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Enhancing Value-Based Care Through Laboratory-Assisted Identification of Care Gaps

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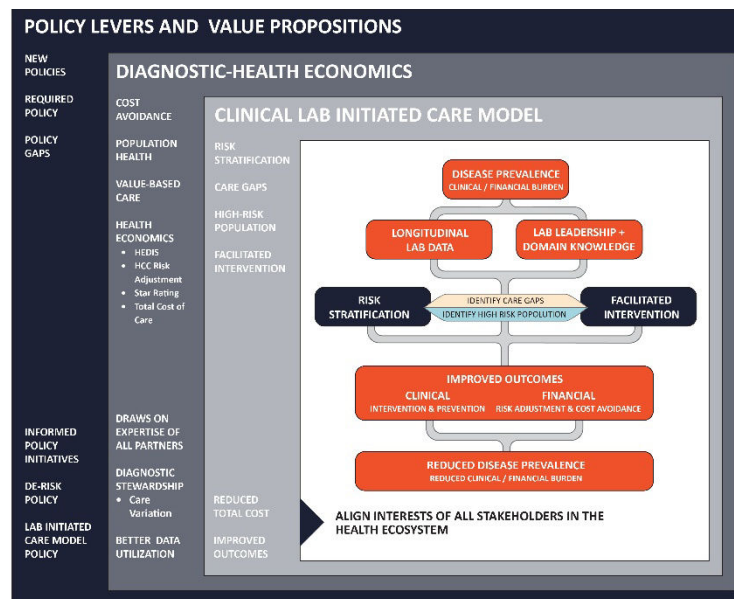
ABSTRACT

The shift from fee-for-service to value-based care is transforming the role of clinical laboratories. Instead of being transactional providers of test results, the most forward-looking aim for laboratorians is to serve as strategic drivers of patient and population health. This idea is at the core of the Clinical Lab 2.0 movement^{1,2}, which emphasizes how structured, longitudinal laboratory data can be transformed into insights that drive early detection, preventive interventions, and optimized outcomes.

In this framework, the laboratory is no longer only a responder to physician orders. Rather, it becomes an active contributor to the patient care pathway by stratifying risk and identifying patients at elevated risk, surfacing missed tests or incomplete workups to close gaps in care, ensuring timely follow-up and evidence-based management to facilitate interventions, ultimately reducing both disease burden and healthcare costs through improved outcomes.

CL2.0 Model

FRAMING THE MOVEMENT



¹ Crawford JM, Shotorbani K, Sharma G, et al. Improving American Healthcare Through “Clinical Lab 2.0”: A Project Santa Fe Report. Academic Pathology. January 2017. doi:[10.1177/2374289517701067](https://doi.org/10.1177/2374289517701067)

² Crawford JM, Shotorbani K, Swanson K. The Role of the Clinical Laboratory in Diagnostic Stewardship and Population Health. J Appl Lab Med. 2025 Jan 3;10(1):140-147. doi: 10.1093/jalm/jfae113. PMID: 39749450

Inspired by this concept, we conducted a study to evaluate how a proactive laboratory-assisted platform can close diagnostic gaps and ensure alignment with clinical guidelines.

Objectives

Our study evaluated the effectiveness of a proactive laboratory-assisted platform designed to improve patient outcomes, strengthen physician decision-making, and deliver cost savings for payers by aligning diagnostic testing with U.S. clinical guidelines. Specifically, the system was designed to flag patients with incomplete or non-compliant test profiles, such as cases where diagnostic testing did not align with evidence-based guidelines like HEDIS measures³ or where follow-up was unclear and therefore never completed. By surfacing these gaps, the platform supported guideline-based care through improved test selection and alignment with established clinical protocols. In addition, it helped physicians and laboratories improve compliance by strengthening patient engagement, which in turn translated to better clinical outcomes. To demonstrate these capabilities, we focused on two common testing patterns where care gaps have significant clinical consequences.

