Transformation of the Laboratory Science
Emergence of the discipline of Laboratory Medicine

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Laboratory for patient's investigations has two scenarios. In one side, an old pathologist owns a laboratory, examines urine sediments or blood smear under a monocular or rarely a binocular microscope and the serum investigations are conducted by technician by manual, semi-automatic and rarely by a fully automated machine without appropriate calibration of the equipment and without running the patient's samples with adequate number of 'control'. All over the nation there are mushrooming of such technician-run non-accredited laboratories, which are dependent on the signature of a qualified pathologist, appointed part time or full time. On the other side, in a teaching hospital/institute, the data of laboratory investigations form the backbone of patient's diagnosis and management and remain the authentic source of credible evidence-based research publications.

In a world-class Institution or in a medical college hospital of repute, clinical management of patients is heavily dependent on Laboratory investigations. Wish lists of a clinician from the laboratory have expanded enormously. From the patients' point of view there is emergence of a concept of central blood collection center, central hospital laboratory with one window solution for investigations pertaining to clinical pathology, hematology, clinical biochemistry, clinical microbiology, immunology and certain rapid molecular tests. Because of shifting of a large number of investigations from research premise to a clinical diagnostic laboratory, because of growth of automation in pre-phlebotomy, post-phlebotomy, pre-analytical, analytical and post-analytical phase, development of laboratory information system (LIS) with almost complete elimination of human errors, and practice of defined methods of quality assurance on accuracy and precision of the investigation results as per the standard of National/International Accreditation body, the old wine of all–inclusive Clinical Pathology which did establish the initial foundation for evidence-based medical practice has come up enriched in a new package, in a new bottle with a charming label known as the Discipline of Laboratory Medicine. The equipments like HPLC, chemiluminescence analyzer, flowcytometer, gene sequencer and PCR technology have broken the barrier of sub-disciplines of the laboratory. The clinicians want investigation reports of quality, accurate and precise, with minimum turn-around-time for diagnosis management and follow-up of patients. Clinical consultant often needs Laboratory Physician as colleague who can assist him in proper test selection, test referral and test interpretation. The situation demands a radical transformation of the discipline of laboratory science, which is sustainable for at least next hundred years. At this point of time, emerges a discipline, the discipline of Laboratory Medicine. The diploma course in old clinical pathology can no longer sustain the knowledge economy of the subject and has been aptly replaced by a postgraduate degree in Laboratory Medicine.

The term “Laboratory Medicine” could be used as a generic umbrella name overarching all disciplines of laboratory sciences. It could also be used as a basic post- graduate discipline for laboratory science, which through a central hospital laboratory takes care of most of the investigations required in a tertiary care hospital. This basic understanding is necessary for organizational and academic reform of the science, art and commerce of the discipline of laboratory science.

Organizational reform is to bring all laboratories of the institution/hospital under one roof, if not under one Head, which offers 24 hours x 7 days a week one-window solution for quality results stopping running of patients from pillar to post for giving samples and collection of reports. This is also to offer a comprehensive training of laboratory physicians in all kind of investigations under one roof within ‘one-lab’ concept. Academic reform encompasses (i) undergraduate sensitization to the laboratory discipline, (ii) creation of a multifaceted laboratory physician at the postgraduate level, and (iii) opening up super specialty expertise in specific areas of laboratory science.

The academic reform is in the line as it had already happened in the disciplines of Medicine, Pediatrics and Surgery. As in the discipline of Medicine, three year residency leading to MD degree in general Medicine/Pediatrics has become a basic postgraduate degree followed by super specialty three year residency leading to DM degree in Cardiology, Neurology, Nephrology, Gastroenterology (and neonatology in case of Pediatrics) etc., and as in the discipline of Surgery, three year residency leading to a basic postgraduate degree MS, followed by super specialty three year residency leading to M.Ch. Degree in Pediatric Surgery, Neurosurgery, Cardiac surgery, Uro Surgery, GI Surgery etc., so also in Laboratory Medicine three year residency leading to MD degree is envisaged to be the basic postgraduate degree in Laboratory discipline followed by three year residency leading to DM degree in Histopathology, Hematology, Transfusion Medicine, Infectious disease, Virology, Parasitology, Mycology, Nano Medicine, Metabolic Medicine, Clinical Immunology and Molecular Medicine etc.

