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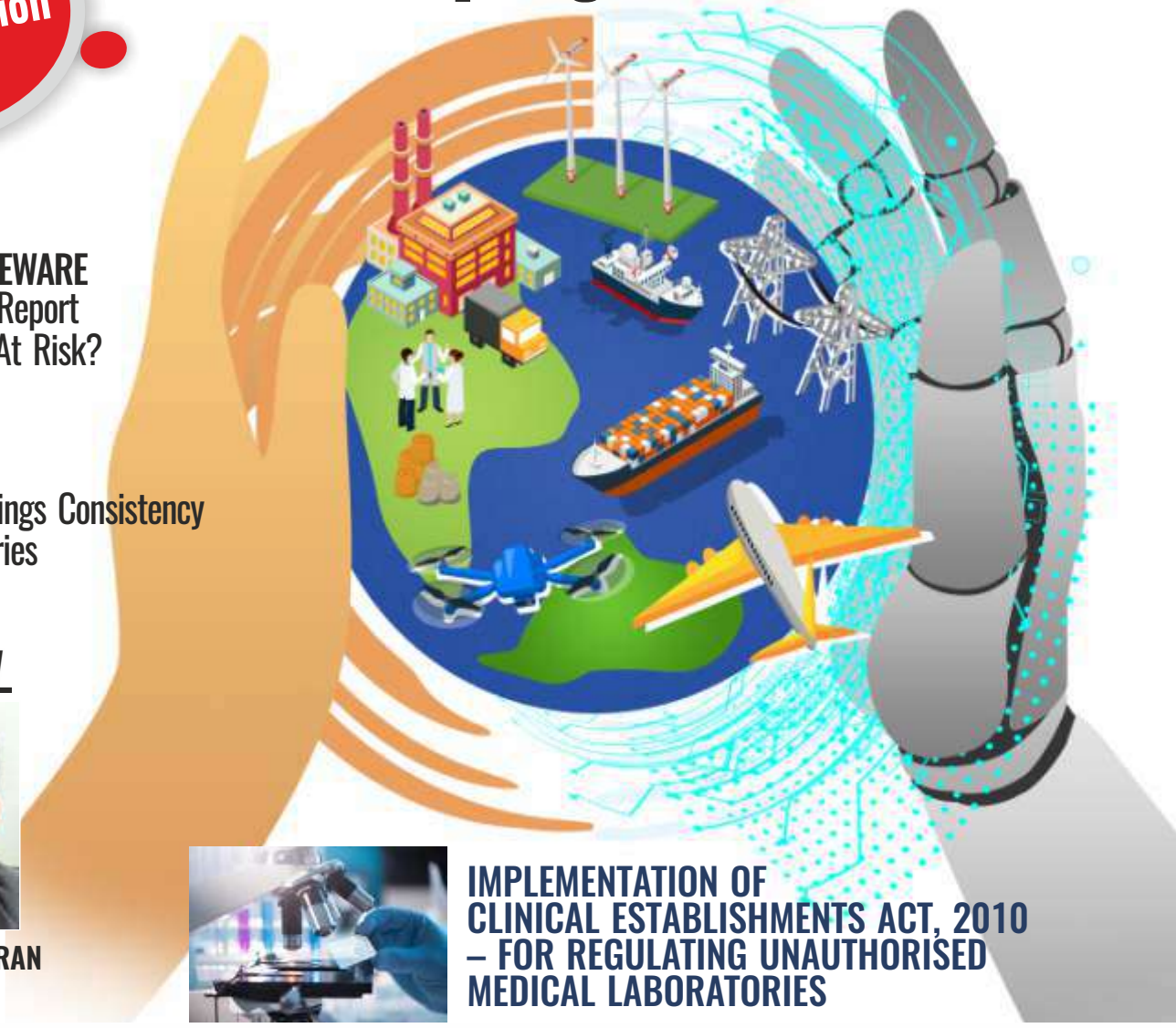
Theme

Accreditation: Empowering Tomorrow and Shaping the Future

#World Accreditation Day



CONSUMERS, BEWARE
Could Your Lab Report Be Putting You At Risk?

IN FOCUS
Accreditation Brings Consistency Across Laboratories

INTERVIEW

N. VENKATESWARAN
CEO, NABL

IMPLEMENTATION OF CLINICAL ESTABLISHMENTS ACT, 2010 – FOR REGULATING UNAUTHORISED MEDICAL LABORATORIES

PLUS ROUND UP • RESEARCH FEATURE • MY MARKET

National Accreditation Board for Testing and Calibration Laboratories

NABL Accreditation of Medical Laboratories

NABL grants accreditation to Medical Laboratories in accordance with ISO 15189, an international standard for Medical Laboratories Specifying Requirements for Quality and competence for following scope

2000+ ACCREDITED MEDICAL LABORATORIES ENSURE RELIABLE AND TRUSTWORTHY RESULTS HELPING IN ACCURATE DIAGNOSIS

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✓ Haematology	✓ Histopathology	✓ Cytogenetics
✓ Clinical Pathology	✓ Cytopathology	✓ Molecular Testing
✓ Medical Imaging		

NABL also Grants accreditation to Calibration and Testing laboratories in accordance with ISO/IEC 17025 for the Medical devices used in Diagnostic centre and Hospitals

Important Accreditation Documents (Available on NABL website - www.nabl-india.org)

NABL 100A General Information Brochure	**NABL 100B** Accreditation Process & Procedure	**NABL 112** Specific Criteria for Accreditation of Medical Laboratories	**NABL 126** Specific Criteria for Calibration of Medical Devices	**NABL 136** Specific Criteria for Accreditation of Quality Assurance Testing Facilities for Diagnostic Radiology X-Ray Equipment

Why Choose Us?

NABL Accreditation in the field of Medical Testing is beneficial in following ways:

- Ensures the competence of the laboratories and Assurance of accurate and reliable results
- International recognition/ equivalence
- Robust Quality Management System

MC- XXXX

Look for NABL symbol on test reports of NABL Accredited Medical Testing Laboratories

NABL as an accreditation body complies to ISO/IEC 17011: 2017 and is a full member (signatory) to Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRA).

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VIEW POINT

MESSAGE FROM PUBLISHER & EDITOR

CRAFTING A SUCCESS STORY FOR Registration of Medical Laboratories

HEALTHCARE INSTITUTIONS ARE supposed to be the Messiah for the people at large. They diagnose diseases, treat ailments and nurse people back to good health.

A matter that has always got my back up is that the health and well-being of patients is in the hands of scores of unregulated healthcare institutions. I am especially irked by unqualified and inexperienced people running medical laboratories and literally holding the health of the nation at ransom!

Think about it – what choice do you and I really have here? We blindly rely on the diagnostic reports of the pathological labs which, in turn, dictate our medical treatment. Can we even gauge the quantum of health hazards when majority of these labs are unauthorised and issue unqualified reports?

This is despite the central government enacting the Clinical Establishments (Registration and Regulation) Act, 2010, which, unfortunately, continues to remain mere words on paper!

Not one to take such things lying down, I moved a Public Interest Litigation (PIL) in the Delhi High Court in September 2018 against unauthorised pathological labs being run by unqualified technicians in the national capital while also calling for strict implementation of the Clinical Establishments Act (CEA).

After a number of hearings and affidavits over the past six years, I finally breathed a sigh of relief two months back when the Delhi health minister and health secretary agreed to forward the Delhi Health Establishments (Registration and Regulation) Bill to the Government of India for necessary approval. Meanwhile, they will implement the central government's CEA statute to regulate clinical establishments in the NCT.

This is a BIG VICTORY in favour of the citizens and will finally ensure that patients have the right to quality in medical laboratory testing. We are buoyed by the resounding success of the court's intervention as it has to be implemented pan-India now. In case the states falter in implementation, we will not hesitate to knock on the doors of the Supreme Court of India to implement this landmark legislation in the interests of the safety of patients and health of the consumers!

Rest assured, we will not rest until the CEA is implemented across every hospital, clinic, dispensary and diagnostic centre in every nook and corner of the country!

Prof. Bejon Kumar Misra
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PRAFULL D. SHETH
Editorial Board Member

DESKTALK

ENHANCING COMPETENCE, ENSURING CREDIBILITY:

WORLD ACCREDITATION DAY

COME 9TH JUNE, accreditation bodies across the world will celebrate World Accreditation Day. It is a global initiative to raise awareness on the crucial role that accreditation plays in various aspects of our life. This year, the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) have chosen the opportune theme of 'Accreditation: Empowering Tomorrow and Shaping the Future' to highlight the transformative power of accreditation in the rapidly changing world.

The theme will stress on the role of accreditation in shaping everything from technology to transportation, sustainability to security, and inclusivity to innovation, as digitalisation, new technologies and growing sustainability concerns continue to change our world. It will explore how accreditation enables the development of innovative technologies, and how it can facilitate the integration and adoption of these technologies, particularly where precision, safety and quality are critical.

The National Accreditation Board for Testing and Calibration Laboratories (NABL), a constituent board of the Quality Council of India (QCI), uses this platform to recognise the efforts of accredited Conformity Assessment Bodies and emphasises their commitment to upholding standards and best practices. It also showcases the role accreditation plays in ensuring accuracy, reliability and quality in the testing fields, especially medical diagnostics.

Currently, NABL has around 8078 accredited laboratories that are dedicated to ensuring that products meet the specified requirements. Of these, 1978 accredited medical laboratories are ensuring that proper diagnosis is possible through trustworthy test results.

We urge more and more diagnostic centres to get accredited to uphold the sanctity of patient health and safety in the community. Additionally, once the Clinical Establishments Act is properly implemented pan-India, each and every path lab will have to be registered and operate under the stipulated requirements, thus ensuring maximum safety and affordability in healthcare!

Meanwhile, you and I, as patients, should always opt to get our medical tests done in accredited labs, which is a symbol of consistency and precision in the results.

INSIDE

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THE AWARE CONSUMER
UNLOCKING CONSUMER POTENTIAL
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There are no two ways about it – medical diagnostic test results need to be right!

COULD YOUR LAB REPORT BE PUTTING YOU AT RISK?

Laboratory testing is the first line of defence for recovering from any kind of adverse health condition. We have blind trust in the medical reports - but, can 'wrong reports' signed by 'unqualified technicians' secure us the appropriate treatment? The consequences can be grave, posing a threat to our health and even life!

WE ARE WELL aware that when we visit a doctor for any kind of pain, sickness or injury, he/she will prescribe a list of tests before making any diagnosis, let alone starting any treatment. Medical testing is considered an almost foolproof tool for detecting a variety of diseases and conditions, including infections, diabetes, heart disease, cancer and genetic disorders.

A medical laboratory conducts tests on clinical specimens like cells, tissues, blood, urine and other body fluids to obtain information about the health of a person. Similarly, imaging techniques (x-ray, ultrasound, MRI, etc.) are used to examine the human body from the inside.

The results are analysed and relayed in the form of reports. Physicians read and interpret the data to identify, treat and prevent diseases. In fact, everything from diagnosis and line of treatment to monitoring treatment efficacy and planning continuum of care is determined after conducting some test or the other.

Think about it – lab tests guide almost all big and small medical decisions – Do you need antibiotics? Should you be started on insulin medication? How much blood thinner should you take after a heart attack?

The Covid-19 pandemic shone the light on the critical role of diagnostics in saving lives – it was timely and accurate testing that helped doctors to quickly begin appropriate treatment, undertake effective contact tracing and thus control the spread of this novel disease. Without the weapon of medical reports, they would just be shooting in the dark while the invisible virus was spreading its deadly web around the world…..

Question Mark on Quality and Reliability

It follows that any kind of shortcoming in the test results will translate into misdiagnosis, delayed diagnosis or mistreatment which can prove to be life-threatening. For instance, a false negative - like missing diagnosing leukaemia - can keep the patient from getting timely treatment and even cost him his life. On the other hand, a false positive – like diagnosing a breast cancer when none exists – will unnecessarily put a patient through painful and costly treatment when it was not needed at all.

While human error is inevitable and we cannot expect 100% accuracy in testing, what if the fault lies in the fact that the medical laboratory is unauthorised or operated by unqualified staff? What if substandard or expired equipment, consumables and reagents are used to conduct the tests?

A study by Harvard professor ASHISH JHA revealed that over 5.2 million medical error cases are reported in India annually, most of which are triggered due to lack of skills and proper training.

The incident in 2015 of a couple in Bengaluru continues to raise goosebumps for parents – they would have put the life of their newborn at risk had they not taken a repeat test for thalassemia!

Commenting on this shocking case, Dr. Jayaram, a pathologist working in a private laboratory affirmed, "Some variation in the values is inevitable between reports of tests conducted using two different methods, or between tests conducted using two different machines or at two different labs. But the upper limit of acceptable error, in case of Hb electrophoresis, is 10%. Hence, 2350% is quite a dramatic error."

And, what if the lab does not run the tests at all and issues fabricated reports (known as 'sink tests' as the specimens literally go down a sink drain)?

DR NAVIN DANG, who runs a leading laboratory chain in the National Capital Region recalls a case where the blood samples of a 22-year-old girl, running a persistent fever for nearly two months, had failed to detect leukaemia. “It was beyond bizarre, as a simple complete blood count test ought to indicate something that is so clearly wrong. However, in her case, none of the labs could detect the obvious abnormality in her samples,” he said, hinting that it was possible that her samples were probably never examined at all!

News reports about unaccredited, fake laboratories and inaccurate test results abound in the media. In the capital city of Delhi alone, a 'lab' operated by an arts graduate was 'testing' samples and generating reports for seven long years! Another such 'lab' issued 30,000 fake reports in a year. One more was found collecting samples under a tree on the footpath right outside the gates of AIIMS!

However, in most cases, the patients - even the doctors themselves – don't even come to know that there was a mistake with a test result. And even if they do, the labs will go to any length to avoid responsibility.

Like the CEO of the reputed maternity hospital (which had misguided the Bengaluru couple with an incorrect report) contended that there was no mistake on the part of the hospital and that it is possible to get wrong reports in medical science, without caring to explain the colossal difference of values in the two reports.

A report by the Tata Trusts' non-profit, Health Systems Transformation Platform reveals that the health minister of Uttar Pradesh once acknowledged that the state was unable to ensure quality in over 90% of the laboratory services that were in the private sector!

Root of the Problem

Even today, there are numerous pathological laboratories operating in a grey area in India. Thankfully we now have the regulation (Clinical Establishments Act, 2010) which along with the accreditation body (National Accreditation Board for Testing and Calibration Laboratories - NABL) would ascertain the reliability of results, if mandated.

The CEA mandates registration of medical laboratories and prescribes minimum standards for regulation – including calibration of equipment and other standard operating procedures. It also has a provision for guiding the labs to get accredited with recognised bodies such as NABL. This kind of accreditation will enable the laboratories to attain pre-defined standards that ensure reliability of results.

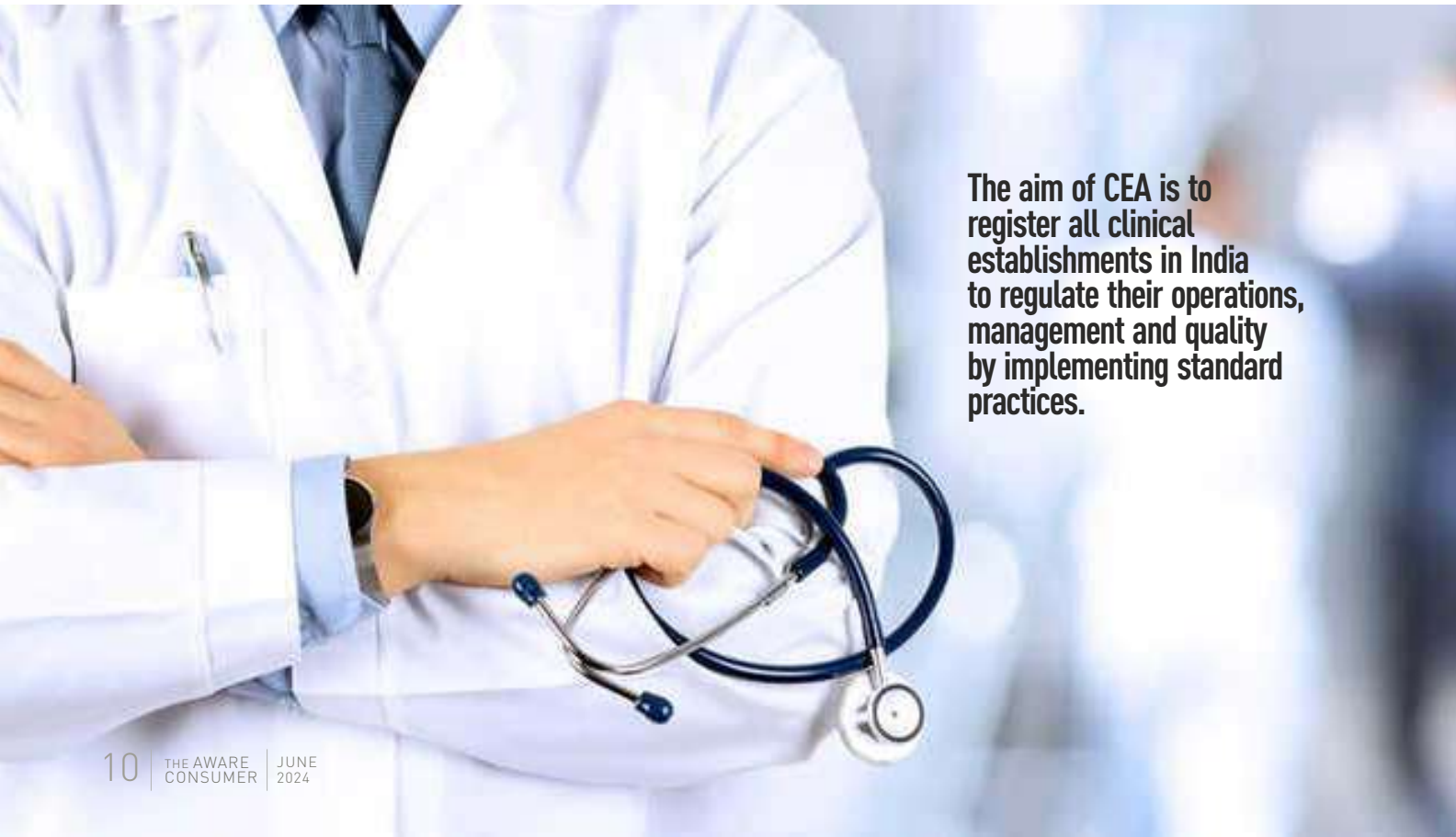
However, with the lackadaisical approach in implementing the registration requirements and minimum standards, the labs operate like any other commercial enterprise with negligible quality control!

