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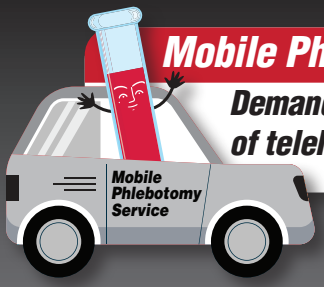

Mobile Phlebotomy on the Rise

Demand for service grows as use of telehealth services explodes.

See pages 3-5.

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

INSIDE THIS ISSUE

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Consumer Trends, Quality Management, and Labs

TODAY'S HEALTHCARE SYSTEM IS MARKED by uncertainty and unprecedented pressures. Every clinical laboratory and pathology group faces the triple whammy of shrinking budgets, staff shortages, and a rate of inflation that drives up the cost of supplies and salaries.

There are effective ways that labs can attack that triple whammy.

In this issue of THE DARK REPORT, you will read about a growing trend that is both a threat and opportunity to many clinical laboratories. It is consumer use of telehealth services and virtual physician visits. The threat is that consumers and patients using telehealth—and who may need clinical lab tests as part of that care—are redirected to other labs that partner with virtual care providers, thus causing your laboratory or pathology group to lose market share and revenue.

However, there is opportunity in that same situation. Your lab or practice can be proactive about establishing its own mobile phlebotomy service and leverage that to win new physician clients, along with consumers wanting to buy their own lab tests. *(See pages 3-5.)*

Another opportunity to cut costs is for your laboratory to consider simultaneous accreditations of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and ISO 15189: Medical Laboratories—Requirements for Quality and Competence. One lab in Texas did just that, and it has opened overseas markets for its testing because of its ISO 15189 accreditation, which is accepted in about 100 countries across the globe. *(See pages 6-9.)*

It's no coincidence that we follow the story about CLIA/ISO 15189 dual accreditation with an intelligence briefing about the value of Lean and Six Sigma methods to help labs cut costs and reduce errors while boosting quality. The link between the two stories is this: ISO 15189 is a quality management system that incorporates many of the principles of Lean and Six Sigma. There is also an added benefit lab leaders might not have considered: Using Lean Six Sigma may also improve employee retention through its quality measures that streamline work processes. *(See pages 10-13.)*

Collectively, the opportunities presented in this issue of THE DARK REPORT offer you ways to successfully address your lab's major challenges—with the added benefit of keeping your lab ahead of its competitors. TDR

Telemedicine Firms Offer Home Phlebotomy Service

Following virtual doctor visits, home blood draws are a way to provide more convenience to patients

CEO SUMMARY: Telemedicine provider Teladoc Health has announced new services for certain primary care customers that include at-home phlebotomy appointments. The move is evidence of the consumer demand for increased convenience and flexibility in their healthcare. Scarlet Health, a division of BioReference Laboratories, will handle the on-demand phlebotomy arrangements for Teladoc Health.

In July, TELADOC HEALTH announced it was adding home phlebotomy draws to what it calls its "virtual primary care platform." Adding interest to this development is that **Scarlet Health**—a business unit of **BioReference Laboratories** that launched in January 2021—will provide home phlebotomy services to Teladoc Health.

Teladoc reports that its membership is 56.6 million people and it delivers about five million telehealth visits per quarter. It has more than 10,000 providers in its network and the company projects revenue of $2.4 billion for 2022. In 2020, it paid $18.5 billion to acquire **Livongo**, a company that provides diabetes monitoring and other types of health monitoring.

The actions by Teladoc to add home and workplace patient collections to its app is evidence that consumers want this service. This is the latest marketplace confirmation that consumer and patient acceptance of virtual physician visits and telehealth consultations is generating demand for phlebotomy and specimen collection services that come to the homes or workplaces of consumers and patients.

For several years, THE DARK REPORT has signaled clients and regular readers that the newest generation of consumers would be accessing healthcare differently than their parents and grandparents. That included use of virtual doctor visits and telehealth services.

This is now becoming reality. More evidence of consumer demand for phlebotomy services that come to the home or workplace is the rapid growth of a California-based mobile phlebotomy company called **Getlabs**. Founded in 2018, the

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company services are used by **Labcorp**, **Quest Diagnostics**, and **Sonora Quest Laboratories**, along with other lab clients.

Getlabs is enjoying explosive growth. It operates mobile phlebotomy services in 25 states plus the District of Columbia and is expanding into other states. Earlier this year, it closed on a $20 million Series A financing round. Among the investors are Labcorp, Anne Wojcicki (co-founder and CEO of **23andMe**), and her sister Susan Wojcicki (CEO of **YouTube**).

In recent years, several companies and labs begin providing phlebotomy services to consumers in their homes and workplaces. The Teladoc Health/Scarlet Health arrangement is simply a recent example.

Long-time readers of THE DARK REPORT remember our coverage of one of the first "mobile phlebotomy services" offered to the public. In October 2019, the clinical laboratory division of **Northwell Health** launched its LabFly mobile phlebotomy service. *(See TDR, "COVID-19 Patient? Northwell Has Mobile Phlebotomy App," Mar. 9, 2020.)*

The Northwell Lab created a mobile app that patients and consumers could download and use to arrange a specimen collection at their homes and workplaces. LabFly currently charges $27.99 per visit and will perform up to three collections during one stop. The service is offered in the areas served by Northwell Health hospitals and physician clinics, mostly on Long Island and in New York City.

Draws Ordered via App

Teladoc intends to use its app as the primary vehicle to allow consumers to request phlebotomy services to collect lab specimens at their homes or workplaces.

The app Teladoc offers is called Primary360, and the new services being added to the app include:

- In-network referrals and care coordination capabilities.
- Same-day prescription delivery.
- On-demand home phlebotomy appointments in conjunction with Scarlet Health.

Teladoc views at-home blood draws as beneficial for patients who lack reliable transportation to a hospital, clinic, or physician's office, and who want a more convenient option.

"Our traditional care delivery models are not meeting the modern-day experience consumers expect," said Kelly Bliss, U.S. Group Health President at Teladoc Health. Bliss' comments came via email from Teladoc in response to questions from THE DARK REPORT.