The first step for such transformation is to create a central hospital laboratory for the patient care. In an academic institution, next step will be to designate this patient care area as a department, the Department of Laboratory Medicine. No academic department is viable without a postgraduate course. Therefore the third step is to start a residency program leading to MD degree creating a multifaceted, Multiple in One, laboratory physician. This is a felt need not only for the multidisciplinary diagnostic laboratory of a tertiary care hospital but also for the diagnostic laboratory at the level of district, sub-division, community and primary health centers of the Nation, where it is not possible and is not worthy to employ three laboratory specialists for one laboratory. The nation needs a laboratory physician, following acquisition of qualification of MBBS, who can handle investigations pertaining to clinical pathology, hematology, clinical biochemistry, clinical microbiology, rapid molecular tests and has knowledge and experience in laboratory management with safety, ethics and legal aspects of laboratory medicine. Creating a continuous flow of human resource of laboratory physicians, the idea in one stroke takes care of space-economy, time-economy, manpower economy, knowledge economy, expenditure economy and management economy.

The proposition is also in consistent with a three-tier laboratory science concept (see Tables 1 & 2) in an ideal situation of a tertiary care hospital attached to a medical college/institute. Tier one is related to laboratory medicine discipline, which caters one-window solution of almost all laboratory investigations. Tier two encompasses super specialty laboratory of the department of pathology, microbiology, biochemistry and transfusion medicine. Tier three is the high-end common research facility laboratory of the medical college/institution hospital. Cell sorter, Confocal microscope, Cell Image analyzer, Equipments for detection of

circulating tumor cell, High-end molecular equipments, Next generation gene sequencer (NGS), MALDI-TOF, Mass Spectroscopy, Liquid- and Gas Chromatography Mass Spectrometry (LC-MS and GC-MS), Inductively Coupled Plasma MS (ICP-MS) have become part of common research facility.

Table 1

Redefined

Three-Tier Discipline of Laboratory Sciences

Laboratory

Tier I	Tier II	Tier III
Central Laboratory	**Respective Dept. Laboratories**	**Common Central Research Facility Laboratory**
1. TOT: 2-8 hours	12 hours-72 hours	Usually a week
2. Timing: Round the clock	Routine hours (9.00 AM to 5.00 PM)	Never closed
3. Run by: Laboratory Physician; MD (5 in one)	Respective MDs	Scientists (Cadre as per ICMR guidelines)
1. Cl. Pathology, Cl. Hematology, Cl. Biochemistry, Cl. Microbiology, & Rapid Molecular investigations including Immunology	Departments of Pathology, Departments of Microbiology, Departments of Biochemistry, Dept. of Transfusion Medicine	Molecular labs Mass spectrometry Cell imaging etc.

Table 2

Three Tier Discipline of Laboratory Sciences Academics

Tier I	Tier II	Tier III
Central Lab	**Respective Department Lab**	**Common Central Research Facility**
1. Sensitization of MBBS students 2. MD course in Laboratory Medicine 3. Medical Laboratory Technology Course 4. Quality Management course 5. DM course Molecular Medicine Immunology 6. Ph.D. program	1. MBBS teaching 2. MD in respective subject 3. DM program in Metabolic Medicine Nanomedicine Infectious diseases Virology, Parasitology, Hematology, Anatomic Path Neuropath etc. 4. Ph.D. program	Ph.D. Program Helping MD and DM students in their Thesis

To conclude, we should not refight the last war. The Organizational and Academic Reforms of the Discipline of Laboratory Sciences have far-reaching effect in transforming the discipline at the National and International levels in the context of Service to Patients, Service to Students and Service to Science. Remember what Victor Hugo told long back, " Nothing is more Powerful than an Idea whose Time has come."