devices where the same are a shared responsibility of the manufacturer, medical practitioners, product user and the regulator."

He further stresses, "The Ministry of Health should clearly define that its current regulations to define devices as drugs and their regulation by CDSCO is a temporary measure till the Niti Aayog-drafted separate medical devices law becomes a law and a competent regulatory authority is formed, as devices are not drugs."

Mr. K.L. Sharma, former joint secretary in MoHFW and author of 'Healing the Pharmacy of the World' also implores that medical devices and drugs are essentially distinct and underlines the fact that the non-existence of a suitable framework to regulate medical devices is admittedly the failure of the existing governance structures to respond effectively to the changed environment in which medical devices/med tech plays a crucial role in every aspect of healthcare.



K.L. Sharma
Former Joint Secretary, MoHFW

He decrees, "Lay down standards for different kinds of medical devices/equipment without any further delay and take steps for immediate regulation of all devices". His contention is that, "measurement of quality without specifying standards is not possible and the standards are meaningless without the authority to enforce them. The defects in medical devices or their non-conformance with the specified standards can expose patients to serious risks including injury, sickness and death. Deviations from expectations and claims could threaten patients' health and increase their pain, discomfort and suffering."

Even the NATHEALTH report assessing India's laboratory diagnostic industry points out, "Undefined standards lead to varying levels of quality and clinical standards compliance. Defining the minimum norm will help patients avail quality diagnostic services".

A voluntary certification scheme - Indian Certification for Medical Devices (ICMED) was launched in 2016 to fill the regulatory gap by providing functional quality assurance through the product certification system. Later, QCI and AiMeD added some more features and brought in the ICMED 13485 PLUS so as to ensure product quality and safety while limiting the threat of counterfeit products and fake certification. These mechanisms should be further refined so that the medical devices industry is able to demonstrate compliance with various international product standards to enter the global market.

Since September 2021, the MoHFW is working on drafting a new Drugs, Cosmetics and Medical Devices Bill. Yet, what the industry needs is a distinct law altogether! In October, Mr. Nath again pushed for the passage of a separate medical device law saying that, "The advantages of a separate Act will be that there will be less criminal action, most offences can be decriminalised which cannot be done in the pharmaceutical industry. When both medical devices and pharmaceuticals are treated under the same Act, this is a constraint to the industry."

In fact, according to a 2021 Niti Aayog report, India's diagnostics market is currently valued at USD 4 billion. It is expected to grow at a CAGR of 20.4% to reach USD 32 billion by 2022. Given the distinct nature of diagnostics (vis-à-vis other medical devices) coupled with the immense size and potential of the sector, doesn't the diagnostic segment itself warrant a separate law for itself?

Conclusion

India is already shining on the global stage as the 'Pharmacy of the World'! Medical and diagnostic devices need the right ecosystem of regulation and support to showcase its competence to the world. This will also prime the segment to deliver quality, safe and effective healthcare to the consumers, leading to tremendous improvement in public health!

Dr. Alka Mukne
Ph.D. (Tech.)
Board Member-PSAIIF

Cybersecurity Vulnerabilities A Growing Challenge in Medical Diagnostics

"Technologically driven tools and interconnectivity is defining the future of healthcare. The unbelievable advances are facilitating linkages at every touchpoint of the patient journey - from diagnosis to treatment to monitoring to follow-up – thus improving patient outcomes. However, the diagnostic devices should possess cybersecurity measures to protect patient information and lives."

– Dr. Alka Mukne

Information and telecommunication technologies are transforming medical care including diagnostics. But are they secure?

TECHNOLOGY IS INCREASINGLY permeating the medical industry leading to interconnected healthcare. All aspects of health management are interlinked through internet-connected tools like wearables, skin sensors, mobile apps and more. They are in place in multi-speciality hospitals as well as stand-alone clinics, thus enabling them to provide remote healthcare services.

This delivers significant benefits by bridging the gap between the patient and doctor and delivering proactive and personalised care to the patients. Connected devices can monitor the patient's blood glucose spikes, heart rates and other vital health statistics in real-time, record the health data and transfer it to the doctor.

It is not just about pacemakers and infusion pumps enabling virtual monitoring of vitals and regulation of dosages; even interconnected imaging and other diagnostic equipment are facilitating improved decision making leading to more effective diagnosis and treatments.

In fact, laboratory diagnosis is not confined to a single diagnostic centre anymore. Part of the analysis can be transferred to a specialised lab while point-of-care tests can deliver additional measurements. The results are constantly exchanged and aggregated by using the IT infrastructure. The patient records can even be electronically transmitted to the healthcare providers at the point of treatment.

