Turf-war among Indian Medical Laboratory Professionals over Signing Powers in Clinical Lab Practices: Emerging Issues and Possible Solutions

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The Clinical Laboratory professionals are currently facing a serious legal challenge across India due to absence of a proper Central Regulatory framework for regulation of professional education and practices of clinical lab services. Recently, in case of Gujarat State matter, the Hon'ble Supreme Court has upheld the stand taken by the Medical Council of India (MCI) that laboratory report can be counter signed only by a registered medical practitioner with a post graduate qualification in pathology. This has created a controversy among various sections of Laboratory professionals including MBBS MD doctors of Biochemistry and Microbiology. Many of these left out groups are also demanding signing powers at par with MD Pathologists and have approached the Hon'ble Court for modification of said order.

This issue has become more intricate as Central Government has notified the Clinical Establishment (Central Government) amendment Rules-2018 related to minimum standards for clinical laboratories which appeared in Gazette of India on 18th May, 2018. Surprisingly, said rules are completely silent about the scope of practice of all technical laboratory professionals having a dedicated professional diploma, bachelor and master degree i.e DMLT, BMLS/BSc MLT and MMLS/MSc in MLT, Biochemistry, Microbiology, Genetics, Molecular Biology etc which are representing a major workforce presently.

Majority of these lab technologists and scientists are engaged in research and lab practices even in country's premier private and government health & research organizations. Some of them are even the head and director of their respective departments. As per these rules and present legal scenario, even a PhD laboratory scientist is not sure about his/her scope of practice. While ground realities are entirely different as lakhs of medical technologists and laboratory scientists even diploma holders are presently performing and validating lab results even in leading government health care establishments, national health programmes, medical colleges, universities, ICMR, CSIR, CGHS, ESIC, OFB and Railway Hospitals & dispensaries.

Astonishingly, these rules authorize even a plain MBBS doctor without any experience to sign routine lab reports in basic composite laboratories and for running a medium and advanced laboratory, MD degree from any related subject i.e Pathology, Biochemistry or Microbiology is essential. If the above rules are not properly defined to include technical lab professionals, it will really be challenging situation for the Central and State governments to manage its lakhs of laboratory settings, as there is already an acute shortage of doctors particularly in rural health system across the country.

Further, it is also relevant to mention here that merely signing the lab reports by a MBBS doctors is not going to resolve the quality concerns as there are specific scientific tools, techniques and scientific knowledge & competencies required for lab testing and validation. Simply the countersignature by a MBBS doctor on a lab report does not make any sense as there are defined quality control and quality assurance procedures on the basis of which a report is validated in labs. These are based on international quality standards. which are presently not the part of educational curriculum of a MBBS doctor.

Turf-war over signing powers: In fact the clinical laboratory work is a complex multidisciplinary scientific work, performed and validated at different level by many subject specific medical doctors, laboratory scientists, laboratory technologists who are trained and qualified for medical lab tools, techniques and procedures. Historically, in majority of clinical laboratories even in Government own health establishments, medical laboratory reports were reviewed and validated by many groups of medical doctors like MD degree

holders in Pathology, Microbiology, Clinical Biochemistry and Professional degree/diploma holders of medical lab sciences i.e. BSc, MSC and PhD etc in respective subjects. Initially this issue cropped up in various states between two private professional groups i.e. MBBS MD private practicing pathologists doctors registered under MCI and the Clinical Laboratory Scientists, Technologists and Technicians who are not part of MCI who are running laboratories since last many decades.

Since laboratory diagnostics is a 5 billion dollar business annually in India and one of the fastest growing health care industries. Therefore, turf-war for business of private laboratories has now transformed into a legal battle. Before the situation becomes more complicated, the Central Government should come forward with some practical legal solution to settle this national health issue on priority which may have larger impact on the quality of health care services. The laboratory Services are one of the important parts of health care establishments having direct impact on the lives of millions of people in the country. However, the regulation of professional education, practices and professionals is a big challenge due to very diverse cadre of human resources, yet is very necessary step for providing qualitative and accredited lab services. The most of the developed and developing countries have specific laws to regulate this profession and its professionals but in India we do not have regulatory body for this purpose which is posing a serious threat for quality of lab services and patient safety. It is an alarming fact that less than 1% of Indian clinical laboratories are accredited through ISO-15189 International clinical laboratory quality standard and on the other side there is a big tussle over the control of business and signing powers. There is plethora of regulatory bodies in health nevertheless more than 50% of health workforce is still unregulated. Medical Laboratory Services including its professionals is one of the major unregulated fields.

