

WhitePaper

Clinical Laboratories Under Pressure:

Exploring Options to Re-establish Critical
Relevancy and Maintain Independence

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Introduction

Powerful forces are reshaping the clinical laboratory industry, and this will be a critical year as hospitals determine whether retaining the laboratory in-house or selling it is the better path.

Mergers, acquisitions, and joint ventures, along with the development of new testing technologies have considerably changed the profile of the medical laboratory footprint across the U.S. Now, downward reimbursement reform combined with impending integration of clinical care are predicted to again challenge the traditional laboratory service model in significant ways beyond 2020.

Medical laboratory leaders need to know that selling the laboratory will not solve the core problems facing healthcare organizations today: overutilization, low-value testing, inappropriate use of high-cost testing, and provider confusion over best test choice leading to irrelevant results and the need for a repeat study.

This white paper is the first of a three-part series developed in collaboration with Mayo Clinic Laboratories and Change Healthcare. It is intended to assist clinical laboratories in rationalizing the laboratory's value and relevance in ways that support appropriate and high-quality patient care, fiscal strength, and program integrity for payers.

The white paper series provides industry perspective, commentary, and insight on the use and value of decision support in building an effective laboratory stewardship program. It will also highlight case-study proof points developed in collaboration with Mayo Clinic from early-adopter hospital laboratories that have successfully implemented third-party decision support—to their value advantage.

Chapter 1:

Industry Update: Commoditization of Common Tests Puts Clinical Laboratories Under Pressure to Validate Value

These are challenging times for the clinical laboratory. Regulations grow while predictable downward reimbursement is expected to continue. Changing business models collide with shrinking budgets and disappearing margins. Expensive and once well-reimbursed esoteric tests are missing from your catalog.

No sector of healthcare has been immune to the ongoing effects of decreased reimbursement and competitive pressures. Hospital-based clinical laboratories have been especially hard hit.

On the one hand, medical laboratories have struggled to manage and overcome the impact of successive Medicare reimbursement cuts mandated by the 2014 Protecting Access to Medicare Act (PAMA). The law, designed to more closely align Medicare payments with rates paid by commercial carriers, began in 2018 ratcheting down reimbursement on approximately 75% of laboratory tests that qualify for Medicare payment.¹

The Centers for Medicare and Medicaid Services (CMS) estimate the cuts will shrink total Medicare laboratory spend by up to 30% over three years,² with a commensurate impact on individual laboratory revenues. Hospital reference laboratories are further bracing for additional reductions of up to 15% annually across the subsequent three-year period.³

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The cuts, which some observers believe will drive many smaller laboratories out of business,⁴ are exacerbating an already difficult financial situation brought on by an extended period of price competition in the industry. Initiated by national reference laboratories in pursuit of market share, the ongoing price pressure and resulting commoditization of most common tests show no signs of abating as payers increasingly limit network participation to the lowest-cost clinicians and ancillary providers.

On the other hand, the impact of Medicaid program reform and integrity measures is just beginning.

In the face of these economic pressures and the uncertainty that lies ahead, clinical laboratories are especially vulnerable given that U.S. clinical lab expenditures represented a minimal, approximate 3.3% of overall national health expenditures as of 2017, and hospital laboratory departments themselves roughly 6% of a hospital's costs.⁵

Considering the relatively low line-item budget impact of the hospital laboratory on U.S. healthcare expenditures and individual hospital costs, laboratory directors and administrators now are on the defensive to show the lab's value or risk seeing it put on the block.

Given some prognostications, it may seem prudent to sell the laboratory or enter into a managed services agreement, but those decisions are not without risk.

As medical laboratory leaders well know, it is the lab's impact on the greater continuum of healthcare that matters. It is important for organizations to recognize the central role that laboratories can play in optimizing value-based care.

Establishing the relevance of the hospital's clinical laboratory is more important than ever before, especially as the integration of care delivery and the shift away from fee-for-service payment will become more urgent challenges for clinical laboratory managers and pathologists during 2020.

While selling the laboratory or entering into a managed services contract may seem prudent, such decisions will not solve core lab problems that include overutilization, low-value testing, inappropriate use of high-cost testing, and provider confusion over best test choice.

Chapter 2:

Critical Factors That Make Stewardship Work Toward Clinical Laboratory Value and Value-Based Initiatives

Hospital laboratory departments comprise 12% of total hospital ancillary department costs, according to a recent report from *Laboratory Economics* that is based on federal Hospital Cost Reports. The same report notes that the total hospital outreach testing market accounted for 19% of overall hospital revenue as of 2017.⁶

By retaining the medical laboratory and committing to effective stewardship through better laboratory test utilization, hospitals will positively affect not only clinical outcomes and financial performance, but ultimately the viability of the organization as a whole.