Then again, laboratory reports are not limited to the medical specialists alone. They are electronically accessed by software programs and machine learning algorithms to evaluate the retest intervals, prevent unnecessary testing, predict the disease progression and other aspects of the medical interventions.

Apart from treatment, the lab data is also analysed in healthcare research projects – for instance, test results are constantly being aggregated and influencing public health decisions during the ongoing COVID-19 pandemic.

Cyber Threats in the Offing

We are well aware that anything that connects to the internet can be hacked – and the domain of healthcare with its profusion of networked devices and information systems is no exception. In fact, the greater the interconnectivity, the higher the risk of a security breach.

Consider this – a diagnostic lab will have a treasure trove of patient data – names, dates of birth, contact numbers, addresses, credit card numbers, bank account information, medical details, lab results and even social security numbers. The tempting prospects of using this sensitive personal information to steal money, commit identity theft or just sell the valuable data on the dark web attracts malicious cybercriminals in droves.

Patient health and lives hang in the balance as hackers can alter the test results, manipulate device functioning, disrupt its performance or even shut something down completely.

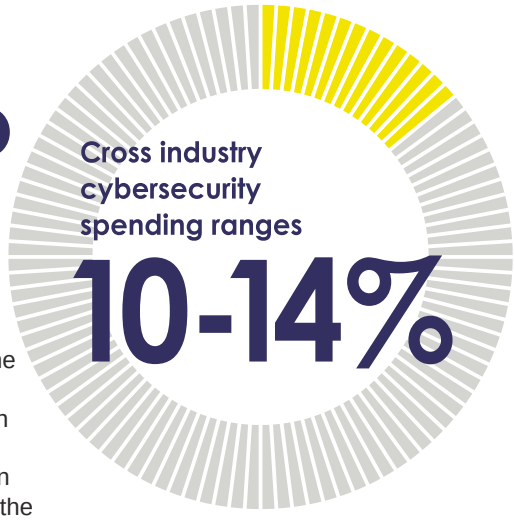
Quest Diagnostics, one of the largest providers of clinical laboratory testing services in the United States, was the hapless victim of a third-party data breach in June 2019, which exposed the confidential data of almost 12 million customers. This was followed by a ransomware attack on the same company's fertility-focused laboratory subsidiary in August 2021 that compromised the personal information of approximately 350,000 patients.

Cybersecurity has become a chronic problem over the years in the field of medical devices, diagnostics and healthcare. Clicking on an inconspicuous email or a malicious attack can jeopardise the effectiveness of the device and even the safety of the patient. The issues are further exacerbated by the COVID-era healthcare challenges.

Managing the Hazard

There is a veritable minefield of cybersecurity threats – the biggest challenge is to keep the patient data secure while it is being exchanged with other devices on the same or different networks.

The onus is on the designers and manufacturers to ensure that the diagnostic devices are secure. The American Food and Drug Administration requires manufacturers to, "take steps to assure that appropriate safeguards are in place to reduce the risk of failure due to cybersecurity threats."



The potential risks can relate to:

- Accuracy of the medical diagnosis
- Reliability of the device
- Access to private patient information
- The device posing a threat to other devices on the network

This requires them to perform a thorough threat assessment for every new diagnostic device and use it as

The healthcare industry has seen a boom in digitization in recent years. Cybersecurity is one of the most critical aspects of the healthcare sector as it protects valuable insights, healthcare information, and patients' personal information.

the base for the security strategy. This should cover:

- Vulnerability - The exploitable weaknesses that exist in the system
- Access – How a malevolent user or program can get into the system
- Capability – The type and amount of damage that can be caused by the malicious user or program.

The assessment should be followed by continuously monitoring, evaluating and updating the strategy over the lifetime of the device. It is also imperative to be on the lookout for new threats (both external and internal) and analyse whether the device is equipped to handle them. This kind of vigilance will enable the companies to mitigate or neutralise the imminent threats and ensure safety and effectiveness of the devices.

In case this is not possible, the next approach is to focus on detection. The diagnostic device should be designed with the capacity to detect security breaches and issue alerts to the users and manufacturers so that immediate actions can be taken to control the harm.

Following are some of the measures that cybersecurity experts suggest as defence against such attacks:

- A data breach can have massive repercussions not only for the patients but even the labs and the manufacturers of the diagnostic equipment. Encryption is an efficient and effective approach for safeguarding the health records and other data. This kind of encoding will make the data useless to the hackers. In fact, automatic encryption of transmitted data will completely secure the communication.
- The diagnostic devices and equipment itself should be configured so as to protect the data stored on them.
- Multi-factor authentication can make it difficult for hackers to access the data as it calls for additional validation by way of SMS code, fingerprint or retinal scan rather than just the username and password.
- Install intrusion prevention systems like anti-virus software and firewalls to block unauthorised connections to the wi-fi network.
- It goes without saying that the devices should only be connected to secure networks and not public or open ones.
- The manufacturers should regularly release security patches for the systems and the labs should download and install them on a timely basis.

