

PRACTICE OF LABORATORY MEDICINE IN QUALITY HEALTH CARE

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Debates continues whether the test reports are accurate, valid or reliable in accomplishing the quality care in the modern era of Information Technology, advanced equipment's and guided by many specialty and super & sub-specialties practices in health sciences. A medical laboratory is a recognized facility where clinical pathology tests are carried out on clinical specimens to obtain information about the health of a patient to aid in diagnosis, treatment, and prevention of disease¹. The aim of performing a test on a patient is to reduce uncertainty about the patients diagnosis or prognosis and to aid the clinical in making management decisions². More comprehensive services can be found in acute-care hospitals and medical centers, where 70% of clinical decisions are based on laboratory testing³. An effective quality management system is the cornerstone for delivery of superior patient care and high-quality test results in the lab.

The principal purpose of this article is to create awareness and to sensitize the professionals, professional bodies, hospital managers and policy makers to appraise the existing situation of lab services to address the felt need to reorganize and strengthen of Laboratory Medicine with an aim to facilitate clinical decision making to provide further quality care.

So far evidence proves in the undergraduate teaching institute, emphasis has been given on acquiring knowledge, attitude and clinical related laboratory competencies which is pertinent to both Pathology & Micro Laboratory practices in Bangladesh⁴. Contents and techniques of teaching-learning process and practicing of Laboratory Medicine by establishing and organization of optimum quality laboratory is paramount importance in postgraduate teaching institute.

Renaming of Pathology by Lab Medicine was enacted and established by enforcing the ICMH

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(Institute of Child & Mother Hospital) act 2002⁵. Afterwards in leading Medical University, BSMMU the name of Clinical Pathology was renamed as Laboratory Medicine⁶. Government of Bangladesh planned and built to start National Reference Laboratory which is yet to be functional. It is essential for brilliant, experienced, committed but dedicated specialist in the field of Lab Medicine to make this reference laboratory effective and global standard. Modern diagnostic labs and imaging centers are being organized and campaigned with adequate physical facilities and modern equipment attracting for quality of Laboratory. Of course, standard machine may exert precision to minimize error during analytical period. But man behind the machine with appropriate management is to be more considered and concerned for effective^{7,8}.

In a hospital setting in Bangladesh, sample processing initiate with a set of samples arriving with a test request, either on 'Advice Form' or prescription pad or requisition slip in lieu of prescribed and affiliated form or electronically via the Laboratory Information System (LIS) except in one or two center of excellence.

Professional glamour of Pathology and its allied discipline is to be explored by an evidence based inquiry survey. One of my favourite and veteran Pathology Professor discouraged me and opined that this is a dependent subject rather than independent clinical entity while I desired for seeking career in this subject at beginning of my career. Pathology, Haematology and Blood Transfusion Medicine are the para-clinical subjects which were not duly honoured by the professional colleagues in few cases.

The staff of clinical laboratories may include: Pathologist, Clinical Biochemist, Pathologists' Assistant (PA) Biomedical Scientist (BMS) in the UK, Medical Laboratory Scientist (MT, MLS or CLS) in the US or Medical Laboratory Technologist in Canada, Medical Laboratory Technician (MLT in US) Medical Laboratory Assistant (MLA) Phlebotomist (PBT). Histotechnologist / Histology Technician and so on. In some countries are exclusively directed by a specialized pathologist. In others, a consultant, medical or non-medical,

may be the head the department. In Europe and some other countries, Clinical Scientists with a Masters level education may be qualified to head the department. Others may have a PhD and can have an exit qualification equivalent to medical staff (eg, FRCPath in the UK). In France, only medical staff (Pharm.D. and M.D. specialized in-anatomical pathology or clinical biology) can discuss pathological results.

In Bangladesh, FCPS & MCPS of BCPS and M Phil & MD degrees and Diploma (Especially in Clinical Pathology and Anesthesiology only) are conferred by the Public University and BSMMU. They are deeply engaged in both teaching-training and clinical lab services. The clinical pathology of Medical College hospital is manned by Consultant of Pathology or allied discipline. The importance of component of Health System Strengthening (HSS) ie. manpower and management is to be given weightage in our health facilities including academic organization. Good news is that MOHFW initiated for running the degree courses in Medical Technology and Nursing science education⁹.