"Travel time and expenses, crowded waiting rooms, and repetitive paperwork are all disincentives to complete follow-up recommendations within a traditional system," Bliss added. "Virtual care has emerged as a path forward that not only provides a full spectrum of healthcare needs, but seamlessly blends the virtual and physical components of care."

Lab Order Completion Rate

Scarlet Health is a division of BioReference Laboratories in Elmwood Park, N.J., Teladoc reported that during a pilot trial with Scarlet of the at-home phlebotomy services, laboratory order completion rates for patients jumped up 22.5%.

That figure is significant because there are many factors that can lead patients to discontinue lab orders, such a driving distances, time wasted sitting in a lab's waiting room, or the inability to travel.

"Many consumers may forego lab or blood work due to these circumstances, which doesn't just impact completion rates but ultimately health outcomes," Bliss said. "On-demand phlebotomy allows patients to realize the full benefits of whole-person care, and we see more members following through on completing these orders because the access to specimen collection services is more flexible and convenient."

BioReference started Scarlet in January 2021 as an in-home digital platform to access on-demand diagnostic services. The timing of that launch is seen by some clinical lab professionals in the New York area as a competitive move in response to how patients

and consumers responded to Northwell Health's LabFly app.

There is a further point of interest. Some lab managers noted that the SARS-CoV-2 pandemic generated an immediate demand by consumers willing to pay for at-home COVID-19 specimen collection. This was about more than convenience, they said. By having their specimen collected at home instead of a public collection site, consumers minimized their risk of exposure to the coronavirus.

In the Scarlet arrangement, on-demand phlebotomy works as follows: After visiting a physician face to face or virtually, the patient receives a Scarlet link that lets that individual schedule an in-person appointment to draw the specimen at a convenient location, such as at home or a workplace. Specimens are sent to BioReference for testing and the results are shared online with the patient and ordering physician.

The new partnership with Teladoc will give both companies a chance to tout their respective features while capitalizing on growing awareness and use of telemedicine among healthcare consumers.

Access to Healthcare

Prior to the pandemic, demand for virtual office visits and telehealth consults was limited. Thus, clinical laboratories were under no market pressure to offer their own mobile, on-demand phlebotomy service. The COVID-19 pandemic opened new doors in that regard.

"COVID-19 educated consumers as to new and different ways to access medical care and the clinical laboratory tests they needed," observed Robert Michel, Editor-in-Chief of THE DARK REPORT, who spoke on the topic during April's *Executive War College Conference on Laboratory and Pathology Management*.

"The acceptance of telehealth visits was substantial," he added. "For example, the number of adults who used telemedicine jumped 400% from December 2019 to June 2020, according to a study done by **CivicScience**."

How Many At-Home Blood Draws?

TELADOC HEALTH IS SILENT on how much demand it expects for at-home phlebotomy visits over the next 12 months. However, U.S. Group Health President Kelly Bliss noted that spreading the word about the service will be vital to its success.

"It's difficult to forecast how many of our members will choose to make use of this service," Bliss explained. "For most, access to this level of flexibility when completing care recommendations has never been available, so we can predict that consumer awareness will be a key variable in volume growth over the course of this year."

Further, among adults with a child in the household, 19.7% of respondents reported that their kid had used telehealth in the prior four weeks, the U.S. Office of the Assistant Secretary for Planning and Evaluation noted in a report published in February 2022.

Because so many primary care visits result in the physician ordering clinical laboratory tests for their patients, the increased use of virtual doctor visits naturally generates the need for the patients to provide a specimen for clinical laboratory testing. It is this documented demand for mobile phlebotomy services that confronts clinical labs with both a dilemma and an opportunity.

The dilemma is knowing when a lab should offer on-demand phletobotomy that comes to home and workplaces. Existing client physicians are seeing more of their daily patient visits virtually. Many of these patients would prefer to pay for a home or workplace draw, rather than driving across town to a patient service center.

The opportunity is for clinical labs to add mobile phlebotomy to their service mix. This will help them retain existing client physicians while positioning themselves to serve consumers who want to order their own tests (where state laws permit it). TDR

Texas Lab Details Dual Accreditation Journey

Existing quality processes go a long way to help satisfy CLIA and ISO 15189 accrediting requirements

Tamara Kirby

***CEO SUMMARY:** In seeking dual accreditation for CLIA and ISO 15189, Advanced Diagnostic Laboratory of San Antonio adapted existing processes to meet accreditor expectations. The result was stronger staff empowerment to suggest improvements in quality, combined with increased recognition of the clinical laboratory's testing capabilities in global markets.*

For clinical laboratories interested in pursuing business in the global lab market, obtaining both U.S. and international accreditations can be advantageous. Why? Though meeting Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements is mandated for U.S. labs, those regulations mean less in other countries.

Instead, ISO 15189—Medical laboratories: Requirements for Quality and Competence, holds greater sway outside the American market. ISO standards are published by the **International Organization for Standardization**, based in Geneva, Switzerland.

Dual Lab Accreditation

Advanced Diagnostic Laboratory (ADL) in San Antonio accomplished both accreditations simultaneously through the deeming authority **American Association for Laboratory Accreditation** (A2LA) earlier this year. Tamara Kirby, Lab and Quality Manager at ADL, provided insights into the process of obtaining accreditations for the two standards during a presentation at April's *Executive War College Conference for Laboratory and Pathology Management*. The session was titled, "Benefits and Key Lessons Learned after Accrediting Our Laboratory to Both CLIA and ISO 15189."

"As we branch out into other testing, we're partnering with companies in Europe on that testing," Kirby noted. "Having the ISO 15189 accreditation—something that everyone understands outside the U.S.—has been beneficial."

In broad strokes, in the United States, CLIA requires clinical laboratories and pathology groups to be certified to perform testing on human specimens. Meanwhile, ISO 15189 is the globally-accepted standard that specifies requirements for quality and competence in medical laboratories.

There are similarities between the two standards, but also notable differences in documentation and personnel needs.

