WhitePaper

Translating Clinical Laboratory Science Into Business Objectives

How an Educational Program Measured and Analyzed Performance and Transformed the Approach to Improving Laboratory Operations

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Introduction

Perhaps now more than ever before, clinical labs are under pressure to operate efficiently, accurately, and timely, all while still making money. Doctors and patients have come to expect a 24-hour turnaround for most tests.[1] Clinical labs throughout the United States have been slashing budgets, many literally to the point of no return. At least 13 public health labs in four states have shuttered since 2003, which posed a serious problem when COVID-19 hit because resources did not meet demand.[2] Those still in business know the challenges of maintaining budgets while operating at capacity and could list the obstacles categorically.

Issues related to equipment, staffing, data management, and workflow are well known, from the techs and managers in the lab all the way up the administrative chain to the finance managers and business improvement teams. "Cost containment" is on the lips of nearly everyone, but not at the expense of quality, turnaround time, flexibility, and accuracy. To benefit the bottom line, labs are looking for ways to improve overall operations, whether they think every area is running as smoothly as possible or whether they've already diagnosed a weakness in their processes.

But where do clinical laboratory directors begin? How do they perform diagnostics of their own systems? Benchmarks can be deceiving.

This white paper considers how using an educational program, developed for virtually anyone associated with a clinical lab—technicians, technologists, managers, pathologists, finance managers, business improvement teams, and learning and development managers—can help medical labs measure systems and practices, identify problems, correct those problems, and ultimately ameliorate overall operations. This paper concludes that by following a specific process, learned through an educational program, labs can strengthen their overall performances and improve their bottom lines.

Chapter 1:

Realizing Operational Weaknesses in the Clinical Laboratory and Mapping a Way Through

In defining their most basic mission, clinical laboratories are expected to deliver accurate lab test results in a timely manner. They are expected to be nimble enough to accommodate routine work while pivoting with alacrity to respond to urgent requests. Yet, meeting those foundational objectives proves challenging, particularly while doing so within a budget. More than 13 billion tests are performed in more than 250,000 certified clinical laboratories each year in the United States, making it likely all citizens will each have at least one test done in during their lives.[3]

"Much of what we do to look at efficiency is based on benchmarks to others like ourselves. It is often difficult to find and compare groups and understand the nuance of those groups."

—Heather Dawson
Allina Health Laboratory
Minneapolis, Minn.

Additionally, a 2014 study estimates that diagnostic errors happen about 12 million times annually in the United States—that's one error in every 20 adults.[4]

The key to preventing these medical errors lies in understanding where in the laboratory's process they happened. Did the error occur at the time of collection? Was there a failure with equipment? Was there a miscommunication or misinterpretation of the results? Was the lab too slow in turning the sample around? Whatever the root cause, lab staff know well the struggles related to turnaround time; accurate data collection, reporting and management; flexibility and workflow; safety; equipment; and staffing.

In short, medical errors result from breakdowns in operations.

Add in the layer of cost containment, and labs are carrying a lot of weight. LTS Health USA Chief Consulting Officer Christoff Coetzee

says, "Labs are constantly trying to balance cost efficiency (i.e. limiting the resources necessary to do the work) with service delivery (getting results out within the agreed turnaround time) and continuity (built in redundancy). Budgetary pressures are forcing labs to do more with less, so continuous improvement efforts are needed to align capacity with testing demand."[5]

According to case studies by a lab operations consultancy with headquarters in Chicago; Cape Town, South Africa; and Dubai, numerous factors contribute to the quality of a medical laboratory's operations. Even when a lab seems like it is running efficiently and smoothly, problems arise, some of which are obvious and others that are concealed. Problems stem from design and flow of the lab, outdated or downed equipment, costs, turnaround time, or misappropriating staff or underutilizing them, for example.[6]

POOR LAB FLOW AND DESIGN STAFF DESIGN OUTDATED AND DOWNED EQUIPMENT	Operational issues affect quality, accuracy, cost, and turnaround time. Larger labs may experience inefficiencies based on layout combined with historical silos by testing specialty.