In a national survey of 22,000 people by leading community social media platform and pollster, LocalCircles in 2020, only 17% of the respondents fully trusted the laboratories they used, and 34% reported receiving one or more incorrect laboratory reports.

A combination of voluntary and statutory mechanisms - accreditation and regulation – are the key to ensuring quality in medical diagnostic services.

Mandatory Registration and Regulation for Laboratories

The entry barrier for medical laboratories and diagnostic centres is low and almost anyone can open a lab today without any questions asked about the quality of services. The Clinical Establishment Act 2010 aims to fill the regulatory vacuum and organise the health sector so as to make quality medical facilities available, accessible and affordable to the consumers.



The aim of CEA is to register all clinical establishments in India to regulate their operations, management and quality by implementing standard practices.

IT IS VERY easy to establish and operate a medical/imaging laboratory in India. The entry requirements are almost non-existent.

In 2010, the central government sought to regulate the pathology and imaging laboratories by enacting the Clinical Establishments (Registration and Regulation) Act, 2010. It provides for the registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Act makes it mandatory for all clinical establishments - across all recognised systems of medicine (including Ayush) both in the public and private sector – to register themselves and provide standard treatment/testing to the consumers. This covers hospitals, maternity homes, nursing homes, dispensaries, clinics, laboratories and diagnostic centres. The only exception is clinical establishments run by the Armed Forces.

The Act aims to bring uniformity in the healthcare sector in terms of treatment protocols, testing methods and pricing structures.

Subsequent amendments have been made 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'.

Salient Features of the Act

- The Central Government will determine the rates for procedures and services to be charged by the clinical establishments from time to time in consultation with the state governments. All registered entities are required to maintain prices within the prescribed range. Additionally, the details of rates and facilities available should be displayed prominently in both English and the local language.
- Mandatory registration will enable the generation of a reliable and comprehensive database (digital registry) of all types of clinical establishments in the country at the national, state and district level. This composite information will be particularly valuable for public health interventions including outbreak and disaster management.
- The clinical establishments will be classified into distinct categories and basic minimum standards will be determined for every category. These standards for operation (both *Mandatory* and *Desirable)* will be defined using a participatory and consultative approach to ensure uniformity across all establishments.
- The clinical establishments have to maintain records and reporting as prescribed and provide information and statistics when asked by the authority.
- The clinical establishments will have to provide emergency medical treatment within the staff and facilities available.
- Multi-stakeholder bodies will be established - National Council for Clinical Establishments at national level, State/UT Council for Clinical Establishments at state level and District Registration Authority in each district. Implementation of the Act is by respective states through the State Council and District Registration Authority.
- The designated authorities can monitor and inspect the clinical establishments to ensure compliance with the prescribed standards and guidelines. These inspections will identify and address any deficiencies or violations that may compromise the safety and quality of healthcare services.
- The authorities can impose fines for non-compliance – Rs. 50,000 for running an unregistered establishment (first offence), Rs. 25,000 for knowingly working in an unregistered establishment and Rs. 5,00,000 for obstructing investigations, withholding information or giving false information. Severe violations can invoke imprisonment or even cancellation of the registration.

Hence, no one can run a clinical establishment without registration!

Procedure for Registration

There is a two-step process of registration:

- Provisional registration (valid for a year) is done through a process of self-declaration, without any inquiry or inspection.
- Permanent registration will be granted after verifying conformance with the notified standards prescribed for that category of clinical establishments.

Application for registration can be done by post, in person or online.

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

Registration will be granted only if a clinical establishment adheres to the following conditions:

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

The Act places the entire process of registration and the data of clinical establishments in the public domain which ensures transparency.

The certificate of registration should be displayed at a prominent place from where it is clearly visible

Medical labs and diagnostic centres have been classified into three levels -

- Basic Composite (Small)
- Medium
- Advanced

The *Essential* and *Desired* tests that should be conducted at the said labs is clearly listed. Specific manpower, infrastructure, recordkeeping and legal requirements have also been defined for each type of medical laboratories.

The registration can be cancelled at any time if the conditions for registration are not complied with.

Benefits for Consumers

- Improved quality of healthcare and patient safety through compliance to minimum standards, standard treatment guidelines and preventing unqualified persons from running clinical establishments.
- Better management of emergency medical conditions.
- Clinical establishments cannot charge exorbitant prices.

Taking Action

The union Health Ministry notified the Clinical Establishments (Central Government) Rules, 2012 vide Gazette notification dated 23rd May, 2012. The National Council for Clinical Establishments was established and has held 13 meetings till date.

The Council defined clear classification and categorisation criteria for clinical establishments. It has also laid down the minimum standards and standard treatment guidelines. They cover various aspects of healthcare service delivery, including infrastructure, human resources, equipment, patient care and safety protocols.

There is an inequitable and imbalanced distribution of medical testing and diagnostic services across different regions in India (although their exact number and distribution remain unknown). A national registry of medical laboratories will shed light on their number and geographical spread, thus helping the authorities assess the adequacy and formulate plans to meet the shortfall.

It also created a National Register of Clinical Establishments which lists the registered entities across 13 states and union territories. *However, medical laboratories are not included in the registry as yet.*

The Act has faced significant challenges in ensuring uniform standards and compliance, overcoming resource and infrastructure limitations, addressing resistance from the private sector, coordinating and collaborating with other healthcare stakeholders, effectively monitoring and enforcing compliance, and balancing patient privacy and transparency.

What's more, the Act itself does not provide for grievance redressal of patients. Additionally, once a clinical establishment submits the paperwork and proof of compliance, no checks are conducted after registration.

This calls for continuous refinement, strengthening and adaptation of the regulatory framework to address the evolving challenges in the healthcare sector.

Dr V K Paul, member (health) Niti Aayog and former chairperson of the Medical Council of India's Board of Governors, admitted that lack of specified standards in infrastructure, qualification and transparency in case of laboratories has been a 'huge concern' for the government. Although standards exist for labs, these are mostly not mandatory in our country. Only specific sectors have mandated.

Conclusion

The CEA is a significant milestone, which, if implemented in letter and spirit, will ensure that all clinical establishments provide safe, effective and quality healthcare services, thereby safeguarding public health and maintaining high standards of healthcare in the country.

Indian diagnostics is one of the fastest growing markets in the world and is expected to grow at a CAGR of 11.53% till 2028. Hence, the imperative need to strengthen the regulatory framework for the diagnostics sector cannot be sidelined anymore!

Current State of Clinical Laboratory Practice in India

Comparing current practices of medical laboratories using peer-to-peer benchmarking will set the stage for continuous improvement and upskilling, thus enabling better and safer patient care. The Indian Clinical Chemistry Laboratory Benchmarks (ICCB) Survey 2023 establishes relatable performance benchmarks in quality, speed, operational workflows and productivity for clinical laboratories in the Indian operating environments.

Benchmarking enables the labs to measure their performance vis-a-vis similar organisations in the industry. It also defines measures of what world-class means for the industry as a whole!

MANAGING AND PROCESSING samples and performing and reporting tests are the two fundamental functions of every laboratory. A successful service is one in which these activities are guided by the concepts of quality, speed, operational process and productivity. Here, quality is determined by meeting accreditation standards and successful participation in external quality assurance with an emphasis on continuous improvement methods.

CAHO
COMMITTED TO SAFER HEALTHCARE

Roche

Roche Diagnostics India partnered with the Consortium of Accredited Healthcare Organisations (CAHO) to redefine laboratory practices in India. It initiated a benchmarking study for clinical chemistry laboratories in April 2023 to assess their performance on a wide range of quality, speed and other indicators. This will enable the labs to identify areas for improvement and maintain a competitive advantage, thus ensuring highest level of care to the end users.

The benchmarking of diagnostic practices was done not just at the individual lab level, but also at an international level, to understand where Indian laboratories stand in terms of quality, productivity, costs, patient experience and clinical value generated - which are considered as the pillars of excellent patient care. Following on the survey, an upskilling programme was also conducted for laboratories in the country.

The benchmarking survey was started in 2011 and as of date, has surveyed over 4000 labs across 20 countries in the Asia Pacific region. It is one of the largest benchmarking and most systematic surveys of its kind in the world, providing valuable insights for laboratories.

Roche Diagnostics provides diagnostic solutions for screening, early detection, evaluation and monitoring of diseases. It is working with the objective of 'Doing now what patients need next', thus preparing for the future needs of healthcare in India.

CAHO is a not-for-profit body that aims to enable quality and patient safety initiatives in Indian healthcare. It serves as a common platform for NABH, NABL and JCI accredited healthcare organisations, facilitating communication and sharing of best practices, while promoting and continuously improving the quality and safety of healthcare services across India.
The members include healthcare institutions, diagnostic centres and quality professionals and works to promote patient safety through training for healthcare professionals.

At CAHO, we are constantly working towards continuous quality improvement, patient safety and capacity building in the arena of healthcare delivery. We are extremely excited about our partnership with Roche Diagnostics India that brings a unique and one-of-its kind bench-marking survey that will enable laboratories to learn best practices in clinical diagnostics through peer-to-peer global knowledge sharing.

- Dr Vijay Agarwal, President, CAHO

Highlights of White Paper

The ICCB survey covers responses from 103 laboratories across India including private hospital labs, university hospital labs, commercial labs and government hospital

The Lab Insights benchmarking survey gives a perfect opportunity for evidence-based learning that focuses on four major parameters – improvement in lab management, upskilling bench scientists, providing access to global best practices and facilitating labs in India to align with global standards.

- Narendra Varde, Managing Director, Roche Diagnostics India and Neighbouring Markets

labs. It had a good representation of laboratory classes based on samples per day, tests per day, number of beds and the like. (see Figure 1) The performance of Indian labs was contrasted against peers from 311 labs from 12 countries across the Asia–Pacific region.

Accreditation – According to the survey results, ISO 15189 accreditation (requirements for medical laboratories for quality and competence) is highly favoured by the medical laboratories. A substantial 74% of the labs reported having obtained ISO 15189 accreditation and another 16% indicated that they planned to acquire the same.

The National Accreditation Board for Testing and Calibration Laboratories (NABL) remains the key body for providing accreditation to medical testing laboratories in accordance with ISO 15189. It is closely collaborating with the labs to facilitate the transition to ISO 15189:2022. There is a collective effort to increase the number of labs that obtain accreditation, ensuring a higher standard of quality across the industry.

Indian laboratories are also increasingly participating in international accreditations like Joint Commission International (JCI) and College of American Pathologists (CAP), with 9% and 24% of labs respectively indicating plans to start this process. (see Figure 2)

FIGURE 1 Distribution of Participating Laboratories

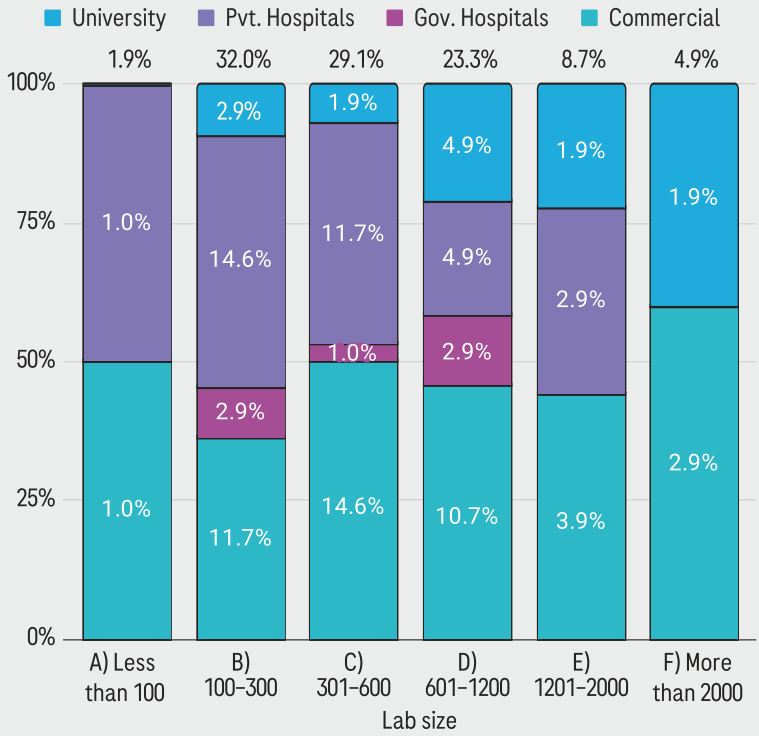
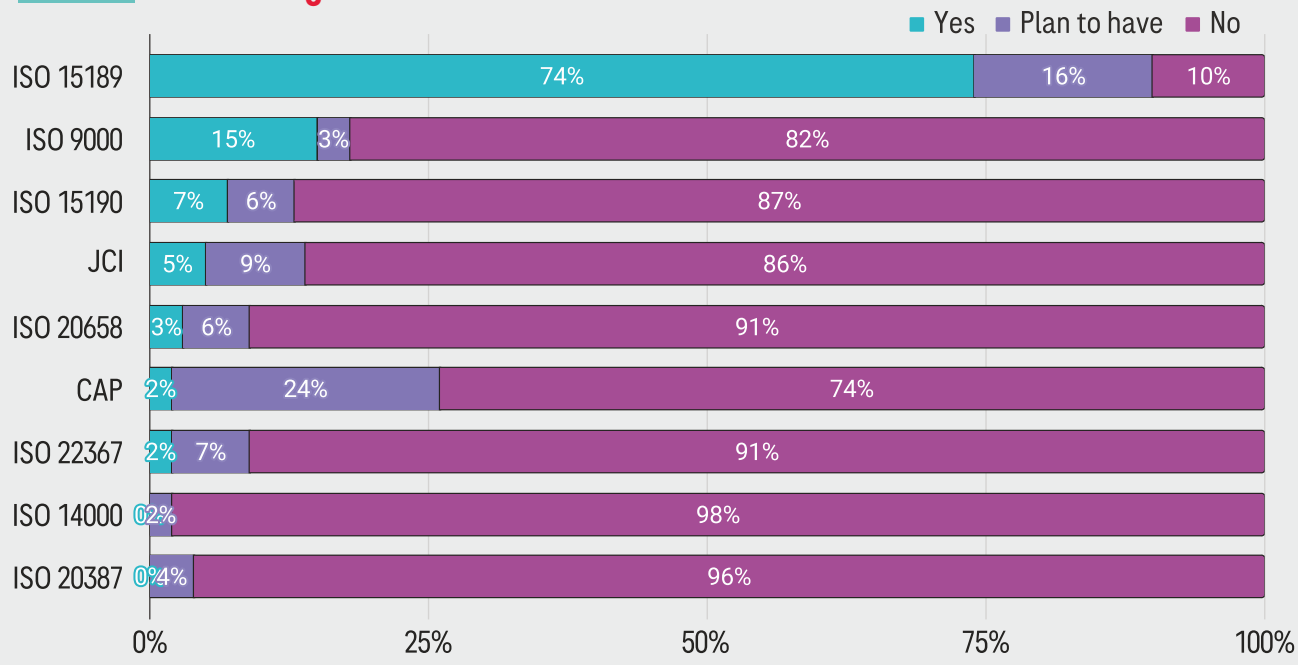


FIGURE 2 Labs having ISO 15189 Accreditation and other Certifications



Continuous Improvement Initiatives – Every organisation needs to enhance all aspects of its service operations and delivery in an ongoing manner. Whether it be a change in the volume of tests handled each day or personnel changes within the department, medical laboratories should constantly be adapting to the surroundings. An encouraging 82% of labs surveyed stated that they have a dedicated team in place for continuous improvement. (see Figure 3) The top 5 tools are: complaint feedback system, employee continuous training, customer satisfaction surveys, employee performance measurement and accreditation tied with employee satisfaction surveys in the fifth place. (see Figure 4)

Operations – The survey examined a number of laboratory operating procedures to understand how both the pre-examination and post-examination procedures differ from lab to lab. This covered test ordering, sample quality check, sample rejection, critical result notification, add-on testing, etc. (see Figure 5)

The survey highlights valuable information related to clinical laboratory practices. It is evident that while many laboratories have similar problems, there are also common solutions that can be found by applying a quality systems approach that incorporates lean concepts, automation, increased use of IT, accreditation and productivity metrics.

To conclude, with measuring indicators, relevant data and industry comparisons available from India and the Asia Pacific region, every laboratory has the opportunity to reflect on and review their current operations in order to identify potential for improvements.