"CLIA, having more of an analytical specific focus, mentions accuracy, reliability, and specific conditions that labs have to meet," Kirby said. "ISO 15189 has a broad focus on quality: quality and competence for testing, having a management system, monitoring and evaluating the quality system, and then a focus on constant improvement."

Across the world, ISO 15189 is increasingly becoming a widely-acknowledged accreditation for clinical labs. Because ADL provided global testing from the day it opened in July 2020, it needed ISO 15189 accreditation from the beginning.

For labs interested in pursuing dual accreditation to both CLIA and ISO 15189, Kirby suggested spending some time reviewing the two standards, becoming familiar with the specific lingo of each one, and identifying ways in which they can be consolidated instead of treating them as two separate entities.

"Previously, I worked in another lab that looked at CLIA and the ISO standard independently and had different procedures for both," she noted. "It's not a pleasant way to do it. It is very hard to keep up with them, and lab staff must deal with a lot of duplication. The more the lab can integrate the two standards, the better."

Quality Improvement Tactics

Kirby referred to quality improvement as the "big kahuna" of ISO 15189. Other clinical laboratories that pursued ISO accreditation also mentioned this observation to THE DARK REPORT. *(See TDR, "Achieving CLIA, ISO 15189 at Same Time with A2LA," Feb. 7, 2015.)*

Under CLIA, labs must have written procedures for monitoring, assessing, and correcting any problems in the lab. The regulation also requires review and staff discussion of the effectiveness of any corrective actions.

However, ISO 15189 puts more emphasis on developing a system of prevention supported by continuous improvement. The standard requires internal audits, management reviews, quality management system evaluations, and risk assessments.

Kirby observed that quality monitoring requirements for both standards can be smoothly implemented into a laboratory's existing culture. As a first step, it is important to discuss the organization's goals with staff and reiterate why the lab will benefit from having both CLIA and ISO 15189 accreditations.

"Many of your lab's existing procedures can be enhanced to cover both standards, so don't feel the need to start over with existing procedures," Kirby explained. "Look for ways to implement the processes into your lab's current flow.

"Adding 15189 doesn't have to be an overhaul," she continued. "Your lab is already doing many quality processes. Think of your lab's regular meetings and documentation that's already in use. Then simply create tools to make it easier for your lab staff to remain on top of things."

To ensure the dual accreditation process was seamless at ADL, the laboratory team held department and management meetings as needed. Tasks were combined and staff was encouraged to submit ideas and suggestions.

ADL also created a quarterly quality assessment tool that included many of the elements required by CLIA and ISO 15189. "Each quarter, we evaluate a different part of our quality system," Kirby said. "This has become one of the best aspects of our meet-

A2LA Dual Accreditation Recognized Worldwide

ADVANCED DIAGNOSTICS LABORATORY received its dual CLIA and ISO 15189 accreditation from deeming authority **American Association for Laboratory Accreditation** (A2LA). A2LA is a signatory to a mutual recognition agreement with the **International Laboratory Accreditation Cooperation** (ILAC). This means an A2LA accreditation is accepted by other ILAC-accredited labs worldwide.

The **College of American Pathologists** (CAP) also offers CLIA and CAP 15189 accreditations. Currently, CAP is not shown as a signatory on the websites of ILAC or the **InterAmerican Accreditation Cooperation** (IAAC).

ings, as people bring ideas or concerns they have as they go about their jobs.

"We also do vendor evaluations as part of this process," she added. "We review them each quarter. The next review for that particular vendor is then scheduled, usually between six and 12 months depending on how frequently we use that vendor."

Evaluating the Lab's Systems

ADL utilized existing meetings to help fulfill the management review requirements of the accreditations. The lab continues to have quarterly assessment meetings and designates one of those meetings each year as a full management review meeting.

"We simply adapted our existing meeting times to cover these new requirements," Kirby said. "And just to clarify, we try to keep our meetings very concise and very productive because nobody wants to have meetings just to have meetings."

Kirby added that the quarterly assessments typically last about an hour. Annual management reviews last from one to two hours. "Ultimately, your laboratory must decide how these requirements fit into what your lab is doing," Kirby noted. "It's important that these meetings are not simply to check off boxes, but something that's going to serve your lab's quality processes."

Attributes of Quality Manager

Quality management with ISO 15189 has the requirement to have a laboratory quality manager, something CLIA does not mandate. However, CLIA and ISO 15189 do intersect in their directives for medical laboratories to employ a lab director.

When selecting someone to serve as the laboratory quality manager, Kirby proposed that labs look for the following attributes:

- Ability to control situations and not let situations control them.
- Knowledge of and experience in the clinical laboratory industry.
- Creativity.
- Capacity to solve problems as they arise.
- Decisiveness.
- Openness to listen to ideas and suggestions from other staff members.
- Integrity.

ISO 15189 also requires labs to have a quality manual with a distinct hierarchy of policies that illustrate the lab's procedures, descriptions of how tasks are to be performed, and documentation of what has been done. Kirby explained that writing ADL's quality manual was the most time-consuming part of the process.

"We basically took the ISO 15189 standard and went through it step by step to write our quality manual alongside it," Kirby said. "As we came to each step, we would write a procedure for it."

Further, ISO 15189 requires the following: a risk assessment; evaluation of vendors and referral labs; management review; and job descriptions for the positions within the lab.

For personnel, CLIA has stringent guidelines regarding education and technical experience, while ISO 15189 has more general provisions. The two standards have different but complementary requirements regarding documents and records.

"Both standards give requirements for the content of procedures, but ISO 15189 also provides explicit directions on how to label documentation to include information such as title, page number, a unique identifier on each page, version numbers, and date of use," Kirby said.

Documentation Requirements

"Each standard also defines steps for record retention and documentation," she added. "However, ISO 15189 provides a longer list of terms, including information such as supplier selection records, lab notebooks, quality control records, incident reports, and risk assessments."

On the subject of purchasing and lab test referrals, CLIA includes provisions governing where items may be acquired and states that labs must use a CLIA-certified lab or an equivalent for test referrals. In contrast, ISO 15189 declares that

labs must have a documented procedure on how to select and purchase services, equipment, reagents, and supplies.