Furthermore, operational challenges impact medical labs of all sizes.[7] Recently, independent labs saw an opportunity to increase revenue by setting up small offices for patients' routine health check-ups. Instead of seeing the desired gains, they lost some of the economic optimism to hampered operations.[8]

In 2019, LabCorp and Quest, two of America's largest laboratories, made headlines for security breaches. Although neither company was directly responsible—the failure occurred with third-party American Medical Collection Agency, which both lab organizations use, the breach falls under the purview of data management.

"Larger labs can experience inefficiencies based on layout combined with historical silos by testing specialty,"[9] explains Heather Dawson, Vice President of Allina Health Laboratory, based in Minneapolis. "Understanding throughput from the front end to the final result of *all* testing specialties is essential to running an efficient lab. It is incredibly easy to create inefficiencies in one part of the laboratory that have a negative downstream effect on the efficiency of another part of the laboratory." Staffing, she adds, plagues smaller labs that may operate around the clock because they're not generating enough volume; thus they become inefficient and strain the bottom line. In these cases, the lab would need to examine the balance of staffing with productivity. She notes, "Labs can measure efficiency by understanding minimal staffing matrix and billed test per full-time equivalent."[10]

Her experience has led her to observe that operational efficiencies (or inefficiencies, as the case may be) also vary by audience. Lab staff are more often hit with rapid turnaround time than, say, a pathologist, whose workload may be less acute in nature (with the exception of frozen sections); therefore, the efficiencies of both categories of workers are specific to their caseload workflow and day-to-day operational challenges.[11]

Coetzee echoes those ideas: "Pathologists are most concerned about issuing accurate results timeously to ordering physicians, so they might benefit from an over-resourcing of the laboratory. Laboratory staff and management have an added workload due to distributed testing, and they should be focused on streamlining processes, reducing hands-on time, and removing manual interventions where possible."[12]

Chapter 2:

Need for Business Knowledge Presents Unexpected Learning Curve for Rising and Seasoned Medical Laboratory Leaders

As labs tighten their financial belts and ask staff to look for efficiencies to drive cost containment, many staffers are finding they need to understand business as well as they understand a petri dish. Yet, they are not trained in business; they are trained in science. Tension evolves and sows the environment so operational inefficiencies can take root.

Elite Learning, a division of Elite Healthcare and a nationally accredited online platform for continuing education, cautions students pursuing certifications as medical laboratory professionals (MLPs) that one of the top 10 challenges they face is becoming a manager without the training.[13] "Many MLPs become managers without any formal managerial training."

Managerial training has traditionally been geared toward learning to manage people, to be a better communicator, to delegate, and to diffuse conflict. Nowadays, however, knowing how a lab runs from a business perspective is just as critical.

A recent article on *LabManager.com* outlines the expectations best: In the quest to run their labs like businesses, lab leaders must have a solid understanding of legal questions and a strong grasp of financial and budgetary questions that form the basis of cost controls; service (test) offerings; price-setting; and future investments in equipment, facilities, and the engagement of talented personnel.[14]

This intersection has been building for some time. An article published roughly five years earlier on the same website warned that changes were coming.

"Now, lab leaders need to be profoundly conversant with the business side of their operations as well. ... Lab managers and directors no longer have the luxury of concentrating solely on science while relying on other players in their organizations to administer processes and make strategic business decisions.

In a 2011 business of science report that dealt with R&D leadership development, Deloitte consultants stressed that today's higher stakes make it imperative that lab leaders strive for the utmost operational efficiency while doggedly pursuing additional revenue streams…To stay in the game, lab administrators have to become quite adept at business critical decisions, such as the correct balance between in-house testing and outsourcing, which has implications for recruiting, hiring, and overall staffing. They have to keep acute focus on the supply chain, on their budgets, and the purchasing of capital equipment and consumables."[15]

"In my opinion, it is the specific cultures, systems, and processes unique to a lab that cause many inefficiencies, so if you do not understand your own drivers and your ability to improve or change those drivers, benchmarks have limited value."

