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The Future of Clinical Laboratories in Value-Based Care

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Editor's note: We'll start with a brief foreword by David W. Johnson, CEO, 4sight Health

The laboratory is dead. Long live the laboratory.

That's the paradox we find ourselves in as we navigate America's high-stakes transformation from a volume-based to a value-based healthcare system. The transactional laboratory — isolated, reactive, commoditized — is nearing the end of its run. What comes next is a reimagined model: connected, proactive, indispensable.

This comprehensive position paper from the Project Santa Fe Foundation doesn't just argue for relevance. It demands leadership. It outlines how clinical laboratories, armed with diagnostic intelligence, longitudinal data and frontline insight, can guide systems of care toward precision, equity and sustainability. More importantly, it maps out how laboratorians can, and must, build a new business model that aligns with value-based incentives.

At 4sight Health, we call this alignment the "business model of care." When payment supports doing the right thing at the right time for the right reason, everyone wins — especially patients. The lab can be the ignition switch for

this transformation. But only if its stewards step outside the confines of historical identity and into the arena of systems strategy and patient engagement.

What you're about to read is not only a call to action. It's a blueprint for relevance in tomorrow's health economy. The lab's value doesn't end with the test. That's where its true influence begins.

—David W. Johnson CEO, 4sight Health

IS THIS OUR TOMORROW TO LOSE?

The transition to value-based healthcare, emphasizing quality outcomes over service volume, presents challenges and opportunities for pathologists and clinical laboratorians.

To remain relevant in this evolving landscape, lab professionals must adapt their roles and focus on delivering value. Others are seizing this opportunity. Laboratories risk being left not as an asset for driving the delivery of high-quality, cost-effective healthcare, but as a commodity supplier focusing only on lowest cost for a resulted test. We must emphasize that our use of the term "clinical laboratory" is inclusive of laboratory medicine, anatomic pathology, molecular pathology, pathology informatics, and the broad intersection of these domains.

We argue that a new role for pathologists and the clinical laboratory, along with a new business model to pay for this role, is not only possible but essential to survival. If value-based care is the future, what can pathologists bring to that future? Can pathologists and the clinical laboratory serve as a linchpin in driving improved patient and population outcomes? Can pathologists and the clinical laboratory, as the first to know the diagnostic information they provide, be responsible for triggering coordinated care pathways for the patient's healthcare journey? Will pathologists provide leadership for the multidisciplinary and interprofessional programmatic delivery of healthcare? We believe that the answer to all of these questions is yes. After examining the current market dynamics of value-based care, we will explore each of these questions in turn.

VBC AND CLINICAL LABS: AN INFLECTION POINT

In the book "Only the Paranoid Survive: How to Exploit the Crisis Points That Challenge Every Company," Andrew Grove defines a "strategic inflection point" as a major change in the competitive environment that requires a fundamental change in business strategy. Depending on how organizations adapt to the change, they can either grow or suffer decline. [1] The evolving landscape of U.S. healthcare has brought the laboratory industry to its own inflection point.

In 2011, 11% of healthcare payments were tied to quality and value. By 2020, that number had grown to 60%. [2] While the transition from a fee-for-service economy to one that ties payments to quality and value may seem remote to the practice of pathology and laboratory medicine, it is critical to recognize that diagnostic intelligence and process design are central to value-based care, which rewards early diagnosis and intervention, and the optimized use of healthcare resources. While the actual performance of laboratory testing is being progressively devalued, the optimization of patient care on the basis of that testing is being assigned greater and greater value. This dichotomy is central to the arguments made in this treatise.

