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The hierarchy of needs for laboratory medicine requires a foundational care delivery model

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ABSTRACT

Under the collective weight of growing test volume, staffing constraints, and Medicare reimbursements cuts, an enhancement-based, alternative payment structure focused on rewarding the laboratory's care delivery efforts via benchmarking is appealing. However, achieving a value-based payment model requires the development of an inclusive laboratory care delivery model (LCDM) framework. Today, a holistic, practical LCDM framework for laboratory medicine does not exist. However, such creation is essential for establishing unifying tenants of practice for value-tracing by which standardized key performance and population health indicators can be derived. LAB-CARES is the first step in formulating an LCDM with the primary objective of defining and streamlining the processes and strategies necessary to deliver and articulate the value of diagnostic excellence across the healthcare system. The goal of LAB-CARES is to maximize efficiencies, enhance quality, disseminate clinical expertise, increase patient safety, and promote integrative practice. LAB-CARES is designed to improve an individual patient's quality of life (longitudinal laboratory results – beyond one test) and their surrounding communities (e.g., through surveillance and prevention – beyond one patient). Further professional conversation and efforts are paramount to integrate LAB-CARES as a formalized structure within the healthcare landscape.

1. Introduction

The demand for clinical laboratory testing in the United States surpasses ten billion tests annually and continues to climb [1]. The unrelenting need for routine screening and specialty testing has exacerbated the diagnostic burden which subsequently risks delivery of timely, accurate, high-quality results. In addition, emerging scientific breakthroughs are constantly translated into diagnostics that impact patient care in specialties such as oncology, immunology, and infectious disease. Complex diagnostic assays such as these generate large datasets where interpretation requires leveraging a multidisciplinary team inclusive of non-traditional clinical scientists, including Ph.D. scientists, bioinformaticians, database managers, software engineers, and variant curation scientists. Further, the incorporation of precision medicine [2] has necessitated new specialization for technical laboratory staff [3]. While resourcing such staff is a fundamental concern, budget reductions and testing reimbursements are also prevalent.

Often assessed under scale economy, laboratories are historically undervalued for their clinical impact [4]. Survival requires intentionality toward articulating the value of the local laboratory in care delivery. For this reason, an enhancement-based alternative payment structure (EAPS) focused on rewarding health systems for the laboratory's care delivery efforts via benchmarking is appealing, albeit utopian [5]. A professional shift from a service nomenclature to a patient-centered care taxonomy is revolutionary in the current fee-for-service approach in laboratory medicine [6]. Future EAPS creation

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requires an inclusive laboratory care delivery model (LCDM) to establish unifying tenants of practice for value-tracing by which standardized key performance and population health indicators can be derived [7]. Recent efforts to provide expert opinion and a curated Code of Ethics regarding the value of the laboratory's duty to patients, colleagues, profession, and society fall short of establishing a scalable framework for practical integration. Similarly, an international checklist for the value proposition of laboratory testing exists but limits its focus to test implementation and clinical effectiveness [8].

Herein, we draw on the successful approaches of similar healthcare professions which developed patient-centered care models to define their unique, clinical impact and springboard visibility for greater integration into care teams [9–12]. We propose a culture shift where a holistic LCDM is applied by the diverse, mainstream cohorts of laboratory professionals who function within a multidisciplinary team to deliver patient care and communicate their significance. Practical applications of an LCDM initiative will require a chain-link approach inclusive of laboratorians, associated clinical specialties, healthcare leadership, professional societies, and government agencies.