The first included **patients with diabetes requiring Albumin-to-Creatinine (A/C) ratio testing** as a follow-up to elevated A1C^{4,5}.

The second cohort included **patients with low hemoglobin levels requiring follow-up testing** (Iron, Ferritin, and Vitamin B12) to establish the underlying cause of anemia⁶. The focus was on a widespread challenge: many patients never receive the full spectrum of recommended tests, creating risks for delayed diagnoses and suboptimal care.

These gaps arise for a variety of reasons, including fragmented records between providers, inadequate or unclear follow-up after initial testing, and the limited time physicians can devote to reviewing guideline requirements during routine visits. Patient-level barriers such as cost concerns, transportation, or low health literacy further compound the problem, leaving a significant portion of at-risk individuals without the evaluations needed for timely detection and intervention.

Methods

For this pilot study, the Vivica® LabReports system—designed as a proactive laboratory-assisted platform for identifying care gaps—was integrated directly into the routine clinical laboratory workflow to analyze large volumes of historical testing data. The implementation was carried out in collaboration with Accu Reference Medical Laboratory, a CLIA-certified and CAP-accredited reference laboratory headquartered in New Jersey. This laboratory is widely recognized for its extensive diagnostic capabilities, rigorous quality standards, and broad operational footprint, which includes services delivered across multiple states. The dataset analyzed in this study consisted of laboratory records collected during the year 2024.

Patient cohorts were defined based on two diagnostic pathways where follow-up testing is frequently incomplete. The first included patients with diabetes requiring Albumin-to-Creatinine (A/C) ratio testing after elevated A1C or other risk factors. The A/C ratio is a key marker for early detection of diabetic kidney disease, yet it is often under-ordered despite guideline recommendations for regular monitoring. Missed A/C testing eliminates

³ “HEDIS measures” — NCQA. HEDIS® Measures and Technical Resources

⁴ American Diabetes Association. 11. Chronic Kidney Disease and Risk Management: Standards of Care in Diabetes—2025. *Diabetes Care*. December 2024. doi:10.2337/dc25-S239

⁵ Lian H, Wu H, Ning J, Lin D, Huang C, Li F, Liang Y, Qi Y, Ren M, Yan L, You L, Xu M. The Risk Threshold for

Hemoglobin A1c Associated With Albuminuria: A Population-Based Study in China. *Front Endocrinol (Lausanne)*. May 2021;12:673976. doi:10.3389/fendo.2021.673976

⁶ Killip S, Bennett JM, Chambers MD. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician*. 2013;87(2):98–104

opportunities for timely diagnosis and intervention, allowing kidney damage to progress unnoticed to advanced stages.

The second cohort included patients with low hemoglobin levels requiring follow-up anemia workups. Appropriate testing—Iron, Ferritin, and Vitamin B12—is necessary to distinguish between iron deficiency, depleted iron stores, or B12 deficiency, each carrying distinct management implications. When these follow-ups are not performed, anemia remains unexplained, treatment is delayed, and more serious underlying conditions are sometimes missed.

These two pathways were selected because incomplete follow-up in either area represents a major care gap with significant consequences for outcomes and costs.

Within this environment, the platform's advanced algorithms were applied to patient-level laboratory testing patterns, systematically comparing them against U.S. evidence-based clinical guidelines, with particular emphasis on Healthcare Effectiveness Data and Information Set (HEDIS) measures. The goal was to evaluate how effectively the platform could detect deviations from recommended care pathways.

The system was designed to deliver actionable insights in response to provider requests by automatically identifying patients with incomplete test panels and classifying these gaps according to their clinical significance. Once identified, the platform generated targeted recommendations for appropriate follow-up tests, ensuring that the information provided was directly relevant to physician decision-making. In doing so, the system supported both physicians and laboratories in aligning practice with guideline-based care while reinforcing the role of the laboratory as a proactive contributor to the patient care pathway.