To wit: The 2023 report of the Healthcare Payment Learning and Action Network (HPLAN) found that 24.5% of all healthcare payments (commercial and government) were already in a two-sided risk model — both "upside" and "downside." [3] This migration toward risk-based payments is in alignment with the goal of the U.S. Centers for Medicare and Medicaid Services (CMS) to have all of Medicare and the greater part of Medicaid beneficiaries enrolled in Accountable Care benefits programs by 2030. [4] Payers also recognize the trend in alternative payment models, with 73% believing these models will continue to rise. [3]

From the provider perspective, while there are growing pains in the primary care community as fee-for-service transitions to value-based payments, [5] Medicare's value-based care models have seen a 25% increase in healthcare provider participation from 2023 to 2024 alone, based on data from CMS. [6] Additionally, 11,000 Americans turn 65 each day and become eligible for

Medicare, and the Congressional Budget Office projects that Medicare enrollment will rise from 60 million in 2023 to 74 million in 2034. Both points emphasize the importance of providers becoming proficient in managing Medicare-enrolled patients under value-based benefits plans.

Additional major changes already impacting the laboratory in today's healthcare market include the following:

- Significant financial reductions in clinical laboratory reimbursements due to the Protecting Access to Medicare Act (PAMA) of 2014.
- Bundled Diagnosis-Related Group (DRG)-like payments on capitated per patient per month models more than likely impacting surgical procedure pathology payments (e.g., for Current Procedural Technology codes 88305, 88307, and 88309).
- Shrinking markets available to independent laboratories, owing to increased physician employment by integrated delivery networks, bringing physician practice laboratory work under preexisting relationships with other clinical laboratories.

For laboratories within integrated delivery networks and hence part of the integrated health system budgeting process, health system leaders increasingly view the clinical laboratory as unable to deliver positive margins from the fee-for-service market, and with steadily decreasing monetizable value as a system asset. In-system laboratories are thus at risk of full or partial divestment to commercial laboratories, disempowering the in-system laboratory from being an active player in health system strategic initiatives. Conversely, independent laboratories that depend on fee-for-service for their financial viability face their own financial reckoning under downward pressure on revenues. To the extent that both in-system and independent clinical laboratories base their financial future on "doing the same thing over and over again" (fee-for-service), our version of potential insanity is expecting this business model to sustain our future. This assumption may no longer be true. The result will be different, especially since fee-for-service does not provide funds flow for value-based activities. The business model that is value-based care must now be part of our collective "tomorrow."

WHAT DO PATHOLOGISTS AND THE CLINICAL LABORATORY BRING TO VALUE-BASED CARE?

The asset that the clinical laboratory brings to the table is the structured local data that informs the delivery of both patient-centered healthcare and regional population health. The asset that pathologists and board-certified clinical PhDs bring is profound and deep expertise in the medical science of human disease. Along with the administrative managers of the clinical laboratory, we bring extensive knowledge and experience in strategic planning and tactical operations to bear on the creation of coordinated care programming for a regional population. We also recognize doctorates in clinical laboratory science (DCLS) as high-complexity laboratory directors and contributors to the goals of value-based care.

