The Role of the Clinical Laboratory in Diagnostic Stewardship and Population Health

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Background: As healthcare identifies new opportunities to provide patient services and moves from volume to value payment models, the clinical laboratory is in an ideal position to serve as a catalyst for these changes. In 2017, the Project Santa Fe Foundation (PSFF) was founded to support the clinical laboratory's role to promote the objectives of population health and value-based healthcare. The initiative, known as Clinical Lab 2.0, uses longitudinal laboratory data to create actionable insights that can lead to improved patient and population outcomes, optimize the total cost of care, and reduce financial risk for stakeholders.

Content: The Clinical Lab 2.0 model was developed by a coalition of laboratory leaders to support clinical laboratories in the implementation of this new paradigm that moves beyond the provision of high-specificity and high-accuracy transactional test results and promotes "well care" and population health.

To provide leadership for Clinical Lab 2.0 across healthcare, promote dissemination of these concepts to clinical laboratories, and create evidence of laboratory's value; the Foundation has several ongoing initiatives. The first initiative is the conduct of both single-site and multisite demonstration projects at PSFF member sites. The second ongoing initiative for the Foundation is the provision of guidance documents to support clinical laboratories in the implementation of Clinical Lab 2.0 and promote policy development. PSFF has developed 2 types of guidance document tools: Position Statements and Laboratory-Driven Care Models.

Summary: This review summarizes the history, background, and initiatives for Clinical Lab 2.0 supported by the Project Santa Fe Foundation.

BACKGROUND

As healthcare redesigns how it provides services by engaging patients, moving from volume to value payment models, creating equity for the provision of services, and proactively identifying how to partner with community health, the clinical laboratory is in an ideal position to serve as a catalyst for these changes. Laboratories became the center piece of activities during the COVID-19 pandemic (1). Post pandemic, clinical laboratories need to continue their efforts as diagnostic stewards in population health. Laboratories have the capabilities to identify subgroups of patients with the

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IMPACT STATEMENT

The clinical laboratory can serve as a catalyst for diagnostic stewardship supporting population health and value-based health care. In 2017, the Project Santa Fe Foundation (PSFF) was founded to support the clinical laboratory's role to promote these objectives. The initiative, known as Clinical Lab 2.0, uses longitudinal laboratory data to create actionable insights that can lead to improved patient and population outcomes, optimize the total cost of care, and reduce financial risk for stakeholders.

highest risk, improve patients' health outcomes, and support payers and integrated health systems with risk adjustment payment models. So how can laboratories play a leadership role in this new era of healthcare payments and quality?

The Project Santa Fe Foundation (PSFF or Foundation) was founded in 2017 to support the clinical laboratory's role beyond the provision of high-specificity and high-accuracy transactional testing, in order to promote the objectives of population health and value-based healthcare. The initiative, known as Clinical Lab 2.0, takes longitudinal laboratory results to create actionable insights that can lead to improved patient and population outcomes, optimize the total cost of care, reduce financial risk for stakeholders (including patients), and promote "well care" as compared to the current healthcare model of "sick care." While diagnostic stewardship for an individual patient is practiced in many organizations, Clinical Lab 2.0 is an extension of the laboratory's existing order single test/result single test system, referred to as Clinical Lab 1.0. Clinical Lab 2.0 concentrates on early detection, risk management, intervention, and prevention both at an individual patient and population level (Fig. 1) (2). Laboratories are often the first to know about a patient's diagnosis or condition. Early recognition of a disease or condition provides the opportunity for intervention before the condition progresses, thus reducing long-term costs and poor patient outcomes. Conversely, the clinical laboratory is a sentinel for when a patient with a chronic condition is not receiving care with the cadence required for chronic disease management, thus identifying gaps in care.