To achieve this, the study relied on aggregated laboratory data drawn from Accu Reference's broad testing database. **All data were collected during**

2024, providing a recent and comprehensive snapshot of testing patterns. This centralized dataset allowed for population-level analysis and addressed a common limitation of fragmented Electronic Medical Record (EMR) systems, where incomplete or siloed patient data often obstructs the identification of care gaps. In bypassing these EMR constraints, the study was able to focus on the value of laboratory data as a unified, longitudinal source for predictive analytics and treatment decision support.

Results

The system revealed striking diagnostic gaps: the pilot showed that in some cohorts, well over 50% of patients did not receive a full spectrum of recommended tests.

Further analysis revealed key diagnostic gaps:

Albumin-to-Creatinine ratio (A/C) testing

Only 4,037 out of 26,949 patients (15%) with high A1C and normal creatinine received an A/C ratio test. No meaningful gender-based differences were observed.

Among those tested, evidence of kidney damage was identified in 46% of males and 40% of females. For the purposes of this analysis, kidney damage was defined according to established clinical guidelines as an elevated albumin-to-creatinine (A/C) ratio, specifically values at or above 30 mg/g, which indicate the presence of microalbuminuria and are widely recognized as an early marker of diabetic kidney disease progression. When combined, the male (46%) and female (40%) rates correspond to an overall prevalence of approximately 43% across both genders in the tested cohort. Based on these findings, 43% of the 22,912 patients across genders (≈9,852 individuals) who did not receive A/C ratio testing are projected to be at risk of kidney disease, since this critical test is an early and actionable marker of kidney damage and progression toward chronic kidney disease.

Hemoglobin follow-up

Among 57,310 patients with low hemoglobin (below 11.3 for females and 13.1 for males), 85% received none of the following follow-up tests: Iron, Ferritin, or B12.

These findings highlight a critical care gap: the majority of patients with anemia are left without the diagnostic workups needed to determine the origin of their condition, delaying treatment and increasing the risk of complications. This demonstrates the importance of tools that can systematically detect and flag such lapses in testing.

To address these gaps at scale, the Vivica® LabReports was developed as a proactive, laboratory-assisted platform that transforms routine laboratory data into an actionable workflow. It begins by aggregating and standardizing data from across the laboratory, ensuring that results are captured in a consistent format. Then, the platform maps each patient to the applicable evidence-based protocol, using it as the benchmark to verify completion and the timing of required tests. When deviations are found, it flags overdue or incomplete items, prioritizes them according to clinical significance, and generates guideline-aligned recommendations in provider-ready worklists. Finally, the system tracks whether follow-up actions are completed, updating records and reporting on gap closure and patient outcomes over time.

It empowers faster clinical decision-making, supporting improved patient compliance, preventive care, and overall outcomes.

Discussion

While certain patients may have completed follow-up testing outside of the analyzed laboratory network, the proportion of this likelihood is expected to be small relative to the total cohort. Several factors support this interpretation: the large sample size of more than 84,000 patients analyzed across two independent cohorts, the magnitude of the observed gaps (e.g., 85% of patients with low hemoglobin

received none of the recommended follow-up tests), and the statistical improbability that external testing alone could compensate for such a substantial shortfall. Taken together, these considerations suggest that any external testing would not substantially alter the overall conclusions.

Laboratory-Assisted Platforms Within the Patient Journey

Requests for analysis of under-tested patient cohorts are typically initiated by physicians during routine monitoring or follow-up care. At this stage, diagnostic decisions are critical to the patient journey, yet gaps frequently appear due to non-compliance, fragmented records, and/or lack of time.

Without support from laboratory-assisted platforms, physicians face major challenges in tackling these gaps in care, including:

- a) incomplete data scattered across Electronic Medical Records (EMRs),
- b) insufficient time to configure and apply algorithms at scale, and
- c) reliance on reviewing individual patient histories, which is rarely feasible in a busy practice.