Conclusion

Medical and diagnostic devices are not governed by any legal norms for personal information privacy and breaches. Yet, the manufacturers and laboratories have to create an effective and efficient system for maintaining data privacy, security and safety!

MR. RAJIV NATH

MR. JATIN MAHAJAN

AiMeD's Mr. Rajiv Nath (Forum Coordinator) and Mr. Jatin Mahajan (Joint Coordinator) share their studied views and experiences on the opportunities and challenges faced by the sunrise diagnostic devices industry. Additionally, Mr Rajiv Nath is the MD of Hindustan Syringe & Medical Device Ltd. and Mr Jatin Mahajan is the MD of J Mitra & Company.

Indian In-vitro Diagnostics Industry – Opportunities and Challenges

THE INDIAN DIAGNOSTICS industry has finally emerged from the shadows. In the backdrop of the pandemic, diagnostics became the primary battle against the Covid-19 infection. Moreover, 70% of the medical decisions and treatments are dependent on the various diagnostics tests, and the pandemic has brought this backend diagnostics sector right into the forefront of the healthcare industry.

When corona hit us in Dec 2019-Jan 2020, the healthcare industry had no idea about the disease. The Indian IVD industry was quick to rise to the occasion. It quickly developed tests based on different technologies – Antibody tests, Antigen Tests, RT-PCR tests, amongst others. These locally manufactured test kits did an absolute yeoman service when there was a real scarcity of test kits in the market. India was finding it challenging to attain the testing momentum critical to counter the threat of Covid-19. The Indian test kit manufacturers, driven by their extensive R&D, were quick to develop highly potent test solutions across various technologies.

This fast and effective action of the Indian diagnostics manufacturers slowed the spread of the coronavirus in India. Most of these test solutions were better on sensitivity, specificity and quality parameters than foreign kits.

India's IVD story is a remarkable example of leadership and planning at various diagnostics and policy ecosystem levels. The Government and IVD corporates came together to tackle the pandemic effectively. The Government of India, through its flagship "Aatmanirbhar Bharat" initiative, encouraged Indian Medical Devices and IVD manufacturers to meet the ever-increasing demand for essential diagnostics, including Covid-19 test kits and secondary bio-marker tests like D-dimer, Ferritin, CRP and IVD Analysers etc

The Association of Indian Medical Device Industry (AiMeD) relentlessly worked at the forefront to combat the crisis. COVID-19 crisis has shown that Indian medical devices sector can rise to the challenge. When imports got disrupted, specific devices detailed with quantified production shortages and a focussed inter-ministry group coordinating with domestic manufacturers via AiMeD addressed production bottlenecks and challenges to utilise and enhance capacities.

India holds tremendous potential in the IVD segment and a significant sway in the global diagnostics industry. India is the international centre for frugal medical devices engineering and also among the leading exporters of IVD solutions across the world. The opportunities, therefore, in this segment are tremendous. The in vitro diagnostics (IVD) is recorded to mark a year on year growth of 30% in 2020 which will be double the market rate in average 10 years. The size of IVD industry in the year 2019 was Rs. 7500 crore which was slated to grow at a CAGR of about 15% before the COVID crisis. The Indian IVD market is likely to reach USD 2 billion in 2026, from USD 1.3 billion currently.

The focus of the Indian IVD companies has been on creating an innovation-driven ecosystem for resource-poor settings. The industry strives to develop tests and analyser platforms to address the need for precision and reliability, domestic production (self-reliant), affordability, and reaching closer to point-of-care.

The factors that are catalysing the growth of the Indian IVD market are – an increase of chronic diseases, focus on point-of-care (POC) diagnostics by consumers themselves.

Another growth area within IVD is molecular diagnostics e.g. RT PCR Test for COVID. Bacterial and viral epidemics, demand for POC devices, and evolving technology are driving the growth of this segment. In addition, molecular diagnostics test costs have become affordable due to multiple testing machines and centres established during COVID which will continue to help patients suffering from other infectious or genetic diseases. All these will further drive growth for the IVD industry in India and consumers will gain from indigenous availability and increased competition.

While the above scenario paints a very rosy picture, there are several critical challenge areas as well. Various aspects need attention to ensure that we genuinely become indigenous suppliers to the world. These could be in the form of partnerships, collaborations, incentivisation, regulations and certifications.