FIGURE 3

Labs following Continuous Improvement

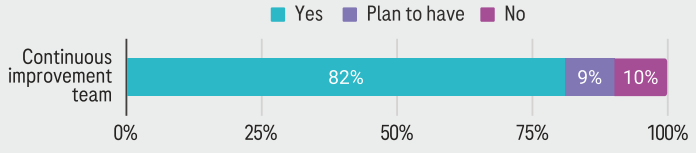
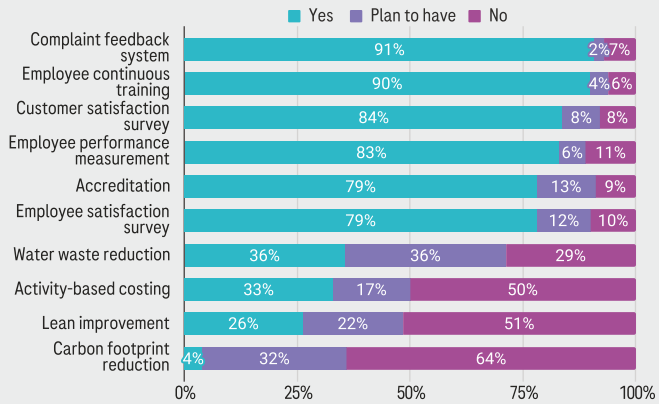


FIGURE 4

Continuous Improvement Tools in Labs



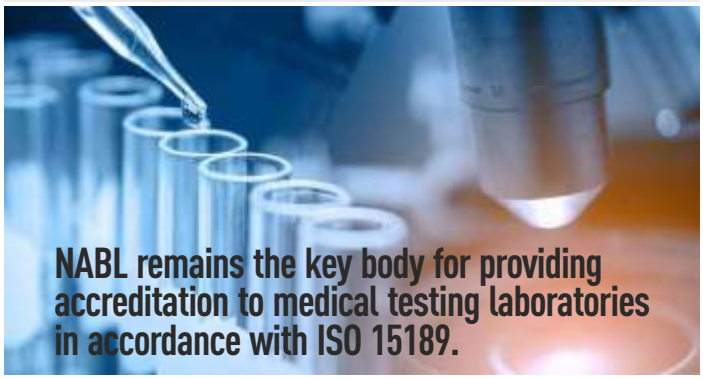
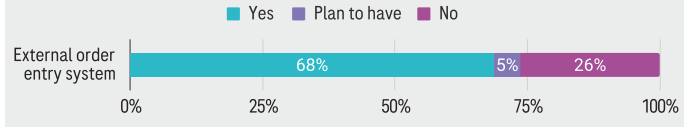
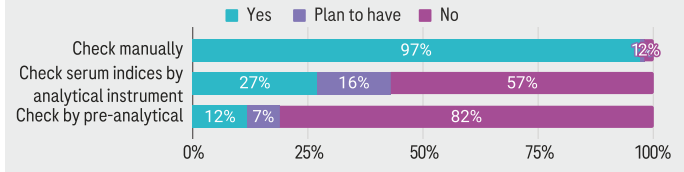
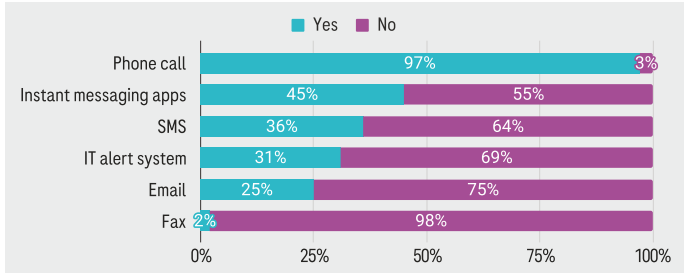


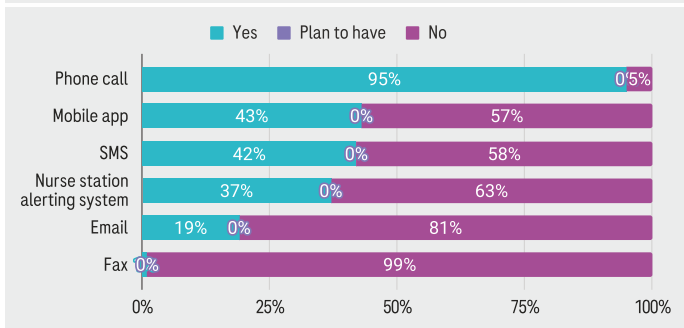
FIGURE 5

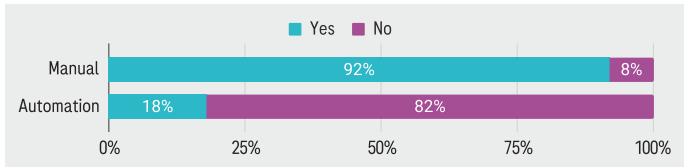
Variations in Laboratory Operations











Hauling Up Unauthorised Medical Labs in the Capital

A voice has been vehemently and repeatedly calling for tougher government regulation for clinical testing service providers in view of the fact that around 20,000 to 25,000 illegal pathological and diagnostic labs are operating in the national capital alone. Our litigation has made a difference… and how!

PROFESSOR BEJON KUMAR Misra, our editor and Founder-Director, Patient Safety and Access Initiative of India Foundation moved a Public Interest Litigation (PIL) in the Delhi High Court in September 2018 stating that unauthorised laboratories and diagnostic centres, managed by unqualified technicians, are conducting tests and providing unqualified inferences in the test reports. They unnecessarily endanger the lives and safety of the common people and should be closed down. The writ petition (filed through his counsel Shashank Deo Sudhi) also sought the formulation of a policy to regulate setting up and running of such entities and, as an alternative, guidelines be framed for implementation of the Clinical Establishment Act (CEA), 2010 to deal with the entire issue.

Following this plea, the court had directed the Delhi government to take appropriate steps in accordance with the Supreme Court guidelines to contain illegal and unauthorised labs, but no concrete steps were taken by the authorities.

We raised our voice in another hearing in November 2021 which made the Delhi High Court direct the government to apprise it on how pathological laboratories in the capital are being regulated and asked if any action has been taken against those running in violation of the laid down framework.

Faced with this diktat, the Delhi government filed an affidavit which stated that it is regulating diagnostic centres and labs in the city and an online public grievance monitoring system has also been set up for filing complaints. It further said that while there was 'no specific complaint alleging violations' as per the Delhi Medical Council, action was taken by the council on its own or on the basis of information received by it with respect to irregularities by some path labs. The affidavit disclosed five instances when action - including suspension from the state medical register - was taken against negligence, professional misconduct and association with unqualified medical practitioners. It also stated that all path labs are being governed as per public notices issued in accordance with the Clinical Establishment Rules, 2018!

> **Encouraging existence of only accredited path labs in the country is important - irrespective of whether it is commercially viable or not. We cannot and should not allow mushrooming of path labs managed by unqualified professionals and non-calibrated testing equipment. The state governments need to engage them professionally and encourage them with business in the interest of the poor. It has to be part of the Public Health Delivery System supported by the government and managed by qualified pathologists. Citizens' health is paramount and we can never compromise on patient safety and quality!**
>
> ***– Prof Bejon Misra***

Jumping Through One Hoop After Another

In the wake of the Covid-19 pandemic, the leading consumer activist filed another application (November 2020) seeking urgent and strict implementation of the Delhi government's Health Bill, 2019 or the CEA, 2010, alleging that illegal and unauthorised laboratories continue to operate without any checks and balances. Some are run illicitly, some do not have qualified pathologists and so do not even meet the other norms, leading to serious health repercussions, including death.

It also sought issuing of directions to the government to formulate a 'robust policy' in the interests of patients for regulating the opening and functioning of pathological laboratories in the National Capital Territory (NCT) of Delhi and to constitute an appropriate authority for regular checking of such laboratories. *The plea contended that the efforts by the government continue to be an eyewash as only 10% of the 1000-odd diagnostic labs in Delhi are actually accredited by the NABL.*

In the October 2022 hearing, the Delhi government further informed the High Court that it is taking active steps for drafting, finalising and enacting the Delhi Health Establishments (Registration and Regulation) Bill, 2022. It stated that meanwhile directions had been issued to all pathological labs to bring uniformity and standardisation in their functioning.

Relief in Sight

In February this year, the Honourable Court expressed dismay over the prolonged delay and finally took a stern stance, asking the Health Minister (Saurabh Bharadwaj) and Health Secretary (S.B. Deepak Kumar) to appear personally before it on 21st March.

During the next proceedings on the said date, the bench reprimanded the minister and the secretary – who were present – that they are 'servants of government' and cannot have 'large egos'. They were warned that

ACTING CHIEF JUSTICE MANMOHAN

JUSTICE MANMEET P.S. ARORA

We can only say it is a sorry state of affairs. This has been pending for the last five years.

– Acting Chief Justice Manmohan and Justice Manmeet P.S. Arora (Delhi High Court)

they will be sent to jail for their failure to comply with judicial orders on enactment of a law to regulate clinical establishments.

In what is a resounding victory for the consumers, the Delhi government informed the court in April that the health minister and the department's secretary agreed to forward the Delhi Health Bill to the Government of India for necessary approval. In the meantime, the central government's CEA statute will be implemented in Delhi (in compliance with a July 2023 letter of the central government and a May 2022 order passed by the High Court).

The court order clearly stated, "The GNCTD is directed to ensure that the gazette notification for adoption of the Act of 2010 is issued expeditiously and no later than four weeks."

The Honourable Court connected this matter with the main matter in consideration, i.e., Court on its Own Motion vs. Union of India, in which the court took suo-motu cognizance of the deteriorating health infrastructure and facilities in New Delhi. It is relevant to mention that various PILs and writ petitions were filed raising the same concern of Delhi health facilities.

Vide order dated 13.02.2024, the Delhi High Court formulated a committee under the chairmanship of Dr. Sarin. The objective behind the formulation of the committee was to look into all the problems the State of NCT of Delhi is facing on the health and medical front. The committee has submitted the draft recommendations with a timeline to execute the steps for the solution of the prevailing problems. The Govt. of NCT of Delhi had to submit the status quo of the steps it has taken in compliance of the recommendations and the order of the court on 23rd May, 2024.

ROUNDUP

High Court Constituted Committee's Report for Improving Medical Services in Delhi

FOR IMPROVING THE medical facilities in the State of NCT of Delhi, the Honourable Delhi Court took *suo moto* cognizance of the deteriorating condition of the health and medical infrastructure in New Delhi (registered as W.P. C. No. 8548 of 2017, titled as Court on Its own Motion vs. Union of India & Ors). Vide order dated 13.02.2024, the Court constituted a committee of six persons - with Dr. Sarin as chairperson - for the purpose of solving the problem of lack of ICU beds and ventilators in the government hospitals of Delhi.

On the Court's directions vide this order, the Dr. SK Sarin's Committee report was prepared and submitted within 5 weeks. To prepare the report on recommendation on improving the medical facilities in Delhi, the committee listed out the following steps:-

- Sorted out the issues first on the basis of the data that is available with the department of Health and Family Welfare, GNCTD.
- Requested the Govt. of NCT of Delhi for providing the necessary support and data.

- Coordinated with Directorate General of Health Services, Govt. of India and Commissioner, Municipal Corporation of Delhi for providing the required information on the status quo of the hospitals in Delhi.
- Continuous meetings with the Medical Directors and Superintendents of 38 Delhi hospitals to understand their difficulties and challenges and help optimise the clinical outcomes.

Based on the above-mentioned steps taken by the Committee, it was found by it that there are numerous vacancies of staff of different categories at all levels - including faculty, resident doctors, nurses, technicians, biomedical engineer, physiotherapists, pharmacists, etc. - which need to be filled on high priority. Other than this, there are many other problems that came into light like:-

- There is a shortage of radiologists, anaesthesiologists, critical care and emergency medicine specialists, neurosurgeons, among others who are not available during regular working hours of the hospitals and during emergency hours.
- Inadequate and insufficient staff
- Inefficient mechanism for filling up the posts on different categories
- Lack of robust administration
- Absence of infrastructure maintenance cadre for health services
- No proper support is provided by the district administration

These problems draw our attention towards the fact that the government hospitals of Delhi lack proper human resources. On the infrastructural front also, the committee - on the basis of the data provided by the different sources as mentioned in the preceding paragraphs - found that there was lack of basic facilities. Seeing the committee report, one could come to a conclusion that the people of Delhi were deprived of the basic right to health and medical facilities all these years. There are inadequate emergency beds and inefficient services, trauma and accident emergency centres at each of the districts of Delhi, in the premises of the major and moderate size hospitals present in the region.

To solve all the above-mentioned issues, the committee devised some of the recommendations for improving the present scenario in a time-bound manner. The committee has fixed a timeline for completion of the tasks which have been defined as below:-

a) Immediate – within 30 days (subject to Model Code of Conduct)

b) Short- term – within 31-90 days

c) Intermediate term – within 91-365 days

d) Long term – within 1-2 years

The committee devised recommendations for different problems in different sectors. These are divided into eight parts and relate to problems like lack of manpower, infrastructural problems, lack of equipment, lack of support from the district administration, lack of basic medicines, emergency beds and ventilators, etc.

The committee has proposed to create the 'Delhi State Health Authority' (DESHA) via which the committee proposes that a High Power Delhi Health Authority be set up directly under the control of Principal Secretary, Health Department of Health and Family Welfare, Govt. of NCT of Delhi. The proposed authority would comprise of:-

1. DGHS (Govt. of India)
2. DGHS (Govt. of Delhi)
3. Director, Lok Nayak Hospital
4. Director, GTB Hospital
5. Director, Hindu Rao Hospital
6. Director IBHAS

The proposed authority will have district level DM/DC as in-charge & they will be accountable for the implementation of the recommendations made and to ensure that all the recommendations made by the committee are implemented within the time-frame devised by the committee. The committee also proposed that the DESHA will have a grievance redressal mechanism. The proposed authority is supposed to carry out routine audits and arrangement of hospitals in terms of service.

To solve the problems of the government hospitals in Delhi, the committee also suggested that the involvement of private sector is a must so that the basic necessities are fulfilled.

A control room/call centre is proposed to be established along with the referral coordinator who will keep information related to the following:-

- Number of ICU beds
- Beds with ventilator
- Specialised ICU
- Availability of CT, MRI, Ultrasound
- Facility for Dialysis
- Emergency OT

A post of Chief Engineer - who will only be dedicated to the hospital staff - will be created to oversee the PWD related requirements of hospitals and ensure execution of required PWD related work by the hospitals.

The committee further pointed out in the report that there is no structured referral system or mechanism, and absence of centralised control room. Therefore, to curb this problem the committee is yet to devise a structured referral system as top priority.

In conclusion, the committee has performed a thorough study and came up with a number of other valid suggestions as well. We will persevere to ensure that the authorities implement them in letter and spirit!

NABL – Championing Excellence in Testing

The National Accreditation Board for Testing and Calibration Laboratories (NABL) is raising standards, recognising reliability, promoting integrity, assuring competence, building trust and delivering confidence by way of accreditation.

IT WAS WAY back in 1973 when the Planning Commission of India suggested that the Department of Science & Technology (DST) should look into different aspects of testing facilities. Following this, the DST set up the National Coordination of Testing & Calibration Facilities (NCTCF) in 1982 for providing accreditation services to testing and calibration laboratories.

Over a decade later (in 1993), it was renamed as National Accreditation Board for Testing & Calibration Laboratories (NABL) and registered as an autonomous body (Societies Act 1860) under the aegis of DST in 1998. Come 2016, NABL was merged with the Quality Council of India (QCI) as a constituent board (based on a 1996 Cabinet decision).

NABL continues to function as a constituent board of QCI as an autonomous body under the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, GoI. The primary objective is to provide a scheme for third-party assessment of the quality and technical competence of testing for the government, industry associations and industry in general.

Role of NABL

NABL's accreditation system is established in accordance with ISO/IEC 17011 'Conformity Assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies'. It provides accreditation services to the following types of conformity assessment bodies for the specific scopes as mentioned:

- Testing Laboratories - in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories'
- Calibration Laboratories - in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories'

Here, the conformity assessment bodies are the laboratories, third-party is NABL and competence is the ability to apply knowledge and skills to achieve intended results.

> "Accreditation is the third-party attestation related to a conformity assessment body conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities."
>
> *Source: ISO/IEC 17000:2020*

- Medical Testing Laboratories - in accordance with ISO 15189 'Medical Laboratories - Requirements for Quality and Competence'
- Proficiency Testing Providers (PTP) - in accordance with ISO/IEC 17043 'Conformity Assessment — General Requirements for Proficiency Testing'
- Reference Material Producers (RMP) - in accordance with ISO 17034 'General Requirements for the Competence of Reference Material Producers'.

NABL offers accreditation services for specific disciplines of testing in a non-discriminatory manner. These services are accessible to all testing - including medical and calibration laboratories, proficiency testing providers and reference material producers - in India and other countries in the region, regardless of the size of the applicant conformity assessment body (CAB), its membership of any association or group, or number of CABs already accredited by NABL. They can be private or government-operated, an independent entity or part of a bigger organisation, site facility or mobile laboratory, restricted to small operations or operate on large multi-field areas, etc.

NABL is self-financing and charges fees to CABs to cover operational costs and other expenditure.

NABL accreditation delivers various benefits, like:

- International recognition
- Access to global markets
- Time and money efficient
- Robust quality management system
- Continuous improvements
- Better operational control
- Prevent loss due to defects
- Assurance of accurate and reliable results
- Enhanced customer confidence and satisfaction

Accreditation is voluntary in nature. Although it is considered as a prerequisite for recognition in many fields by the Government, it is not mandated in all fields.

NABL accreditation is recognised by various government bodies and regulators. In India, it is usually the precursor to various government/regulator/statutory body recognitions.

International Recognition – It is not just in India alone – CABs have to demonstrably operate at an internationally acceptable level of competence.

NABL has linkages with international bodies like the International Laboratory Accreditation Cooperation (ILAC) and Asia Pacific Accreditation Cooperation (APAC). The national accreditation body is a Mutual Recognition Arrangements (MRA) signatory to both ILAC and APAC based on mutual evaluation and acceptance of other MRA partner laboratory accreditation systems. These international arrangements reduce technical barriers to trade by facilitating acceptance of test/calibration results between countries represented by MRA partners.

This system of international mutual recognition agreements between accreditation bodies enables the accredited laboratories to achieve a form of international

Test reports issued by an NABL accredited laboratory are considered equivalent to those issued by ILAC/APAC MRA partners.

ILAC @ILAC_Official - 19 Dec
Congratulations to Natarajan Venkateswaran on his election as the ILAC Accreditation Committee (AIC) Chair for the period 2024 - 2026.

recognition, and allows the test data (accompanying exported goods) to be readily accepted on overseas markets amongst the relevant countries. This effectively reduces costs for both the exporters and the importers, as it reduces or eliminates the need for products to be re-tested in another country.

Accreditation of Medical Laboratories

The importance of diagnostic testing in healthcare cannot be undervalued. This is an intricate and sensitive process that calls for the right expertise and experience. When done right, laboratory studies reveal a lot of information about what is happening inside the body. Hence, it requires highly-trained technicians who use the right equipment and techniques to analyse body samples to make the correct deductions.

Considering that medical test results form the foundation for decisions regarding diagnosis, course of treatment and more, they have a significant impact on the health of patients, making accreditation a crucial tool for establishing accuracy and reliability.

In the field of medical testing laboratories, NABL grants accreditation in Clinical Biochemistry, Clinical Pathology, Haematology, Microbiology & Infectious Disease Serology, Histopathology, Cytopathology, Flow Cytometry, Cytogenetics and Molecular Testing disciplines.

A total of 8009 laboratories have been accredited by NABL (as on 3rd May, 2024). Of these, 1987 are accredited medical labs (including 3 overseas) that ensure proper medical diagnosis is possible by providing accurate and trustworthy test results.