The fundamental pivot that pathologists and clinical laboratories must make to realize the value of our asset, is: 1) to be active members of the multidisciplinary and interprofessional teams that are designing and delivering the integrated care required for risk-based and value-based care (two arms of the same system), [7] and 2) to be the experts to interpret and make actionable the data that our clinical laboratories generate. The actions must be in the healthcare delivery space of risk stratification, wellness care and prevention, early detection and intervention, and ultimately patient-centered coordinated care, with attendant avoidance of downstream healthcare costs. [8] The intersection of the laboratory practice and value-based care can be visualized in Fig. 1. The laboratory's shift from a reactive approach (subject entirely to receipt of test samples from physician-ordered clinical workflow) to a proactive approach (being part of the team for clinical management, inclusive of when to perform testing, on what samples, and on which patients)
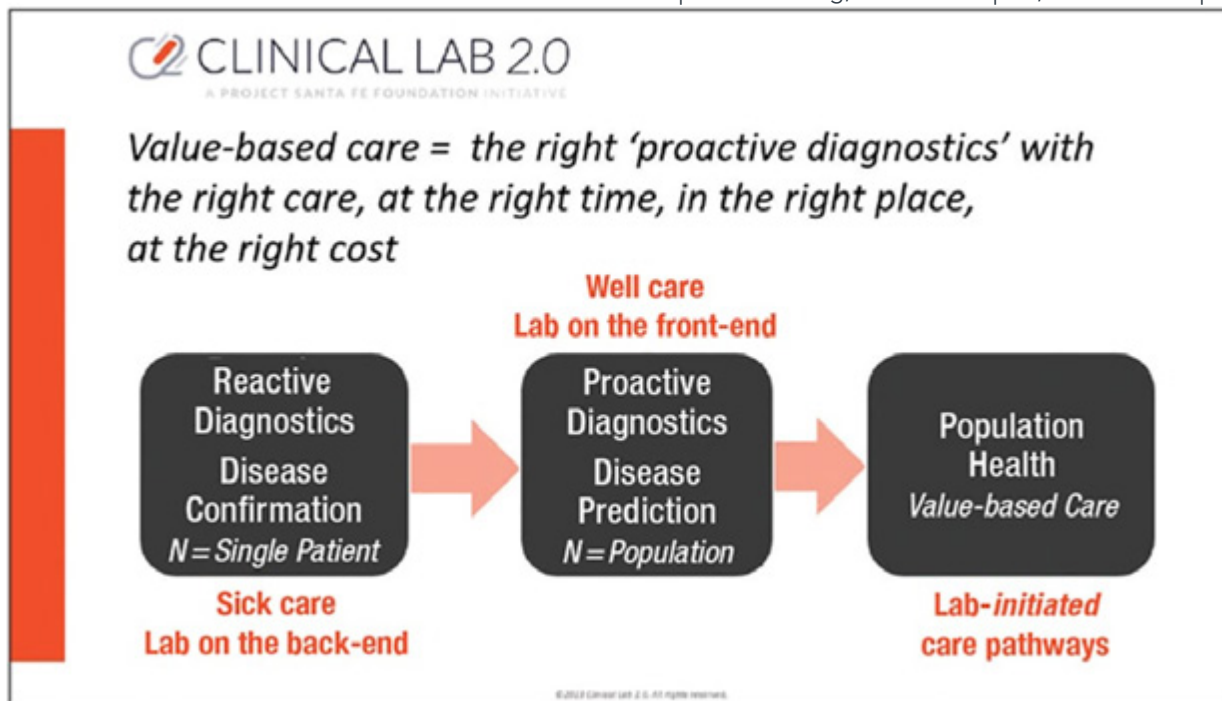

Fig. 1. The intersection of the laboratory and value-based care.

empowers laboratories to be active contributors to population health management. This shift supports value-based care, defined by the CMS as focusing on the quality of care, provider performance, and the patient experience. [9]

CAN PATHOLOGISTS AND THE CLINICAL LABORATORY SERVE AS THE LINCHPIN IN VALUE-BASED CARE?

Reach: Clinical labs and pathology touch more lives than any other sector in healthcare. Each interaction generates structured data that influences a substantial majority of clinical decisions (whether 70% or otherwise). [10] Being among the "first to know" about the onset of a health condition, clinical labs can act as frontline

first responders in patient care (Fig. 2). Indeed, one can argue that, having provided clinically actionable information for the management of a patient, the laboratory carries a moral responsibility to ensure that information is acted upon. While the laboratory cannot do so for the millions of patients it touches in any given year, that moral responsibility can be discharged by providing leadership in ensuring that clinical programming delivers effective healthcare to the regional population served by that laboratory.

Fig. 2. The clinical laboratory as a first responder.

Cost-effectiveness: One can also argue that the clinical laboratory is the most cost-effective source of information for management of a population. It touches virtually every patient receiving healthcare. Innovation and programmatic initiatives involving laboratory services can be propagated broadly through a health system owing to the high level of integration and standardization that are an essential part of laboratory operations. Perhaps most importantly, both at the individual patient and at the programmatic level, pathologists and clinical PhDs are highly knowledgeable experts in the meaning and impact of their informational product. The opening quote of Sir William Osler rings true well over a century later.