—Christoff Coetzee
LTS Health
Deerfield, Ill.

Looked at together, it becomes clear that promotions without training coupled with undeveloped business acumen equals inefficiency in the medical laboratory.

Clinical laboratory directors and pathologists know some of the obstacles that can prevent labs from operating at optimal efficiency. Countless articles tell them to evaluate their systems and processes—but only in vague terms. So, these laboratories start by comparing their inefficiencies to other labs. Dawson and Coetzee both acknowledge this fact.

Coetzee advises, "They should gain a solid understanding of how laboratory capacity aligns with true demand." One of the best ways to get this understanding is to enroll in an educational course that addresses every aspect of laboratory operations.[16]

Chapter 3:

How an Educational Program Measured and Analyzed Performance to Improve Clinical Laboratory Operations

Preparing medical laboratory staff to understand business critical thinking and decision making

Gwendolyn Makura, lab manager at Lancet Laboratories, embarked on a course offered by Power of Process. A 20-year veteran of the industry with an honors degree in medical laboratory sciences and a degree in quality management, she is no stranger to lab operations. When her supervisors requested that she and seven others from the company, one of the two top laboratories in South Africa, enroll in the course, she did not know what to expect.

"My main expectation was to learn how to think outside the box when it comes to process and operational improvement," Makura wrote in a letter to the course leader Andre Gouws. But she got so much more. "The Power of Process course has literally changed my life as a manager," she wrote.[17]

"I feel very empowered. I look at work differently now. I'm so aware and alert to constraints in our processes. I'm alert to the motion issues, wastage of space, and the flow of work ... I can see myself transforming not only my unit, but the whole of Lancet with the skills I have gained. The confidence that I have now, due to the knowledge gained, is what is making me even more effective."[18]

Her confidence stems from her new understanding of business thinking. Coetzee explains, "Laboratory staff and management are usually predominantly trained in biomedical science and although they are extremely well skilled in laboratory science, they might not be

proficient in the process engineering concepts necessary to improve laboratory processes."[19]

Coetzee advocates for an educational program to correct those issues in order to then address the lab's operational inefficiencies. "Educational programs that give lab stakeholders the ability to understand how the resourcing and process design of a lab affects the clinical and financial performance thereof is invaluable."[20]

Neil Gaskell agrees. As the pathology manager at Warrington and Halton Teaching Hospitals NHS Foundation Trust in the United Kingdom, he used the Power of Process to analyze his laboratory's performance. "The Power of Process Champion and Master courses add another dimension beyond the LEAN principles we have been using for years and equip you with tools that allow you to map out and break down a process into constituent parts," he says.[21]

One of the problems Gaskell wanted resolved through the educational course was related to the timeliness of results. Essentially, he wanted to issue laboratory results earlier in order "to aid the movement of patients within the Trust and discharge to community care."[22]

What Gaskell and his staff knew was that "the majority of samples from phlebotomy ward rounds typically entered the laboratory at a period of low specimen reception staffing (12-1 p.m.) in preparation for courier deliveries, which started at 1 p.m.

"This led to a delay in registering these samples and a prolonged processing time as the analysers got busy with GP samples," Gaskell explained.

POWER OF PROCESS (POP) PROJECT PROFILE

The laboratories of Warrington and Halton Teaching Hospitals of the NHS Foundation Trust in the United Kingdom process approximately 450,000 requests for blood tests annually.

The aim of the POP project was to reduce the time to test result of routine ward samples collected by laboratory phlebotomists on ward rounds. The improvement initiative was in response to demands for earlier result availability to facilitate patient flow and ultimately patient discharge.