NABL accreditation is not a one-time phenomenon. Once the CAB gets accredited, the accreditation is valid for a period of 2 years and NABL conducts periodical surveillance on an annual basis. The CAB has to apply for renewal of accreditation at least 6 months before the expiry of the validity of accreditation.

Apart from the scheduled surveillance, NABL conducts unannounced assessments to verify continued compliance by the CABs. This is done based on random selection by an independent NABL team responsible for compliance monitoring. The accreditation can be suspended or withdrawn in case any unethical practices are observed.

Results of NABL-accredited medical labs are accepted by the Ministry of Health and Family Welfare, Government of India

The accreditation process itself is rigorous, involving assessments and corrective actions for non-conformities and evaluations to meet the relevant requirements for granting accreditation. NABL on its part, offers easy entry level schemes for labs which are not confident of full accreditation. It also expedited the approval mechanism - with fast-track approval being granted to proficient labs - to meet the testing challenges when the Covid-19 pandemic was in full swing.

How to Find NABL-Accredited Labs? -
Accreditation serves as a ready means for consumers and patients to find reliable medical testing and diagnostic services. You can search for NABL-accredited CABs by visiting the website: www.nabl-india.org >> Laboratory search >> accredited labs >> Country: India >> field: Testing/Calibration/Medical/Proficiency Testing Provider/Reference Material Producer >> Discipline >> (Please click on the relevant discipline) >> group >> (please click on the relevant group) >> search. The details of relevant CABs will be displayed below the open menu. Click on 'Click here to view the scope of accreditation'. To see the scope, click on the certificate number TC/CC/MC/PC/RC-XXXX (in blue colour).

For instance: to find a NABL-accredited medical testing laboratory in Kolkata for swab testing, visit www.nabl-india.org. Click on Accredited Laboratories under Laboratory Search. Select Country: India; select State: West Bengal; select City: Kolkata; select Field: Medical; select Discipline: Medical; select Group: Microbiology & Serology; select Subgroup: Swab and click on Search. After authentication, the details of relevant laboratories will be displayed. Clicking on 'Click to View the Scope of Accreditation' will open a new window. To see the complete scope of accreditation, click on the certificate number (MC-XXXX) mentioned in blue colour. The complete scope will be available for download. You can check the details of test parameters, test method, range of testing/limits of detection and CV %.

Furthermore, NABL – in association with the union Ministry of Electronics and Information Technology (MEITY) and other institutions – has developed an online portal called **PARAKH** (https://parakh.ncog.gov.in/) that maps all the NABL accredited and government recognised laboratories in the country on a Geographic Information System (GIS).

This unified network is an interactive and user-friendly system for finding laboratories and tests based on various parameters - people can search labs for a particular product, standard, test method in a state or a city and also find nearby labs. The portal even enables finding the scope of accreditation and test methods of a laboratory. It is hailed as a huge step towards strengthening the national laboratories' quality infrastructure in the country.

World Accreditation Day (WAD)

NABL celebrates World Accreditation Day (WAD) every year to spread awareness of accreditation and how it benefits the various stakeholders.

You can easily search for accredited laboratories on the NABL website at https://nablwp.qci.org.in/laboratorysearchone.

WORLD ACCREDITATION DAY 2024

The World Accreditation Day (WAD) is a global initiative jointly celebrated every year by the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) to raise the awareness on the importance of accreditation amongst all relevant stakeholders

NABL is celebrating WAD 2024 on

MONDAY, 10 JUNE 2024

across 20 cities in India

The registration is open for all conformity assessment bodies (Laboratories, Proficiency Testing Providers, Reference Material Producers etc.), Stakeholders, Assessors and Regulators.

NEW DELHI *	AHMEDABAD	BENGALURU	KOLKATA	RAJKOT
CHENNAI	TRIVANDRUM	VIZAG	HYDERABAD	LUCKNOW
MUMBAI	PUNE	PATNA	RANCHI	GUWAHATI
BHUBANESWAR	RAIPUR	BHOPAL	CHANDIGARH	JAIPUR

*Jointly with NABCB at New Delhi

REGISTER NOW

INTERVIEW

N. VENKATESWARAN

CEO of National Accreditation Board for Testing and Calibration Laboratories (NABL)

Mr. N Venkateswaran is the CEO of NABL since the last 5 years. He has more than 29 years of experience in the industry and accreditation bodies. He is the current chair of the ILAC Accreditation Committee (AIC) and member of APAC Executive Committee, ILAC Executive Committee and IAF-ILAC Joint Executive Committee. He is also the member of ISO TC 212, ISO TC 69, ISO TC 334 and several other technical committees at the national level apart from being an APAC Evaluator.

Q The theme for World Accreditation Day, 2024 is 'Accreditation: Empowering Tomorrow and Shaping the Future'. Can you elaborate on the key objectives of the theme and what role NABL can play in achieving them?

Every year World Accreditation Day (WAD) is celebrated to promote accreditation. The celebrations are in line with a theme jointly decided by International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). This year's theme **Accreditation: Empowering Tomorrow and Shaping the Future** focuses on how accreditation can help shape various aspects of life in our ever-changing world.

The theme highlights the role of accreditation in harnessing emerging opportunities and addressing global challenges. Digitalisation and emerging technologies like IoT, AI, etc are significantly altering how we interact, produce, and innovate. Accreditation provides a framework of trust and reliability, enabling organisations to confidently embrace new technologies and drive innovation. Testing in NABL accredited laboratories provides confidence in product safety and regulatory compliance.

This years' theme also focuses on the role of accreditation to strike a balance between rapid growth and sustainability. Rapid growth has resulted in sustainability concerns. Environmental, Social and Governance (ESG) considerations have gained significant importance for consumers, businesses, regulators, and investors. Accredited conformity assessment allows companies to demonstrate their commitment to socially and environmentally responsible practices in their operations and supply chains. It provides consumers and regulators with trust in ESG performance data. NABL accredited conformity assessment bodies ensure that products used by the common man meet the required standards.

A test/calibration report with NABL symbol, gives confidence to the users about the competency, impartiality and consistent operations of that specific activity carried out by the laboratory imbibing trust in the issued report.

NABL provides government, industry associations and industry with a scheme on conformity assessment body's accreditation involving third party assessment of technical competence of laboratories testing the products related to emerging technologies. These test reports generated by NABL accredited laboratories are relied upon by regulators for public benefits. Accreditation allows businesses to build confidence in their product performance and reliability. Accreditation enhances customer confidence in accepting testing/calibration reports, developing trust amongst the users to adopt these novel technologies, accelerating trade and market development through consumer confidence and established networks.

Government bodies and regulators are constantly called upon to make decisions related to health, safety,

privacy and security. The results generated by NABL accredited CABs are trusted by them, in order to make these decisions. If a CAB is accredited, it means that the CAB has achieved a requisite level of technical competence to perform specific types of testing, medical testing, calibration, proficiency testing services and reference materials production activities as applicable.

Accreditation is an assurance that the CAB is capable of generating result that is accurate, traceable and reproducible.

Increased liberalisation and globalisation have created quality consciousness in domestic trade and provided greater thrust for export. As a consequence, testing and calibration laboratories have to demonstrably operate at an internationally acceptable level of competence. NABL accredited laboratories are recognised internationally, which allows their results to be more readily accepted in overseas markets, thus providing a channel for adoption of innovative products tested in India.

NABL has been proactive in keeping pace with the everchanging requirements of conformity assessment. NABL has been expanding its wings to cover various areas that affect the citizens. This includes Soil Testing Laboratories Recognition Program to support the Soil Health Card programme, recognition of temporary site laboratories testing concrete and aggregates in building projects, Government Drinking Water Laboratories Recognition Program and Medical Entry Level Testing M(EL)T labs program.

Benefits of Accreditation:

- International recognition
- Access to Global market
- Time and money efficient
- Enhanced customer confidence and satisfaction
- Robust Quality Management System
- Continual improvements
- Better operational control
- Assurance of accurate and reliable results
- Cost Reduction
- Prevent loss due to defects

Q What events do you plan to organise on the occasion of World Accreditation Day?

NABL organises World Accreditation Day (WAD) every year bringing all stakeholders including laboratories, assessors, consumers on a single platform. Last year, the celebrations were organised in 6 cities- Delhi, Ahmedabad, Mumbai, Kolkata, Lucknow and Bengaluru. This time NABL is organising WAD in 20 cities across India with a thrust on regional connect. The message from ILAC and IAF Chairs will be displayed along with their translation in local languages.

In each of these programs, we aim to bring awareness about how NABL accreditation has benefited across sectors and is playing a key role in the quality infrastructure of the country.

This occasion brings various stakeholders such as consumers, laboratories, end users of laboratories, industries and regulators on one platform and this facilitates exchange of ideas and forging strong connect.

Additionally, the post lunch session will focus on interacting with the quality managers of NABL accredited laboratories while updating them on NABL policies and procedures, through our program QualMaCon (Quality Managers Conclave), which is a closed session only for laboratory Quality Managers.

Q How do you see the future of accreditation unfolding, particularly in light of emerging technologies, globalisation and evolving regulatory frameworks?

Trust in NABL accreditation is evident in the enforcement of regulations by authorities such as Bureau of Energy Efficiency, Telecommunication Engineering Centre, Ministry of New and Renewable Energy (MNRE), Export Inspection Council (EIC), Agricultural and Processed Food Products Export Development Authority (APEDA), Food Safety and Standards Authority of India (FSSAI), Commodity Boards, etc. This ensures that the end user gets quality products. A win-win situation has emerged with the role played by NABL in supporting regulators in enforcing regulations through accreditation.

Accreditation is a mark of quality, security and trust. Emerging technologies and globalisation have promoted a highly competitive market with focus on increased quality, reduced cost and time. Accreditation plays a key role in removing the technical barriers to trade and promoting confidence among the trading partners. The essence of MRA between National Accreditation Bodies operating in various economies is based on mutual evaluation and acceptance of each other's accreditation systems and results of accredited conformity assessment bodies. These arrangements enhance the acceptance of products and services across national borders by removing the need for them to undergo additional tests, inspections or certifications at each country of entry. This helps to reduce the cost to exporting organisations and contributes to operational efficiency.

Q How has accreditation evolved over the years to meet the changing needs and challenges of medical diagnostics?

When the entire world was in the grip of Covid-19 pandemic, India emerged as a leader in the supplies of vaccines, PPE kits and masks to several countries. Apart from this, the medical testing facilities in our country were ramped up and NABL worked 24x7 to ensure availability of NABL accredited labs across the length and breadth of the country, for testing of SARS-CoV2 virus. As always in the past, accreditation has helped in creating and sustaining trust in NABL accredited medical labs' results during the pandemic. This continues to build confidence in the mind of common man who looks for quality medical testing in his town/city. With new technologies emerging in the medical field, NABL has always taken proactive steps to bring them under accreditation so that the citizens benefit from the technology enhancement.

Q How do you plan to bring more laboratories under the ambit of NABL accreditation and enable them to harvest the immense benefits of accreditation?

Accreditation is voluntary. Though the number of NABL accredited laboratories is increasing year by year, still a large number of laboratories are yet to embrace accreditation.

The primary reason is lack of awareness - not just about the benefits of accreditation but also about the accreditation process. NABL is constantly working towards percolating awareness in all sectors which are not aware about accreditation and the benefits it accrues in their business growth.

We are conducting awareness programmes throughout the country to make the industry and labs aware about NABL accreditation. Many of the labs having obtained accreditation acknowledge that they had not envisaged the benefits that accreditation would bring to their business - the increase in number of customers, meeting qualification in tendering process and also test requests from foreign countries.

Also, some laboratories have a misconception that elaborate preparations are required to gain NABL accreditation. This creates hesitation among laboratories to apply for NABL accreditation. NABL is constantly working towards removing this misconception through awareness programs, newsletters, stakeholder meetings and interactions with industries and regulators.

Q NABL is a symbol of confidence and trust in the field of Quality. How does NABL demonstrate its competence and ensure that it is known as benchmark of Quality, not only in India but throughout the world?

NABL has an established accreditation system in

"A test/calibration report with NABL symbol, gives confidence to the users about the competency, impartiality and consistent operations of that specific activity carried out by the laboratory imbibing trust in the issued report."

accordance with the requirements of ISO/IEC 17011:2017 "Conformity Assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies". NABL maintains linkages with the international bodies which are International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Accreditation Co-operation (APAC). NABL is a full member of the Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC). NABL is a signatory to the Mutual Recognition Arrangement (MRA) for Testing, Calibration & Medical Labs, Proficiency Testing Providers (PTPs) and Reference Material Producers (RMPs).

Besides rigorous internal audits and management reviews, NABL also undergoes peer evaluation once in every four years. The peer evaluation is an internationally accepted mechanism used to formally evaluate and recognise accreditation bodies. To obtain mutual recognition arrangements, NABL demonstrates equivalence through the 'peer evaluation' process.

NABL has successfully undergone 8 peer evaluations since inception, i.e., year 2000, and there were no non-conformities in all the 8 peer evaluations.

Q NABL has recently initiated few recognition schemes, which are not covered under APAC & ILAC MRA. Can you briefly highlight their importance?

These schemes are based on successful participation in proficiency testing programs. Laboratories that are quality conscious but are yet to structure their system in accordance with the international standard can avail these schemes. Once they get the exposure to the quality practices, it becomes easy for them to move up the ladder and obtain NABL accreditation. We have schemes for medical labs, soil testing labs and water testing labs of the Ministry of Jal Shakti. The farmers can get assured results about the nutrients in the soil and can hence make informed decisions on the next crop. Similarly, drinking water being tested at district and block level has ensured safe supplies to the citizens under Jal Jeevan Mission.

Q What message would you like to share with our readers? How can our readers become aware of the current and upcoming activities of NABL?

NABL symbol in test reports helps build trust and confidence among consumers by ensuring products and services meet quality and safety standards. Critical products related to human health and environment ought to be tested in accredited laboratories whose competence has been assessed by a third party in a non-discriminatory manner.

I urge everyone to read the NABL monthly newsletter to stay abreast of all NABL activities and announcements, thus joining the quality ecosystem of our country.

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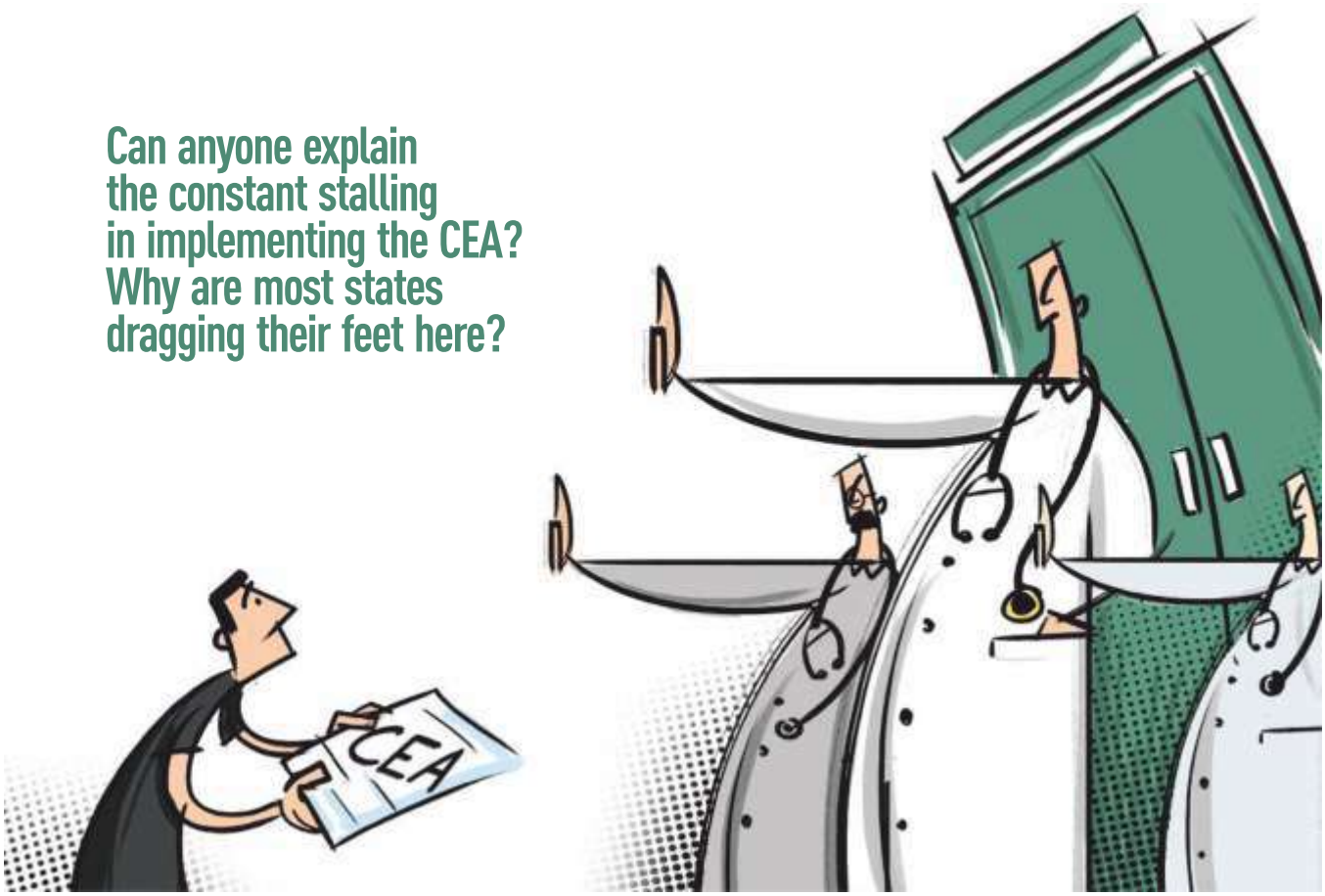
AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

CEA
Getting Lost in Implementation

> "The CEA could have become a cornerstone for bringing in minimum quality assurance in the healthcare sector – including medical diagnostics. However, it has been fraught with delays and is floundering in implementation since almost 15 years!"
>
> – *Pyush Misra*

Can anyone explain the constant stalling in implementing the CEA? Why are most states dragging their feet here?



THE CLINICAL ESTABLISHMENTS (Registration and Regulation) Act (CEA), 2010 was a brave foray given that health is a state subject in India. The central government cannot mandate that the Act should be directly applied to all states and union territories. The states have the choice of passing a resolution to adopt the bill or formulate a similar bill.