Zero latency: The information emanating from the clinical laboratory is part of the clinical workflow: There is zero latency. A resulted test (whether anatomic pathology or laboratory medicine) can be acted upon immediately. It is from this wellspring that laboratory leadership begins: Diagnostic optimization can then lead to therapeutic optimization, with the clinical laboratory being an essential partner to the patient and provider in monitoring the success of treatment outcomes.

Real-time clinical surveillance: For the regional population, clinical laboratories serve as real-time surveillance systems for clinical conditions and population health. By continuously monitoring their own data, clinical laboratories can identify trends and patterns that indicate the onset or progression of diseases within the population. In partnership with the population health initiatives of a health system, this proactive approach empowers early intervention and management of patients with or at risk for disease conditions, leading to improved patient and population outcomes.

Moreover, the consumer and market demand for noninvasive diagnostic testing that previously required invasive procedures will continue to catalyze the commercialization of technology that supports comprehensive diagnostic workups in convenient ambulatory settings. This movement to using technology to "diagnose patients where they are" will continue to highlight the lab's strategic role at the forefront of early detection and care optimization. Under the value-based care paradigm, the metrics of such optimization are both better clinical outcomes (including under the quality measures of pay-for-performance systems) and more cost-effective delivery of healthcare.

Longitudinal data: Clinical laboratories daily produce thousands to millions of unique data points that can demonstrate changes in a disease or health condition over time. This data set is of value only when those data are connected one to another, and to associated clinical metadata, so as to facilitate proactive prediction and early detection of clinical conditions. Trends in the structured data of the clinical laboratory can provide information on disease progression and comorbidities that alter the risk profile of that disease condition. The architecture of that data can establish whether a patient is being monitored in accordance with national treatment guidelines, the converse being gaps in care that will need to be closed. The assembled data informs healthcare entities on the health status of the regional community they serve, so as to guide strategic design and implementation of overall healthcare programming for that region.

Health equity: The clinical laboratory sits at the crossroads of patient access to healthcare and patient health outcomes. Laboratories have an untapped opportunity to influence key features of health equity: access, wellness, continuity in care, gaps in care, structural inequity, disease burden and population outcomes. [11] The laboratory cannot remain on the sidelines; it must contribute to strategic programming in health equity. This includes having knowledge about inequitable practices in medicine, data intelligence to identify and prioritize opportunities for intervention, expertise in and a commitment to broad partnerships in program design and execution, and clearly defined outcome objectives with measures for assessing the value of the laboratory contribution to such programs.

Pathologists as caregivers: While not traditionally thought of as caregivers (aka, "clinicians"), pathologists are increasingly embracing roles as caregivers, enhancing patient-centered care through innovative approaches. The establishment of Pathology Explanation Clinics (PECs) allows pathologists to engage directly with patients, providing personalized explanations of laboratory results and addressing individual concerns. [12] Patient-pathologist consultations offer patients the opportunity to view their biopsy slides and discuss their diagnoses directly with pathologists, fostering a deeper understanding of their conditions and empowering them in their healthcare journey. [13] Additionally, the development of patient-centered pathology reports, which

*Fig. 3. Laboratories practicing the medicine of tomorrow.*

present complex medical information in accessible language, [14] has been demonstrated to enhance patient comprehension and reduce anxiety. [15, 16] With ever-increasing patient consumerism, these initiatives underscore the evolving role of pathologists as integral members of the frontline patient care team, committed to improving patient outcomes through direct communication and education. [17]

CAN THE CLINICAL LABORATORY TRIGGER COORDINATED CARE PATHWAYS FOR THE PATIENT'S HEALTHCARE JOURNEY?