ISO 15189 also includes a standard requiring labs to have an approved vendor list, along with procedures for selecting those vendors, then monitoring their performance. For lab referrals, ISO 15189 requires labs to have detailed procedures for selecting and evaluating outside labs and to execute periodic reviews of those external labs.

"ISO 15189 requires more substantial procedures and records for these processes, so this is a good example of how ISO 15189 enriches and adds details to CLIA," Kirby explained. "Of course, that can also be looked at as more things to do, but as long as your lab team develops ways to work it into regular work processes, it does bring benefit in how your lab conducts business."

Key Takeaways for Labs

Prime benefits that Kirby identified from the dual accreditation to both both CLIA and ISO 15189 include:

- Having global recognition for the quality of its testing and acceptance of its test results.
- Becoming preemptive in its processes.
- Obtaining a focus on what can be improved in the lab.
- Empowering staff to look for ways to make improvements.
- Encouraging employees to express their ideas and constructive suggestions.

Kirby also said that one of the greatest benefits to ADL's ISO 15189 accreditation turned out to be the required risk assessments. "We are identifying concerns and addressing them before they become problems," she declared. "More importantly, we are addressing these items before they become nonconforming events.

"We address things like lack of clarity in our procedures and inconsistencies in our processes, and we recognize areas of risk where there is not a current protection in place," she explained. "This is why the risk assessment has become a very important part of our ongoing discussions in the lab."

Kirby endorsed obtaining both CLIA and ISO 15189 certifications. Labs can take on the process without feeling overwhelmed. "Don't fall prey to the idea that you have to have everything perfectly in place before you start the process," Kirby suggested.

"It's a learning process and—as ISO 15189 requires—it is an ongoing improvement of quality," she concluded. "Overall, I believe this is a very achievable dual accreditation, and it can be very beneficial if your lab gives full attention to its implementation." TDR

Contact Tamara Kirby at tamara@adl-health.com.

Lab's Testing Capabilities Enjoy International Reach

ADVANCED DIAGNOSTICS LABORATORY (ADL) OPENED IN JULY 2020 during the early stages of the SARS-CoV-2 pandemic with the intent of providing a broad range of testing services for doctor's offices, hospitals, and clinics.

"When the lab initially opened, it did not plan on doing COVID-19 testing, but quickly pivoted to performing rapid antibody and PCR testing for both home collection and a drive-thru mobile site in San Antonio," stated Tamara Kirby, Lab and Quality Manager at ADL.

By the end of 2020, ADL had performed COVID-19 testing on nearly 15,000 samples, and it completed approximately 65,000 of those tests in 2021. Most of its COVID-19 testing has been performed in the U.S., but the lab has also done travel testing in more than 20 other countries, including Australia, China, and Canada.

In Q4 2021, **EKF Diagnostics**, a global medical diagnostics company headquartered in Cardiff, Wales, U.K., purchased ADL. The acquisition positioned ADL to rapidly expand its testing capabilities nationally and globally.

Lean Is Smart Approach to Major Lab Cost Savings

By engaging staff, Lean methods also improve morale and potentially increase employee retention

Rita D'Angelo

CEO SUMMARY: It's a time when clinical labs are under extreme pressure to cut costs, even as they deal with understaffing. One proven approach to reducing expenses while preserving quality is to apply Lean methods in conjunction with Six Sigma tools. It is often true that successful use of Lean to streamline workflow engages lab personnel in ways that help staff retention.

CUTTING COSTS IS NOW A MAJOR PRIORITY AT CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS throughout the United States. The challenge is how to reduce expenses by substantial amounts while sustaining quality in all aspects of the lab's operation and clinical service mix.

There is a powerful cost-cutting secret in use by savvy lab managers in labs both large and small. It is the use of Lean methods—distinct from Six Sigma tools. Effective deployment of Lean in a clinical lab can produce swift and substantial reductions in lab costs while at the same time reducing or eliminating systemic errors (that increase lab costs) and raising the quality of services.

It has been almost 20 years since pioneering labs and hospitals began to implement Lean and Six Sigma methods. While some organizations made it their goal to not only implement Lean, but to infuse a permanent culture of continuous improvement and system of prevention, there were other labs and hospitals that used Lean Six Sigma on a per-project basis, without attempting to change the existing culture.

This background is important because it sets the stage for those clinical labs and pathology groups that have an urgent need to cut costs by a large amount, but are worried about cutting quality at the same time.

This is to remind those lab managers that Lean, as developed by Taiichi Ohno of **Toyota** and others, is designed to be a *fast*, *low-cost approach* to savvy cost cutting. By contrast, basing an improvement initiative using primarily a Six Sigma philosophy is usually a more deliberate, slower approach that focuses on driving down the variation in work processes, thus producing higher quality outcomes at a lower cost.

Today most labs face higher supply costs, increased labor costs, and a shortage of enough skilled staff to accomplish daily test volumes without paying overtime or using temporary medical technologists. It is apt to observe that these are "desperate times" and there are lab administrators desperate to drive down costs in their lab.

One expert who is hands-on helping labs deploy Lean methods to maximum effectiveness is Rita D'Angelo, PhD, owner of **D'Angelo Advantage** in Rockwood, Mich. D'Angelo founded her

company in 2013 to offer consulting and training for healthcare organizations. She previously spent nearly eight years as Manager of Quality Systems for Pathology and Laboratory Medicine at **Henry Ford Health** in Detroit.

D'Angelo is also the instructor for THE DARK INTELLIGENCE GROUP'S 2-day *Lean Six Sigma Boot Camp for Clinical Labs*.

"Many lab managers will be surprised to learn that a well-executed Lean initiative will actually help with two problems," D'Angelo observed. "Its first and immediate benefit is to generate significant cost savings that compound and continue growing over time.

"The second benefit to labs is that the introduction of Lean methods—including continous improvement—makes staff feel a part of the whole and makes them feel like they're contributing" she noted. "Streamlining work processes reduces stress and that directly improves retention of staff."

