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EDITORIAL

ACCREDITATION REQUIREMENT OF LABORATORY MEDICINE IN INDIA

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Current scenario of Medical testing laboratories in India

In our country it is generally believed that over one hundred thousand medical testing laboratories are functioning at various capacities providing diagnostic services to clinical decisions to be made for treatment protocol. India is also one of the destinations for the health tourism for rest of the world. One of the major requirements for health tourism is the accreditation status of hospitals and labs. It is unfortunate that less than 200 laboratories in India are accredited for management and technical requirement complied as per the International standard and few are certified under ISO 9001-2000 for their Quality Management System (QMS). The existence of most of unaccredited or uncertified the labs all over the country do not have any legal identity except for the fact they are only registered under shops and establishment act. It is also found that very few labs are managed by experts in the field and majority of the laboratories are owned or supervised by unqualified personnel. With this kind of situation unique to all developing countries, quality laboratory services for reliable test results are lacking. *Under these circumstances the chances of a healthy person becoming sick is very high and the chances of a sick person becoming health is very low.* We need to reverse the existing situation in all developing countries through a Good Laboratory Practices (GLP) and accreditation of medical testing laboratories implemented as per the International standard ISO 15189:2007 addressing the quality and competence of medical testing laboratories.

The National Accreditation Board (NABL) for Testing and Calibration of Laboratories (NABL), in India is providing guidance and facilities for accreditation to medical testing laboratories. NABL is under the Department of Science and technology (DST) of the Ministry of Science and technology of Government of India. Accreditation being voluntary, few laboratories have gone in for the accreditation on their own. As a result there is no compulsion for laboratories to go in for accreditation. Since Clinical Establishment Act is also not in existence in most part of our country, there is no mechanism to even identify the existing laboratories in most part of our country. Many laboratories are found functioning in car garages in cities operated and owned by single individual. Apart from this large number of collection centers are also found with no or minimal facilities. Some of the collection centers are franchised by major laboratories. Samples are collected for high end complicated tests transported to major cities where testing facilities are available. Details are available on its website www.nabl-india.org.

Registration of medical Testing laboratories to be mandatory

Medical testing laboratory registration through the minimal essential standards of Quality Control of India (QCI) is initiated with a simple document prepared by QCI. With self declaration by the laboratories registration process is made easy. Laboratories registered can go in for certification after demonstrating their quality and subsequently can go in for the accreditation. In most part of the world medical testing laboratories can not conduct the tests on the patient samples unless they are registered. Quality council of India has entrusted the registration process to the implementation partner One World Lab (OWL). QCI can be reached on its website www.qcin.org.

Accreditation requirement

Laboratories can identify the scope of various sections in the laboratory medicine and go in for their accreditation as per the International standard requirement detailed in ISO 15189:2007, (which is also the Indian Standard) and complying with all requirement stated in NABL-112. ISO 15189 standard

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copies can be procured from Bureau of Indian Standard (BIS) and all other NABL documents can be down loaded from the NABL website www.nabl-india.org. Laboratory going in for accreditation need to establish the laboratory management committee with representatives from the management and all sections of laboratory medicine going in for the accreditation for their tests. Committee is required to have designated laboratory Director, Quality Manager and the Technical Manager apart from the Safety Officer. For all key positions there is a requirement of deputies. Laboratories are classified by NABL in to small (up to 100), medium (101 to 400) and large 401 and above) depending upon the number of patients to whom the laboratory caters. All major equipment is required to have their annual maintenance through an approved agency and all measuring equipment needs to be calibrated in NABL accredited calibration laboratories. For all tests measurement of Uncertainty is to be calculated with the use of third party human matrix compatible controls. All technical staff with adequate qualifications is required to have training in the area of their technical operation to demonstrate their competence. The environmental conditions must be conducive to the tests performed and the waste disposal to be as per the norms of the local regulatory agencies (respective pollution control board). Laboratories are expected to have their internal Auditing as per the guidelines provided in the standard referred above followed by the management review. Laboratories need to ensure adequate space with clear demarcation for non compatible activities with good environmental monitoring and protection to their staff handling the highly infectious specimens. Documentation of all activities in the form of records with predetermined retention time or archiving is part of GLP. Laboratory as part of the accreditation need to have test are validated by both Internal Quality Control (IQC) and External Quality Assessment (EQA) schemes. Where ever they do not have EQA for certain tests can go in for Inter laboratory Quality Assessment (ILQA) through exchange of commercial controls and avoiding exchanging patient samples or pooled specimens. Laboratory policy in their Quality System Manual (QSM), must have the system procedure for its implementation through second level document popularly known as Quality System Procedures (QSP). All formats prepared in consultation of its use need to be maintained to generate records. All tests referred or outsourced in the laboratory need to comply with the standard requirement. Laboratories are required to demonstrate through objective evidence their continual quality improvement.

Clinical chemistry tests and its significance in patient care

Over 60% of the tests are carried out under clinical chemistry and hence the stress for clinical chemistry to be of high quality is realized by the clinicians for better patient care. Most of the tests under clinical chemistry are carried out with sophisticated auto analyzers of semi auto analyzers. It is rare to find manual tests. However the Point of Care Tests (POCT) are gaining popularity with the advent of hand held measuring instrument for wide range of analytes from glucose to lead. It is in the area of clinical chemistry the objective evidence for the disease was first provided. With wide range of instruments, methodologies adopted the Turn Around time (TAT) for various tests in clinical chemistry varies from laboratory to laboratory. NABL regularly conducts assessor's course and under the banner of NABL Internal Auditors courses are also held in various parts of the country. It is strongly recommended that laboratories going for accreditation to make use of these facilities. Unlike other disciplines in laboratory medicine it much easier for the clinical chemistry sections to go in for the accreditation as most part of the laboratory system is automated. Test reports generated in accredited labs are accepted all over the world. There are many drivers such as corporate, insurance regulatory bodies and CGHS urging their clients to get laboratory services from accredited centers. With this development it is recommended that our clinical chemists will go in for the much needed accreditation process available in our country.

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