1.1. Defining the problem

The US Bureau of Labor Statistics forecasts a 5% increase in the need for clinical laboratory scientists and a 10% increase for individuals with science-based doctorate-level degrees by 2032 [13]. Despite this, staffing forecasts for the clinical laboratory have grown increasingly dire and are heightened by an aging workforce. National Accrediting Agency for Clinical Laboratory Science (NAACLS)-accredited clinical laboratory training programs face closures and enrollment challenges with graduates failing to keep pace with the workforce vacancy [14]. In addition to the currently recognized state-level licensure and board certifications for traditional laboratory scientists (e.g. Medical Laboratory Scientist, Medical Laboratory Technologists, Molecular Biologists, Clinical Geneticists, etc.), there is presently no clinical certification pathway available for non-traditional laboratory scientists (e.g. Data Scientists, Bioinformaticians, Software engineers, Variant Curation Scientists, Computational Biologists, and other Translational Clinical Scientists) who are essential for precision medicine diagnostics. This lack of credentialing creates apprehension within traditional clinical laboratories to integrate these skill sets. Such trepidation can hinder clinical scientific advancement in the wake of emerging technologies and public health need.

Personnel shortages notwithstanding, the clinical setting requires regulatory oversight, which may include compliance with international (ISO-15189), federal (Food and Drug Administration, Center for Medicare and Medicaid Services, Occupational Safety and Health Administration), state (Clinical Laboratory Improvement Amendments '88) or specialty-specific organizations (e.g., American Society for Histocompatibility and Immunogenetics, Association for the Advancement of Blood and Biotherapies, College of American Pathologists, Joint Commission). Renewal charges and accreditation fees accompany good standing with these entities. Quality assurance processes, such as enrollment in mandatory proficiency testing programs and inspection readiness, impose additional financial and workforce burdens [15]. A single Laboratory Developed Test (LDT) full validation can cost $15,000 to $40,000 USD in addition to instrumentation acquisition or operational overhead expenses [16]. Laboratories performing LDTs have incurred immense financial risk as new technologies and disease outbreaks are often not reflected in the existing International Classification of Diseases, Tenth Revision (ICD-10) or Current Procedural Terminology (CPT) nomenclature. Thus, LDTs are validated and implemented as independent costs to the laboratory with the risk of uncertain reimbursement.

Hospital-based laboratories, dependent on reimbursement from The Centers for Medicare and Medicaid Services (CMS), were stunned in 2014 by the announcement that payments were to be restructured under the Protecting Access to Medicare Act (PAMA) Section 216. This reform addressed laboratory testing covered under Medicare Part B and did not include tests under other CMS payment systems, such as the Outpatient Prospective Payment System. The goal was a single national fee schedule for laboratory tests known as the Clinical Laboratory Fee Schedule (CLFS). Notably, the first round of CMS data collection excluded over 90% of laboratories. Laboratory payments were estimated to decrease by 670 million USD in 2018 under the new CLFS structure [17]. At the initial rolling cut rate of 10%, CMS experienced a 3.6 billion USD return over a three-year time span [17,18]. This equates to an almost 50% reduction in Medicare Part B reimbursements from 2017 to 2020 [18]. Additionally, there were forty-eight acquisitions of local hospital laboratories between 2017 and 2022 [19]. A striking example of laboratory closures are those supporting skilled nursing facilities which places a greater strain on the delivery of healthcare to vulnerable populations. Primarily attributed to health system needs for immediate capital, these buyouts and closures impacted the availability of real-time diagnostic testing and consultation.

On three separate occasions, bipartisan interventions to halt further CMS reimbursement cuts temporarily protected laboratories. The financial margins in these settings are razor-thin yet cuts of 15% year over year loom ominously in 2025. Broader congressional actions, such as the Saving Access to Laboratory Services Act (SALSA), are crucial efforts to protect laboratory infrastructure. Simply put, the fate of laboratory medicine, the largest medical activity in global healthcare with a direct impact on patient care and public health, hinges on recruitment, the executive boardroom, and the U.S. Senate floor [20].

1.2. Addressing the problem

The provision of high-quality patient care requires a patient-centered focus. Cooperative science is paramount when executing universal healthcare goals. Thus, high-quality patient care is contingent on accessibility to diagnostic laboratory resources. Emerging from a commodity mindset requires the creation of a formidable evidence base that demonstrates the value impact of laboratory expertise to patient outcome [21]. An imposing barrier toward compiling comprehensive data is the need for a collective LCDM. To date, no clinical laboratory accreditation entity or professional society has published a universal LCDM.