Lean and Six Sigma Defined

D'Angelo uses a Lean Six Sigma model that emphasizes the speedy improvements that Lean methods deliver, complimented by appropriate use of Six Sigma tools. A prime example is the use of three-day or five-day kaizen events to identify opportunities, implement opportunities, and assess the success of those improvements over the course of the kaizen event.

D'Angelo briefly described these methods during the DARK DAILY webinar, "Improving Clinical Lab Performance: How Lean Six Sigma Methods Help Eliminate Waste, Save Money, and Increase Productivity."

To start, Lean is a systematic approach to identifying and eliminating waste. A typical example of waste comes from D'Angelo's own lab experience: "If our lab lost a biopsy, we'd go into the biohazard closet where we kept months of biohazard waste. We'd haul out those bags and spend days finding the lost biopsy. This

Five-Step Program to Decrease Waste

LEAN SIX SIGMA uses a five-step approach to eliminate waste. An acronym sums up this process: DMAIC, or Define, Measure, Analyze, Improve, and Control. Let's explore the elements of DMAIC in more detail:

- **Define** centers on discovery. "Maybe somebody hands off a problem to you," said Rita D'Angelo, PhD, owner of D'Angelo Advantage. "You need to understand how the problem happened and where it happened." The result is a problem statement and ideally a map that shows each step in the relevant process.
- **Measure** involves collecting relevant data, such as hold times for patients on a call center line. "What are we going to collect? How are we going to collect it? Where are we going to collect it? And who's going to collect it?" she asked. This gathering of information needs to be formalized as a plan because eventually it is shared with the entire team assigned to address the issue.
- **Analyze** digs at the root cause of a problem, such as why the patients are waiting so long for their call to get off hold. "We might create a fishbone diagram, which identifies causes of a problem," D'Angelo explained. "We'll brainstorm with our team. We'll run statistical tests."
- **Improve** involves redesigning an existing process or putting a new one in place. Then, the team pilots the new approach in a simulation to see how it works. "If it's a great fit, perfect, we'll validate it," she said.
- **Control** brings the new process to an "owner"—in other words, the person responsible for enforcing it. "We will work with the new owner to ensure that this will not fail and that they're monitoring it, maybe with a quality control chart," she noted.

is waste that doesn't add value to the lab. Nobody pays for it."

In differing from Lean, Six Sigma is a statistical methodology for identifying and reducing defects and process variations. "A Six Sigma organization has work processes that generate only 3.4 defects per one million opportunities," D'Angelo explained.

"The Six Sigma tools help identify variation and sources of errors so we eliminate them," she continued. "As such, it's a data-driven approach. Decisions are not based on opinion. Rather, we collect the data and analyze it."

A laboratory call center provides a simple example: Patients might complain about waiting too long on hold. Suppose an analysis reveals that wait times for about half the calls are six to eight minutes, but the lab has a customer service requirement that patients not wait any longer than three minutes.

"Using Six Sigma tools, I can explore the problem," D'Angelo said. "A lab would investigate the cause of the wait times through observation and a root cause analysis, with the goal of eliminating the defect. Six Sigma is a measure for quality. We strive for near perfection."

These examples demonstrate how Lean methods and Six Sigma tools are combined, with the common element that data is gathered and used to identify and eliminate waste.

Dissecting Lab Processes

Employees in clinical laboratories and pathology practices play a critical role in the success of Lean Six Sigma efforts to identify inefficiencies.

"Where are defects occurring? What happens daily when something goes wrong and the lab is constantly putting out fires?" D'Angelo asked. "Nobody knows this better than the staff, and that's who we consult with to identify waste in their areas of the lab."

This, she said, involves observing a lab process from start to finish. It might begin where specimens are collected, after which a courier delivers the specimens to the lab, where they go into a centrifuge and then to testing and interpretation.

The goal is to discover what happens at each stage, she added, ultimately resulting in a "process flow" where the laboratory identifies bottlenecks and other inefficiencies.

"Then we can work to eliminate some of these events or defects from happening," she said.

Fixing Problems Immediately

Curiosity serves Lean Six Sigma well, D'Angelo notes.

When advising clients, "we'll go to the workplace and ask the staff, 'How do you do your work?' This is a simple question. But we learn a lot when we ask these questions," she observed. "How do staff know their work is correct? Once they pass it off, how do they know that it's defect free? What if it's not defect free?"

D'Angelo points to an example at **Ford Motor Company** manufacturing plants. As cars come off the assembly line, vehicles with defects are diverted to a quality control area for repair. The lesson from Ford? "Build a culture to fix problems immediately," she said.

Such thinking applies to labs as well and starts with small but effective changes.

"In anatomic pathology labs, if pathologists find errors, they can fill out a short form, place that form with their slides, and put the slide in a bin," she explained. "Then the person who delivers the slides picks up that form, fixes whatever is wrong, and puts the slide back into service."

Simple, Effective Changes

D'Angelo described another lab that discovered inefficiencies related to courier specimen pickups.

Deliveries came in at 12:15 p.m. and 6:20 p.m., leaving a large gap in the afternoon in which specimens were not being tested. That setup led to bottlenecks at night for laboratory staff.

So, the lab added a pickup time while also working with clinics to get their specimens earlier in the day. "It was a simple, but very successful, improvement," she noted.

D'Angelo advised labs to assemble a core team, preferably consisting of volunteers so people don't feel left out if they want to help.

Key roles include "champions" who ensure that the team has adequate support and resources, "executives" who have the authority to approve actions, "coaches" who teach and guide other members, and "process owners" who enforce successful outcomes.

Using this team structure can lead to better staff morale because employees feel more engaged with their work, D'Angelo explained.

Helping Retain Lab Staff

As THE DARK REPORT has noted previously, one way to retain more clinical laboratory staff during the "Great Resignation" is to provide workers—particularly younger members of the staff—with a sense of purpose and community in their jobs. *(See TDR, "'Lab Workforce Crisis Takes Top Spot–CAP Today," April 25, 2022.)*

"Give your lab team members a project where they can participate and feel good about themselves," she added. "They can work toward eliminating all this waste and inefficiency.