- **The supply of raw materials** has always been an issue with few domestic suppliers and manufacturers depending on foreign suppliers. An adequate supply of indigenous raw materials and other inputs made by scientific institutions or with industry partners will guarantee seamless production and safeguard against unnecessary delays and help in further bringing down the cost of production.
- **Quality Assurance and Certification –** Buyers need to seek ICMED (Indian Certification for Medical Devices) certification from manufacturers which is granted by Certification Bodies accredited by NABCB (National Accreditation Board of Certification Bodies) under QCI (Quality Council of India).
- **Separate law for Medical Devices** that provides innovation and quality access by consumers while addressing patient safety concerns and disciplining manufacturers without treating them as criminals for minor offenses. The Indian approval systems need a lot of tweaking to launch products quickly. Currently, there are too many institutions involved, and the process needs to be streamlined to ensure ease of doing business for Indian companies.
- **Rational Tariff Structure** - It's high time the aspect of inverted duty structure is appropriately addressed as done for mobile phones and consumer electronics. Inverted duty goes against the spirit of Make in India and Aatmanirbhar Bharat. There must be incentivisation for investors to make the medical products in India.
- **Financials and Incentivisation** - The Government must also give preference to Indian products for government procurements on basis of quality certification and design Indian certification to incentivise quality and indigenous innovation. Increasing government spending in healthcare from 1% of GDP to 3% of GDP will positively alter healthcare services and promote affordable access to Indian consumers. Reforms in the insurance sector can stimulate health insurance, thereby providing the financial incentives for medical technology innovation. Set up a venture investment fund to address the lack of early-stage venture capital for commercialising Academia led proposals to incentivise innovation.

The current Indian IVD Market is becoming significantly robust and has tremendous potential, not just for the domestic requirement but also for the international market. COVID has provided right opportunities, incentives like the PLI Scheme and evolving environment like Med Tech Parks schemes to showcase its true might.

Shashank Sudhi
Advocate

Mushrooming Illegal Pathological Labs Cause Of Major Concern Across The Country

- Common People Pay The Price!

"Our constitution guarantees right to health to its citizens but lack of uniformity of regulation of pathological labs are causing serious concern as existing statutory protections are too fragile to prevent the prevalence of illegal pathological labs. This is on account of separation of power between the centre and state and lack of uniformity of legislation in the centre and state"

– opines Advocate *Shashank Sudhi*

WHILE THE GOVERNMENT of India had enacted the Clinical Establishment Act, 2010 with a clear objective to regulate pathological labs, majority of the states have not implemented or if implemented at all, the state governments are not serious about the strict regulation of pathological labs. Laboratories are consequently being set up illegally and do not take proper measures while conducting tests. The common patients, who are not familiar with these processes, are often lured into fake and false tests. It is not uncommon that the cost of a particular test in these laboratories may vary depending on the owners and the helplessness of patients.

Lab owners were hesitant to share the rates for tests, saying they were not authorized to disclose the information. “Rates can be fixed through bargain,” said one lab's owner on the condition of anonymity. The government authorities, however, lack the required staff to keep a check on illegal medical practices or to visit labs across the state. The government does not hold any specific data on registered and unregistered labs and clinics either. The reason for this too, is said to be shortage of technical staff.

Substandard or fake diagnostic centres are extremely dangerous while considering that common people go there for conducting medical tests as prescribed by the doctor. But these centres, devoid of skilled manpower and necessary equipment, often deliver faulty pathology reports, which in turn may lead to inaccurate treatment and wrong medication, putting patients' lives at risk. A news report details a man having several health issues; when he conducted some tests as prescribed by a doctor in a diagnostic centre, the doctor asked him to repeat the tests in a better diagnostic centre. This time the problems were detected.

Sadly, such malpractices of private diagnostic centres are not uncommon in the country. Too often we hear of fake diagnostic centres, faulty test reports and wrong treatment. So many substandard diagnostic centres, private hospitals, clinics and diagnostic laboratories have been running in different parts of the country to cater to a growing demand of healthcare services.

At times, gross irregularities are found even in some well-known diagnostic centres. The condition of less known dubious diagnostic centres is anybody's guess. These so called health service providers are functioning more like commercial enterprises than service centres, where profit gets first preference. Such healthcare outlets have been doing business holding sick people hostage, thanks to the indifference of the authorities concerned.