Leadership, Advocacy, Best practice, Community, Access, Research, Equity, and Sustainability are fundamental to laboratory medicine and can be abbreviated by the acronym LAB-CARES [Fig. 1]. LAB-CARES is the first step in defining a LCDM to inform diagnostic-related practices to optimize patient outcomes with accentuation on accessible healthcare permanency. LAB-CARES is intended to be a scalable umbrella structure in a similar capacity to a patient care delivery model (PCDM). A PCDM is an intentional framework for optimal delivery of intervention and prevention strategies that generate quality outcomes. By functioning as a PCDM, the primary objective of LAB-CARES is to define and streamline the processes and strategies necessary to deliver and articulate the value of diagnostic excellence across the healthcare system.

The goals of LAB-CARES are to maximize efficiencies, enhance quality, disseminate clinical expertise, increase patient safety, and promote integrative practice. Dedicated laboratory liaisons operating within an integrative practice model can also demonstrate success with this framework. Therefore, LAB-CARES implementation will require careful planning, organization, and implementation of laboratory operations to meet the needs and expectations of patients while maintaining the financial stability of the laboratory. This level of operational effectiveness can be achieved through adherence to quality standards and evidence-based laboratory practices.

The number of incidents associated with laboratory testing and patient safety has increased in recent years. Subsequently, the Joint Commission National Patient Safety Goals® developed a specific list of laboratory service programs to improve patient safety. LAB-CARES

Fig. 1. A proposed visual representation of the LAB-CARES professional practice model. The patient is represented by the DNA molecule. Each complementary strand represents the foundational backbone of providing top tier laboratory diagnostics: safety, operational effectiveness, clinical expertise, etc. The inner bonds of the strand support the comprehensive diagnostic strategies that laboratorians must consider in practice. The interconnectedness of the DNA molecule represents the diversified unity of the laboratory team for optimal patient care.

adoption could bolster the implementation of a patient-centered approach to laboratory-related errors including those that occur beyond the walls of the laboratory, such as diagnostic test result interpretation, requiring clinical expertise unique to laboratory personnel [22].

1.3. The foundational components

The foundational components of this LCDM are Leadership, Advocacy, Best practice, Community, Access, Research, Equity, and Sustainability (LAB-CARES).

Laboratory leaders must be knowledgeable about laboratory science and advancements in the field, understand the changing environment of laboratory medicine, and be able to manage the technological, regulatory, and financial forces acting on the laboratory [23]. In today's complex healthcare climate, laboratory leadership plays an integral role in establishing a culture of equity which is founded on excellence and inspiring a safe and effective environment for providing patient care. Additionally, the role of the laboratory professional includes advocacy for policy change that impact patients and their communities. This is critical when important medical decisions and individualized treatment algorithms are based on the most difficult form of interpretative data in the patient chart. The 21st Century Cures Act and the increased utilization of patient portals have made laboratory results more readily available, often before physician review [24,25]. Given the accessibility to laboratory data, patients are more empowered to have an active role in the management of their care. As an LCDM, LAB-CARES could incentivize the creation of laboratory-owned bridges by which patients can be informed consumers.

Guidelines provided by regulatory agencies outline best practices and govern the pre-analytical, analytical, and post-analytical components ensuring the accurate reporting of test results to the clinical care team. The field is constantly evolving. Thus, it is pivotal for laboratory professionals to understand and apply the most recent clinical findings not only to provide accurate results but also to safeguard patients [26]. As an LCDM, LAB-CARES places value on quality-minded innovation often disregarded by traditional models.