"At the same time, we want to stay away from groupthink," in which the process is driven by opinion, she advised. "Six Sigma is a data-driven approach, and we really can't make change unless we understand what the true problem is."

For clinical laboratory directors and pathologists, Lean Six Sigma works in an area they are familiar with—data collection—to uncover process flaws that can lead to improved efficiency. Labs looking to gain a competitive edge will gain value in taking a Lean Six Sigma approach. TDR

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How Much Can Labs Save with Lean? Plenty!

IT WAS IN 2003 WHEN THREE MAJOR HOSPITAL LABORATORIES WERE FIRST IN THE NATION to use Lean methods to reconfigure the layout and workflow in their high volume core labs, involving primarily chemistry, immunoassay, and hematology.

Each project was a total makeover of the core laboratory. The lab administrators at these three large hospitals were taking a huge risk, because no other lab in the United States had applied Lean methods in such a dramatic, all-encompassing fashion.

The three pioneering labs were **Naples General Hospital** (Naples, Fla.), **Fairview Health** (Minneapolis), and **Jackson Memorial Hospital** (Jackson, Tenn.). Each engaged the **ValueMetrix** Division of **Ortho-Clinical Diagnostics** to lead the Lean project. It was a three-month process to make the changes in the core lab and the outcomes were remarkable.

When interviewed by THE DARK REPORT, the three lab administrators reported impressive gains. The 12-week Lean project allowed them to slash turnaround times by 40% or more. Errors were reduced by 38% to 45%. Staff productivity skyrocketed by 35% to 46%. *(See TDR, Sept. 8, 2003.)*

To give these accomplishments more context, prior to this Lean makeover of their core labs, these three lab leaders were confident that their labs were operating at maximum efficiency. They expected gains in the range of 10% to 15%. Thus, the 40% gains in TAT, error reduction, and staff productivity in just 12 weeks made them the envy of the lab industry.

At a time when pressure to cut costs is intense, all lab managers should consider using Lean and Six Sigma methods. This is a proven and speedy way to realize lower costs and better quality.

Legal Update

Attorney Advises Labs to Track Genetic Test LCDs

Cardiovascular genetic testing raises fraud-related concerns when coupled with telemedicine services

Danielle Tangorre

CEO SUMMARY: Skyrocketing numbers of genetic test referrals and telehealth claims since 2016 are getting the full attention of both federal prosecutors and auditors from Medicare and private health insurers. The DOJ has filed criminal cases against a growing number of telehealth providers. Genetic testing lab companies are often charged in the same criminal cases.

Clinical laboratories performing genetic tests based on test orders generated from telemedicine consults may find themselves at higher risk of payer audits and even federal prosecution. That's becoming a common element in a growing number of federal criminal fraud indictments.

"Prior indictments in years past have mentioned telemedicine, but haven't truly focused on it," said Danielle Tangorre, JD, a partner at law firm **Robinson & Cole LLP** in Albany, N.Y. "That's changed, because with these new federal indictments, there's this common thread of telemedicine. And then it just spawns out from there to include clinical laboratories and others. That speaks volumes to the government's focus. So, I think this is just the start of the indictments that we're going see in the telemedicine space that also ensnare clinical labs providing lab tests to telemedicine providers."

In some of the investigations, which The Dark Report details on pages 16-18, the **U.S. Department of Justice** (DOJ) alleged that a slew of defendants defrauded the federal government by ordering or referring medically-unnecessary genetic cardiovascular lab tests for patients. Often, these alleged actions occurred via telemedicine visits.

Genetic Testing Concerns

Though it is not clear what prompted the DOJ's investigations into genetic tests, Tangorre pointed to clues in a report published in December 2021 by the **Office of Inspector General** (OIG) of the **U.S. Department of Health and Human Services**. That report chronicled the rise in referrals and payments for genetic tests from 2016 through 2019. For example, Medicare payments for genetic tests quadrupled during that 48-month period, to $1.4 billion in 2019.

In a press release about the indictments, the DOJ characterized fraudulent cardiovascular genetic testing as a "burgeoning scheme" in healthcare fraud.

Tangorre said she suspects such testing has further risen in volume since 2019. "Notably, the OIG report detailed some testing related to the cardiovascular disease profile," she observed. "We don't know current volume of that testing

because the same data hasn't been published from 2020 to now. But with the DOJ saying cardiovascular genetic testing fraud is a 'burgeoning scheme,' the question is whether such tests have now topped some of the other cancer genetic testing that was previously on the list."

Tangorre noted that it would be wise for clinical laboratories to monitor local coverage determinations (LCDs) for genetic services, particularly LCDs made by Medicare Administrative Contractors (MACs) about genetic tests.

Coverage Determinations

"Labs need to keep on top of the coverage determinations," Tangorre warned. "In the infectious disease testing space, an LCD went into effect recently which lists specific criteria for who can order the test. The same might happen for a cardiovascular test that's under review. These LCDs include specific criteria for when the test is appropriate and when it's medically necessary."

For example, proposed LCD DL39082—which covers genetic testing for cardiovascular disease—lists restrictions, including that such a test is not considered medically necessary for asymptomatic patients.

Tangorre said laboratories also should consult a new Special Fraud Alert, "OIG Alerts Practitioners to Exercise Caution when Entering into Arrangements with Purported Telemedicine Companies." Released on July 20, the OIG alert outlines seven characteristics of telemedicine that might point to fraud. *(See the sidebar for more details.)* "Looking at the suspect characteristics is a great way for labs to review compliance," Tangorre said.

