

EDITORIAL

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Value Addition Through Process Excellence – The Futurescape of Laboratory Medicine

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Abstract

The last century has witnessed paradigm shifts in the way in which laboratory medicine is practiced. This is largely due to the “industrialization” of health-care and with it laboratory medicine, the ever-increasing demands for error reduction with containment of cost, and also consolidation and need for evidence based disease management. The focus has also moved from “patient” to consumer – with changing expectations to be fulfilled. An easy access to high end technology, standardized analytical systems, diagnostic kits and to accreditation has landed most good diagnostic laboratories on level platform. In such a situation, the differentiation for the diagnostic laboratories has come to lie in the value it can provide in excess of the basic accreditation requirements. Customer service experience defines the laboratory’s reputation. The customer footprint includes patients, physicians, community and the laboratory personnel. The pursuit of process excellence has emerged as a critical strategy to ensure efficiency, reliability and value creation. It involves refining of every step of the total testing process in the laboratory to ensure optimal resource utilization and error reduction.

Laboratory personnel as consumers

Building a workplace environment with positive energy vibes goes a long way in achieving higher goals. This involves building a good staff morale by providing ample opportunities for growth and innovation, building efficient workflow processes that reduce time and wasteful effort, clear definition of job responsibilities and providing appropriate authority and resources, and above all recognizing an individual’s contribution to the

organizational growth. Though important, financial increment is not the only motivating factor for most personnel.

The Laboratory Value Pyramid

This strategic model, first conceptualized by the Clinical Laboratory Management Association (CLMA), encapsulates how clinical laboratories can demonstrate their essential contribution to patient care, health outcomes and healthcare system efficiency.

The traditional assessment metrics of laboratory performance such as turnaround times, test accuracy and cost per test though foundational, do not capture the broader clinical and economic values provided by laboratories. The Laboratory Value Pyramid essentially comprises four hierarchical levels, each representing a different dimension of value.

- **Level 1:** Quality and Compliance (Base Level – to achieve normalcy and predictability) with emphasis on analytical accuracy, QC and QA practices and regulatory and accreditation compliance. The focus of these laboratories is on technical excellence and standardization of processes to ensure patient safety and data integrity. The outlook of the laboratory moves from being reactive and correct errors to being proactive in preventing occurrence of errors and hence mitigating risk.^{1,2}
- **Level 2:** (Establishing and meeting standards of value) Aim towards operational efficiency with emphasis on optimization of internal processes and utilization of resources through Lean Six Sigma methodologies, Workflow automation and LIS integration, waste reduction and TAT optimization.³
- **Level 3:** (Delivering value that exceeds expectations) Ensuring Clinical Effectiveness with the laboratories actively contributing to clinical decision making.⁴ Until a few decades ago, the role of laboratory test result was to confirm the clinical diagnosis and to monitor disease progress or response to treatment. In the current context of advanced technology, availability of biomarkers and the “omics” revolution however, laboratory medicine plays an increasingly dominant part in influencing clinical decision making. This is a significant step towards value based laboratory medicine and a step away from the volume based transactional model. The primary goal of value-based laboratory medicine is to maximize the effectiveness of laboratory testing by leveraging disruptive technologies and patient based algorithms to improve patient outcomes, optimize resource utilization and minimize unnecessary wastage and costs. This may be achieved by a) providing context-rich, actionable test reports b) Supporting evidence-based diagnosis and therapy monitoring c) Reducing diagnostic errors and unnecessary testing. Smart test

reports with interpretative comments by pathologists, advice on reflex testing algorithms, notes explaining how test reports need to be interpreted with knowledge of their utility and limitation in the given clinical situation are other options. Current evidence shows that misinterpretation of laboratory information is the second most common cause of medical errors.⁵

The key step towards personalized laboratory medicine is the transition from subjective to objective interpretation of laboratory data. Providing personalized reference intervals, decision limits and action limits are important components of this change.

The laboratory also plays a vital role in promoting shift from the emphasis on “sick care” to “well care”. The diagnostic laboratory has wealth of data based on which algorithms can be created which would enable analytical and predictive conclusions to be made for a given individual.⁶

Large laboratories having multiple departments working in tandem on samples from a single patient need to move out of silos and ensure that the results get collated into a comprehensive report that should ideally integrate clinical and laboratory data along with other ancillary investigations like imaging.⁷

- **Level 4:** Healthcare System value (Apex Level – Best in class) – This level embodies transformational leadership where laboratories partner with clinicians, payers and administrators to shape healthcare delivery through a) Population health analysis b) Risk stratification in chronic disease management c) Precision medicine and companion diagnostics d) Public health surveillance and outbreak response.⁸

Conclusion

As healthcare systems are re-designing service delivery systems with strong focus on volume based payment models and increasing return on investments, clinical laboratories in contrast, are ideally placed to serve as catalysts to a value based practice. Process excellence is no longer a luxury but a necessity in modern laboratory medicine. As laboratory medicine continues to evolve in complexity and scope, embracing a culture of continuous improvement will be the key to sustained value and excellence in patient care.

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