The best time to plant a tree – state of diagnostic laboratories in India

The paper on medical diagnostic laboratories provisioning of services in India by Jain et al. in this issue touches upon a vital issue regarding the healthcare system in India. Their study gives an overview of the spectrum of diagnostic facilities available across India along with their structural and functional division. It has also brought out the heterogeneity in the diagnostic facilities across the government, private and the unorganized sectors. With very diverse administrative, financial and staffing patterns, it is no surprise that uniformity is non-existent among laboratories with regard to the daily operation and quality standards.

Keeping pace with India’s journey to greater economic prowess in the global scenario, the health care sector in India has made significant improvement as well. State of the art medical care comparable to the best in the world is now available in some centers. Medical tourism, which remained limited to premium health care centers during the earlier years has now percolated to smaller centers many of which strive to deliver good quality health care.

In India, along with the healthcare boom, there has been a simultaneous increase in the number of diagnostic laboratories. However, the overall state of many of these services, although having shown some improvement over the years, remains gloomy. Standardization and emphasis on stringent quality control still lacks across many laboratories all over India. Laboratory services may makeup <5% of the hospital’s budget but influence 60–70% of all critical decision-making such as admittance, discharge, and medication.[1] Hence, the emphasis of accurate diagnostic facilities in the endeavor to improving healthcare cannot be over emphasized.

The diagnostic industry in India is worth nearly $5-billion and is growing at over 15% annually. It is estimated that there are over 100,000 diagnostic laboratories in India majority of which offer pathology services. The unorganized sector accounts for about 90% of the diagnostic facilities.[2]

There are currently no laws that regulate the diagnostic services. Organizations like the National Accreditation Board for Testing and Calibration Laboratories (NABL)[3] exist, but the laboratories accredited by them are miniscule (1–2%). Few of the larger players with more financial resources also opt for College of American Pathologists (CAP) certification in addition. Furthermore, the accreditation is still voluntary, and many laboratories do not feel the need due to ignorance or are purely profit driven and hence do not invest in quality initiatives.

Maintaining the quality of a laboratory involves routine daily quality control measures and external quality assurance (EQA). Although commercial quality control material is available, its use is limited to a minority of laboratories due to cost constraints or ignorance. Some of the premier institutions in India do run cost-effective EQA programs on hemostasis, complete blood count, clinical chemistry, and transfusion medicine. These services are largely used by institutions or select quality conscious private laboratories.

In addition to many areas of the healthcare sector, the Clinical Establishment Act enacted in 2010 by the Government of India[4] also addresses the minimum standards for diagnostic laboratories. However, its implementation is still not underway, and states can choose not to implement the same. Malpractice and commission practice is rampant in the diagnostic laboratory setting in the country, an issue not seriously addressed by any agency. Most laboratories also lack adequately trained manpower, and the ever increasing numbers of institutes offering laboratory courses by correspondence and sham practical sessions adds on to the problem.
Many corporate laboratories with a nationwide network of collection centers have emerged in the last decade as major players in the diagnostic arena. Most of these have accreditation for NABL or outside agencies like CAP. However, the growth of numerous collection centers for these laboratories in an attempt to capture large sections of the market share is a cause for concern considering the geographical enormity of India and the extreme climate conditions, which affect the sample integrity. Controlling pre-analytical variables in such a setting is vital for accurate diagnostic results.

Quality always comes at a price. Many quality initiatives require funds, which usually get diverted to the ever in focus clinical areas in comparison to diagnostic services. Some of the standalone laboratories do not even have a doctor supervising results and do not even meet minimum quality standards. One of the reasons for the laboratories lagging behind the clinical growth is the lack of co-ordination between different laboratories. Laboratory heads and institutions need to come together on a common platform akin to the CAP or the Royal College of Pathologists (UK) to be able to influence decision making by the government health agencies. State medical councils need to define regulatory guidelines for laboratories, which should be regularly inspected.

In the future, like in the West, as medical insurance becomes more common, we may even have the insurance companies requiring laboratory tests to be done only in accredited laboratories. The laboratories need to wake up to the challenge of improving quality sooner than later. As an old Chinese saying goes ‘the best time to plant, a tree was 20 years ago. The next best time is now’. Laboratory standardization and accreditation is no different.

Naveen Kakkar
Department of Pathology, Christian Medical College and Hospital, Ludhiana, Punjab, India
E-mail: kakkar.naveen@gmail.com

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