WARRINGTON AND HALTON HOSPITAL

POWER OF PROCESS (POP) PROJECT OVERVIEW

GOAL

REDUCE THE TIME TO TEST RESULT OF ROUTINE WARD SAMPLES COLLECTED BY LABORATORY PHLEBOTOMISTS ON WARD ROUNDS

FROM

3HR 25MIN

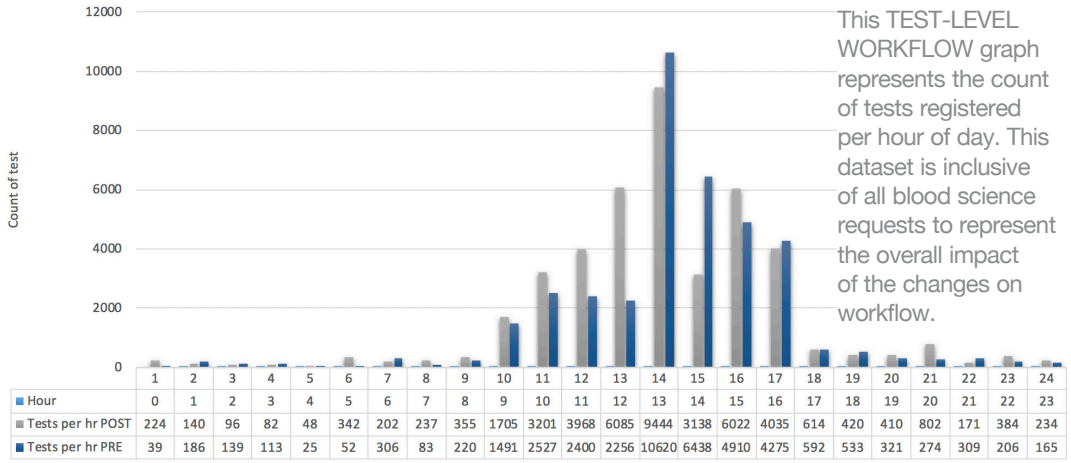
TO NEW TARGET

LESS THAN 2HRS

Instrument platforms included Siemens Chemistry and immunoassay, Sysmex Cell Counters and Coagulation platforms.

Unique characteristics affecting laboratory outcomes include the order to which wards are visited, team deployment, and route between wards. The wards are located on three floors of the hospital in adjacent wings, with the pathology department central to each wing. During the route, pathology is passed at 10 a.m., and the samples that have been collected are dropped off and are updated as collected, with the final dropoff at noon and samples updated as collected.

The 10 steps of the phlebotomy process were evaluated. Key decisions included introducing a sample handling change to the phlebotomy process post sample collection, removing the human sample registration procedure, and adapting the interface between the MOLIS and Aptio Lab Automation to perform the sample receipt and activation function performed by reception staff. Samples are no longer placed in individual sample bags but placed directly into the analyzer rack.



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Hour	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
Tests per hr POST	224	140	96	82	48	342	202	237	355	1705	3201	3968	6085	9444	3138	6022	4035	614	420	410	802	171	384	234
Tests per hr PRE	39	186	139	113	25	52	306	83	220	1491	2527	2400	2256	10620	6438	4910	4275	592	533	321	274	309	206	165

(Source: Neil Gaskell, Warrington and Halton Teaching Hospitals, NHS Trust)

By formally mapping out their process, Gaskell and his staff found that the phlebotomy ward round route was optimal with the existing number of staff; that providing more reception staffing from 12-1 p.m. had a negative impact on the bulk registration of samples that arrived during that same period and resulted in analysis delays; unpacking samples was time consuming; and samples were sorted into analyzer racks; but they were not presented to the automation in a consistent timeframe due to staffing. They saw the areas of weakness and made changes.