The Act was passed by Parliament after four states - Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim - agreed to enforce the Act after notification. It took effect in these four states and all union territories (except Delhi) from March 2012.

Since then, the Model State Rules (under Section 54 of the Act) have been circulated among the States/UTs. The Union Ministry of Health is repeatedly appealing to the Chief Ministers of various states to adopt and implement the Act. Additionally, central schemes - like National Health Mission - offer funding to states to induce them to follow the vision of the national regulation.

Over the years, different states like Assam, Bihar, Haryana, Jharkhand, Rajasthan, Telangana, Uttarakhand and Uttar Pradesh have adopted the Act by passing resolutions in their respective state assemblies.

Meanwhile, many other states like Andhra Pradesh, Chhattisgarh, Goa, Gujarat, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Nagaland, Odisha, Punjab, Tamil Nadu, Tripura, West Bengal and Delhi (UT) contend that they have enacted their own legislations.

The CEA website states that the Act has been notified in 12 states and 7 union territories in its original form. Actual implementation on the ground is actually missing all over the country. We will file a PIL to obtain clarity on the exact status from the government.

Concrete Reality

The reality is quite self-defeating. Most of the states that notified the Act have failed to bring in rules and mechanisms to implement the same.

Many states that purport to have updated their own legislation have actually brought in diluted versions of the CEA. They seem to be paying mere lip service without any actual implementation. Some of them have even failed to include laboratories and diagnostic centres in the ambit of the regulation. In many other states, the relevant regulations are applicable only to private laboratories, with state-run laboratories being exempt. Most of them have ambiguous and inadequate provisions for personnel requirements and their minimum qualifications.

The harsh fact is that the private sector hospitals, diagnostic centres and even the Indian Medical Association is strongly opposing the CEA and 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.

In July 2023, the state of Telangana informed the High Court that it started regulating and monitoring clinical establishments under the Act over a year ago. It claims to be the first state to implement the legislation – clinics, hospitals, labs, etc. that are not registered with the State Health Department will be punished with hefty fines, suspension or cancellation of the license. However, in reality, no action is being taken against the errant private healthcare facilities!

If it is truly followed, all hospitals, clinics, labs and diagnostic centres will have to be duly registered in accordance with the provisions of the Act. Any clinical establishment found to be operating without registration

The CEA has a provision requiring diagnostic centres to get accredited with recognised bodies such as the National Accreditation Board for Testing and Calibration Laboratories (NABL). However, none of the states which notified the Act have made it mandatory for laboratories to get accreditation.

A pressing question is – why is the Act being implemented directly by the state governments? Why is there no independent regulator for clinical establishments, including hospitals, medical laboratories and diagnostic centres?

"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," owner of a leading laboratory chain.

will face a stiff monetary penalty and can also be shut down by the district administration. **All labs will also have to be accredited with NABL.**

Facts on the Ground

Many states in India still do not have any entry barriers or minimum requirements to set up medical laboratories. Anybody can simply hire a space, a pathologist and some equipment to start a medical lab!

There is no legal framework to validate their existence and most of them are simply registered under the provisions of the Shops and Establishments Act, that too, only in respect to the holidays, standards of cleanliness and hours of work. Some laboratories are mandated to obtain registration under the Biomedical Waste Management Rules, 2016. And, since the diagnostic kits and reagents used for testing are labelled as 'drugs' under the Drugs and Cosmetics Act, 1940, approval from the Central Drugs Standard Control Organisation (CDSCO) is mandatory. **Accreditation by NABL remains voluntary and not mandatory.** Thus, medical laboratories are only regulated by some ancillary regulations and India lacked an exhaustive all-encompassing regulation governing medical testing for many years.

Given such a lack of regulation, the industry has flourished, recording rapid growth. Several substandard laboratories, that ignore the regulations and have inadequate or inexperienced medical staff, continue to spring up all over the country. They function under market-led and self-imposed norms leading to non-standardisation of quality. And the one who suffers is the consumer as usual, with his health and safety hanging in the balance!

Here, it cannot be denied that the central government needs to persevere to build consensus with the various stakeholders. 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 registration authority. A more proactive approach is the need of the hour.

Why does NABL accreditation remain voluntary? Why can't it be made compulsory for all pathological laboratories and diagnostic centres so that they start on the accreditation journey as soon as possible?

Only when it is properly implemented, can the legislation ensure that the Indian healthcare system becomes systematised and is equipped with the basic minimum standards of medical care.

Regulation and Accreditation for Medical Labs Around the World

The importance of quality in the functioning of healthcare laboratories is recognised globally. Quality is equated with meeting standards - which can be international or defined at the national level. What is crucial is that compliance should be mandatory and strictly enforced to ensure patient safety.

Maintaining quality standards is a must for laboratories in the international arena!

THE FIELD OF healthcare calls for utmost regulation and full compliance, more so for the clinical laboratories. In fact, labs are one of the most regulated health-related entities in many parts of the world. This compliance is required on two-levels:

- Government maintains oversight over the operations and practices of clinical laboratories by enacting laws and regulations that are mandatory. These primarily relate to basic design and implementation requirements such as construction, space allocation, biological safety, physical security, fire protection, electricity consumption and sewage discharge. Failure to comply can lead to civil and criminal penalties.
- Accreditation involves assessments and formally approving the laboratory's practices by a third-party that promotes specific standards of practice. They cover everything from specimen collection to result interpretation. In contrast to regulation, the accreditation process is voluntary, but considered a must-have to establish accuracy and reliability of the testing results.

Why is Compliance So Important?

Poor quality in medical testing can lead to disastrous consequences – inaction, inappropriate action, overtreatment, mistreatment, lack of treatment or inadequate investigations. Delayed or suboptimal responses can be life-threatening. In contrast, reliable lab results improve the decision-making capacity of physicians.

Standards and Regulations Around the World

ISO - The International Organization for Standardization (ISO) has developed quality systems to assess specific aspects of healthcare. ISO/IEC/17025 sets out the general requirements for the competence of testing and calibration laboratories (not necessarily medical labs).

In 2004, ISO 15189 was officially announced for adoption as the international quality standard for medical laboratories globally. It specifies the requirements for quality and competence in medical lab environments and involves developing a robust and reliable quality management system (QMS). Since then, many countries, including India, have switched over to this comprehensive standard and also follow the latest ISO 15189:2022 revised version.

However, this certification remains voluntary. Most labs do not even attempt to conform to the standard as it is very resource-intensive with an exhaustive list of requirements.

In the Indian context, there is a wide gap between what exists and what is required to achieve the standard. The high cost of purchasing equipment required for the competency development programme, difficulty in programme coordination and shortage of personnel are additional hindrances. Hence, only a handful of well-established private laboratories can manage to achieve them.

ISO 15189 is a globally recognised accreditation standard that establishes the competent, impartial and consistent operation of a clinical lab's practices.

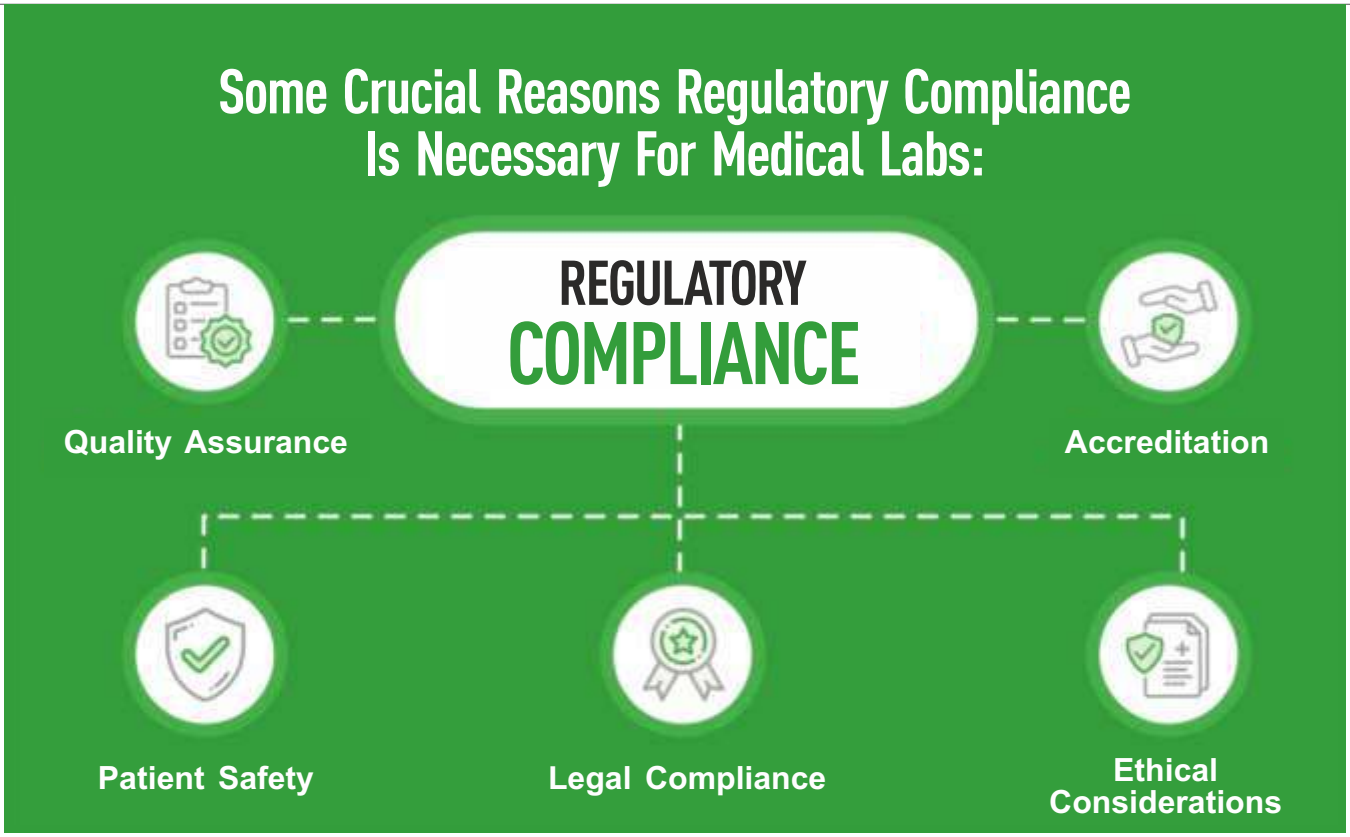
WHO - Given the stringent requirements of ISO standards, the World Health Organisation (WHO) formulated the Laboratory Quality Standards as a simplified and flexible step-wise approach to encourage Member States to follow them.

The WHO's minimum set of standards can be readily adapted by countries and applied to laboratories at every level of the healthcare system. They can also assist policymakers and regulators in developing National Quality Standards for health laboratories to help ensure the quality of laboratory results. The guidelines can become a stepping stone to achieving the ISO standards.

WHO has also published a handbook that serves as a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes. It also has the Good Clinical Laboratory Practice Guidelines for clinical laboratories processing specimens from clinical trials.

The Indian Council of Medical Research (ICMR) released the Guidelines for Good Clinical Laboratory Practices (GCLP) in 2008 to establish minimum criteria which should be followed by clinical laboratories involved in examining human samples. They were revised in 2021 in tune with the recent advances.

JCI – Joint Commission International is an independent not-for-profit accreditation and certification organisation recognised as a global leader for quality of healthcare and patient safety. It published its evidence-based Accreditation Standards for Laboratories in 2003. These are frequently revised based on global assessments to identify new regulations and widely-accepted practices. Currently, the 4th edition is addressing the needs of the increasing number of JCI-accredited facilities. The Gold Seal of Approval is a clear sign that the accredited organisation has demonstrated compliance with the most stringent standards of performance.



CAP - The College of American Pathologists is the world's largest organisation of board-certified pathologists serving the global laboratory community. It fosters accountable, high-quality and cost-effective patient care apart from advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP Laboratory Accreditation Program – with a unique peer inspection model - has emerged as a world leader in laboratory quality assurance which is deemed more stringent than the US government's own inspection program.

USA - The Clinical Laboratory Improvement Amendments (CLIA) establishes consensus-based standards for all clinical laboratory testing in the USA. This primary regulatory program regulates laboratory examinations and other procedures based on the complexity of the lab tests - methodology of the procedure, number and type of tests and examinations - to ensure the labs produce accurate and timely patient test results, regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) - in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) - administers the CLIA laboratory certification program.

United Kingdom - In the UK, the Public Health Department issues regulatory standards, detailed advisories and guidance notes for clinical laboratory investigations. This aids in the selection of the most appropriate method of testing and accuracy in results through evaluation tests (comparison against existing method), validation (evidence-based testing) and verification (compliance check) of diagnostic methods. This ensures that the variables affecting the results are controlled.

The Good Clinical Laboratory Practice Guidelines adopted by the WHO were first drafted by a working party of the Clinical Committee of the British Association of Research Quality Assurance (BARQA).

European Union - The EU has adopted the principles of Good Laboratory Practice (GLP) developed in accordance with the Organisation for Economic Cooperation and Development (OECD). Moreover, the national accreditation bodies work together with the European Cooperation for Accreditation (EA) to regulate the medical laboratories.

Japan - The Japanese Committee for Clinical Laboratory Standards (JCCLS) and the Japan Accreditation Body (JAB) implements a national medical laboratory accreditation based on the ISO 15189.

In essence, many international organisations and national governing bodies have established laboratory regulations and standards for the field of pathology. There is a need to harmonise the standards globally to bring the operations on a standard platform.

Accreditation Brings Consistency Across Laboratories

When it comes to unaccredited and unregistered medical labs, everything from the prices of various tests to the results can vary. The difference can be quite sharp in many cases, harming not just your budget, but also your health and life. Having the same basic policies and procedures across labs will bring an element of consistency!

Accreditation denotes that a lab meets accepted standards of quality and integrity. It works as a seal of approval of professionalism, safety and confidentiality.

MANY QUESTIONS ARE being raised on the accuracy of medical testing and competence of diagnostic centres. However, the consumers obviously cannot judge the quality and efficacy of lab results on their own. Moreover, the test results between different labs tend to vary. So, even if a patient tries to reaffirm the diagnosis with a repeat test, he/she has no way of knowing which one is reliable! And, the financial burden of repeat tests, in case of a second opinion or referral, can be significant.

Obviously no one wants to pay twice for the same thing!

Then again, there can be considerable variance in the prices of various tests between labs. For instance, the Economic Survey 2017-18 had revealed that a thyroid profile test can cost anywhere from Rs 100 to Rs 3,100! What is the consumer to infer from this? When one diagnostic centre prices an MRI scan at Rs 6000 while another offers to conduct it at just Rs 1000, does it mean that the former is using advanced equipment and qualified personnel and the latter is cutting corners and lacks credibility? Or is the converse true – the latter is a genuine lab with reasonable prices while the former is charging inflated rates?

How is the harried consumer to know which is a red flag and which isn't?

Indeed, diagnostic labs across the country are infested with systemic issues. Some use expired products to test and screen the specimens. Samples may be labelled incorrectly or swapped between patients. Blood for transfusion may not be kept as cold as it is supposed to be. Basic quality control to ensure accuracy in testing is also lacking in most places.

Hand-in-Glove

Then there is the nexus between labs and medical professionals with the former giving commissions to the latter for prescribing tests in their labs. The labs get steady business and pass on substantial incentives to the doctors, which can account for nearly 40%–50% of the cost. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 expressly prohibited such practices, however, the 'cut' continues unabated. In fact, in the LocalCircles survey mentioned earlier, 66% stated that their doctor had suggested a specific pathology lab for getting medical tests done and 50% believed that their doctors had ordered more tests than were needed!

In 2019, police in Vadodara, Gujarat unearthed a fake medical pathology laboratory run by a quack based on an audio clip. In the telephonic conversation, the lab owner was found promising a doctor that he could prepare concocted reports showing malaria, typhoid or whichever disease and also offer 40% commission to him!!!

Benefits of Accreditation

Fact of the matter is that many of the pathological labs conduct tests without any registration/accreditation and generate false/inaccurate reports. There is no way to quantify how many patients are being harmed by laboratory errors and wrong reports leading to mistreatment.

Accrediting organisations help the government in implementing the policies by creating an infrastructure of competent laboratories. Everything from the management system to technical operations are assessed. For instance, NABL accreditation involves a rigorous, transparent and comprehensive assessment by an external and independent accreditation body. Inter-laboratory quality control mechanisms are also mandatory for accreditation.

The accredited labs are closely monitored, lab personnel are trained to instil processes that minimise errors and fix problems whenever they arise. They are also re-evaluated at regular intervals to ensure continued compliance with requirements and standards of operations.

It is the accreditation symbol on the reports or a NABL certificate hanging on a wall of the diagnostics lab which assures patients that they can trust the facility and its results.

Hence, NABL accreditation is a confirmation of the efficient standards maintained by the labs in terms of testing, personnel and quality management systems. It is a formal declaration of both technical competence and quality.

Reliability - The test reports bear the NABL logo or endorsement which not only assures that the results are credible, but will be consistent across other accredited labs as all of them follow the same procedures and processes. It saves both time and money by eliminating the need for repeat testing to reaffirm the results. Any doctor or hospital will rely on a report from an accredited lab and not ask for repeat tests.

Confidence – Both patients and healthcare providers are assured of test quality and reduced risks of laboratory errors. The strict regulations and guidelines will meet industry standards, thus generating trust in the performance levels and practices.

Competence – Accreditation signifies that the equipment and methods used for testing are up to date, staff is competent and qualified and best practices are in place in the laboratory.

Global Acceptance – Accreditation is a gold standard for quality services and reliable reports; hence, it ensures international acceptance of test data. It also denotes a culture of continuous improvement in laboratory practices, which benefits not only the lab and patients, but the entire industry.

Benefits of Implementing CEA

The cost of diagnostic investigations comprises a significant proportion of the total cost of healthcare. Alas, there is no regulation on diagnostic pricing in India.

The Clinical Establishments Act, 2010 prescribes that the rates should be fixed by the regulatory authority and followed by the laboratories. However, none of the states or UTs where the Act is in force have actually done so.