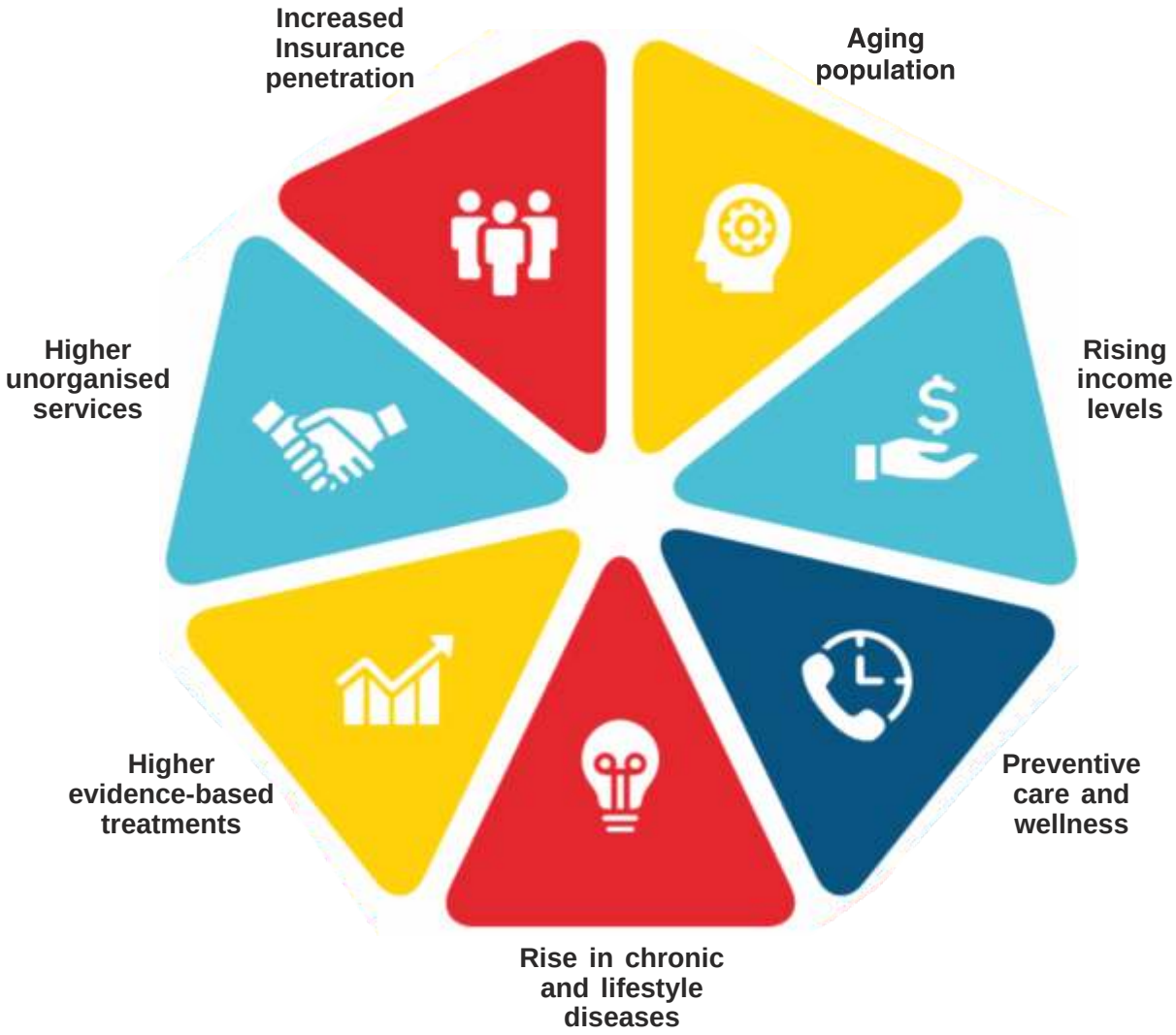
It is a constitutional right of every citizen of the country to get the best possible health facilities. But thousands of illegal pathology laboratories are being operated in various parts of the country by varied names viz, Pathology Laboratory, Clinical Laboratory, Medical laboratory etc. In these laboratories samples of blood, urine, sputum, various body fluids are collected by laboratory technicians, tests are carried out on these samples, reports are prepared and certified by these technicians and issued to the patients or doctors. Some of the technicians issue reports in the name of result analysis sheet and print some disclaimers like “Above readings are to be certified by the pathologist”, “strictly for the use of Medical Practitioners & Pathologists”, “these are not medical diagnostic results”, to confuse the implementing authorities. In these laboratories, MCI registered pathologists are not appointed for supervision of process of testing and certifying the reports. These laboratory technicians don't have the requisite qualifications to run such laboratories independently. Due to this, patients get erroneous reports leading to wrong diagnosis and wrong or delayed treatment. This is causing a major health hazard.