To understand this health matter in comprehensive manner, we must know about the following important facts related to clinical laboratory practices and education regulation.

Statistics of Medical Laboratory Professional Education & Services

* (Estimated laboratory statistics based on database of professional associations affiliated to ICMLS including Government & private health care establishments)

Indicators	Number	Detail
Total Laboratories	3 Lakh	Government & Private, every size
Total NABL Accredited Laboratories (as per ISO-15189 International Lab Quality Standards)	<1%	Less than 1% and in Government only few numbers
Total MBBS MD Doctors- Less than 15000 (Pathologists, Biochemists and Microbiologists who are in Practice-Governed by MCI		
Pathologists, Biochemists Microbiologists	Less than 15000 (in teaching research and lab Practice)	As no live membership database of these professionals are available on MCI website. Number is based on the database compiled by ICMLS affiliated associations. More than 50% of these doctors are associated with teaching and research activities in Government and around private medical colleges and rest 50% are engaged in private laboratories.
Total Technical Laboratory Workforce-More than 5 lakhs- No regulatory body at present **(**Laboratory Scientists, Medical Laboratory Technologists, Medical Laboratory Technician Diploma/ Certificate holders)		

Laboratory Scientists/ Faculty MSc, PhD in related field	10 Thousand (in teaching research and lab Practice)	2% of total workforce, mostly posted in research and teaching in medical colleges and ICMR, CSIR network of laboratories
Medical Laboratory Technologists BSc MLT/BSc MLT	1.5 Lakh	30% of total workforce mostly placed in Government and private health care laboratories network of secondary and tertiary care hospitals and health institutions.
Medical Laboratory Technician Diploma/ Certificate holders	3.25 Lakh	65% of total technical workforce mostly placed in Government and private health care laboratories network of primary health centre/dispensaries like CGHS, ESIC, Railway, OFB (Defence), State run PHC/CHC/Rural Health care centers and private health laboratories performing routine laboratory testing.
Medical Laboratory staff without any formal professional qualification of diploma/ Degree	15,000	Most of these staff were recruited a long back in Government at a time when no formal degree/ diploma was available, few of them may be part of private health laboratories.
Medical Laboratory Professional Educational Courses		Though, previously there was no uniformity in educational courses, course curricula, duration of courses due to absence of a regulatory body. Nevertheless, to fulfill the demand of trained and qualified lab manpower, the Ministry of health & FW has recently revamped Course curricula of Professional Diploma, Bachelor and master Degree Courses available on Ministry website also. Duration of Professional degree is 4 years and master is 2 years
Professional Diploma Courses	>1500 Government and Private institutions	
Professional Bachelor Degree Courses	>300 Universities/Colleges	
Professional Master and Doctorate Degree Courses	>70 Universities	

Absence of a central regulatory body/ Council and its implications in clinical laboratory professional education and practices- The medical laboratories are important and leading segment of modern health care system. This segment is representing one of the largest groups of health care professionals after nurses and doctors. This service of health care is largely managed by the medical lab technology professionals' i.e Medical Lab Technologists and Lab Scientists who are mostly professional graduates and post-graduates including those holding doctoral degree in lab sciences to their credit. However, there is no facility for registration and licensing of professionals due to absence of a regulatory council at central level yet, it is estimated on the basis of data provided by their professional associations that presently around 5 lakhs of medical laboratory technology professionals are working in private and government health care establishments.

The Medical Laboratory Sciences and its professionals often work behind the scene have made significant strides and contribution during the last few decades to the amazing development of medical sciences. Considering the importance of it, several small and big countries have set up a systematic regulatory framework for medical laboratory profession and professionals. It is, however, regrettable, that in India, no such thing exists even after 70 years of Independence. There is no mechanism to regulate the professional education and practices of medical lab profession and neither the state governments nor the Centre in past have shown seriousness to tackle this situation.

In the absence of such a Central body, thousands of educational institutions in India have mushroomed in a haphazard manner; a number of them are there only to reap huge profits though they do not have any basic facilities. There is also a lot of problems for professionals working in government and non-government

institutions, due to lack of necessary legislation for regulating education system and laboratory services, such as lacking the right to work (license) unclear scope of practice despite having the necessary professional qualification; There is a plethora of designations, posts, salaries, allowances, recruitment rules and terms of service in different departments for the same work. While, on the one hand, many unqualified people control the education system and laboratory services, highly educated laboratory professionals are also deprived of their right to work on the other hand.

