

**Editorial**

## Mushrooming of Medical Laboratories in Pakistan

**Usman Waheed, Ph.D.**

Department of Allied Health Sciences, Islamabad Medical and Dental College, Islamabad, Pakistan

Accurate and dependable laboratory diagnosis serves as the foundation for managing and preventing diseases. Sustainable laboratory services that adhere to international standards of quality and safety play a vital role in robust health systems, and their proper functioning is essential for improving healthcare services.<sup>1</sup> Inadequate laboratory services incur significant costs, manifesting as the inefficient use of scarce public resources and increased private out-of-pocket spending on ineffective treatments.<sup>2</sup> This deficiency also results in the diminished economic productivity of the population due to prolonged illnesses, both chronic and acute, and contributes to the loss of human lives.

Over the past two decades, there has been a sharp increase in the number of clinical laboratories in all parts of the country especially in semi-urban areas and near the major hospitals of big cities. This upsurge was more evident during the COVID-19 pandemic when many new laboratories came into existence providing various categories of testing for SARS-CoV-2.

While the growth of clinical laboratories can bring about positive developments in healthcare, it also raises concerns related to quality control, standardization, and adherence to ethical and regulatory standards. Proper oversight and quality assurance mechanisms are essential to ensure that the mushrooming of clinical laboratories results in improved healthcare outcomes without compromising patient safety.<sup>3</sup>

A common observation is that many medical laboratories are managed by technicians who possess diplomas or certificates in laboratory techniques. While these qualifications allow individuals to perform tests, but exclusively under the supervision of a pathologist or, in certain instances, under the guidance of a qualified technologist. Some of these technicians issue reports in the name of result analysis sheet and print some disclaimers like “Above values are to be certified by the Pathologist”, “strictly for the use of Medical

Practitioners or Pathologists”, “these are not medical diagnostic results”, to confuse the relevant authorities.

Some registered medical practitioners refer their patients to these laboratories for various pathological investigations. The patients are unaware of the difference between a registered or non-registered/illegal laboratories. Although, the prescribing doctors are aware of difference between legal and illegal laboratories, they are referring patients to the said illegal laboratories and are advising numerous often unnecessary investigations for monetary gain. This amounts to doing unethical medical practice which is a criminal offence. Some pathologists engage in unethical practices by signing blank letterheads of laboratories, enabling the subsequent printing of reports on those letterheads. This deceptive tactic creates a false impression that the reports are certified by the pathologists, deceiving unsuspecting patients. Such unethical actions have detrimental effects on the overall health of the public, as they compromise the integrity and reliability of diagnostic reports.

Another common observation is that in many settings, laboratory technicians use the electronic signature of a pathologist who, for financial considerations, agrees to sign reports that were not prepared under their direct supervision. Pathologists often have associations with multiple laboratories, and while norms dictate their physical presence during testing and analysis, there are no specific guidelines on the maximum number of laboratories a pathologist can be affiliated with simultaneously. Exploiting this regulatory gap, pathologists engage in the sale of their signatures, certifying reports for tests that have not been conducted under their direct supervision. This illicit practice extends beyond small cities, reaching into larger urban areas, pointing to policy and regulatory failure on a massive scale.

Quoting Prof. A. H. Nagi, “quacks are seen in every field of medical practice, but quackery in medical laboratories

is unique because it is created and blessed by the medical practitioners of various specialties. These medical practitioners start medical laboratories with the help of technicians - some qualified but mostly unqualified. Most of these laboratories are run in different private hospitals and clinics and the technicians are projected intentionally as 'pathologists' to the lay public. That is how quacks in are born medical laboratories".<sup>4</sup>

These observations underscore the importance of ensuring that diagnostic testing is carried out with the appropriate level of oversight and expertise. Currently, individuals intending to operate a clinical laboratory are required to obtain a license or registration from both the federal level (Islamabad Healthcare Regulatory Authority) and the respective provincial healthcare commissions. This regulatory framework guarantees compliance with healthcare standards and regulations at both the federal and provincial levels, contributing to the overall oversight and quality assurance of clinical laboratory services. Although these regulatory bodies do carry out due diligence to ensure that a laboratory is run by a qualified laboratory professional and follows all required criteria (Minimum Service Delivery Standards, MSDS), there are limitations to their operational capacity mainly due to limited resources. Due to weak regulatory oversight, quackery is not an uncommon phenomenon in clinical laboratory diagnostics. It is pertinent to mention here that there are islands of excellence and to this date, more than 30 laboratories have been awarded ISO 15189:2012 accreditation in the country.

The implementation of International Health Regulations (IHR) (2005) is an important concern for all UN member states including Pakistan. IHR require that all countries have the capacity to detect, assess, report, and respond to public health events. It is important to note that laboratory services are included in the IHR (2005) framework as a core public health capacity.<sup>5</sup> Therefore, a wide-ranging strategy to strength and regulate clinical laboratories across Pakistan is essential to synchronise efforts to implement disease prevention and control efforts in the country.

Medical laboratories have a decisive role in the diagnosis, treatment, and monitoring of various diseases. Therefore, it is vital that laboratory tests yield results that are dependable, accurate, and reproducible. The reliability of these test results is central to guaranteeing

effective healthcare results and guiding correct medical interventions.<sup>6</sup> For this reason, it is compulsory to ensure that laboratory tests have been performed methodically, following the SOPs, MSDS, and under the supervision of a qualified laboratory professional.<sup>7</sup>

#### References:

1. Ahmad M, Khan FA, Ahmad SA. Standardization of Pathology Laboratories in Pakistan: Problems and Prospects. *Clin Biochem.* 2009;42(4-5):259-62.
2. Erdal EP, Mitra D, Khangulov VS, Church S, Plokhoy E. The Economic Impact of Poor Sample Quality in Clinical Chemistry Laboratories: Results from a Global Survey. *Ann Clin Biochem.* 2017;54(2):230-239.
3. Ahmad SA, Aamir M, Ahmad M, Javed M, Memon A. Standardisation of Pathology Laboratories in Pakistan: Where We Stand Today. *Clin Biochem.* 2018;53:38-42.
4. Quackery marred the ethics of the profession. *Daily Business Recorder.* 2012 May 12. Available at <https://www.brecorder.com/news/3982998> accessed on 10 Dec 2023.
5. World Health Organization. International Health Regulations (2005) 3rd Edition [Internet]. Geneva, Switzerland; 2016..
6. Waheed U, Arshad A, Malik MA, Zaheer HA. The Evolution of Medical Laboratory Technology in Pakistan. *Critical Values* 2014; 7(2):18-23.
7. Fenta DA, Ali MM. Factors Affecting Quality of Laboratory Result During Ordering, Handling, and Testing of the Patient's Specimen at Hawassa University College of Medicine and Health Science Comprehensive Specialized Hospital. *J Multidiscip Healthc.* 2020;13:809-821.