

## Views on point of care versus core and more

February 2023—Point of care or core lab? An old question but a new conversation, this one on Jan. 12 between Stan Schofield, formerly of MaineHealth (until his retirement on Jan. 6), Werfen chief commercial officer Brian Durkin, and CAP TODAY publisher Bob McGonnagle (asking the questions). Here's what they said about that and health care economics, autoimmune testing, tube supplies—and, of course, the labor shortage because it affects nearly everything in health care. "We know the labor shortage isn't going to turn around," Durkin said.

**Stan, give us a brief history of your consciousness and then your deployment of the question of where we put the testing—core lab, highly efficient, low cost per test versus at the point of care, which has the advantages of the patient being close by, where it's convenient, and the physician getting a result that can be acted on quickly. Give us a summary of where you've been in the past 10 years on those questions.**

*Stan Schofield, vice president and managing principal, the Compass Group; former president of NorDx and senior VP of MaineHealth:* We've watched point of care evolve and grow, but running a core lab was all about economics, speed, and enhancing technology. Centralizing allowed us to lower our costs and compete in the outreach program and lower the costs of hospital operations dramatically. A standalone lab without the core lab in a network hospital without efficiencies has operating expenses that run 15 percent higher. So the core lab concept has always been solid.



Schofield

Point-of-care technology has evolved and improved in the past 10 years. It's convenience versus cost. In hospitals, in the lab, and in health care in general, cost is a huge consideration and will continue to drive selection. Point of care has demonstrated its ability, especially with COVID. Prior to COVID, it was convenient, and a few assays made a difference, if compliance was a problem, when the patient was onsite—hemoglobin A1c, for example. But \$35 for a test result versus \$3 is a big differential, and insurance companies don't pay that kind of differential. Economics drives the core lab, but COVID technology allowed people to make better cost-related decisions around isolating patients, protective personal equipment, room allocations. And without a test result around, say, COVID or the respiratory viruses, you'd spend a lot more money than what you spend on the point of care.

**Werfen has a foot in both of these solutions because so many coagulation tests are done at the point of care, but it also has an automated coagulation solution. Brian, give us your view of this point-of-care versus core question.**

*Brian Durkin, chief commercial officer, Werfen:* Rather than say central lab versus point of care, we should talk about how they coexist. That's the philosophy of Werfen. We have three core business units: autoimmunity, acute care diagnostics, and hemostasis. Our strategy for hemostasis testing is to help our customers manage it from the central lab to the point of care. The ACL Top series systems and HemosIL reagents lead the hemostasis worldwide market for instrument and reagents, but we also have a handheld point-of-care hemostasis device, the Gem Hemochron 100 system. When I'm asked where testing should be, my answer is wherever it's more efficient and effective.

The pandemic changed everything. But it validated that in vitro diagnostics, whether lab or point-of-care testing, is crucial to patient care. We were proud to contribute to the care of patients with our hemostasis and blood gas products. And while health economics is always a key question, our philosophy is that it's about the total cost of ownership, not cost per test. Looking at cost per test can be shortsighted. We bring a different approach to the

labor- and blood-shortage challenges—we talk about automation, cost efficiencies, and total cost of ownership.

**As you deploy this strategy, is there an 80/20 adoption? In other words, do about 80 percent of customers have similar approaches to how they roll out the total coagulation solution, or do you find there's quite a bit of individual variation depending on the systems and locations?**

*Brian Durkin:* From my perspective, 100 percent of our customers have a central lab hemostasis solution. There is more variability at the point of care, where we see approximately 50 percent or more of our hemostasis customers testing. A good example of this is activated clotting time testing using the Gem Hemochron 100, which is performed routinely in the cardiovascular operating room.

**Stan, what's the distribution in the NorDx system?**

*Stan Schofield:* We have ACL Top instruments in all our labs, but point-of-care coagulation is limited to our physician practices, mostly for economic reasons, and in more remote satellite locations. It's not more than five or six percent in our 800 employed physician practice sites.