Ultimately, Gaskell's team met its goal of turnaround time at less than 2 hours at the 95th centile, a marked improvement over the previous 3 hours and 25 minutes at 95th centile, and realized other measurable benefits:

- TAT at 95th centile was reduced to 1 hour and 47 minutes;
- Auto-reception functionality based on 22% of samples received in this way released 3.4 hours of sample handling time daily;
- Phlebotomists saved time because plastic transport bags were removed from the process;
- They reduced plastic waste and therefore laboratory waste-handling costs; and
- Identified future areas for development, such as phlebotomy bedside application and pre-labeled tubes.[23]

Elsewhere in the U.K., Viapath, provider of pathology services for Kings College Hospital NHS Trust, Guys and St. Thomas' NHS Trust, Princess Royal University Hospital NHS Trust, and Bedford Hospital NHS Trust, as well as referral work from other NHS Trusts and private practices, wanted a program that would engage its operational teams as Viapath looked to consolidate its pathology services into "one hub laboratory site with essential service laboratories at each trust site."[24] Nicola Kirkman, Head of Operation Design at Viapath, felt an educational course like the ones offered through Power of Process would help the operational teams "buy into the changes that were being proposed."

"We used the Power of Process to understand our current services and the proposed future service and what benefits the proposed service could bring to the organization," she says. "We already knew/felt there were inefficiencies within our current services from resource allocation, equipment and space utilization but needed to understand whether those inefficiencies were really at the level we thought they were, as well as what changes could be achieved by consolidating those services."

Ultimately, 26 employees in positions from laboratory assistant and biomedical scientists to clinical scientists and laboratory managers participated in the Power of Process Champion course. Four employees holding leadership positions within service performance and business analysis completed the Master course. Their work through the courses was "used to help develop the business case and project plan for Viapath's Optimal Target Operating model.

"An educational program helps staff understand the changes they can make and implication of those changes," Kirkman adds. "[They] understand if the changes being proposed have the potential to work, taking into consideration patient/sample flow or external factors. The program also allows the staff to continue to make changes and understand/monitor the impact of those changes."[25]

In addition to feeling empowered by being part of the change and helping to guide it, medical laboratory staff gain exposure to best business practices as part of educational courses that integrate business thinking. Lancet's Makura came away with that knowledge. She was charged with figuring out ways for cost containment, figuring out how to do more with less.[26] When she completed the Power of Process Champion course, she had learned about flowcharts and how to use them to map lab processes. She also became familiar with business lingo, such as KPA and KPI. "I wasn't sure what KPAs are," she admits, but now she is monitoring performance monthly of various key performance areas and key performance indicators.[27]

Conclusion

Science has always been the paramount focus of laboratory managers, but that is no longer sufficient.

Using an educational program, such as Power of Process, to equip clinical laboratory staff and business administrators with the skills to evaluate, measure and analyze their clinical laboratories can improve operations and practices, thereby improving the labs' bottom lines. In addition, lab staff gain enough acumen to think about the laboratory as much like a business as a place of science.

In these ways, educational courses prove beneficial to clinical laboratories evaluating possible changes, those that want to diagnose areas of weakness, those with new or inexperienced leadership, those seeking ways to contain costs, and those wanting to improve virtually every aspect of medical laboratory operations.

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About Power of Process

Power of Process uses innovative blended group education programs and workshops to enhance and transform the skills of all laboratory employees. Through knowledge sharing, process improvement workshops, a community of expertise, and coaching on demand, Power of Process programs develop skills to drive identified performance improvement programs in the laboratory using the 8 Principles of Laboratory Performance for improving and sustaining performance. Power of Process Master certification provides the ultimate level of process knowledge to improve laboratory performance, directly impacting the bottom line. Power of Process programs have achieved accreditation through the American National Standards Institute (ANSI), American Society for Clinical Laboratory Science (ASCLS) Professional Acknowledgment for Continuing Education (P.A.C.E.), and the Royal College of Pathologists. Power of Process stands for operational performance, which is defined as the ability to respond timeously to quality, volume, turnaround time, and cost pressures in a rapidly changing environment, while delivering measurable outcomes not only for the C-suite, but also for the communities the laboratory serves.

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