It is common knowledge that registered medical practitioners normally refer their patients to these illegal laboratories for various pathology investigations. The patients are unaware of the difference between legal and illegal laboratories. Though the registered medical practitioners are aware of the difference, they are referring patients to the said illegal laboratories and are advising numerous unindicated investigations for monetary gain. This amounts to unethical medical practice which is another major health hazard.

Also it has been noticed that few pathologists offer their names and/or signatures to these illegal laboratories. They do not visit these laboratories or supervise the process of testing on regular basis. Some even give signatures on blank letter heads of the laboratory and reports are printed on those letterheads afterwards. Thus they pretend that the reports are being certified by them and cheat the unsuspecting patients. It is again an unethical practice by pathologists causing ill effect on health of people at large.

It is heartening to know that the Hon'ble Supreme Court of India had passed judgment on 12.12.2017 in Special Leave to Appeal (C) No(s). 28529/2010. It states that “We dispose of all these special leave petitions and other pending applications, if any, by taking the view that the stand of the Medical Council of India that laboratory report

INDIAN DIAGNOSTIC INDUSTRY – MAJOR GROWTH DRIVERS



can be counter signed only by a registered medical practitioner with a post graduate qualification in pathology is correct." Govt. of Maharashtra is sitting quietly on the Supreme Court judgment dated 12.12.2018.

It is strange that many of the state governments have not taken a single step to stop the illegal laboratories, majority of which are functioning in urban areas. Government is reluctant to start action against these laboratories; in fact it is patronising these illegal labs.

Many states are still asleep to the impending dangers of the ubiquitous existence of illegal pathological labs and are endangering the health and safety of the common people. It is not that well-informed people are not aware of the deleterious impact of wrong diagnosis and wrong consequences but question remains as to who will bell the cat?

The renowned consumer activist, Prof Bejon Kumar Misra had risen to the cause of the common people for the need of quality diagnostic facilities and had filed Public Interest Litigation in year 2018 before Delhi High Court which was pleased to issue notice and directed Delhi Government to immediate action against illegal pathological labs. His efforts bore fruits and Delhi Government was constrained to legislate the law, i.e. Delhi Health Bill 2019.

Conclusion

The issue of regulation is a serious concern for public health and safety and it needs to be addressed urgently. In this regard, it is hoped that the authorities concerned will regularly monitor all private clinics and diagnostic centres. It may bring some positive changes in private hospitals, clinics and diagnostic labs. The Directorate General of Drug Administration should also improve its management of private clinics by strictly enforcing relevant laws and regulations.

Where can consumers have their say about policies and legislation, about their needs and requirements, about products and services, about genuine and fraud companies? We provide you the platform to share with our readers your experiences.
Write to us: bejonmisra@consumerconexion.org

Diagnostic Devices – Boon or Bane?

Diagnostics are playing a decisive role in our fight against COVID-19. With the demand for healthcare growing exponentially, so is the volume of laboratory testing. Let us take a look at what consumers feel is plaguing the diagnostic segment.

THE DIAGNOSTIC PROCESS is complex and collaborative. It involves intricate clinical reasoning and information gathering to determine what is actually wrong with a person's health. It sets the stage for making informed choices like the right treatment or appropriate preventive interventions. It also yields vital prognostic data that enable health professionals to optimise care pathways and management.

However, the Indian diagnostic industry itself is reeling under shortfalls like inadequate infrastructure, insufficient domestic supply chain and logistics, high finance and power outlays and unsatisfactory research and development. Investments in diagnostic development and scale-up is crucial now. Even on the regulatory front, there is a pressing need for greater clarity on assembled devices and imported parts used for putting together a device meant for end use. If these issues are sorted out properly, India can surge on the global front as well.

– Priti Mehra, Mumbai

Diagnostic technology is allowing doctors to thoroughly test patients. Latest advancements are enabling earlier detection of diseases and more reliable monitoring of treatments. The government needs to do its bit by supporting innovation so that the benefits to patients get accelerated and the sector also flourishes.

A steady focus is essential on safety as there are varied concerns about the risks of some diagnostic devices. Why is there no talk on the serious health consequences of unnecessary tests which can extend to adverse drug effects and superfluous invasive procedures too? The price tags are also worrisome as they cause an excessive strain on our wallets!

– Aarti Bharadwaj, Bangalore

The World Health Organisation estimates that a quarter of death and disease globally is caused by hazards and environmental burdens in developing countries with little to no access to preventative care and diagnostic devices. It further reckons that at least 80% of premature heart disease, strokes and diabetes and 40% of cancer can be prevented through early diagnosis and lifestyle change. We have to focus on diagnostic tools as they will be our arsenal for the next pandemics.