Central Government's Initiatives in the past- the Central government has taken various initiatives in the past to set up a regulatory body. In this regard, an attempt to set up Central Paramedical Councils failed due to the insensitivity of the previous governments towards the Allied Health Sciences staff. The Central Paramedical Councils Bill 2007, even after the examination of the Parliamentary Committee was shelved under the pretext of setting up a single regulatory body- NCHRH, for the entire health sector. After more than three years of discussion and debate, NCHRH Bill-2011 was also turned down by the Parliamentary Committee. Ultimately, the decades-old demand of millions of Allied Health Professionals for the regulation of education system and the profession has been hanging in the balance. After this setback, the Ministry of Health, in the year 2014, decided to form the National Board for Allied Health Sciences but the proposal did not materialize due to administrative insensitivity. Once again, the Health Ministry, in an inexplicable haste came up with a poor draft Allied Health Professional Council Bill-2015 and once again, the issue has been shelved. All the associations affiliated to the ICMLS, even as they expressed their cautious optimism also voiced their resentment towards the wavering attitude of the Ministry of Health on this long standing important national issue.

Health Councils for various Categories of Health Professionals

S. No.	Name of Council	Category
1	Medical Council of India	For Allopathic Doctors-MBBS
2	Dental Council of India	For Dentists- BDS
3	Central Council of Indian Medicine	For Ayush Doctors- BAMS,BUMS
4	Central Council of Homeopathy	For Homeopathy Doctors-BHMS
5	Indian Nursing Council	For Nurses
6	Pharmacy Council of India	For Pharmacists
7	Rehabilitation Council of India	For Rehabilitation Professionals & workers
8	The Clinical Establishments (Registration & Regulation) Act-2010	For Registration & Regulation of health care establishments
9	**The Allied Health Professionals Council-**Bill-for establishment of Central Council for AHPs including Medical Lab Professionals	**Pending**

Common Professional Qualification in Lab Sciences:-		
Diploma	DMLT	
Degree	BSc MLT/BMLT/BMLS	
Master Degree	MSc MLT/ MMLS	Microbiology Virology Biochemistry Pathology & Transfusion Medicine Molecular Biology Genetics Immunology Total Quality Management Clinical Research Other related subjects
PhD	PhD in related Lab subjects	

Registration & Regulation of Clinical Laboratories under the Clinical Establishment (Central Government) Amendment Rules, 2018: Instead of establishing a proper statutory mechanism, recently, the central government has, without any comprehensive and practical thinking, notified draft of Clinical Establishment (Central Government) Rules 2017 related to minimum standards for clinical labs which have been finalized and notified again on 18th May, 2018. The legal purpose of the Clinical Establishment Act 2010 is to register and regulate all the health related establishments in the country, to set standards for health related services and facilities, but it does not have a legal provision for the registration of various professionals related to the medical profession. And if not they should register all unregulated categories under this Act. For the said purpose, there are professional councils/bodies of different occupations, such as MCI, INC, DCI, PCI etc. which regulate standards of professional education and qualification and practices etc of the respective professionals. The Clinical Establishment (Central Government) Rules 2018 notified under Clinical Establishment Act 2010 which decides professional qualifications and authority of Lab Professionals are therefore, illegal, not supported by any professional body's advice and practical thinking.

Emerging Issues & Possible Solutions: - if the above CEA Rules are implemented for clinical lab practices, without finding some practical solutions, serious questions and difficulties may arise before health care providers.

1. Medical laboratories handle highly sophisticated machines, diagnostic tools, techniques and procedures that require a sound professional knowledge, training, skill and expertise in the related field. Astonishingly, even after acquiring professional post-graduate and doctorate degrees in a relevant area, Lab professionals are not trusted to do their professional work independently. As per these rules they may perform all Lab-related tasks but not authorized to sign the report which they generate after detailed analysis and scientific procedures. What does it mean? A MBSS doctor, trained for medicine only and having no expertise in performing Lab practices or analyzing results, who as a part of his MBBS course takes a Lab orientation programme lasting up to a month takes over as an empowered person to authenticate the report prepared by a bio-medical lab professional/scientist, more competent than a MBBS doctor to certify his own conclusions.

2. Strangely, he/she can be a Scientist/ Researcher in ICMR, CSIR or even world best organisation or may be a teacher of medical sciences in Indian universities in the same stream. So, they can teach the subject but cannot practice in their own field for which they are qualified and trained – is it not very surprising?

3. All the above mentioned Health Professionals are extensively utilized as resource person for teaching, training, research and practice in their respective fields but are not authorized as per present rules, they may ask what the use of such professional academic degree is?