The Clinical Lab 2.0 movement was established by a coalition of regional laboratory leaders who realized the importance of the clinical laboratory's role in the changing healthcare landscape and the important transition from volume to value payment models. These leaders understood the role of the diagnostic laboratory as a conduit to identify opportunities to improve healthcare well beyond the paradigms of laboratory test utilization and laboratory stewardship. The foundation of the Clinical Lab 2.0 movement is to utilize real-time laboratory results to identify risk in patient populations: risk for development of chronic disease; and risk for high-acuity events occurring in the setting of chronic disease. By moving upstream in the care continuum to wellness care, and by helping to optimize clinical management for patients who have chronic disease, the Clinical Lab 2.0 movement also highlights opportunities for reducing healthcare costs and improving revenue capture under value-based payment models. Additionally, risk management can include factors such as social determinants of health, patient demographics, and other data elements available to clinical laboratories.

These principles were first published in 2017 in a Project Santa Fe Report entitled "Improving American healthcare through Clinical Lab 2.0"' (3). This report described the purpose of PSFF to

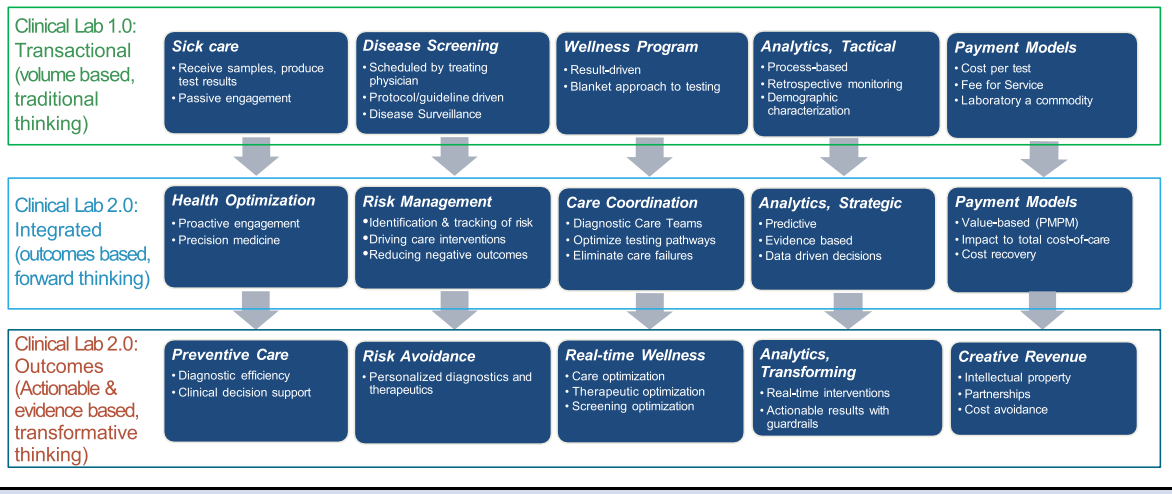

Fig. 1. Differences between Clinical Lab 1.0 and Clinical Lab 2.0 (Reprinted with permission from Geisinger Health).

provide leadership and develop a base of evidence to demonstrate the value of clinical laboratory services beyond the current model. The report also identified new opportunities for laboratory leadership and participation in population health. As stated in 2017, the mission of PSFF is to create a disruptive value paradigm and explore alternative business models that expand the role of diagnostic services in the future healthcare ecosystem. Published information shows only cents on the dollar are spent on in vitro diagnostics, but this testing is essential to almost two-thirds of medical decisions (4).

CONTENT

To support clinical laboratories in achieving this vision and demonstrating their value, the Foundation developed a 3-component model for successful implementation of Clinical Lab 2.0 (Fig. 2). The first component is actionable knowledge that emanates from the clinical laboratory. This would include diagnostic, prognostic, and theranostic information gained from laboratory testing, financial information about the cost of such testing in the context of overall costs of delivering care, having longitudinal laboratory data for the patient's course of disease, and importantly, the leadership and domain knowledge that laboratory leadership can bring to bear on management both of individual patients and the population of which they are part.