Meghalaya alone provides that the diagnostic charges need to conform to the norms prescribed by the state government. Andhra Pradesh and Madhya Pradesh merely require that the prices must be disclosed to the registering authority and cannot be revised more than once a year. The legislation in Karnataka, Kerala and West Bengal only mandates that the rates should be publicly displayed. However, none of them have actually followed through even on these rules!

Proper implementation of price regulation will bring transparency and equitability in the industry.

Both price control and standardisation in procedures – by way of accreditation – should be made a statutory requirement, in all states to ensure quality. This will also negate attempts to cut costs and save money which can put patients' health and lives at risk.

Regulatory Obstacles

On the other hand, the labs face their own challenges. They already bear huge economic costs for purchasing expensive equipment and supplies, deploying trained manpower and carrying out the testing.

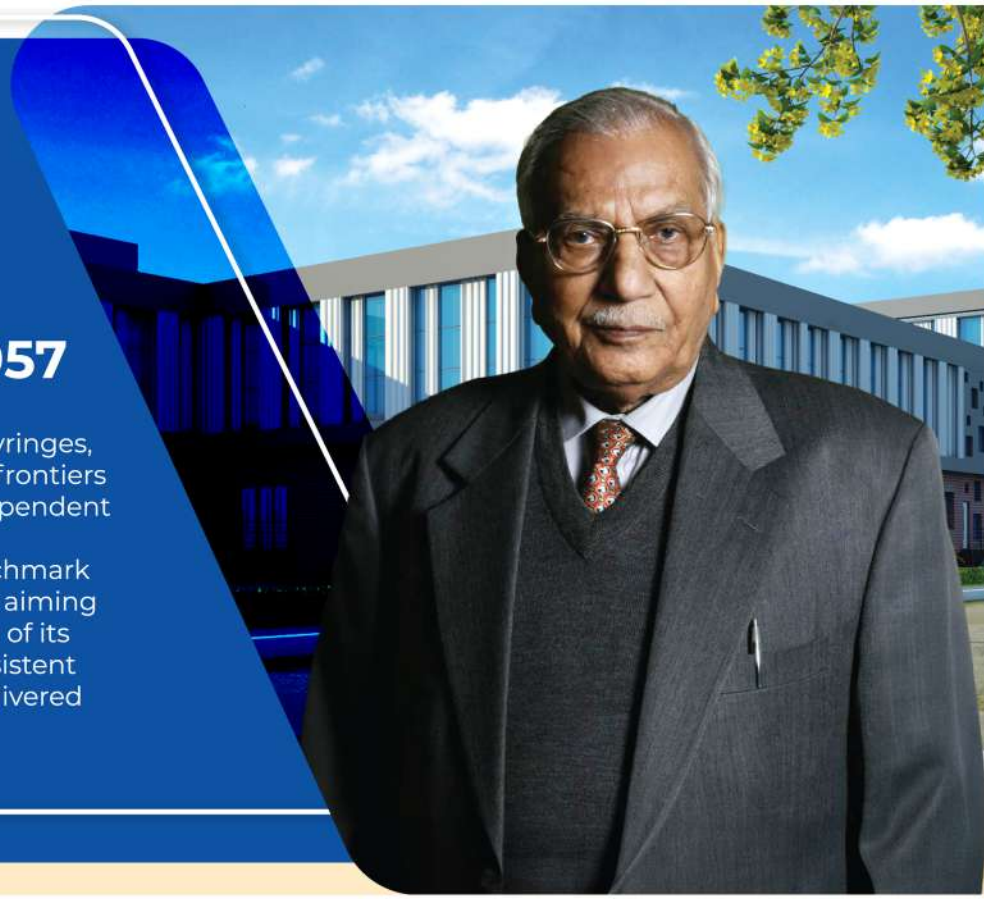
A classic conundrum comes into play - Accreditation involves heavy expenses for fulfilling the diligent processes of test runs, record maintenance, infrastructure and trained human resources. This forces the labs to increase their prices which will only end up in loss of existing clients as well. Moreover, there is no empirical evidence correlating accreditation with increased revenue generation.

Hence, there is a need to make it feasible for small and medium labs to adhere to the NABL standards of minimum equipment and human resources. There should also be incentives for getting accredited and focusing on providing the right quality. The authority should devise a one-stop platform for the accredited labs with ratings, costs and reviews while ensuring standardised pricing or price ranges for the diagnostic tests.

Above all, most of the consumers are not even aware of NABL accreditation and its significance. Why will they even bother to look for the NABL certificate or logo when they have no clue what it stands for? Creating awareness about the implications and benefits of accreditation remains crucial.

These measures will make accurate diagnosis more accessible, available and affordable for all consumers.

Late Mr. Narindra Nath,
Founder, Hindustan Syringes and Medical Devices Ltd.



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Who Is Signing On Your Lab Reports?

Given the crucial role of diagnostic testing, who is the actual authorised signatory for the test reports? Not only has this issue been embroiled in dispute and ambiguity for years, but unqualified and proxy signatures continue to put a blackmark on the reliability of lab testing.

We may skip noticing the name and qualification on a test report; but it matters a lot!

MEDICAL DIAGNOSTICS ARE the cornerstone of clinical decisions. Most doctors rely on diagnostic investigations – and not physical examination and symptomatic diagnosis - to make a prognosis and to guide treatment. The lab report is supposed to provide precise information about the condition of the patient, the malady and so on.

But do we know what is happening behind the scenes? Who is actually taking the samples, running the tests, measuring the results and writing the reports?

Given the questionable quality of testing and reports rampant in many stand-alone labs, is it any wonder that some hospitals and even doctors mandate repeat testing (in their premises or at a renowned lab) as they are worried that the lab technician may not be qualified to conduct the tests or assess the results.

It was way back in the early 2000s that medical pathologists in Gujarat had moved the court asking not to allow laboratory technicians who are not pathologists to run any laboratory independently. They argued that a large number of unauthorised private laboratories were being run by persons who are unqualified and do not have a degree in medicine. It was contended that the unscrupulous practitioners carry out various pathological tests and give unauthorised diagnosis on the basis of which the persons are treated. Their test reports are not certified by a registered qualified pathologist which can prove dangerous for the patients.

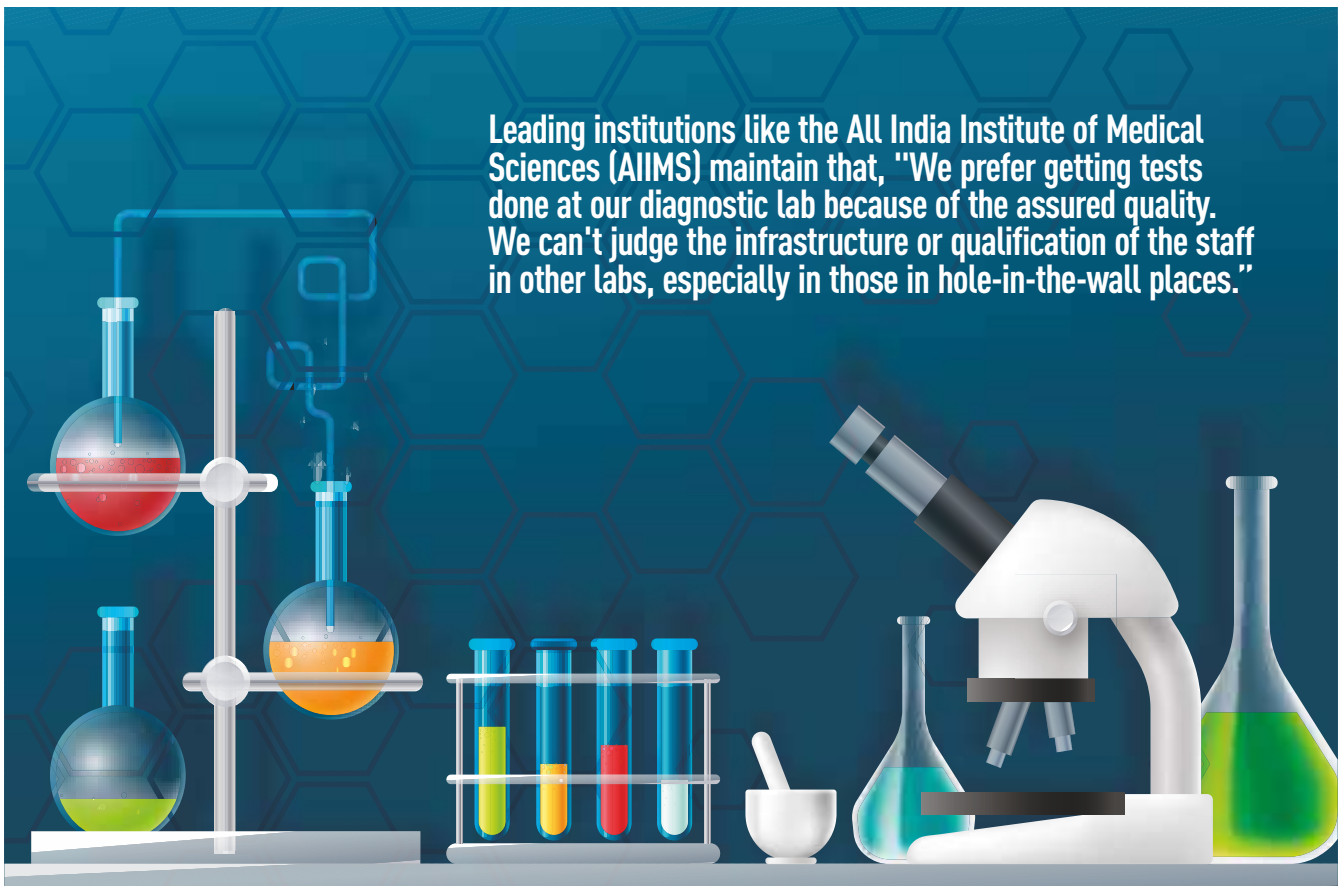
In 2010, a Division bench of Gujarat High Court held that no medical report can be issued without the signature or counter signature of a practicing pathologist recognised by the Medical Council of India (MCI). The MCI had also clarified that any qualification other than MBBS or MD (pathology/biochemistry/microbiology) is not eligible to sign a lab report.

After this, the Rules issued under the Clinical Establishment Act in 2012 clearly laid down that lab reports should be signed only by qualified doctors.

To further ensure quality of testing and accuracy of reports, the Supreme Court of India had ruled in 2017 that all laboratory and diagnostic reports can be signed only by a qualified pathologist (MD in pathology). It not only banned technicians and other underqualified staff from signing lab reports, but also forbade such persons from operating laboratories independently and mandated them to work under the supervision of pathologists.

Three years later, the Union Ministry of Health and Family Welfare took cognisance of this extreme shortage and followed the advice of the MCI to allow even non-doctors, with relevant degrees, to issue the reports. MCI had noted then that there were about 6000 doctors in the country with a degree of MD in pathology while the number of labs was estimated at over 3.2 lakhs with nearly 38,000 technicians working in them.

Accordingly, the Clinical Establishment (Central Government) Amendment Rules, 2020 provide that any



registered medical practitioner having a postgraduate degree in medicine can sign the lab reports. Therefore, qualifications of MBBS, MSc or PhD and others are acceptable. However, the order qualifies that such persons cannot offer any medical opinion or interpretation. There should be a mandatory disclaimer, 'Report is for the use of medical practitioners and is not a medical diagnosis as such.'

The Gazette notification reads, 'Candidates with MSc in Pathology or Medical Microbiology or Medical Biochemistry from a recognised university or institution with at least three years training or work experience in a medical diagnostic laboratory of same or higher level in a government or recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of laboratory results'.

Situation on the Ground

Many laboratories continue to operate only with technicians. They easily circumvent the orders by 'purchasing' signatures from qualified professionals for around Rs 15,000–20,000 a month. Some even bear the forged signatures of well-known pathologists.

The MCI even issued a notification expressly stating that qualified registered practitioners (like pathologist, microbiologist, bio-chemist) should not associate with unqualified persons and lend their name/sign multiple reports without supervision of the pathological tests. This constitutes professional misconduct and renders such doctors liable to disciplinary action.

Apart from the issue of proxy signatories, it has come to light that many small and medium labs choose to avoid the NABL accreditation because it does not abide by the modifications in the CEA regulations which allows lab reports to be signed by medical practitioners qualified in pathology instead of a doctor. Hence, removing the discrepancies between the regulation and accreditation and maintaining consistency is crucial!

The signature of a pathologist employed with the government of Gujarat was used by nine private laboratories!

Obtuse Angle by BP Acharya

Payal Agarwal
Editorial Consultant

Testing Comes Home – Not as Rosy as it Sounds!

> "The business of pathology has been severely disrupted by the advent of home collection centres and even online health service aggregators that offer laboratory testing and diagnostic facilities. The issue here is that they are operating outside the purview of the law and without any regulation. Health and lives are at stake again!"
>
> – *Payal Agarwal*

You no longer have to go to a lab to get a blood or urine report done. The lab can come home to you.....but at what cost?

TECHNOLOGY HAS PERVADED each and every corner of our life. The ease and convenience afforded by the internet and mobile apps is unparalleled. You can order clothes, gadgets and food while sitting at home, work remotely from a location of choice and even book medical tests online. A technician will visit your home to draw your blood or take other samples which will then be taken to the laboratory for testing. The reports will be delivered to you – either as a physical or digital copy. You can even send them to your physician or get an online diagnosis, without ever having to step outside the house!

Several of the top medical laboratory chains as well as standalone centres now rely on collection centres that operate on the franchise model. Many even use a technology platform – a mobile app or website – where patients can book medical tests. Then there are scores of online healthcare service providers that offer everything from physician consultations and treatments to delivery of medications and laboratory tests direct to the consumers. They act as aggregators for multiple laboratories.

Indeed, technology is playing a significant role in enhancing access to medical diagnostics by bringing services right to the doorstep. Apart from enabling the convenience of home care (especially for the elderly, bedridden or limited mobility patients), they also provide tracking and traceability of the services.

Points to Ponder

Blinded by the convenience, do we bother to check which laboratory is actually providing this service and what is its registration status, let alone whether it complies with the minimum standards? Can you be sure that the samples collected from your home are properly stored at the right temperatures? Are the conditions for transfer to the processing centre conducive to keeping them from getting spoiled or contaminated? Do we check the qualifications of the staff providing the laboratory services on these online portals? Who is to know whether they are actually tested or fake reports are generated at random?

Rocking the Boat

The Clinical Establishments (Registration and Regulation) Act (CEA), 2010 states that the collection centres are part of the parent laboratory, which is held responsible for their compliance with the minimum standards. The fact that the CEA has hardly been implemented in any state is another story altogether. Moreover, the existing regulation in certain states require the centres to be registered independently of the parent laboratory. However, many of these outfits do not even bother to register themselves as a medical facility.

Then there are a number of innovative point-of-care medical devices that can be used at home to gauge the blood sugar, blood pressure and other health parameters. The quality and calibration of these testing apparatus is crucial as it will affect the interpretation and treatment.

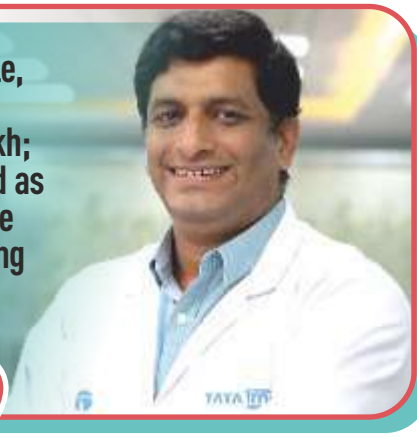
It should be noted that many of the e-pharmacies and teleconsultation apps (like mFine, PharmEasy, 1mg and Practo) started offering diagnostics services as they deliver the deepest profits!

Collection of samples from home is not explicitly mentioned in either the central or any state legislation. Only West Bengal provides for home collection in case the person is 'unable or unwilling to attend the clinical establishment'.

Moreover, the online health service aggregators are not recognised as clinical establishments under the CEA. The National Council for Clinical Establishments clearly specified that there are no standards or regulations drafted for online aggregators under the law. It further stated that the public should be made aware of "such illegal online health aggregators and the online lab service aggregators and service providers should have a registration number and provide information regarding the lab where

Technology is the key answer towards the goal of developing affordable, accessible and quality diagnostics value chain. India having a huge demographic dividend has operational labs with figures around one lakh; approximately 40 labs per million population which is a bit constrained as compared to developed economies with approximately 400 labs per one million population. Technology plays an important role here in improving access by bridging the gap between the patient and quality diagnostic infrastructure.

- Dr. Prashant Nag, Assistant Vice President, Tata 1mg



"From online listings, you can't judge if the lab is authentic or not"
- Dr Jagadish Keska, member of Maharashtra Association of Pathologists and Microbiologists

Ethical issues arise when medical laboratories associate themselves with the aggregators.

the samples are being sent for testing'. In a direct contradiction, the Karnataka government issued licenses to online aggregators under the Karnataka Medical Establishments Act!

Covid Fallout

The pandemic led to the springing up of online platforms that operated diagnostic and lab collection centres to cash in on the Covid-19 testing boom. They operate like franchisees without any physical collection centres. In effect, they have no legal standing and concerns have been raised about the quality of their services.

The lab reports providing fake COVID-19 test results during the 2021 Kumbh Mela are a case in point.

A public-interest litigation (PIL) was filed in the Delhi High Court in August 2020 to ban the online health service aggregators that are providing diagnostic or other services without meeting the regulatory requirements or having registered under the CEA and are running without any medico-legal liability for collecting and testing samples for diagnosis.

The Honourable Court ordered the concerned authorities to take action against these illegal online health service aggregators operating in violation of the applicable laws, including the CEA, if applicable.

In January 2021, the Ministry of Health and Family Welfare (MoHFW), GoI directed the states to take urgent steps to regulate such online health service aggregators that offer laboratory facilities. The then Health Secretary, MoHFW, Rajesh Bhushan sent a letter to all state chief secretaries which unequivocally stated, "This is a matter of grave concern, as it affects the health and safety of citizens who may obtain services from these online aggregators and subsequently be aggrieved." The letter also called attention to the minimum standards for laboratory services notified by the Health Ministry.

The states were asked to prepare a 'time-bound action plan' and implement it to regulate such online health service aggregators and related service providers. They were also advised to engage the home department to investigate such matters to prevent any violation of applicable laws and also send an Action Taken Report to the Department on a priority basis.