– Saurabh Nathany, Kolkatta

While quality of diagnostics is constantly evolving and improving, what about the healthcare professionals? How can they be allowed to operate on outdated medical learning? Continuing education along with upgrading the diagnostic reasoning skills of the practitioners is imperative so that they can correctly interpret the results. Institutional support can encourage practice-based inquiry and other modes of learning. What we need is a learning community!

– Sandeep Malpani, Indore

Healthcare is all about science now. Doctors are relying mostly on diagnostic data to treat patients. All I want to ask is how do we know that the data emerging from diagnostic equipment is accurate and reliable? Suppose there is an error, the patient will become a victim even without his or her knowledge? Is this ethical? Can it be allowed? Some good doctors may be careful, but when will be able to expect this across the board?

– Sriram Lohri, Itanagar

UPDATE ...

Moving a Step Ahead

Update on the November edition on World Quality Day 2021 - Fostering a Culture of Quality Consciousness

WORLD QUALITY MONTH 2021

Global Summit on 'QUALITY & THE CONSUMER'

TO PROMOTE THE mission of quality and sustainability during the World Quality Month, the Chairman and advisory board members of the Patient Safety & Access Initiative of India Foundation and Consumer Online Foundation along with the Pharmaceuticals Export Promotion Council of India and Telangana Information Technology Association (TIT) organised the First Global Summit on 'Quality & The Consumer'. The summit was conducted in hybrid mode on 23rd November with the offline segment being hosted at ITC Kohenur in Hyderabad.

Moderated By Prof. Bejon Kumar Misra, Founder, Consumer Online Foundation, many eminent dignitaries graced the landmark event – some virtually and many others with their physical presence.

Mr. Satish Reddy, Chairman of Dr. Reddy's Laboratories Limited delivered the Shri Labanyendu Mansingh Memorial Oration by highlighting the exemplary sustainability initiatives that are an integral part of his business operations and enable them to meet environmental and social standards. He stressed on the resultant positive impact on the reputation and competitive advantage of the pharmaceutical behemoth.

Many other distinguished personalities shared their views on the way forward to make India self-reliant and stand on four of its biggest strengths – affordability, accessibility, agility and quality. A Lifetime Achievement Award for Promoting Quality was presented to Dr C Gopalakrishna Murty, a renowned mentor in the field of Pharmacy.

Furthermore, this voluntary consumer organisation actually brought all the stakeholders together to deliberate on the need for a National Consumer Policy with focus on 'Quality Without Any Compromise' to sustain the mission of Atmanirbhar Bharat. The future Quality Summits will build focus on different areas of the 'Vision for India' where quality must play a dominant role!

YOUR OPINION MATTERS

letters to the editor

We are truly humbled by the praise and acknowledgment that is flowing in from varied sources. Please feel free to send in your comments, views or feedback on The Aware Consumer magazine at bejonmisra@theawareconsumer.in – we will publish your opinions and implement your feedback while ensuring that your voice is heard on the right platforms.

(November issue - World Quality Day 2021 - Fostering a Culture of Quality Consciousness)

Dear Prof Misra

Your publication 'The Aware Consumer' has undertaken some wonderful quality-related initiatives in India. I have done a quick study of your quality-related work and want to pat you on the back (via this note) for your continuing efforts to bring sustained quality consciousness in India. More importantly, establishing the Consumer Online Foundation with a portal for consumer complaint redressal is a phenomenal effort to bring the Indian manufacturing industry to the pinnacle of quality and reliability. In my own lifetime, I have seen the emergence of countries like Japan, Korea and China into world economic powers, all due to enhancement of quality consciousness within their respective countries.

I would like to take this chance to let you know that your efforts at consumer protection are being noticed outside of India as well. Do let me know how I can assist in your endeavours!

– C. P. Ramani P.E., CBO Retd. Founder-President International Accreditation Service, USA

Nice and very useful articles on quality management issues. The concepts of industry 4.0 and 5.0 as well as quality 4.0 and 5.0 are highly interesting. Provides good directions to the people in industry, research and leadership. Impressive presentation. Congratulations to the whole team.

– RP Singh, Gorakhpur, U.P.

The Aware Consumer is a unique magazine, the publisher, Prof. Bejon, is the champion for the consumer cause for more than 3 decades as I can recall. I wish the magazine and the team very best. Just a suggestion we need to establish one contact point for the consumer grievances and I hope this issue could be addressed by this esteemed magazine.

– Sayed Raza, Jamshedpur

I have been reading this magazine since a year or so. It is very informative and covers almost all aspects of consumer education and interest including what is happening around us. A good and worthwhile initiative.

