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The Next Precipice: Medical Labs in India

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In order to put this subject in its right context, let us start with a bit of background on the Indian healthcare system and services.

For meeting the health needs of our population, a comprehensive and sustained approach is required towards developing a strong health infrastructure throughout the country. There is a sharp rise in health awareness in the population, particularly in the middle and upper class.

Creation of corporatised healthcare facilities in the private sector and the advent of health insurance have opened up demand in many areas of healthcare in India. In this scenario, medical laboratories are mushrooming everywhere to support healthcare needs. These laboratories are an integral part of disease diagnosis, treatment, monitoring response to treatment, disease surveillance programmes and clinical research. The test results, therefore, should be reliable, accurate and reproducible. This is only possible if current Good Laboratory Practices (cGLP) are in place.

And here is the catch: India does not have mandatory accreditation for medical laboratories. All laboratories are required to only register themselves with the health departments in the respective states! The only accreditation agency that is authorised by the central government is the National Accreditation Board for Testing and Calibration of Laboratories (NABL).

Rough estimates show that there are some one lakh medical diagnostic laboratories in the country. Enquiries reveal that NABL has accredited around 450 medical laboratories (0.45%), with the rest (99.55%) having only registered themselves with the respective state health departments. Some laboratories can only be described as mom-and-pop shops. How many applications from laboratories are pending with NABL and what is India going to do to clear the backlog? That is the question to which we need the answer.

Now a word about the various types of medical laboratories. Broadly, they are Clinical Biochemistry, Clinical Pathology, Hematology & Immunohaematology, Microbiology & Serology, Histopathology, Cytopathology, Genetics & Nuclear Medicine (in-vitro only). Laboratory accreditation is important. The concept of laboratory accreditation was developed so that there is third-party certification of the competence of laboratories to perform particular types of testing. Benefits of accreditation accrue to both laboratories and patients. For laboratories, there is potential increase in business due to enhanced credibility and patient confidence. For patients, they can research and identify the laboratories accredited by NABL from the directory available on the website of NABL and expect reliable laboratory results.

Lab accreditation ensures quality that is absolutely essential in diagnostics. Quality consists of functional quality and technical quality. Ethical practices come under functional quality. We often hear that there is an unholy nexus between laboratories and doctors and that commission is paid to the doctor when a patient is referred to the lab for tests.

It is unfair to generalise, but this aspect must not be overlooked. Technical quality is reflected in the latest lab equipment, processes and the soundness of the technician, pathologist or radiologist, etc.

Let us look at lab errors. Studies in the developed nations reveal that 68% of these are pre-analytical errors. Poor-quality samples affect test results adversely. As they say, "a laboratory test is no better than the specimen and the specimen is no better than the manner in which it is collected."

Pre-analytical errors occur due to transport-related causes such as improper handling, reasons such as humidity, specimen integrity, exposure to light, and so on. Then there are processing-related causes such as faulty centrifugation, storage, etc. Phlebotomy (collection of blood)-related causes also result in wrong results.

Would you like lab results to show you are diabetic when you are not, or vice versa? Or that a tumour is benign when it is malignant, or vice versa? Certainly not. So, what is the prescription for NABL (department of science and technology) and the ministry of health and family welfare?

Both the arms of the government can work on a graded plan to be implemented by all the states for different levels of work being undertaken by the laboratories — we do not want pathological laboratories to suddenly disappear — this will adversely impact even good laboratories, and professionally-run start-up laboratories may have to wind up because they cannot provide the needed capital to immediately scale up to NABL standards.

NABL is woefully understaffed and depends on personnel from government laboratories and government institutions, who themselves do not have sufficient domain expertise. NABL will additionally have to involve accredited private laboratories to help them undertake the audits and accreditation. Government may like to at least make ISO 9001 mandatory, moving gradually to NABL accreditation by giving timelines in advance.

Active medical jurisprudence and consumer redressal forums are getting involved with a broad range of medical, legal and ethical issues as well as human rights of individuals. Medical labs will be confronted with these issues as well if they don't gear up for accreditation and consequent improvement in quality services.

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