However, follow-up was missing as usual and the aggregators function brazenly despite the court orders, government directives and guidelines to discontinue operations. The consumers, oblivious to such breach, are attracted by the convenience which puts their health at risk!

Self-Regulation

In the face of the excessive backlash about the absence of minimum standards and quality of services of online health aggregators offering diagnostic facilities, the Federation of Indian Chambers of Commerce and Industry (FICCI) launched a **Self-Regulatory Code of Conduct for e-Diagnostics in India** in May 2022. This was prepared after several rounds of industry consultations by FICCI's e-Pharmacy Working Group.

In the esteemed presence of Ms Manmeet K Nanda, Joint Secretary, Department for Promotion of Industry and Internal Trade, GoI, FICCI announced that the code aims to ensure adherence to the highest professional standards while delivering quality e-diagnostic services till the

PATHOLOGIST DR ROHIT JAIN filed writ petitions in August 2020 in the Delhi High Court (WP(C)-503 I 12020 - Dr. Rohit Jain versus Govt. of NCT of Delhi & Ors.) for immediately banning several healthcare aggregators from collecting diagnostic samples - including for testing of Covid-19 - as they misrepresented themselves as medical diagnostic laboratories. It also claimed that they were illegally advertising and soliciting patients.

An example was cited - LSS Healtheare Pvt. Ltd. (1mg Labs) carrying out clinical tests and submitting reports which is contrary to law.

The plea stated that the lack of regulations for online health service aggregators and their unfettered operation through websites was causing confusion about their legitimacy and legality. It was also highlighted that they were testing for Covid-19 without any legal authority or accreditation by NABL and were acting contrary to the Indian Council of Medical Research guidelines. Neither were they following the Bio-Medical Waste Management Rules. Hence, it called on the government to issue guidelines for registration and minimum standards for sample collection centres operated by online aggregators including the minimum qualification for taking samples by representative of aggregators.

last mile in a safe and compliant manner. This will ensure standardisation of services, quality maintenance and consumer protection.

The key components that the member online health aggregators undertake to adhere to are:

Responsibilities of the Technology Platform Listing Medical Laboratories – They will provide details of the laboratories on behalf of which they are listing the services and various test details so that consumers can make informed decisions. It also covers procedure for evaluation and selection criteria before listing the laboratories.

Requirements for Safe Sample Collection and Transportation - In addition to adhering to all existing norms of safe sample collection and transportation, they will put in place a regular training program for phlebotomists (personnel who collect blood samples), ensure traceability of samples and have provisions to handle urgent requests.

The code provides that the online health aggregators offering diagnostic facilities will only list registered laboratories, ensure that test result reports are generated only by physical medical laboratories, evaluate the quality of training undergone by phlebotomists at the laboratories they are tying up with and carry out a periodic review of their association with the labs.

Requirements for Clinical Sample Processing and Reporting – They will ensure that a physical medical laboratory processes the samples within the stipulated timeframe and generates the reports. In addition to the standards of reporting, the reports shall mention the identification of the laboratory and requester, and date and time of sample collection, sample receipt and report generation.

Requirements for Report Delivery to Consumers - Reports of the users will be provided in a secured manner within the committed timeframe. Systems will be put in place to monitor the turnaround time and act on any breach.

Customer Grievances - A proper mechanism will be created to address any queries or grievances of the end users. The platforms will also be registered with the National Consumer Helpline.

Adherence to Applicable Regulatory Requirements and Technical Specifications – They will adhere to all regulatory norms, standards and guidelines applicable in their respective state(s) of operation, process the data as per the applicable laws, and meet required technical specifications of the equipment used.

Final Word

The unchecked presence of online health service aggregators is snowballing into a major healthcare crisis. Can we rely on self-regulation by the industry? Will the centre/state governments and accreditation agencies continue to ignore their existence?

NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES

NABL

8th PTP/RMP CONCLAVE 2024

Date: 29th and 30th August 2024
Place: Mysore, Karnataka, India

National Accreditation Board for Testing and Calibration Laboratories (NABL) - India, a Constituent Board of Quality Council of India is pleased to announce two days Proficiency Testing Providers (PTP) / Reference Material Producers (RMP) Conclave on 29th and 30th August 2024

KEY OBJECTIVES OF THE CONCLAVE

UPDATE

National / International updates and development in accreditation of PTP and RMP

ABILITY

Showcase ability of conducting PT Scheme and Producing Reference Material in a competitive mode

PLATFORM

Platform for sharing views by PTPs / RMPs / Regulators and Laboratories (Testing, Calibration and Medical)

OPPORTUNITIES

Opportunities for PTPs / RMPs / Regulators and Laboratories (Testing, Calibration and Medical)

Poster

Presentation

Exhibition

Who should attend

- Proficiency Testing Providers (PTP)-Accredited/ Applicant/Potential
- Reference Material Producers (RMP)-Accredited/ Applicant/Potential
- Users of PT schemes & Reference Materials
- Laboratories (Testing, Calibration and Medical)
- Quality professionals
- Manufacturers/ professionals from the Industry having in-house laboratory

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CLICK HERE TO REGISTER

Last date of registration
31st July 2024

Limited seats are available

Registration Fee

Category	Early Bird (till 30th June 2024)	Fee from 01st July 2024 onwords
Individual	Rs 3,500/- (GST 18% Rs 630) Total Fee = Rs 4,130	Rs 4,000/- (GST 18% Rs 720) Total Fee = Rs 4,720
Group registration	Rs 12,500/- (Upto 5 participants) (GST 18% Rs 2,250) Total Fee = Rs 14,750	Rs 15,000/- (Upto 5 participants) (GST 18% Rs 2,700) Total Fee = Rs 17,700
Foreign participant	USD 50	USD 50

- Conclave timing: 9 am to 5 pm (Both days)
- Attendance certificate will be issued upon attending this two-day Conclave
- Venue details and agenda will be shared with registered participants.

Tel No: 91-124-4679700 (30 Lines)

www.nabl-india.org

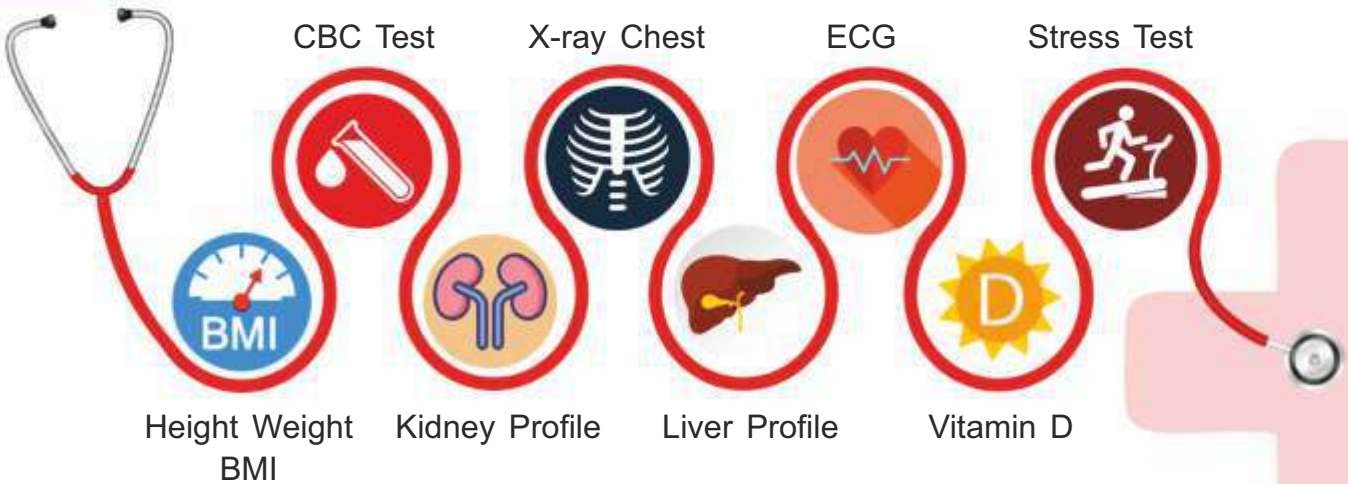
NABL HOUSE
Plot No. 45, Sector 44,
Gurugram - 122003, Haryana

Bina Jain
- Former President, All India Women's Conference (AIWC)
- Chairperson, Healthy You Foundation, New Delhi

Preventive Health Checkup Packages – More to It Than Meets the Eye!

One of the first lines of protection to preserve our general well-being is laboratory testing. Preventive care is defined by periodic full body tests and annual checkups which can save time, money and suffering related to likely illnesses in the future. Reliability of medical testing is in the eye of the storm once again!

Preventive Health Check Up



Prevention is Better than Cure – You can and should take steps to check your wellness parameters before being tagged as a patient!

THE IMPORTANCE OF getting a complete body checkup on a regular basis cannot be denied. This kind of comprehensive testing involves a thorough assessment of the present status of a person's health by evaluating all the systems and organs in the body. It covers a wide-range of tests related to the heart, liver, lungs, kidneys, stomach, bones, thyroid, reproductive organs and so on.

Getting the blood sugar, cholesterol, thyroid, lipids, creatinine, etc. checked regularly has become a way of life. A small bump in the numbers can be indicative of a serious condition and can induce you to change your lifestyle accordingly. Taking charge of our well-being in this manner enables us to continue to stay healthy, pre-empt serious medical conditions and even safeguard our life.

As any disease-related symptoms will come to light at an early stage, they can usually be cured easily and allow quick recovery. For example - in contrast to late-stage cancer diagnosis, if an annual checkup catches it in the early stages, there is a significantly higher chance of survival and faster recovery.

Many health insurance companies offer annual checkups as part of the medical insurance policy or as an add-on at a minimal charge.

Thorn in the Works

Given the incidence of inaccurate and unreliable results in the medical testing and diagnostics domain, do such checkups make sense? Isn't it a waste of time and money – not to mention the risk of getting treated for a wrong or fake diagnosis?

Then there is the growing incidence of unscrupulous online health service aggregators aggressively marketing 'preventive or wellness packages' at steeply discounted deals that are almost irresistible. They even go to the extent of pushing for tests and other healthcare services without medical assessment or prescription. For instance, Healthian offered a full body test for Rs 399 which would cost around Rs 18,000 in regular laboratories. PharmEasy blatantly states that it can conduct tests even without a prescription! This translates into a steady stream of 'customers' while many of the 'labs' rely on automated testing to deliver substandard results.

What's more, some of them even 'convert healthy people into patients' by reporting fake abnormalities and offering medical consultations/treatments at a discount. Or, they push aggressively for further tests/surgery. You may never even get to see a copy of the lab reports! In fact, the social media pages of these healthcare aggregators are filled with complaints of disgruntled experiences of patients ranging from delay in results to faulty results and more.

Not only this, the aggregators conduct a huge array of tests, many of which are not even recommended by any guidelines and have little impact on morbidity and mortality. Apart from being an unnecessary financial burden and wasting resources, it may also lead to over-diagnosis and over-treatment!

The problem is getting compounded by these discounts and offers for medically unnecessary and unwarranted testing in the name of wellness/ immunity packages. It is a price war to offer maximum number of tests at lowest prices which is totally meaningless.

– Malini Aisola, co-convenor of All India Drug Action Network (AIDAN)

Many of them even rope in celebrities as brand ambassadors. “They have all these famous names as brand ambassadors as if they will perform the surgeries or look at your blood in a lab. This confuses the public, who are already bombarded with too much information,” quipped Dr Jagadish Hiremath, Founder & CEO, AASRA Group of Hospitals, Bengaluru.

Taking Action

The medical associations are calling for greater supervision for these healthcare service aggregators. The Association of Practising Pathologists filed a PIL in the Delhi High Court in 2022 (Association of Practising Pathologists (Regd.) v. Union of India & Ors.) seeking action against health service aggregators over misleading advertisements, ridiculous discounts and unsolicited messages.

The association of over 288 'qualified and quality-conscious practising pathologists with standalone medical laboratories' claimed that while they are subject to regulation, the corporate entities/offline and online health service aggregators are permitted to advertise their services - including medical laboratory tests and diagnostics - with incessant advertisements, unsolicited calls and other enticements of huge discounts and concessions, which prejudices their professional interests. They also alleged that the conduct of the online aggregators was a blatant violation of several rules, regulations and guidelines.

The regulations cited were:

- Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 related to misleading and bait advertisements, offering ridiculous discounts, sending unsolicited bulk SMSs, misusing social media, print media and electronic media.

What is happening is that over a period of time, especially the last two years, there are some online aggregators ...these entities are advertising, soliciting and indulging in paid advertisement, calls are received. There are full page newspaper advertisements. Not only advertisements, they say they are giving 90 per cent discount and all those things.

- Advocate Neeraj Grover, appearing for the petitioner

- Clinical Establishment Amendment Rules 2020 mandating a medical prescription by a Registered Medical Practitioner for conducting health checkups.
- National Medical Commission Act, 2019 requiring lab reports to be authenticated by duly qualified medical practitioners.

The plea argued that the aggregators were blatantly avoiding the restrictions placed on registered medical practitioners while at the same time taking the benefit of exemption from GST for being in medical services, thus causing revenue loss of hundreds of crores to the exchequer.

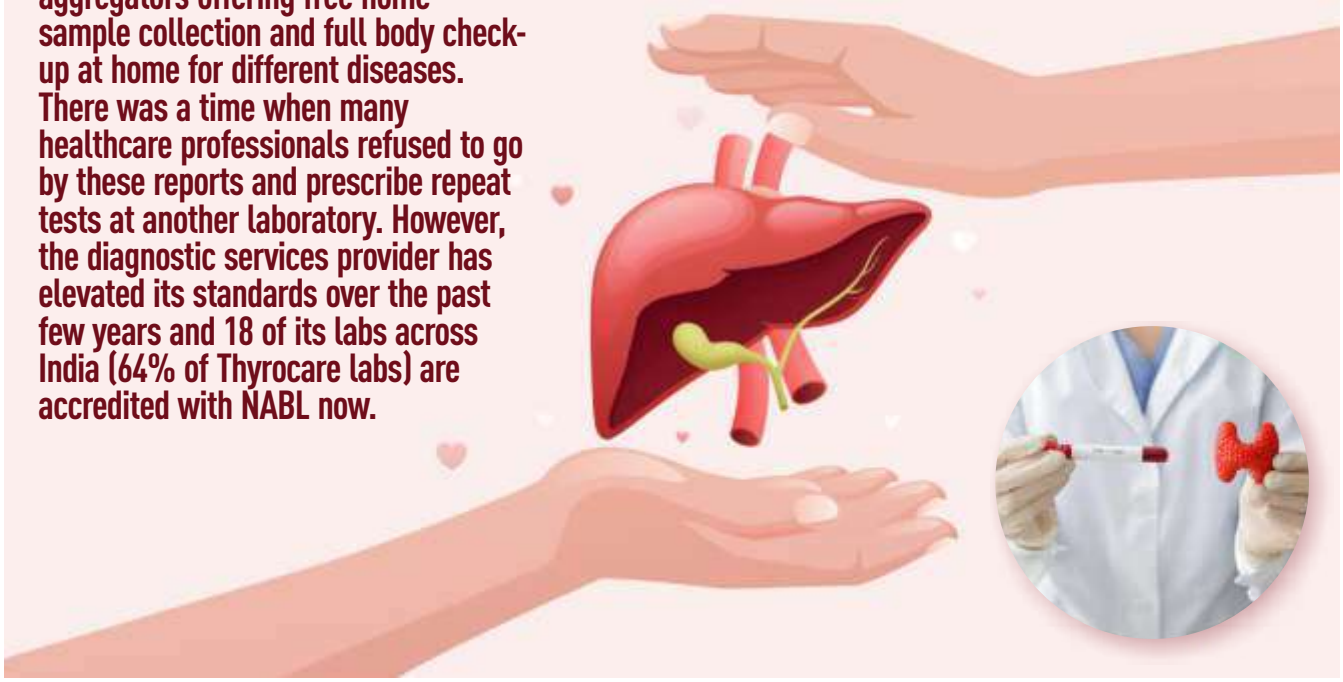
The petitioners sought to be treated at par with offline and online health service aggregators in terms of restrictive regulations for registered medical practitioners as differential treatment of two entities offering similar services is a glaring violation of Article 14 (equality before law) of the Constitution of India.

The petition further asserted that the aggressive advertising was not only misleading the innocent public, but also causing unwarranted and irreparable harm on a daily basis. Hence, it called for appropriate action alleging that inaction by the authorities was 'encouraging quackery' and destroying the dignity of the noble profession of medical science.

Justice Prathiba M Singh made certain online platforms, including Healthian, Tata 1mg and Practo, parties to the proceedings and issued notices to them as well as the central government, Delhi government, GST Council and the National Medical Commission to file their responses.

What actually happened after this is anybody's guess as there are no further updates related to the petition!

Thyrocare is one of the most popular aggregators offering free home sample collection and full body check-up at home for different diseases. There was a time when many healthcare professionals refused to go by these reports and prescribe repeat tests at another laboratory. However, the diagnostic services provider has elevated its standards over the past few years and 18 of its labs across India (64% of Thyrocare labs) are accredited with NABL now.



Leveraging AI in Credentialing and Accreditation:

A Game-Changer for Associations

ADRIENNE SEGUNDO's blog post outlines how AI can be a transformative tool for associations in managing their credentialing and accreditation programs, highlighting its potential in automation, standards review, exam blueprinting, and maintaining accreditation compliance. She is Chairman/COO at Limitless Association Solution Resource, LLC & Founder of National Credentialing Institute, USA

IN THE EVER-EVOLVING world of professional development, associations continually seek innovative ways to enhance their credentialing and accreditation programs. A key player in this transformation is Artificial Intelligence (AI), a tool that offers unparalleled opportunities for automation, efficiency, and quality improvement. Let's explore how AI can revolutionize various aspects of these programs.

1. Automation and Efficiency in Internal Processes

One of the primary benefits of integrating AI into credentialing systems is the remarkable improvement in automation. Mundane tasks like data entry, application processing, and communication can be streamlined through AI algorithms. This not only reduces the workload for staff but also minimizes human error, ensuring a more accurate and efficient process. Additionally, AI-driven systems can adapt and respond to changing data trends, offering a more dynamic and responsive credentialing process.