4. What will be the purpose of their registration and licensing if they are not authorized to do anything legally?

5. Further, some vested interests which are there only for commercial interest in their business are trying to create confusion on present issue that Lab professional cannot sign reports.

6. In this context, it is necessary to note that it is now an established fact that more than 70% clinical decisions are based on Lab reports/data/provisional diagnosis, however, any Lab whether it is diagnostic/clinical lab or imaging centre, never claim to make a final diagnosis. It is the treating Physician who is supposed to make a final diagnosis based on the Lab reports and clinical history and presentations. So, why is such a big turf war for authoritative position? The basic job of a MBBS is to

practice in Allopathic system of Medicine and not in Lab practices which is an independent multispecialty field.

7. As far as MD Pathologists are concerned, yes, they are specialized for various pathological aspects like Histopathology/Histo-cytology etc. They should only be authorized for the said purpose. The statement that a Pathologist can sign any report in pathology is wrong. Simultaneously, there should be an equal and defined scope for other specialists like Microbiologists, Biochemists and Biomedical Technologists/ Scientists of related subjects as per their qualifications and experience.

8. Registration in MCI as a MBBS doctor does not empower them to rule the entire medical profession. As already submitted, no single health stream can claim supervisory rights over the health system in modern medicine. Otherwise, there are many other medical practitioners also, registered and licensed with their respective councils like BHMS, BUMS, BAMS etc, who too will sooner, rather than later, will demand their scope of practice in Lab services on the same pattern as being sought to establish in case of MBBS doctors.

9. One single activity does not make a profession. There are groups of identical function which make a profession. Therefore, overlapping of practices up to an extent with defined scope should be acceptable in present health system.

10. We must understand the difference between technological competencies and theoretical competencies. We cannot apply science without the technological competency which we learn by technological applications. The Clinical Laboratory procedures require both technological competencies and scientific knowledge. This is really very contrary approach of Ministry of Health that, on one side, they have taken many initiatives to manage the acute shortage of doctors and started Nurse practitioner and Pharmacy practitioner courses to support rural health system which is seriously affected due to shortage of doctors, and on the other side they wish to utilize their services for a different task which primarily is not their job. Government may appoint thousands of doctors by outsourcing or contractual process to manage present legal requirement or existing doctors may be asked to supervise lab services as additional responsibility but it is doubtful whether it will fulfill the actual purpose of quality of work and patient safety and accountability.

In view of the above scientific parameters and discussions, CEA Rules-2018 are irrational, biased and unconstitutional that need to be reviewed from a holistic viewpoint towards all professions. There should be a rationalized discussion of experts from related professions. Health care is a team effort in modern evidence based health care and the quality of laboratory results is of the utmost important tool for timely and an accurate diagnosis and treatment of the disease which is presently lagging behind due to lack of a comprehensive view of policy makers and law making agencies. It is also creating ambiguous situation due to lack of licensing and indefinite scope of practice of various professionals stake holders. If Ministry of health & FW is keen on providing a justified scope of practice, it needs to consider carefully the important aspects such as: level of Professional education and training; evidence-based assessment of roles; skill and capabilities of professionals, practicality in implementation; Study Curricula of professional courses and regulatory mechanism etc.

Further, overlapping scope of practice is reality in a rapidly changing health care environment. The criteria related to who is qualified to perform functions safely without risk of harm to the public are the only justifiable conditions for defining scope of practices as per suggested parameters. Government should examine the issue on merits make suitable changes. The poor and the destitute, cheated and deprived of better health service for generations now, look forward to them to fulfill their national duty to prepare a forward looking, all-embracing health system. People have waited for far too long for such a

measure. In the modern medicine, several health sciences and medical technology professions are playing a key role in diagnosis, treatment and patient care and they have a definite scope of practice in health care delivery. No single health provider can claim an exclusive role in diagnosis and treatment. At the same time, due to demographic changes, advancement in allied health science technologies, evidence-based medicine and practices and many other factors, health care delivery is necessarily undergoing a change and, therefore, health care practices also need to be evolved as per present health care needs and capabilities.

Lacking of a regulatory body in this field is a setback, nevertheless, it is important to mention that absence of a Central Act for registration and licensing of Medical Technology and Allied Health Sciences professionals does not mean that they are not qualified enough for practices in their respective fields as above mentioned all professional degree and diplomas are awarded by UGC recognized Universities.

Establishment of a central statutory council at the national level is very important, so that many of the above issues can be solved. Also, all professionals will be registered and their actual number will come into public domain. Therefore, the Central Government should expedite the process for establishing a professional body for medical laboratory professionals in line with other existing health Councils, which can be a viable solution for all professional issues.

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