**Role and importance of clinical laboratory in modern healthcare**

In the modern healthcare system where treatments are evidenced-based, the role and influences of clinical laboratory become indispensable. Merely from an establishment housing testing scientific equipment, clinical laboratories have emerged as complete services as well as an independent diagnostic industry that has enhanced the ability of clinicians to make accurate evidence-based diagnostic and therapeutic decisions for their patients. It is estimated that up to 85 percent of diagnosis and treatment decisions are based on clinical laboratory results whereas the test results comprise about 70 percent of the average patient's medical record. More than 4000 different laboratory tests are available today for clinical use, of which approximately 500 are ordered daily. As such, clinical laboratory services are the most cost-effective, least invasive source of objective health information in modern healthcare targeting disease prevention and diagnosis, improving patient outcomes, assuring patient safety, and fulfilling essential public health surveillance functions.

India, like other nations of the globe, is no exception when it comes to access and demand for clinical laboratory services. Factors like the aging population, rise in chronic and lifestyle diseases, increasing insurance penetration and affordability to access quality healthcare have increased national demands of the laboratory tests. This has transformed clinical laboratory services into one of the fastest-growing industries in the country. The domestic industry currently stands at 675bn and is expected to grow at a compounded annual growth rate (CAGR) of ~10% over the next 5 years with services being offered by hospital-associated laboratories, standalone centers and regional and pan-India diagnostic chains. Undoubtedly, the COVID-19 pandemic has further boosted the demand for testing laboratories. From just 14 COVID-19 testing laboratories during the beginning of the pandemic, India currently hosts 3128 testing labs with over 67 crore tests already done!

While such expansion of clinical laboratories is timely and necessary to augments the growing need of modern healthcare, there is a need to maintain the services accountable, effective, patient-centered, timely, efficient, and equitable. To do so, intrinsic and extrinsic factors need to be critically informed, evaluated and necessary amendments to be introduced in a timely fashion in response to global developments across technology innovation, and modernization.

Today, tremendous scientific advancement in diagnostic tools and technologies has almost swept away previous generation methodologies that were mostly manual and dependent on biochemical and morphological observations. Rapid growth in precision medicine, cell and gene therapy, and its translation in modern healthcare has necessitated functional molecular testings where devices have been developed to analyze large genomes, analyze, interpret and maintain data for accurate and timely assessment. From routine clinical testing, disease diagnostics, and Specialty tests like Genetics, immunology, oncology, endocrinology, etc is now reported on basis of genetic markers and gene functions. In this, the rapid development of AI has introduced machine dependencies, capable of running the service to reporting with minimal manual interventions. A huge transformation has already taken place in medical imaging services where AI-dependent machine learning programs could perform diagnosis with more than 95% accuracy. Many new machine programs have been developed to read and interpret the COVID-19 infections by looking at the chest X-ray of suspected individuals. No doubt, remarkable transformation in the internal ecosystem is on the card and expected that most laboratories will update of infrastructure steadily where the lowering cost of equipment due to competition will further facilitate the transformation.

In this what is required is to remain updated to these new developments and train the manpower including laboratory service providers and the physicians. Periodic training, quality assessment tests will be required for the laboratory staff to help them run the machines, manage the data and produce accurate results. Such efforts need to be done in close collaboration and communication with the physicians to maximally utilize the benefits of these new developments for patient care. In this, inpatient, outpatient, and outreach test results will need to be fully integrated within a new practice model.

Whether it is a matter of time to transform the laboratory services with new developments, the foundation criteria of a lab should remain unchanged. A clinical laboratory shall provide a safe working environment and must produce accurate results. In this, global and/or national norms on the establishment of the safe laboratory facility, good clinical laboratory practices, testing standards, compliances, etc are already available. However, notable will be how newer tools and technologies impact these norms and bring additional guidance in this area. NABL, the nodal agency of India, that grants accreditation to medical testing laboratories in accordance with ISO 15189 has, however, incorporated some molecular testing in its accreditation services. However, the accreditation is voluntary, a clinical lab with accreditation ensures quality and competence in the testing process and increases accountability and trust among patients.

To conclude my talk, I assume that the healthcare sector is going to witness a much higher integration of laboratory services where it will be necessary to create a strong communication and collaborative model exosystem between the patients, clinician, and laboratory staff to derive meaningful health informatics and treatment for the patients. Periodic review and update on the infrastructure, tools, and techniques will be required where training and capacity building shall be deemed essential for the entire healthcare sector to remain sustainable. **We must be prepared and shall welcome the new developments to offer quality healthcare to all.**