"In the Special Fraud Alert and the criminal indictments, the OIG has flagged tests that physicians ordered without patient interaction or with only brief telephonic conversations," she said. "Labs must ensure that when they submit the bills and attest to the accuracy of the billing, that the test has been properly ordered." TDR

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Seven Characteristics of Telemedicine Fraud

OUTLINED IN THE FEDERAL GOVERNMENT'S RECENT SPECIAL FRAUD ALERT about telemedicine are seven characteristics that may suggest a heightened risk of fraud:

- Purported patients for whom a practitioner orders services were identified or recruited by a telemedicine or telemarketing company, sales agent, recruiter, call center, health fair, or through internet, television, or social media advertising for free or low, out-of-pocket cost.
- A practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the services ordered.
- A telemedicine company compensates a practitioner based on the volume of services ordered, which may be characterized to the practitioner as compensation based on the number of purported medical records that the practitioner reviewed.
- A telemedicine company only furnishes services to federal healthcare program beneficiaries and does not accept insurance from any other payer.
- A telemedicine company claims to only furnish services to individuals who are not federal healthcare program beneficiaries but may in fact bill federal healthcare programs.
- A telemedicine company only furnishes one product or a single class of products (e.g., only genetic testing), potentially restricting a practitioner's options to a predetermined course of treatment.
- A telemedicine company does not expect practitioners to follow up with purported patients, nor does it provide practitioners with the information required to follow up with purported patients (i.e., the company does not require practitioners to discuss genetic testing results with each purported patient).

Regulatory Update

Feds Target Genetic Test and Telemedicine Fraud

Latest charges from DOJ allege four lab owners fraudulently billed $463 million in unnecessary tests

Medicare fraud totaling $562 million in genetic and cardiovascular tests is at the heart of recent federal criminal cases involving telemedicine that names clinical laboratory owners, physicians, and healthcare marketers as defendants.

A host of indictments were announced on July 20 by the **U.S. Department of Justice** (DOJ). The 13 defendants collectively are accused of fraudulently billing for tests and paying related kickbacks.

For leaders of clinical laboratories and pathology practices, the court documents outline the efforts that some lab owners allegedly take to evade complying with **Medicare** rules.

The charges also paint a clear picture about the current focus of federal prosecutors when it comes to clinical lab test fraud. *(For more analysis on these cases, see "Attorney Advises Labs to Track Genetic Test LCDs" on p. 14.)*

An important point to note: Medicare only covers genetic tests for diagnostic purposes in limited circumstances, such as when the testing is order by a physician to treat a patient's condition. Medicare does not cover genetic testing done for predictive purposes.

Of interest is fraudulent billing of $463 million allegedly directed by just four laboratory owners. Two of the cases involve not just genetic testing, but also telemedicine. It shows how alleged fraudsters are using virtual consultations as the triggers to large volumes of inappropriate lab testing. Details of this case follow.

Telemedicine Docs Sign Off

Jamie McNamara, 47, of Lee's Summit, Mo., was indicted on nine counts of healthcare fraud and related conspiracy, three counts related to paying kickbacks, and six counts of money laundering.

According to the indictment, McNamara was "beneficial owner" of four labs in Orleans Parish, La., and Harris County, Texas. The DOJ termed these establishments collectively as **McNamara Labs**. A beneficial owner holds shares in a company indirectly, such as through a bank. McNamara also operated three marketing firms in Missouri.

From November 2018 to July 2020, McNamara Labs allegedly submitted $174 million in false claims for cancer and cardiovascular genetic testing that was not medically necessary. Of these claims, Medicare reimbursed $55 million.

McNamara Labs did not perform genetic tests. "Instead, the McNamara Labs referred the specimens collected to other reference laboratories that actually performed the tests, and the McNamara Labs billed for the tests performed," according to the indictment.

The DOJ has prosecuted organizations for using similar arrangements, often referred to as pass-through billing. *(See*

Federal Prosecutors Name Defendants in Telehealth/Genetic Testing Fraud Case

FEDERAL PROSECUTORS NAMED other defendants in the $562 million criminal case:

- Joseph Dauch, 47, Parkland, Fla., charged in a $21 million fraud scheme to send genetic test referrals to labs in exchange for kickbacks through his marketing companies.
- Colby Edward Joyner, 34, Monroe, N.C., physician assistant, charged with ordering medically unnecessary genetic cancer and pharmacogenetic tests via telemedicine visits.
- Marion Shaun Lund, 52, Taylor, Miss., podiatrist, charged in a scheme involving $3.8 million in fraudulent foot bath prescriptions and molecular diagnostic testing of toenails.
- John Manning, 61, Ashland, Tenn., physician, charged in a conspiracy to bill $41 million for medically unnecessary genetic cancer tests, among other services.
- Vinit Patel, 67, Hoover, Ala., physician, charged with accepting kickbacks in exchange for ordering medically unnecessary genetic tests and submitting $3.4 million in false claims.
- Henry Rojas, 66, Hopewell Junction, N.Y., physician, charged with conspiracy to commit $7.9 million in fraud by ordering medically unnecessary genetic laboratory tests in exchange for kickbacks.
- Omar Saleh, 36, Naples, Fla., physician, charged with authorizing more than $2.6 million in billings for medically unnecessary genetic test orders in exchange for kickbacks.
- Todd Shull, 48, Fort Lauderdale, Fla., charged with conspiring to receive $1.3 million in kickbacks in exchange for referring genetic testing orders as part of his marketing work.
- Ronnie Spiegel, 44, Staten Island, N.Y., laboratory representative, charged in $18 million scheme to pay kickbacks in exchange for ordering medically unnecessary genetic testing.

TDR, "DOJ Indicts 10 Individuals for Pass-Through Lab Test Billing Fraud," Aug. 24, 2020.) However, in past cases it has been more common for a rural hospital to bill for the performed lab tests.

The U.S. Attorney's Office for the Eastern District of Lousiana, where the McNamara case was filed, did not respond to a request for clarification about the possible pass-through billing aspect.

McNamara allegedly worked in the scheme with three telemedicine and call center companies in Florida. "These call centers engaged in aggressive telemarketing campaigns, wherein telemarketers lied to and deceived beneficiaries, hundreds of which were referred to the McNamara labs for testing," the indictment said.

Physicians via telemedicine allegedly signed off on the test orders. Further, McNamara allegedly created a "coding framework" for the telemedicine doctors to use when ordering the tests.