Health equity and access to high-quality laboratory testing should be a basic human right [27]. According to the U.S. Centers for Disease Control and Prevention (CDC), health equity is defined as "the state in which everyone has a fair and just opportunity to attain their highest level of health" [28] The attainment of well-being and good health necessitates access to appropriate diagnostic laboratory testing that leads to improved health outcomes. Barriers to achieving health equity are exacerbated by social and structural determinants of health such as limited financial and transportation access to high-quality healthcare services [29]. Furthermore, health equity is a critical part of the laboratory's role in mitigating health disparities, ensuring patient safety, and fulfillment of the professional duty of care to all patients. LAB-CARES functions as a call to action for the integration of an equity framework into the strategic plan for the organization. Thus, this LCDM is designed to promote equitable care for all patients and address preventable health disparities. These endeavors can improve the coordination of laboratory testing services across healthcare systems and increase the diversity of the laboratory workforce to ensure accurate representation of our communities across the fields of education, healthcare, and public health. LAB-CARES' focus on improving equitable access to laboratory testing for all patients creates the potential to make a remarkable impact on reducing healthcare disparities while promoting health equity.

LAB-CARES is designed to prioritize laboratory tests in communities (e.g., mobile testing sites, blood drives); provide education about laboratory testing (e.g., workshops, public service announcements, social media campaigns); support awareness of the role of laboratory testing in public health; and place emphasis on creating opportunities for aspiring future care team members. As an LCDM, LAB-CARES is intended to codify access to laboratory services as a fundamental right for every

patient.

With advances in medical technology and the increasing availability of sophisticated diagnostic tools, clinical laboratories are playing a more integral role in facilitating access to healthcare in areas considered to be testing deserts which impact underserved and rural populations. Through proactive efforts, such as free screenings and tests, communities are given access to crucial health information that would otherwise be unavailable [30]. As an LCDM, LAB-CARES is structured for such efforts to reduce the cost of healthcare and ensure that all persons have the same access to quality healthcare.

Assays performed in the clinical laboratory are the result of meticulous scientific research. Laboratories must continuously invest in research efforts to develop new tests and improve existing testing. Publications related to case studies, new technology translation from research settings to clinical spaces, and LDTs or Lab Developed Testing Procedures (LDPs) are essential to patient care. A more visible linkage and intentional focus on bench-to-bedside applications value the ingenuity of laboratory professionals in such developments. As a LCDM structure, LAB-CARES incorporates the laboratory's impact on medical advancement by including research efforts.

Today, less than 40% of healthcare improvement initiatives are sustainable beyond the adoption phase [31]. Professional acceptance of a LCDM, like LAB-CARES, demonstrates the intentionality of the field to embrace implementation science and promote evidence-based practices that reduce inappropriate diagnoses, admissions, and costs that adversely affect the entire healthcare system. By incorporating Leadership, Advocacy, Best practice, Community, Access, Research, Equity, and Sustainability, laboratories can define quantifiable metrics for each foundational component.

Categorization of LAB-CARES foundational components under model tracks is required for EAPS development. In future-state practice, laboratories could report quantifiable metrics for each track (Quality, Integrative Practice, Operational Effectiveness, Clinical Expertise, Patient Safety) to meet the care standards of the LCDM and qualify for value-

Fig. 2. A strategic Call to Action matrix illustrating the key efforts required for LAB-CARES implementation in laboratories. This highlights the necessity of collaborative efforts and involvement of stakeholders across the healthcare continuum for successful value-based integration and future sustainability of the laboratory profession.

based payment. Record gathering of participation in multidisciplinary practice and clinical scholarship, coupled with documented outcomes and longitudinal impact, would be necessary for evidence of adherence. Thus, LAB-CARES is an early, but critical step in bridging the gap between laboratory medicine and overall healthcare delivery for better patient care, improved population health, and professional sustainability.

1.4. Call to action

Laboratory medicine is a core component of patient care. The expanding portfolio of new therapeutics and companion diagnostics based on the ongoing discoveries of biomarkers in the healthcare market relies on laboratory scientists who are heavily involved in all aspects of the development life cycle. Ethical integration of digital health technologies, like artificial intelligence, requires laboratory stakeholder involvement to ensure transparency and explainability of computational diagnostic algorithms to limit care risks. Even in a resource-limited form, laboratory results wield enormous influence on risk stratification and early disease detection. The clinical normative can no longer be a marginalized population who are largely underutilized and grossly undervalued.