The second component encompasses the laboratory insights into individual patient and population risk stratification, identification of gaps in care and of opportunities for intervention for high-risk patients, and provision of actual leadership in designing the programmatic interventions required—again, for individual patients and for populations. The insights obtained through this second component include the ability to risk stratify the population for a given disease or condition and supporting risk-based payment strategies used by most healthcare organizations. Additionally, clinical insights include the identification of gaps in care against treatment guidelines and performance measures used by the managed care industry such as the Healthcare Effectiveness Data and Information Set (HEDIS) developed by the

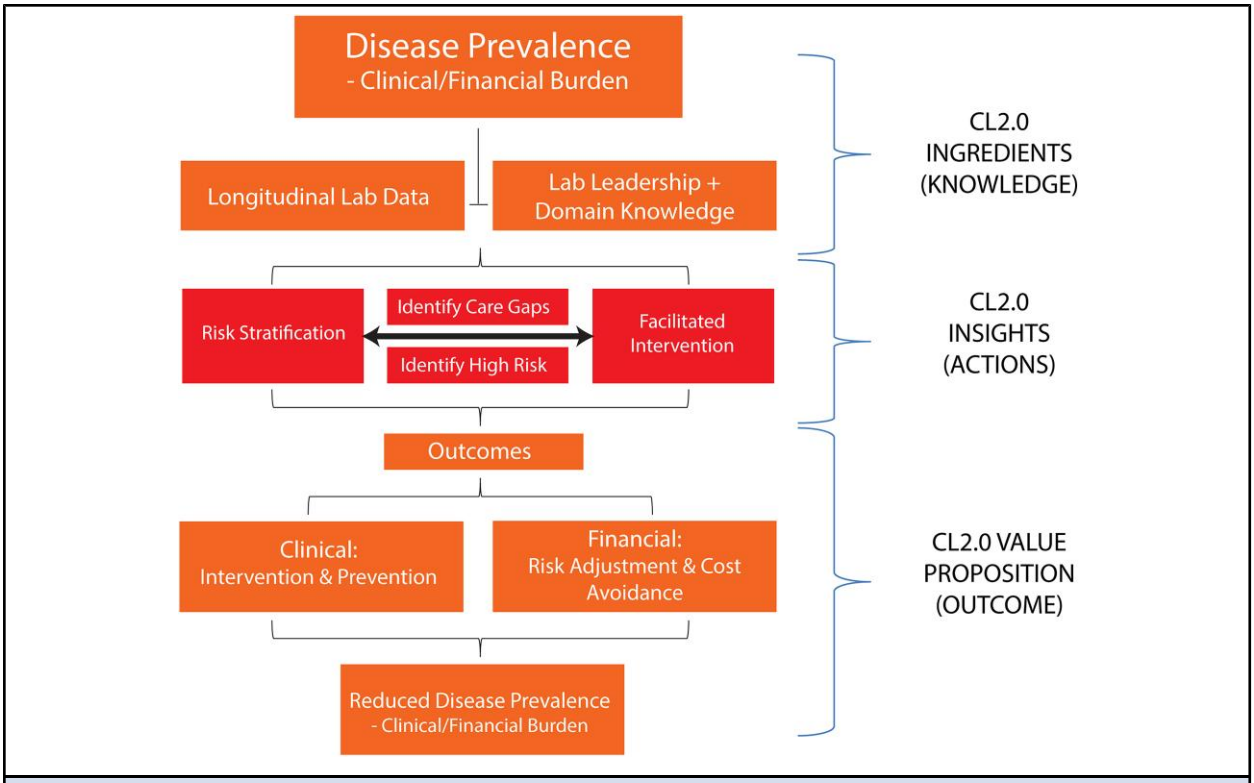

Fig. 2. Clinical Lab 2.0 Model. Copyright 2022 Clinical Lab 2.0, reprinted with permission.