McNamara allegedly paid kickbacks to the call centers and telemedicine companies in exchange for referrals. He concealed payments by making them appear to be for legitimate services, such as account management work, the DOJ said.

The government also alleged that McNamara, co-conspirators, and others laundered their reimbursement money into shell companies and bank accounts signed by various individuals.

McNamara's attorney, Randy Chartash, told *KMBC News* in Kansas City, Mo., "Mr. McNamara is innocent and is looking forward to trial to vindicate his innocence." Chartash did not return a request for comment from THE DARK REPORT.

Emylee Thai, 37, of Santa Ana, Calif., was charged with one count of conspiracy to commit healthcare fraud, one count of conspiracy to defraud the U.S., and three counts of payment of kickbacks in connection with a federal healthcare program.

Thai is a clinical diagnostics lab owner who ran **ApolloMDX** (later known as **Artemis DNA TX**) in Harris County, Texas, which is now closed. Thai currently operates **Artemis DNA CA** in Irvine, Calif.

Multiple Federal Charges

Prosecutors charged Thai with one count of conspiracy to commit healthcare fraud, one count of conspiracy to defraud the U.S. and receive kickbacks, and three counts of payment of kickbacks in connection with a federal healthcare program.

From December 2019 through May 2022, Thai allegedly contracted with marketers in New Jersey and Delaware to refer genetic test orders and DNA samples to ApolloMDX in exchange for a percentage of the reimbursements. The DOJ said the testing was not medically necessary.

During this period, Thai's lab billed Medicare $142 million for genetic testing and received $95 million on those claims.

"Thai and others altered and fabricated doctors' orders to reflect false diagnoses of beneficiaries' medical conditions to make the beneficiaries appear eligible for genetic testing," according to the indictment.

She also allegedly made it appear that certain samples had been collected on multiple dates so that she could bill them as such, when the samples had been collected on a single date.

Owner Runs Afoul of CMS

David Christopher Thigpen, 48, of Hammond, La., was charged with one count of conspiracy to commit healthcare fraud, seven counts of healthcare fraud, and four counts related to kickbacks.

Thigpen owned **Akrivis Laboratories** in Hammond and **Dynamic Diagnostics** in Bay St. Louis, Miss. From March 2014 through January 2021, he allegedly submitted $54 million in claims for urine drug testing and genetic testing that were not medically necessary and tainted by kickbacks to marketing firms, according to the indictment. Medicare reimbursed Akrivis and Dynamic $9.5 million.

He allegedly worked with five marketing companies in Louisiana and Mississippi that solicited providers for Akrivis' urine drug tests and were paid, on a per specimen basis, by Thigpen for specimens referred to the lab.

After being scrutinized for this practice by the local Medicare Administrative Contractor and private insurer **Humana**, the federal **Centers for Medicare and Medicaid Services** (CMS) suspended payments to Akrivis in September 2019.

In response, Thigpen allegedly shifted the urine test billing to Dynamic Diagnostics but continued to run the tests through Akrivis. CMS caught on and suspended payments to Dynamic in January 2021, the DOJ said.

DNA Specimen Kickbacks

Tara Pendergraft, 45, of Chalfont, Pa., was charged with conspiracy to defraud the U.S. government and paying kickbacks.

Pendergraft co-owned **Best Care Laboratory** in New Jersey. Authorities alleged that she billed Medicare for $93 million for genetic testing that was medically unnecessary or procured through kickbacks. Medicare paid Best Care $14 million based on these submissions.

She and an unnamed co-owner paid kickbacks to referral companies in return for DNA specimens and orders for unnecessary genetic tests, according to the DOJ.

Attempts to reach an attorney listed online as representing Perdergraft were not successful. Thai and Thigpen did not respond to requests for comment from The Dark Report. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Déjà vu? Lawmakers in Congress question whether public health officials have done enough to stay ahead of monkeypox, including the availability of diagnostic tests. Concerns about such testing came up during a Sept. 14 hearing before the Senate's Health, Education, Labor, and Pensions Committee. "Access to testing was an early challenge in the monkeypox response, with many people reporting significant delays in both accessing the tests and learning the results," said committee Chair Patty Murray (D-WA). Back at the start of the SARS-CoV-2 pandemic, public health testing capabilities also were criticized.

MORE ON: *Monkeypox*

At the committee hearing, Rochelle Walensky, MD, Director at the **Centers for Disease Control and Prevention**, noted that the U.S. has plenty of monkeypox testing capacity given current cases. "To date, we've used about 14% to 20% of our capacity," Walensky said. Part of the delay with test access stemmed from patients requesting tests without yet having the telltale rash of a monkeypox infection, she added. Approved monkeypox tests require a swab of a rash lesion.

CANCER TEST SCAM: OWNER TO PAY FEDS $97 MIL RESTITUTION

In the latest federal case of **Medicare** fraud and abuse, Daniel Hurt, 58, of Florida, agreed to pay $97 million in restitution and $31 million in criminal forfeiture to settle charges involving three schemes. Hurt will be sentenced in January and faces a maximum jail sentence of 10 years. One of Hurt's schemes was the use of **Ellwood City Medical Center** in Pennsylvania as a pass-through vehicle for "genetic screenings for cancer risk." In its coverage of this case *Reuters* wrote, "Hurt admitted that he and his co-conspirators obtained cheek swab samples from Medicare beneficiaries through mail marketing and purported 'health fairs' around the country and then obtained orders for testing via telemedicine from doctors who were not actually treating the beneficiaries and were not qualified to interpret the tests. The results of the tests were never used in treating patients." This new trial outcome is the newest warning to executives and managers of clinical laboratories that the **U.S. Department of Justice** is more frequently filing criminal charges against owners and managers of healthcare organizations that commit Medicare fraud.

TRANSITIONS

- The **Association for Molecular Pathology** (AMP) named Robyn Temple-Smolkin as Senior Director of Clinical and Scientific Affairs and Director of Guideline Development. She has been at AMP since 2014. Previously, she served at **Capture Resources**, **Big Sky Diagnostic Labs**, and **Mountain West Pathology**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 10, 2022.

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