Recently I had an issue about credit card anomalies with a big nationalised bank who were harassing me for over a month for non-payment of dues which actually was non-existent as the fault was from their side. This speak volumes of how our nationalised banks work and their inefficiency. However after Consumer Foundation took up my case, it took no more than a week to resolve my case. Prof. Misra himself took up my case with the Chairman and CEO of the said bank and the issue was resolved in no time.

There are some minor issues like reversal of penalties and interest payment etc, but they promised to resolve these soon. This is not the first time Consumer Foundation came to my rescue; in the past, two of my contentious issues were solved by them. To my mind this is the most viable, vibrant and effective platform for consumer redressal working in the country at this moment, much better than so called consumer grievance cells set up by central and state governments. Even the Chairman of a Nationalised bank had to acknowledge this!

Keep up the good work.

– Himadri Sarkar, Jamshedpur

Very well written article on Sustainability through the lens of Quality. The quote by former UN Secretary General is very aptly used. Would love to see some real life companies/case studies who have already embedded Sustainability through quality. It will show some path to the fence sitters and onlookers!

– Abhinav Jhunjhunwala, Pune

SOURCES / REFERENCES

https://www.webmd.com/
https://www.ncbi.nlm.nih.gov/
https://www.who.int/
https://www.downtoearth.org.in/
https://www.thehindubusinessline.com/
https://economictimes.indiatimes.com/
https://www.deccanherald.com/
https://www.business-standard.com/
https://www.financialexpress.com/
https://www.newindianexpress.com/
https://www.washingtonpost.com/
https://thewire.in/
https://www.mondaq.com/
https://www.health.harvard.edu/
https://nathealthindia.org/
https://www.sciencedirect.com/
https://ehealth.eletsonline.com/
https://healthcaretransformers.com/
https://www.healthissuesindia.com/
https://www.drishtiias.com/
https://arogyalegal.com/
https://www.mdpi.com/
https://www.invetechgroup.com/

WATCH OUT for the next issue in February 2022 dedicated to Trend of Irrational Bans in India

National Accreditation Board
for Hospitals and Healthcare Providers

QUALITY COUNCIL OF INDIA
Creating an Ecosystem for Quality

NABH AYUSH ENTRY LEVEL CERTIFICATION PROGRAM

TAKING QUALITY TO OUR ROOTS

NABH
is a constituent board of Quality Council of India (QCI).
It is playing a pivotal role at the National level in propagation, adoption and adherence to healthcare quality standards in AYUSH healthcare delivery systems.

With an objective to bring more light to AYUSH related treatments, the Government of India in 2014, formed the Ministry of AYUSH and consequently brought in the National Accreditation Board for Hospitals & Healthcare Providers (NABH) to start implementing quality healthcare standards for hospitals providing AYUSH treatments as well.

In the recent years, there has been a paradigm shift from allopathy system to traditional healthcare. To support this trend, health insurers have started offering AYUSH treatment covers as part of their health insurance policies. NABH Ayush Entry Level Certification Standards provide an objective system of empanelment by insurance and other third parties. These standards also address the need for quality control and quality monitoring in AYUSH healthcare as required by the Pradhan Mantri Jan Arogya Yojana (PM-JAY) under the Ayushman Bharat Scheme.

NABH AYUSH Entry Level Certification standards are easily downloadable from NABH website.

www.nabh.co
nabh@nabh.co

THE AWARE CONSUMER

India's Most Credible
Consumer Monthly

Save upto 50% on subscription

Subscribe today!

Save ₹3,600/- FOR 36 ISSUES

Please accept my subscription of **THE AWARE CONSUMER**

NAME _____

ADDRESS _____

PH. NO. _____ E-MAIL _____

PAYMENT ☐ CASH ☐ CHEQUE CHEQUE/DD NO. _____

DRAWN ON _____

DATE _____ SIGNATURE _____

No. of Issues	News Stand Price	Discount	You Pay	You Save
12	₹ 2,400/-	20%	₹ 1,920/-	₹ 480/-
24	₹ 4,800/-	30%	₹ 3,360/-	₹ 1,440/-
36	₹ 7,200/-	50%	₹ 3,600/-	₹ 3,600/-

Cheque / DDs should be drawn in favour of **HAMARA CONSUMER DOST PVT. LTD.**
Send your subscription to: The AWARE CONSUMER, F-9, 2nd Floor, Kailash Colony, New Delhi-110048
Contact: 9311044424 • E-mail: bejonmisra@theawareconsumer.in

Posted at Lodi Road HPO, New Delhi on 9-10th of every month
Published on 6th of every month

RNI No. DELENG/2015/67140
REG. NO. DL (S)–17/3523/2017-19