2. Enhancing Standards Review and Learning Opportunities

AI can play a crucial role in reviewing and updating the standards of certification programs. By analyzing vast amounts of data, AI can identify emerging trends and skills gaps in various professions. This insight enables associations to refine their standards, ensuring they remain relevant and valuable in the professional landscape. Furthermore, AI can suggest tailored learning opportunities for applicants, aligning educational resources with the evolving industry requirements.

3. Refining Certification Examination Blueprint

Crafting a robust certification examination blueprint is essential for the credibility of any credentialing program. AI can assist in this process by analyzing historical exam data to identify areas that need more focus or restructuring. It can also generate preliminary test questions, ensuring they are aligned with the latest industry standards and learning objectives. This not only enhances the quality of the examination but also ensures a fair and comprehensive assessment of candidates.

4. Maintaining Accreditation and Compliance

For programs accredited through ANAB ISO 17024 and NCCA, maintaining compliance with their stringent standards is paramount. AI can be a valuable ally in this endeavor. Through continuous monitoring and analysis, AI systems can ensure that the programs consistently meet the required standards. They can provide real-time feedback on compliance issues, helping organizations address potential gaps before they become significant challenges.

Conclusion

The integration of AI into credentialing and accreditation programs presents an exciting frontier for associations. By harnessing the power of AI, associations can not only improve their operational efficiency but also elevate the quality and relevance of their certification programs. As we embrace this technological advancement, we open doors to more dynamic, responsive, and effective professional development pathways.

The article is sourced from
https://eventgarde.com/blog/leveraging-ai-in-credentialing-and-accreditation-a-game-changer-for-associations

Be Careful While Using

Social Media Platforms

An initiative of the Government of India to facilitate victims/complainants to report all types of cybercrime complaints online. Complaints reported to the National Cyber Crime Reporting Portal are dealt by respective police authorities of States/ UTs based on the information provided by the complainants.

The increased usage of internet services and smartphones has made social networking one of the most popular online activities. Social media enables users to connect, communicate and share information, photographs or videos with anyone across the globe. Some of the popular social media platforms are Facebook, Twitter, Instagram, YouTube, LinkedIn,WhatsApp, Snapchat, Tinder, Hike, WeChat, Tumblr etc.

The penetration of social media is continuously increasing worldwide. The tremendous growth in use of social media platforms/ social networking platforms has provided a fertile ground to cyber criminals to engage in illegal activities.

Here are some of important steps you should take to protect yourself and your information while using social media platforms:

1) Do not accept friend requests from strangers on social networking sites.
2) Do not trust online users unless you know and can trust them in real life.
3) Do not share your personal information such as address, phone number, date of birth etc. on social media. Identity thieves can easily access and use this information.
4) Do not share your sensitive personal photographs and videos on social media.

BE CAREFUL WHILE USING

Social Media Platforms

5) Share your photos and videos only with your trusted friends by selecting right privacy settings on social media.
6) Immediately inform the social media service provider, if you notice that a fake account has been created by using your personal information.
7) Always use a strong password by using alphabets in upper case and lower case, numbers and special characters for your social media accounts.
8) Do not share your vacations, travel plans etc. on social media.
9) Do not allow social networking sites to scan your email account to look for your friends and send spam mails to them without your consent or knowledge.
10) Always keep location services turned off on your devices unless necessary.

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HOME AFFAIRS

BE CAREFUL WHILE USING

Social Media Platforms

11) Do not announce your vacations, travel plans etc. on social media. Criminals can use it as an opportunity for theft etc.
12) When chatting with someone online and you feel suspicious about your chat partner, try asking some unrelated scientific or mathematical questions. If it does not answer or acknowledge the question, it may mean that you are chatting with an automated computer bot.
13) Do not use public computer/ cyber cafe to access social networking websites, it may be may be infected/ installed with a key logger application which will capture your keystrokes including the login credentials.

BE CAREFUL WHILE USING

Social Media Platforms

14) Many social networking sites prompt you to download third-party applications that lets you access more pages. Do not download unverified third-party applications without doing research about its safety.
15) Do not hesitate to report, if someone is posting offensive and abusive content on social media.
16) Do not share or forward unverified posts/ news on social media forums. These may contain fake news or contain sensitive information which may mislead people.

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MINISTRY OF
HOME AFFAIRS

BE CAREFUL WHILE USING

Social Media Platforms

About Us

An initiative of Government of India to facilitate victims/complainants to report all types of cybercrime complaints online.Complaints reported National Cyber Crime Reporting Portal are dealt by respective police authorities of States/ UTs based on the information provided by the complainants.

If you want to report something other than Cybercrime cases or in case of an emergency please contact your local police by dialing 100.

National Cyber Crime Reporting Portal

www.cybercrime.gov.in

@CyberDost

JAGO GRAHAK JAGO

A snapshot of success stories of consumer activists who are relentlessly battling for consumer rights. We will highlight decisions and awards in favour of the consumers. This should motivate other youngsters to take up the cause of the consumer for not only social benefit, but their own good too! Jai Ho Grahak!

Nursing Home Directed to Shell Out Rs 43.5 Lakh for Sheer Medical Negligence

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A PREGNANT WOMAN is admitted in a nursing home and gives birth to a baby girl by normal delivery the next day. Post-delivery, she develops postpartum haemorrhage (PPH) and other bleeding problems and is pronounced dead soon after.

Who is to blame here? Was it genuinely an unexpected and uncontrollable medical issue or a case of sheer medical negligence? Could the loss of life have been averted with advanced healthcare interventions? Did a newborn baby lose her mother for no reason?

The husband, K. Hari Prasad, a software engineer by profession, requested the doctors to shift her to a super specialty hospital, but the physicians assured him that there was nothing to be concerned about. He was asked to bring two units of blood. He brought the blood within 35 minutes, but by that time, he was informed that the patient's pulse rate was very low. She was declared dead soon after.

The harangued and bereaved husband was convinced that his wife did not receive proper medical care and the hospital was ill-equipped to deal with emergencies. He filed a complaint with the Telangana State Consumer Disputes Redressal Commission (TSCDRC) claiming that his wife died due to the negligence of the doctors and lack of medical infrastructure and demanded a compensation of Rs. 99 lakhs. The hospital administration countered that although they had anticipated the delivery on 28th August, 2013, the patient had been admitted on 8th August itself and delivered a premature child. They even stated that the complainant was not in the hospital at the time of delivery and that the blood was arranged only by 9.30 am.

Over a decade later, the TSCDRC in-charge president Meena Ramanathan and member (judicial) V Seshubabu ruled in the K. Hari Prasad and his daughter vs. Taraporewalla Nursing Home and Dr Shirin N. Taraporewalla case that the hospital did not act swiftly, and stated that nursing homes should be equipped to deal with eventualities, instead of blaming patients. The Commission ordered the Taraporewalla Nursing Home in East Marredpally to pay a compensation of Rs 43,57,000, half of which should be a fixed deposit in the name of the daughter who is now 10 years old.

WATCH OUT

How Safe are the Imported Medical Devices We Use?

We will focus on the need to regulate the import of used and refurbished medical devices into India at the cost of the health and safety of patients. We will also call for an exclusive law to regulate medical devices in our country.

UPDATE ...

Moving a Step Ahead

Update on the April edition

WEBINAR ON Educational Landscape in India is Calling for a Change

THE APRIL MAGAZINE edition was a starting point for creating awareness about 'Educational Landscape in India is Calling for a Change'. We followed up on this by organising a national webinar - in association with RJS Positive Media - on 14th April, Sunday at 11 am.

The event was graced by the presence of Prof. Abhijit Chattoraj, Professor and Chairperson at BIMTECH as the keynote speaker. The Chief Guest was Prof (Dr) Varinder Singh Kanwar – CEO, National Accreditation Board for Education and Training (NABET), a constituent board of Quality Council of India. Our editor and international consumer policy expert, Prof Bejon Misra chaired and moderated the webinar.

A number of noted national and international personalities across domains were in attendance – like, Dr. Ramaiah Muthyala, Mr. Alok Joshi, Mr. Ranjan Verma, Mr. Anil Jauhri, Mr. Pushkar Balaji, Prof. Pramil Tiwari, Mr. Shridhar Reddy, Mr. Dharmendra Kumar, Ms. Shweta Goyal and others.

Ms. Gyan Priya Sahay started the webinar on a beautiful note by invoking a Sanskrit shloka on education and felicitating Dr. Ambedkar on his birth anniversary before introducing our esteemed guests. Ms. Bina Jain delivered the welcome address wherein she highlighted pertinent issues related to education and how societal efforts can make a difference.

Prof Abhijit began his speech by stating that the National Education Policy, 2020 is a step in the right direction and has the potential to shape a vibrant India. He highlighted that India is performing poorly on all the three Human Development Indices of Health, Education and Income.

While touching on various relevant issues like low public expenditure on education, lamentable condition of government schools and the huge fall in gross enrolment ratios when students move to secondary classes, he stated the challenges posed by poor quality of teaching, drawbacks of rote learning and financial impediments in higher education.

Prof Abhijit stressed that education is failing to create interest in the young minds and the teachers should fire ambition in the students. He also called on everyone to step forward – rather than just leaving things to the government – to build a solid education system in India.

Dr. Kanwar continued on the same note by emphasising that the journey of achieving quality in education is our collective responsibility. He highlighted the proactive work done in South Korea which achieved independence at the same time as India. He further spoke about the process-driven approach of accreditation for schools and how NABET is handholding around 128 schools to categorise students and suggest initiatives to improve their performance.

Dr. Kanwar stated that he is witnessing a slow change in parent awareness and how there will be a shift at the grassroot level in the coming years. He informed the audience about the government's research fellowship schemes that are controlling brain drain and NITI Aayog's project to rank medical colleges which will empower students to choose the right ones. He hoped that the mandate will spread to the school-level as well.

The audience participated in an engaging discussion and raised pertinent issues with the speakers. Dr. Ramaiah pointed out that while the quantity of schools is increasing in India, the quality is going down. He asked how the new institutions can provide quantity without the proper quality and called for an emphasis on basic education.

Mr. Ranjan Verma stated that the primary differences between education in India and abroad is that the foreign countries offer better quality and are more focused on practical education – be it in medicine, engineering or at the primary level! Mr. Alok Joshi highlighted that the conventional schools and colleges are overburdened; education should be decentralised with the help of technology like internet, AI and other digital tools. He also emphasised on the need for skill development to improve employability.

There were lively comments on the need for fast-track implementation of the NEP, the recent protests on the highways against the long travel for students and the burning issue of crass commercialisation of education.

Prof Bejon Misra called attention to the fact that more coaching centres are mushrooming across the country than schools and colleges. He recalled his youth when teachers would provide extra tuition to the students after school free-of-cost. Mr. Shridhar followed on this by stating that parents should be counselled on how to be a teacher for their children.

Mr. Prafull D. Sheth summed up the discussion in his inimitable style and expressed gratitude to the dignitaries in his Vote of Thanks.

YOUR OPINION MATTERS

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.

letters to the editor

(April issue: Educational Landscape in India is Calling for a Change)

Education is a basic human right that works to raise men and women out of poverty, level inequalities and ensure sustainable development. But worldwide, 244 million children and youth are still out of school for social, economic and cultural reasons. Education is one of the most powerful tools in lifting excluded children and adults out of poverty and is a stepping stone to other fundamental human rights. It is the most sustainable investment. The right to quality education is already firmly rooted in the Universal Declaration of Human Rights and international legal instruments, the majority of which are the result of the work of UNESCO and the United Nations.

Education has always been a cornerstone of India's rich cultural heritage, and in the 21st century, the country's educational landscape is undergoing significant transformations. With a growing population and an increasing emphasis on innovation, inclusivity and digital literacy, Indian education is at the cusp of a paradigm shift.

The future of Indian education holds immense potential. As the nation continues to invest in infrastructure, technology and pedagogical innovation, the vision is to create a learning ecosystem that nurtures creativity, critical thinking and global citizenship. The ongoing transformations underscore a commitment to empowering the youth and building a knowledge-driven society that can meet the challenges of the 21st century.

In this perspective, I find 'The Aware Consumer' magazine extremely relevant, as it highlights both challenges and opportunities regarding education in India, combined with global best practices as well as recommendations from global bodies like the UNESCO.

Affordable learning paves the way for equal opportunities – and education transforms lives! And transforming education means transforming the world.

- Lars-Åke Söderlund, Sweden
Vice President, International Pharmaceutical Federation (FIP)

Education transcends mere skill development and employability; it encompasses cultivating a society that values democratic principles and human upliftment. Teachers are the architects of nations, as not every parent can guide their child through the complexities of learning. However, teachers require continual motivation and focus to fulfil their noble and larger purpose of nation-building.

Overall, the NEP 2020 provides a comprehensive framework for addressing the challenges facing higher education and promoting transformative change by aligning educational practices with the evolving needs of society and the economy. However, I have a few more suggestions, like:

- Holistic health is crucial for a nation's well-being, where a creative and happy mind thrives within a healthy body. To achieve this, we must prioritise both physical and mental health nationwide.
- Empathy and gratitude are the cornerstone of our human value system. They foster a sense of camaraderie and teamwork among individuals, ultimately contributing to the strength of our team and nation. This should be deeply ingrained in every teacher and student.
- Encourage engagement in community initiatives by organising community service programs that involve students and faculty members in activities like teaching, healthcare, sanitation and skill development in nearby communities.
- Soft skills – like effective communication, team building, leadership, empathetic listening, problem-solving, adaptability and critical thinking - are the new hard skills. By adopting a holistic approach to soft skills training and providing ample opportunities for practice and feedback, higher education institutions can empower students to succeed in their academic pursuits and future careers.
- Scientific temperament is essential for fostering critical thinking, problem-solving skills and a curiosity-driven approach to learning.

- Lt Col Sanjay Srivastava, Mumbai • sansri1967@gmail.com

This magazine edition admirably shines a light on the pressing need for transformation in the Indian education sector. While it adeptly outlines current challenges like outdated curricula and infrastructure deficits, its insightful analysis serves as a catalyst for envisioning and implementing innovative solutions to propel education into a promising future.

- Deepa Shukla, Delhi • deepashukla@live.com

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letters to the editor

I love the topics you covered in 'The Aware Consumer' magazine. I didn't know that we have shortage of teachers in India too. I never got a job as a teacher in India, that's why I had to come to Australia. The main problem is that teachers don't get paid well in private schools, that's why, people don't like to work in teaching.

To overcome this problem, it is better to develop an online platform. I am a teacher in distance education. We have children from all over the world. They don't need to attend classes and whenever they have time, they can hear recordings and send their work to us.

Another point - to overcome the shortage of teachers (I think it's in the government schools and villages), there should be efforts to attract people with more benefits to join teaching profession. And for government jobs, the process should be made easy.

- Shweta Goyal, Australia • goyal.shweta@yahoo.com

'Balance Between Quality And Quantity' In Education - The last 30 years in our country have seen a huge increase in the number of educational institutions; and, this increase at the K-12 level is indeed a remarkable step. It is a matter of pride that the asymmetry in access to schools has been largely plugged. Most remarkable is the improved access of education For Girls.

It is often argued that the enhanced number of schools/colleges should take due care of the enrolment vis-à-vis teachers/mentors and faculty members. This stems from a very reasonable point. In the educational landscape, one cannot reverse the school/college days to 'undo' the not so desirable things. In essence, the time lost is lost forever and that, in my considered opinion, pushes the country back by years. Despite the best of the intentions, the enthusiasm to provide education to all may not bear the fruits that were envisaged at the first step.

Talking of the professional courses in the country, the stake of the respective councils viz. medical council, dental council, nursing council, bar association and pharmacy council becomes vital to draw the balance between the very 'quality' with the 'quantity' of graduands. Elaborating on the 'quality', it would only suffice to say that the graduands should be empowered to fit in the role that was envisaged for them. Wherever this has been lacking, one can find the graduands into functional roles that were never imagined for them.

The observations of the Bar Council of India in April 2024 are extremely relevant and noteworthy, “The Bar Council of India has issued a circular urging vice-chancellors and departments of higher education across the country to help the top lawyer body in its endeavour to uphold the sanctity, and quality” of legal education. Expressing grave concern over the rampant proliferation of law colleges nationwide, the General Council of the Bar Council of India had resolved - in 2015 - unequivocally urging all state governments and universities to impose restrictions on the issuance of No Objection Certificates (NOCs) and affiliations for a period of three years.

The tussle between 'quantity' and 'quality' could not have been captured better.

Three relevant points emerge - Surprise inspections have not met the expected standards; secondly, the level of responsiveness and adherence to directives has fallen short of expectations and finally this lack of proactive engagement undermines the efforts to improve the standards of legal education.

If the respective councils in the country come forward on the subject line, taking the stakeholders in confidence, the quality component shall shine over the quantity. No wonder, our country has had the treasure of becoming 'Vishwa guru'.

These are my views and should not be construed to be the representation of the organisation I work for.

Prof Pramil Tiwari, PhD - Mohali • pramiltiwari@yahoo.com

Empowering Parents: The Case for Decentralising Education in India - In the ever-evolving landscape of education, there's a growing realisation that true learning transcends the confines of traditional classrooms. While formal educational institutions undoubtedly play a pivotal role, the need for decentralisation and active parental involvement has become increasingly apparent. In India, where diversity is not only cultural but also educational, empowering parents to engage in holistic education alongside formal institutions is not just a choice but a necessity.

Beyond Classroom Walls - Education extends far beyond the boundaries of textbooks and syllabi. It encompasses values, life skills, and practical knowledge essential for navigating the complexities of the world. While schools provide a structured framework, they often fall short in addressing the individual needs and unique talents of every child. This is where parental involvement becomes crucial. We need to get out of the mindset that education is only the school's responsibility.

Bridging the Gap - Decentralising education by involving parents doesn't mean undermining the role of formal institutions. Rather, it's about bridging the gap between home and school, creating a seamless continuum of learning. When parents actively participate in their child's education, they reinforce the lessons taught in school, provide additional support where needed, and serve as role models for lifelong learning.

Cultivating Lifelong Learners - In today's fast-paced world we are in the age of Artificial Intelligence (AI), the ability to learn, unlearn, and relearn is paramount. By engaging parents as partners in education, we not only enrich the learning experience but also instil a love for learning that transcends the classroom. When education becomes a collaborative effort between parents, educators, and the community, it paves the way for the development of confident, curious, and resilient individuals equipped to thrive in an ever-changing world.

- Alok Joshi, California • firealok@gmail.com

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