A proactive laboratory-assisted platform changes this dynamic by automatically analyzing populations of laboratory results, identifying patients who have missed or delayed guideline-recommended tests, and surfacing them for follow-up. For patients, this translates into earlier detection of disease risks, more timely interventions, and improved continuity of care. Instead of waiting until complications arise, patients are given the chance to receive preventive testing, clearer guidance, and better support in adhering to their care plans. Ultimately, this leads to better health outcomes and reduces the likelihood of advanced disease that is difficult to treat. At the same time, it generates measurable value for payers by helping to avoid the higher costs associated with late-stage interventions under value-based care programs.

A simplified patient journey supported by such a platform may look like this:

1. Initial testing: physician orders baseline labs
2. Gap detection: the platform flags missing follow-ups (e.g., A/C ratio, iron panel)
3. Physician-laboratory coordination: alerts are generated with recommended next steps
4. Patient engagement: targeted communication informs patients about gaps and encourages compliance
5. Outcome: earlier interventions, improved long-term health, and reduced complications

By scaling this type of population-based approach, laboratories can extend the model across many different patient cohorts, creating new opportunities for earlier detection, preventive care, and measurable system-wide value. In this study, the specific tool used to demonstrate and operationalize these capabilities was the Vivica® LabReports platform.

Conclusions

The study demonstrated that a proactive laboratory-assisted platform can improve care by detecting deviations from evidence-based guidelines and highlighting opportunities for corrective action. It empowers clinicians with real-time, actionable insights into testing gaps, allowing them to intervene more effectively and ensure patients remain aligned with recommended care pathways. By surfacing missed follow-up tests—such as the albumin-to-creatinine ratio in diabetes or iron studies in anemia, among many other guideline-recommended evaluations—the platform enhances diagnostic accuracy and strengthens preventive care by giving physicians a clearer clinical picture enabling them to order additional testing and intervene earlier where needed. Finally, it supports collaboration among laboratories, physicians, and patients, reinforcing a team-based approach to improved outcomes.

Beyond these specific cohorts, the same methodology can be applied across a wide range of clinical conditions where incomplete testing creates

risks for delayed diagnosis. By proactively flagging patients at risk of missing critical follow-ups, laboratories and clinicians can reduce the likelihood of disease progression to advanced stages, decrease the need for costly hospital-based care, and ultimately lower downstream costs for the entire healthcare system.

In effect, this creates a four-fold benefit: better care for patients, stronger clinical outcomes, enhanced value for laboratories, and cost savings for payers through prevention rather than treatment of severe complications.

Placing LabReports in the Value-Based Care Pathway

Reflecting on these results through the lens of value-based care and in alignment with the Clinical Lab 2.0 model, it becomes clear how a proactive, laboratory-assisted platform can contribute to laboratory initiated care pathways.

By aggregating test results into longitudinal datasets, the laboratory can build a structured foundation for monitoring care patterns over time. Within this framework, algorithms highlight patients who are at risk because of incomplete or non-compliant testing, thereby enabling more precise risk stratification and the detection of gaps in care. Once such gaps are identified, the platform generates actionable prompts that empower clinicians to order guideline-recommended tests and intervene earlier in the patient journey. The result of these coordinated actions is not only improved compliance and reduced disease prevalence, but also the avoidance of unnecessary costs that accompany late-stage disease.

Taken together, these functions illustrate how proactive laboratory-assisted platforms strengthen the laboratory's role within Clinical Lab 2.0 pathways: moving beyond test execution to driving insight generation and coordinated action. By transforming raw diagnostic data into targeted interventions, laboratories can directly influence patient journeys and population-level outcomes, demonstrating

measurable value in both clinical and financial terms.

Commitment to Clinical Lab 2.0

We fully support the vision of the Clinical Lab 2.0 movement and view it as the inevitable future for redefining the role of laboratories in healthcare. By aligning with this framework, we are not only endorsing the concept but also illustrating how practical tools, such as LabReports, can enable its real-world implementation. In this way, laboratories gain the capability to operationalize Clinical Lab 2.0 principles, turning diagnostic data into actionable intelligence that improves outcomes across patients, providers, and populations.

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