In terms of accreditation and quality, Credibility of Medical Laboratories is paramount to the health and safety of the patients considering the validity of the services rendered by the respective lab^{10, 11, 13}. Accreditation agencies vary by country. The international standard or **Requirements for quality** and competence in use today for the accreditation of **medical laboratories** is ISO 15189. In the United States, accreditation is performed by the Joint Commission, College of American Pathologists, AAB (American Association of Bio analysts) and other state and federal agencies. The accrediting body in Australia is NATA, in France by COFRAC and in Hong Kong, HKAS-Hong Kong Accreditation Service. In Canada, Accreditation Canada (AC) is the national reference. Different district Public Health Administrators, the Civil Surgeons and Divisional Director of DGHS are the oversight bodies on behalf of Director Hospital and Diagnostics services of the DGHS and Ministry of Health in Bangladesh. These body is mainly responsible for registration eligibility, renewal of the registration and if any adverse or complaint lodge by the mass media or any agency.

Infrastructure mainly physical requirements, such as

temperature, humidity, and lighting is too important. ICDDR, Ban international organization offers a range of diagnostic services to the general public, using its internationally accredited laboratories (ISO 15189:2012 and ISO 15190:2003).

Regarding Quality Assurance (QA) and Quality Control (QC) the maintenance of a quality management system is crucial to a laboratory for providing the correct test results every time. Quality control means, procedures used in each assay to assure a test run is valid and results are reliable. Important elements of a quality management system include: Documentation, Standard Operating Procedures (SOP's), Quality Control samples, External Quality Assessment Scheme, Kit Controls and Quality Control Samples. External Quality Assessment Schemes (EQAS) aims to analyse the accuracy of the entire testing process from receipt of sample and testing of sample to reporting of results. This is also known as **Proficiency testing**.

The purpose of the quality assurance program is to assure that all laboratory testing is performed according to the principles of current Good Laboratory Practice (cGLP). This is carried out by the Quality Assurance (QA) department which has the authority to authorize all quality related documentation. The QA department is staffed by individuals who are knowledgeable of, and familiar with, the laboratory testing. Bangladesh Accreditation Board (BAB) is an autonomous government agency responsible for providing accreditations to laboratories, testing centers and certification bodies Bangladesh which was enacted as BAB act 2006¹³.

WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites. Some laboratories specialize in Molecular diagnostic and cytogenetic testing, in order to provide information regarding diagnosis and treatment of genetic or cancer-related disorders.

The laboratory industry is a part of the broader healthcare and health technology industry. Molecular diagnostics is estimated at 10% of total revenue, and half of that focused on infectious disease testing⁶.

Bangladesh Health Laboratory Services in Bangladesh are functional in the public sector under various ministries, autonomous medical universities, semi-government hospitals, nongovernmental organizations and in the private sector. The public sector comprises the Institute of Public Health (IPH) 13 regional laboratories in medical colleges, 64 district level laboratories and peripheral laboratories in most of the 490 Upazilas (Sub-district units). The IPH consists of the departments of microbiology, poliomyelitis, epidemiology, food and water testing, drug testing, and production units where intravenous fluid, blood bags, laboratory reagents and antisera are produced. In the medical college laboratories, all branches of laboratory medicine are in operation conceptually. The district laboratories perform microscopic examinations and a few clinical chemistry investigations but no culture for isolation of pathogens is carried out. At the Upazila complex laboratories, minimal microscopy and clinical pathology is done. Networking between laboratories for referral of samples, training support and supervisory visits is not in place.

Neither Internal Quality Control nor National External Quality Assessment Scheme (NEQAS) is not practiced in clinical microbiology or in the public health laboratories or even in private sector except a few communicable disease control program of GOB & ICDDDR, B. There are more than 2000 laboratories in the private sector in Dhaka and an estimated 4000 in the rest of the country are in operation.

The International Centre for Diarrhoeal Diseases Research (ICDDR-B) in Dhaka has acted as a reference centre for diarrhoeal pathogens since the 1970s, and coordinates with the Government of Bangladesh in investigations on diarrhoeal diseases. A reference laboratory for safe blood transfusion was established once at the Dhaka Medical College.

In conclusion, there is neither a national policy for laboratories nor a scheme for their accreditation. Establishment of both at internal & external Quality assessment with monitoring & evaluation (M&E) to be implemented without long formalities for the cause of protection and safety of the personnel, patients and by and large for the peoples of all walks of life keeping ethical practice

for care, cure and contact (3 C). In the Lab service delivery at Upazila and district level is crucial & yet to be more cost effective and functional.

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