In 2017, the Project Santa Fe Foundation established the Clinical Lab 2.0 movement [18] for the express purpose of creating a disruptive value paradigm and exploring alternative business models that expand the role of diagnostic services in the future healthcare ecosystem. The starting point for doing so is to convert the transactional activities of resulting laboratory testing (what can be called Clinical Lab 1.0) to the integrated and actionable activities of Clinical Lab 2.0 (Fig. 3). Doing so requires the laboratory to be part of both the health system data analytic teams and the program design teams that are building the requisite clinical programming for value-based care. These programs must achieve target population outcomes and the necessary quality metrics for the following: 1) wellness and preventive care, 2) proactive management of patients with chronic conditions, and 3) closure of the

gaps in care, which can place patients at increased risk for catastrophic health events.

What makes the local laboratory so well placed for coordinated care pathway initiation is that structured and statistically combinable laboratory data informs the activities of value-based care. Published examples from Clinical Lab 2.0 demonstration projects include proactive identification of acute kidney injury during hospitalization, [19] proactive identification and management of prenatal care [20] and persons with diabetes, [21, 22] and proactive identification of evolving chronic kidney disease in regional populations. [7] While these peer-review examples may seem limited, the unifying themes are generalizable: 1) there is an unmet need
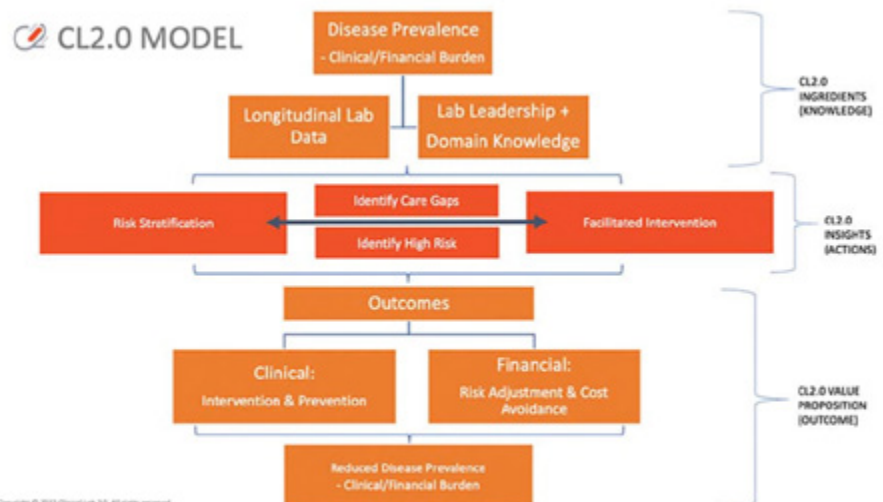
Reproduced from: Crawford JM, et al. *J Appl Lab Med.* Jan 2025;10(1):140–147. doi:10.1093/jalm/jfae113.

Fig. 4. The intersection of the laboratory and value-based care.

on the part of a key stakeholder (e.g., hospital leadership, the health system risk-based population health group, the state Medicaid program); 2) the clinical laboratory provided either or both longitudinal and population-based laboratory data to inform clinical care programming; and 3) the laboratory worked directly with the stakeholders to ensure that these laboratory-based data streams translated into effective clinical programming. The sequence of steps is mapped out in Fig. 4, conceptualized as Clinical Lab 2.0 Laboratory-Initiated Care Pathways. [23]

WILL PATHOLOGISTS PROVIDE LEADERSHIP FOR PROGRAMMATIC DELIVERY OF VALUE-BASED CARE?

Pathologists and clinical PhDs already carry enormous and largely unappreciated responsibility as directors of clinical laboratories, over and above their immediate obligations to patient care. While director-level responsibilities can be delegated, the legal and regulatory responsibility for laboratory performance is nontransferable and must be fulfilled at the highest level of commitment. The question can be asked: Can and should pathologists and clinical PhDs add programmatic leadership outside the laboratory to their scope of practice? For the contributors to this article, the answer is more than yes — we consider leadership outside the laboratory to be essential to the practice of medicine as laboratorians. We must be "present" and serve as members of the strategic planning teams for design of healthcare delivery. Absent such involvement, we are confined anonymously to our clinical laboratories, without ability to bring our expertise and domain knowledge to bear on actual healthcare decisions and delivery models. Collectively, it is the multidisciplinary and interprofessional healthcare team that delivers value-based care.