National Committee for Quality Assurance (NCQA) (5) and to identify high-risk groups for additional care or services that could result in improved health outcomes. Lastly, the laboratory-initiated interventions must interface with the healthcare providers, supporting both their day-to-day management of patients, and their management of the population of patients they are responsible for. As an example of this last principle, real-time hemoglobin A_{1c} (Hb A_{1c}) results in patients with diabetes seen in primary care clinics can be used to identify patients who should be screened for chronic kidney disease based on the National Committee for Quality Assurance (NCQA) Kidney Health Evaluation measure (6), support the capture of risk adjustment payments in this costly population, and develop mechanisms to monitor a patient's disease progression in the primary care setting while referring patients at the appropriate time for specialty care.

The third component of the Clinical Lab 2.0 model is the value proposition that longitudinal data can be provided to support improved clinical and financial outcomes of populations. As described by Anonychuk et al. (7), improved clinical outcomes might include reduced time to diagnosis, accurate diagnosis, improved selection of treatments because of an accurate diagnosis, avoidance of misdiagnosis, improved patient work flow, and improved patient satisfaction or quality of life. Additional clinical outcomes might include improved screening, risk stratification, and monitoring of treatment response (8). With Clinical Lab 2.0, the improved financial outcomes, beyond reducing the cost per test, can be identified in the pre-analytic and post-analytic phases

of testing (9). Examples of these include the identification of missing International Classification of Diseases, 10th Revision (ICD-10) billing codes, opportunities for revenue capture for diseases reimbursed through risk adjustment mechanisms, and missing data for quality metrics such as health plan HEDIS measures or the Medicare Merit-Based Incentive Payment System (MIPS). For example, in one published report, the clinical laboratory was able to identify missed reimbursement for risk adjustment payments not documented in existing billing systems in chronic kidney disease (10). In a second report, the clinical laboratory was able to identify patients with acute kidney injury, enabling early identification of their acute condition at the time of their hospitalization, and accurate coding and billing for that condition following their discharge (11).

Measuring the contribution of laboratories to the clinical and financial outcomes of patient populations is challenging, since these insights are not part of the existing data analytics for many clinical laboratories and require support from departments outside the laboratory to understand and capture quality measures and healthcare costs in a meaningful way. Developing information technology (IT) tools is essential to Clinical Lab 2.0. IT solutions may range from simple data downloads from the laboratory information system (LIS) or the electronic medical record (EMR) to Excel files, hiring IT expertise internal to the laboratory, implementing comment fields for laboratory results in the EMR, or EMR custom-built tools. One mechanism to overcome IT resource challenges is to work with leadership to understand the clinical, quality, and financial value of Clinical Lab 2.0 as part of the corporate strategy. Laboratories without longitudinal laboratory data, such as reference labs, may be more limited in Clinical Lab 2.0 activities but can focus on single data points that indicate risk for chronic disease or partner with laboratories having broader data access. Conversely, artificial intelligence (AI) applied to the field of morphologic and anatomic pathology ("computational pathology") is a field of intense study (12, 13). Application of AI to the structured data emanating from the clinical laboratory is also an important opportunity for the laboratory to provide leadership in advancing population outcomes (14, 15). The identification of appropriate clinical actions based on AI and industry standards for its use are needed.

With few exceptions, published financial outcomes for laboratory services that support population health in value-based care are lacking from the literature. When successfully performed, the return-on-investment for laboratory leadership under a Clinical Lab 2.0 model can be clearly demonstrated (16). Models for documenting financial outcomes for clinical laboratories are not readily available and additional work is needed to define and measure the financial benefits of laboratory medicine in this new environment.

The alignment of the Clinical Lab 2.0 initiative and population health has been published by the Foundation (17, 18). Population health aims to serve the health outcomes of a group of individuals, including the distribution of such outcomes within the group. Population health incorporates 4 interacting concepts or pillars: chronic care management, quality and safety, public health, and health policy (19). Embracing population health principles will require laboratories to collaborate with health systems, payers, state and local health departments, primary care providers, IT, and policy makers.