To understand the power and importance of “lab,” approximately 13 billion laboratory tests are performed annually by more than 200,000 clinical laboratories in the U.S.⁷ About 3,500 laboratory tests⁸ are commonly used to support upward of 70% of all medical decisions made by providers.⁹ Despite the laboratory’s critical role in diagnosis and treatment, lab testing as a percentage of total U.S. healthcare expenditures is expected to decline to 2.8% in 2020.¹⁰

Unfortunately, the ubiquity of testing—combined with low standardization and high variability among physician practices—results in chronic improper utilization of many routine tests. By some estimates, 10–25% of all hospital-performed laboratory tests in the inpatient setting are not indicated.¹¹ A recent European study found that two-thirds of reordered tests were either likely clinically unimportant or unnecessary.¹²

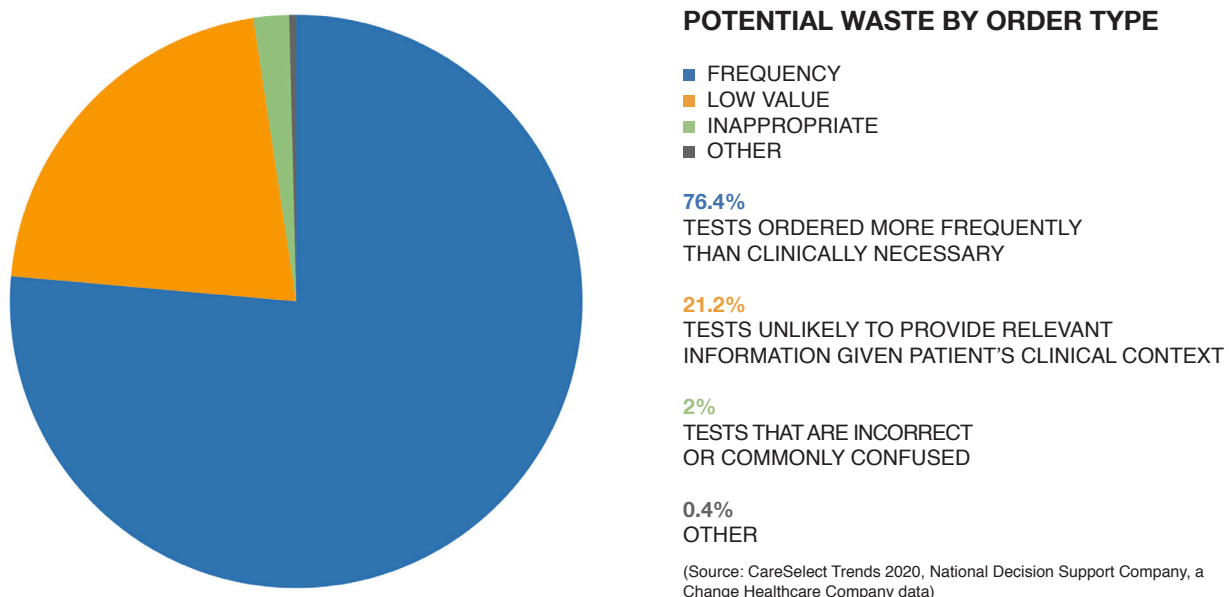
Recently collected data shows that 76.4% of all tests ordered are ordered more frequently than clinically necessary.

In order to serve in a developing value-based landscape, laboratories must invest in stewardship that extends beyond the walls of the laboratory and supports the value-based care mission across the organization. This broader definition of stewardship means that laboratories must do more than work to increase efficiencies within the lab, such as:

- Identify areas of waste that come to the laboratory, but that don't originate in the lab;
- Work within the organization to build waste prevention into laboratory test ordering processes and workflows; and
- Continue to refine and improve over time.

To address potential waste, good stewardship in the clinical laboratory addresses three major categories related to testing.

Downstream effects of good stewardship on the medical laboratory can include less spend on staff and resourcing, and more time to focus on outreach, innovation, and quality. Good stewardship registers positive impact on patient care, such as reduced time-to-diagnosis, better care coordination, more reliable identification of high-risk patients, and improved wellness screening and monitoring.



A recent study on waste in U.S. healthcare systems published in *JAMA* found that between \$76 billion and \$101 billion is wasted on overtreatment/overuse of low-value treatments and testing.¹³

Using an initial set of evidence-based guidelines, good stewardship addresses three major categories: frequency (tests ordered more frequently than clinically necessary); low value (tests unlikely to provide relevant information given patient's clinical context); and incorrect, commonly confused tests.

In response, medical laboratories should implement three critical stewardship functions into their operations:

1. Evidence-based, easily maintainable clinical guidelines.

Clear, respected, clinical guidelines help define which orders are appropriate and which are not. It is essential to understand appropriateness in order to identify waste.

2. Data that shows the current state of laboratory utilization at the organization. Good stewardship is data-driven; looking at the laboratory's data is how to identify waste and target interventions.

3. A way to track progress. Once specific areas of waste have been targeted, these areas will be monitored for changes.

These functions build the foundation for a decision support tool to assist the medical laboratory in eliminating waste. As such, evidence-based clinical decision support (CDS) will integrate with the electronic health record (EHR) and works by applying ordering guidelines at the clinician's point of order; indicates pass or fail of the order based on a patient's unique data; and indicates pass or fail based on the clinical context within which the order was placed.