Which leads us to the stakeholders of value-based care. The first stakeholder is the individual patient. Whether the patient is well or experiencing an acute illness and/or coexisting with a chronic disease condition, design of healthcare delivery to promote the optimal patient experience is very much a laboratory concern. Phlebotomy is an immediate example: The skill and demeanor of the professional performing the venipuncture is a key part of the patient experience. The second stakeholder is the healthcare provider for that patient. The performance of the laboratory is either a source of satisfaction or substantial dissatisfaction to providers. Regardless of the business model for healthcare delivery, these two stakeholders are the reason clinical laboratories exist.

But value-based care requires laboratory leadership to work with a broader array of stakeholders:

- Healthcare organizations, independent provider practices and payers who are at financial risk under value-based payment agreements, which involve quality metrics, patient experience, patient outcomes and cost outcomes.
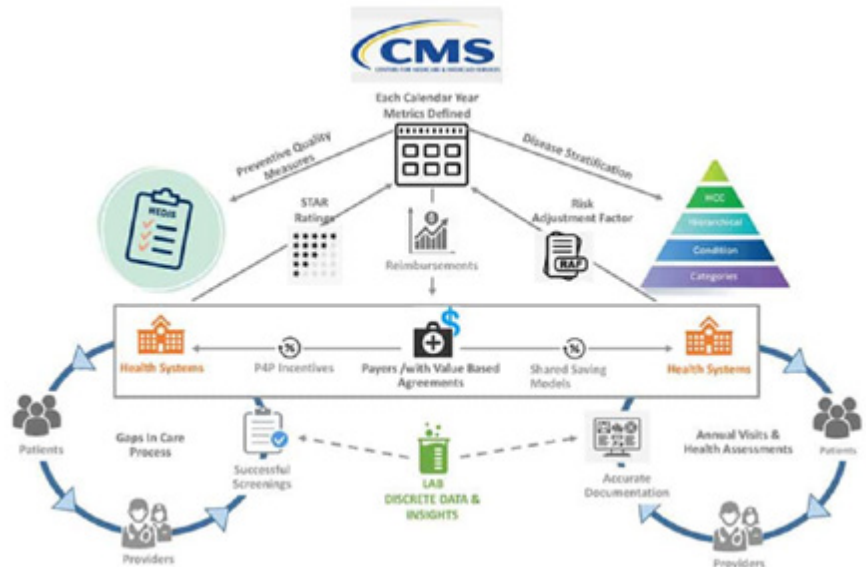
Reproduced from: Fung M, et al. *BMC Nephrol.* 2024;25(1):447. doi:10.1186/s2882-024-03869-4.

Fig. 5. Schematic showing the role of the clinical laboratory in funds flow for value-based payment systems.

- Clients of the laboratory that: a) have influence and authority to implement policies and clinical protocols and to enact workflows that support evidence-based pathways for care and support the Quadruple Aim in healthcare; b) use tools and data to develop clinical insights to identify risk, stratify patient populations, and change provider and patient behaviors in order to focus on improved clinical outcomes; and/or c) focus on cost avoidance in the total cost of care as a key component of meeting value-based payment metrics.

- Employers and government entities that carry the overall financial risk for healthcare coverage of a population.