To provide thought leadership for Clinical Lab 2.0, promote dissemination of these concepts to clinical laboratories, and create evidence of laboratory's value; the Foundation has several ongoing initiatives. The first initiative is the conduct of both single-site and multisite demonstration projects at PSFF member sites. These research projects, with institutional review board approval, put laboratory science in a leadership role to provide value to existing and new healthcare processes. The projects support value-based

population health efforts and help solve existing problems for providers, health systems, or payers. All projects incorporate the use of longitudinal laboratory results and metadata such as patient and provider demographics available inside the LIS, data from the EMR, and information available within the healthcare system's billing and quality data capture systems. Demonstration projects focus on high-prevalence, high-risk clinical conditions that are important for population health and costly for any healthcare system. The aim of each demonstration project is to show the laboratory's value by providing measurable clinical and financial outcomes in a defined group of patients. Clinical outcomes include proactive programmatic efforts by the laboratory, defined as facilitated interventions, to promote early disease detection such as with the use of anemia algorithms or screening patients for concomitant conditions such as diabetes and chronic kidney disease. Additionally, projects may capture financial outcomes that could improve a healthcare organization's revenue capture. After the project's completion, participating institutions work towards implementation as part of the standard patient care work flow. Completed projects have included understanding the role of anemia cascades in the healthcare setting, the use of critical laboratory results as a tool for population health, the value of early sepsis identification on healthcare costs and quality measures, and the early identification and risk stratification of chronic kidney disease (10). Examples of the demonstration projects and publications of this work in available on the PSFF website (www.CL2Lab.org).

The second ongoing initiative for the Foundation is the provision of guidance documents to support clinical laboratories in the implementation of Clinical Lab 2.0 and promote policy development. PSFF has developed 2 types of guidance document tools: Position Statements and Laboratory-Driven Care Models. Lab 2.0 Position Statements are short guidance documents outlining one aspect of Clinical Lab 2.0. Position Statements express basic philosophy and guidelines that offer programmatic recommendations on the laboratory's role in population health and value-based care. Clinical laboratories may be faced with having to prove their value, and these position statements are designed to help laboratory leadership both understand this new role, and effectively communicate this role to stakeholders.

Laboratory-Driven Care Models are evidence-based guidance documents on how to utilize the Clinical Lab 2.0 model for a given high-risk, high-prevalence, or high-cost health condition or disease. Laboratory-Driven Care Models provide "HOW TO" recommendations including developing key partnerships, pathology's role in disease screening, recognition and monitoring, shared accountability, and work flow opportunities for a particular disease or condition. Care Models are clinical protocols for a Clinical Lab 2.0 process as outlined in the Clinical Lab 2.0 model. These documents provide details on what longitudinal laboratory values should be considered. For example, the Anemia Care Model posted in the CL2Lab.org library includes examples of cascades based on the literature. These documents can be a starting point for discussions and creating local clinical protocols with primary care and specialty providers and clinics. Care Models are based on the experience gained through the PSFF single- and multisite demonstration projects. Both sets of documents are available on the PSFF website (www.CL2Lab.org).

PSFF actively encourages all laboratory leaders to utilize information in these guidance documents to generate policy change and educate healthcare leaders, politicians, and policy makers. Implementing Clinical Lab 2.0 will require policy and payment model changes to support the laboratory's role in screening and payment for laboratory-generated insights promoting value-based care. Organizations need to communicate needed changes both to third-party payers and

federal government entities who dictate payment models.

The third initiative supported by the Foundation to promote thought leadership is to foster networking opportunities between PSFF faculty, those attending PSFF events, and in vitro diagnostic companies through the use of presentations at professional meetings and social media channels used by these groups.

SUMMARY

In conclusion, the Project Santa Fe Foundation is providing leadership and the lessons from our demonstration project experience, with the goal of supporting clinical laboratories in the rapidly evolving transition of healthcare from volume to value. The Foundation hopes to leverage laboratory medicine and pathology domain knowledge to establish the standards and evidence for Clinical Lab 2.0. The Foundation facilitates diverse partner collaborations in order to guide policies, transfer knowledge, and accelerate the Clinical Lab 2.0 movement across the industry. We welcome all members of the laboratory community and beyond to be part of this movement and will welcome contact from those interested in working directly with the Project Santa Fe Foundation.

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