It is crucial to continue professional discussions and efforts to formally integrate LAB-CARES into the structure of EAPs within the healthcare landscape. Sustainable transformation toward EAPs development will require team-based collaboration beyond the confines of the laboratory [Fig. 2]. Representative endorsement across executive, governmental, academic, clinical practice, industrial, and research modalities will be vital.

The first transformative step involves leaders of professional societies, many of whom are influential medical laboratory scientists, pathologists, and researchers, who understand the value of the clinical laboratories and can broadly advocate for a universal LCDM. These leaders would champion the effort through transparent conversation and reimbursement education, inclusive of operational insights, across the profession. At the local level, laboratory scientists can apply the LAB-CARES framework within their institutions to improve integration into patient care discussions and evidence-based practice.

Secondly, proposing a pilot alternate payment model framework in collaboration with the CMS Innovation Center is necessary to engage key government stakeholders and policy makers in the conversations from the transition from the current fee-based reimbursement structure to a value-based approach. Recently, CMS developed the Making Care Primary Model which focuses on primary care organizations piloting value-based models in rural and underserved populations [32]. This could serve as a potential integrative template for diagnostics as primary care physicians order laboratory tests at an average rate of 31.4% of weekly patient encounters [33].

1.5. The future of laboratory value-based integration

An illustrative framework is crucial to demonstrate how laboratorians facilitate interventions through collaborative partnerships and implementation science. In this article, we take initial steps to describe and champion such a model. The clinical laboratory continues to be the most cost-effective, least invasive source for obtaining objective health data in disease prevention, diagnosis, improving patient outcomes, and fulfilling essential public health surveillance and monitoring [34]. The value of laboratory medicine continues to evolve and grow in complexity as technology rapidly advances. Therefore, healthcare requires a tailored LCDM which provides a scaffold for the advancement of laboratory medicine.

The LAB-CARES framework articulates the value of the clinical laboratory in patient diagnostics and outcomes. It is designed to improve public health (e.g., through surveillance and prevention – beyond one patient) and individual patient's quality of life (longitudinal laboratory results – beyond one test) [34]. An aligned commitment to LAB-CARES solidifies the clinical laboratories as essential for patient care and promotes future-state EAPs development centered around laboratory expertise. Additionally, LAB-CARES also offers a potential platform for unified national exposure and advocacy campaigns that highlight the laboratory profession and its commitment to patient care. Unified, future-forward campaigning has proven an effective method for recruitment in nursing and other health professions [35]. Commercial representation and public visibility may also improve societal understanding of the laboratory's role in diagnostics [36]. Strategic alignment and incorporation of the core values and tenets of the laboratory sciences into a visual practice model could also generate professional camaraderie. Such solidarity could drive global quality and safety consistency using evidence-based practices to shape the future philosophy, culture, and survival of laboratory medicine. Now is the time to embrace LAB-CARES for the people we serve.

Author contributions

Conceptualization: MBN, MLE, SW, AO, DPB, JN.
Literature Review: MBN, MLE, SW, AO, DPB, JN.
Project Administration: MBN, MLE.
Visualization: MBN.
Writing – original draft: MBN, MLE, SW, AO, DPB, JN.
Writing – significant review & edit: MBN, MLE, JN, AO, SW, DPB.

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Melody Boudreaux Nelson: Writing – review & editing, Writing – original draft, Visualization, Project administration, Conceptualization. **Michelle F. Lamendola-Essel:** Writing – review & editing, Writing – original draft, Project administration, Conceptualization. **Aaron Odegard:** Writing – original draft, Conceptualization. **Stephanie Whitehead:** Writing – original draft, Conceptualization. **Dana Powell Baker:** Writing – original draft, Conceptualization. **Joy Nakitandwe:** Writing – original draft, Conceptualization.

Declaration of competing interest

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