To work with these stakeholders, laboratory leadership needs to understand the mechanics of the value-based payment system. Fig. 5 illustrates the critical role of the clinical laboratory in informing both arms of this paradigm. For a substantial portion of the chronic conditions falling under the value-based payment system, longitudinal data are key. The data must be analyzed both for where there are gaps in care that need to be closed (the transactional pay-for-performance left side of Fig. 5), and where a patient is at risk of going (the predictive risk-stratification/shared savings right side of Fig. 5). These data, and the laboratory professional expertise that can be brought to bear on leveraging these data, are what clinical laboratory leadership brings to the table for stakeholders operating under a value-based payment system. Although the clinical laboratory currently receives no financial incentives through either the pay-for-performance or shared savings set of programs, the clinical information

generated by the clinical laboratory is a crucial component of either system being able to operate. Laboratory leadership will need to articulate the statement-of-work they will carry responsibility for, in order to justify access to the funds flow of value-based care. Eligible deliverables can include the steady stream of actionable laboratory data intelligence, proactive programming to enhance access of a regional population to laboratory testing and thence coordinated care, and specific interventions to improve the ability of an integrated delivery network to meet the metrics of value-based care.

ROLE OF PATHOLOGY INFORMATICS IN GUIDING LABORATORY ENGAGEMENT IN VALUE-BASED CARE

The aspirational role of the clinical laboratory at the center of healthcare delivery has long been advocated through the literature of our own specialty, [24] with strong arguments made for deploying clinical laboratory analytics [25] and computational pathology [26] within the context of the subspecialty of pathology informatics. [27, 28, 29] With the continued maturation of clinical decision support [30] and the entry of artificial intelligence into the "big data" realm of clinical laboratory practice, [31, 32, 33, 34] the potential for these four subdomains of pathology informatics to inform the practice of laboratory medicine and digital anatomic pathology looms large. AI-driven tools can guide digital pathology and clinical laboratory reporting, but remain confined to our own duty cycles. It is essential that pathologists are engaged in the broader AI-driven strategies to streamline the clinical diagnostic pipeline and assessment and management of patient outcomes, boosting the efficacy of healthcare delivery and hopefully its cost efficiency.

The opportunities to apply the power of laboratory-based data analytics to the human condition are immense. Examples range from the importance of data-driven leadership in diagnostic stewardship [35, 36] and the opportunity to reduce care variation in pursuit of clinical quality [37] to the highly integrative Kidney Precision Medicine Project [38] and digital maturity models that improve quality and safety. [39] The patient experience also is a critical component of value-based care, and patient access to laboratory test results is an opportune domain for pathologists to guide AI-assisted patient portals. [40] However, examples of the clinical laboratory extending its data analytical reach into the realm of value-based healthcare remain limited (for example, see reference 41), with calls for greater effort in doing so from around the globe, and not just within the U.S. [42, 43, 44, 45] It is hoped that the strategic principles laid out herein will empower leaders in pathology informatics worldwide to embrace this challenge.

THREATS, RISK IN TAKING ON A ROLE IN VALUE-BASED CARE

Siloed laboratory data and leadership: Many laboratories lack the requisite data infrastructure and the time or expertise to step beyond their traditional role and responsibilities as providers of diagnostic results. While laboratory results are already transferred from the laboratory information system to the electronic health record, we are advocating that laboratory leadership should travel with the data. However, providing leadership is not done in isolation; the practice of medicine is a team effort. The professional expertise embodied in laboratory leadership must be part of the broad teams of health system strategic planners. Then all teams may fulfill their assigned roles in program deployment and execution. Our experience is that, without such proactive engagement, the laboratory will remain consigned to being a commodity and will not be viewed as an asset. This admonition applies regardless of whether the clinical laboratory is an in-system or independent laboratory.

Encroachment: Scope of practice is jealously guarded by each medical specialty. Several contributors to this article have experienced blunt declarations from medical colleagues that pathologists do not have the clinical expertise to understand the meaning of laboratory results emanating from their laboratories. We have found that proactively engaging with medical colleagues as part of strategic planning, and proactively establishing the respective responsibilities of each medical practitioner in the clinical workflow, can help ensure that such accusations are not forthcoming.

Patient-physician relationship: However complex a multidisciplinary and interprofessional healthcare team might be, the treating physician (however defined) is the medical professional carrying ultimate responsibility for the successful provision of healthcare to any given patient. The clinical laboratory supports that singular relationship. Our advocacy is that, in bringing their expertise forward, pathologists can proactively map out their respective responsibilities for data integration, interpretation, and leveraging, as part of ensuring that the chain-of-custody for laboratory-generated diagnostic information can culminate in optimized patient care.