Medical laboratory stewardship as a first step to navigating the medical laboratory value transition need not be daunting.

Decision support, as part of a stewardship program, assists the medical laboratory in eliminating waste. Clinical decision support (CDS) integrates with the electronic health record (EHR) and applies ordering guidelines at the point of order.

Chapter 3:

Good stewardship, through a clinical decision support tool, is designed to prevent unnecessary repetitive testing, provide test cost information at the point of care, and identify test-interfering substances.

Addressing Clinical Laboratory Waste Through Stewardship: 4 Core Categories and Early Results

To address waste, it is important for medical laboratories and hospitals to develop a detailed baseline of existing ordering volume by test type and clinician. While minimizing clinician impact, analytics divides data into four broad categories that show current utilization patterns and the resulting improvement.

TEST UTILIZATION PATTERNS MONITORED

1. **Frequency:** Designed to stop unnecessary repetitive test ordering;
2. **Value-based testing:** Designed to guide appropriate ordering;
3. **Cost information:** Provides generic cost information on selected tests at the point of care; and
4. **Interfering substances:** Identifies laboratory tests which may be affected by medications or over-the-counter drugs.

Once guidelines are in place, analytics used to track pass/fail percentages for orders will determine sources of potentially preventable waste. Intervening to reduce deviations from best practice steers laboratory workload and weeds out low-value, high-cost, and unnecessary testing that hinder success.

Extensive benchmarking and analytics tools integrated with the EHR enable organizations to compare provider ordering patterns, identify gaps in care, and develop organization-specific strategies to manage overall test utilization.

Successful laboratory stewardship strategies include organization-wide education on the importance of appropriate lab utilization, focused provider and department specific discussions based on utilization data, optimization of EHR workflow and build, and point-of-care clinical decision support.

Medical laboratories that have implemented a stewardship program centered on evidence-based clinical decision support have been able to identify, address, and reduce lab waste in their organization. Using point-of-care CDS, here's how:

- One intervention that eliminated clinicians' ability to electronically order daily reoccurring tests, for instance, **reduced per-patient, per-day tests** by up to 20% and cut hospital costs by \$300,000 over a two-year period.¹⁴
- A similar study limiting clinicians to ordering five common tests only once in a 24-hour period produced an **immediate 12% reduction in test volume and a sustained 21% decrease** in all inpatient laboratory draws through the following year.¹⁵
- By addressing over-ordering of four high-opportunity daily labs with education, targeted electronic health record (EHR) build changes, and CDS, one organization saw a roughly **20% drop in labs per discharge in their first month**. They also saw enough of a reduction in daily labs used for morning rounds that they were **able to reduce and/or redirect their lab staff during morning hours**.¹⁶
- A 1,500-bed hospital system in the Midwest has seen a **24% drop in inappropriate ordering** of two commonly confused specialty tests.¹⁷
- A 1,200-bed hospital in the Midwest **reduced inappropriate BNP orders by 33% in one month** by applying a frequency rule.¹⁸

This white paper is the first of a three-part series that is intended to assist clinical laboratories in rationalizing the laboratory's value and relevance in ways that support appropriate and high-quality patient care, fiscal strength, and program integrity for payers.

Conclusion

The evidence has grown in favor of CDS supported stewardship for retaining the benefits of an in-house laboratory while supporting the transition to value-based care.

A best-in-class lab stewardship program uses analytics to benchmark providers against evidence-based recommendations, analytics to identify utilization outliers, and data to inform a thoughtful change-management strategy. Armed with these tools, the medical laboratory can effectively be transformed into a strategic unit that drives clinical and financial value for itself and the organization it serves.

Increasing the clinical laboratory's value to a hospital organization does not begin by reducing or selling the lab. Rather, when laboratories take action to build value within the laboratory, the effort results in selling significant change to the organization in the form of a reinvented, reinvigorated, test-optimized lab.

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Developed by National Decision Support Company, a Change Healthcare company, CareSelect™ Lab is a decision support tool that integrates with leading electronic health record (EHR) solutions and aggregates clinical knowledge around a select menu of routine conditions. Its underlying clinical guidance includes more than 1,800 best practice alerts authored, curated, and maintained by Mayo Clinic physicians and scientists. The technology is an expansion of the CareSelect platform, which has facilitated over 30 million clinical decision support consultations at more than 500 health systems representing more than 3,000 acute care facilities nationwide.

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National Decision Support Company (NDSC), a Change Healthcare company, developed the CareSelect™ clinical decision support (CDS) platform to deliver medical guidelines at the point of order through integration with leading electronic health record (EHR) systems. CareSelect has been widely adopted by healthcare providers across the U.S. These guidelines help organizations comply with regulatory requirements, benchmark and reduce variations in care with the goal of improving care, reducing costs, and streamlining the payer and provider data exchange.

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