Consumerism: While there is opportunity, there also is threat in regard to patient consumerism. An underperforming clinical laboratory can be a singular source of dissatisfaction, to patients and their providers. The willingness of payers, health systems, and clinical strategists to work with laboratory leadership in the value-based space will depend heavily on the overarching performance of the respective clinical laboratory.

Regulatory requirements: All medical professionals are subject to the requirements of patient privacy, data security, and confidentiality. The activities described herein fall within the paradigm of patient quality and safety, and as part of health system programming are permissible. That being said, the regulatory requirements of data curation and transfer must be respected. The

specific challenges of adopting artificial intelligence as part of the practice of medicine are subject to the regulations and statutes of specific countries and jurisdictions. Our advocacy is that clinical laboratory professionals, and the professional societies of which they

are members, have a particularly important role to play in navigating the regulatory and statutory environment of this artificial intelligence-enhanced future.

'NEW' BUSINESS OF THE LABORATORY IN VALUE-BASED CARE

While the fee-for-service system of payment continues to dominate the U.S. advocacy landscape for pathology and laboratory medicine, every major healthcare stakeholder is increasingly subject to and participating in the value-based payment system. As the market opportunity of value-based care becomes visible for the clinical laboratory, embracing the Clinical Lab 2.0 practice model will be essential. Following are the important actions required of clinical laboratories:

- Be knowledgeable and engaged in your hospital, health plan or health system's plans for value-based reforms. Allow and encourage pathologists, clinical PhDs and managers who want to be engaged to attend committees, workgroups or system-level planning events, with time away from the bench or microscope to enable them to be present at these crucial endeavors.

- Implement innovative information technology and diagnostic integration solutions. Empower laboratories to be key partners in delivering integrated, real-time healthcare data to patients and providers across the health system service area. Develop-

ing standards for data aggregation of longitudinal data and interoperability will identify data infrastructure gaps and help guide implementation of AI-enhanced algorithms for supporting early diagnosis and intervention, identifying gaps in care, and identifying patients at higher risk for disease onset or worsening.

- Educate the laboratory workforce to participate in population health management. Create educational opportunities and develop programming recommendations to equip professional and technical/managerial personnel with the necessary skills to design future care models, use advanced risk stratification techniques, and leverage longitudinal data for early detection. Be part of health system implementation of population-level coordinated care management programs such as for diabetes, cardiovascular and renal disease, and colorectal cancer screening.

- Demonstrate the laboratory's role in patient outcomes. Proactively identify the successful programmatic outcomes that can be attributed to laboratory involvement. This enables clinical laboratories to showcase their value across the healthcare ecosystem through reproducible data-driven initiatives. This is a battle won in detail: Every example builds the case for the clinical laboratory as an asset, not just a commodity.

- Define alternative revenue strategies. Participate in redefining the landscape of laboratory services by creating alternative payment and business models within the space of value-based care. Advocate for policies that integrate pay-for-performance and risk stratification payment methods with laboratory data, with funds flow directed toward the clinical laboratory performing such services.

The Project Santa Fe Foundation has formally commissioned working groups to strategize in the latter four domains. Our goal is to

then partner with the broader laboratory industry community to socialize these concepts, and then to represent clinical laboratories in the national healthcare community of value-based care. By embracing these strategies, pathologists and clinical laboratorians can position themselves as essential contributors to the evolution of value-based care.

CONCLUSION

This position paper argues that reengineering the current laboratory infrastructure from "reactive confirmation" of a physician's diagnosis to a "predictive and proactive medicine" approach supporting early detection of chronic conditions is essential and aligned with the definition of value-based care. This realignment requires that clinical laboratory leadership educate themselves in the strategies and mechanics of value-based care, and then proactively engage in population health programmatic efforts in their medical communities. Laboratory leadership must also

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