**How is the immediate follow-up with patients handled? Is there a lot of bidirectional interface in which you're getting back to those sites to say that a particular patient needs their warfarin adjusted as soon as possible?**

*Stan Schofield:* In a nursing home, as an example, if it's drawn at 7 AM and comes into the core lab by noon, results go back electronically by 2 or 3 PM before the nurse or physician leaves for the day, and they make the adjustments. For emergency departments, the laboratories are responsive with ACL Tops and tube systems to transport the specimens.

Our problem is having phlebotomists available at an outpatient setting for a patient to get a routine draw or maintenance. A patient who is supposed to get blood drawn once a month but forgets to make an appointment may not get seen. The staffing is critical, mostly in phlebotomy and phlebotomy outpatient arenas—it's hard to get appointments and be seen on short notice.

**There's a lot of dependence on patient scheduling and a discipline in the system to make it all work, at least optimally, correct?**

*Stan Schofield:* Yes. And if a specimen comes in and it's abnormal and the INR is not therapeutic but dangerous or critical, then we contact the physician and nurse practitioner immediately, based on CAP protocols for critical value calls. It works 24 hours a day. This kind of testing is same day in a maintenance mode. If a patient is critical, then they go to the hospital or the emergency department. Plus, the core lab runs 24 hours a day, even if it's a stat.

*Brian Durkin:* I agree with Stan. The labor shortage in health care, and overall, is dramatic. When we talk to leaders, they're looking for more automation and instruments that are easier to use, that help interpret and provide straightforward results, so someone who is not as skilled can talk to a clinician and take action.

Another big trend I see in health care is the struggle to find experienced staff. We need to invest in educational tools to help our customers train their newer and younger staff members. During the pandemic we improved our digital training capabilities, including operator training and clinical educational content. Customers can watch our online training, 24/7, to learn how to perform certain activities, operate a system, and better understand a variety of disease states. When I started in this business, you were selling an instrument and a reagent. We have evolved to a more consultative approach with a total view of the lab and point-of-care setting.

**Brian, you are based in Barcelona and have global commercial responsibilities. Are there similar labor and cost problems outside the United States?**

*Brian Durkin:* Yes. Every November we look at trends in health care, and number one is labor. Health economics is always there as well, to different extents. So we're changing the mindset of the market away from focusing just on the cost of an instrument or test and shifting it to how we can deliver the full value from the time the patient is admitted to the ED to their discharge.

*Stan Schofield:* As we talk about labor, there was point of care as a convenience and as an opportunity for rapid

results with the patient still there. What has happened is not just in laboratories. Emergency departments and medical practices are short-staffed. In our medical practices, there are hundreds of open positions for medical assistants and in nursing. So nursing staff and medical assistants in practices are pushing back now, saying, "I don't have time, I have to take something off my plate, and I'm going to stay with the nursing responsibilities and next to the patient. I'm not running the labs anymore."

**Does that mean specimen collection is happening increasingly at the main hospitals and clinics and centers as opposed to the offices?**

*Stan Schofield:* Many physician offices stopped drawing blood 10 years ago. They almost always send the patient to a patient service center. Prior to COVID I had 23 patient service centers, and now I have 13 and can staff only nine.

*Brian Durkin:* People are using the ED as their primary care provider, and the EDs are overwhelmed. We're trying to help health care institutions solve that problem, and the best way is through effective information management and products that are easier to use.

**You're implying that over the horizon we have some relief coming through new technology that's easier to use. Am I interpreting your comments correctly?**

*Brian Durkin:* Yes. We're focused on making products that are easier to use, more efficient. We know the labor shortage isn't going to turn around. Fewer laboratorians, clinicians, and phlebotomists are graduating every year.

**Stan, while we're on the question of supplies, what's the situation today with blue-top tubes?**

*Stan Schofield:* It's better than a year ago, better than six months ago. But we're having other tube shortages—pink, gold, the rapid spin tubes are the most difficult, mint green. Those are all problematic because we use them in the emergency department for fast turnaround times. Coagulation tubes were problematic, and it's still not guaranteed we'll get them. Everything is allocated, and sometimes you don't know what you'll get until the first of the month, when the allocation list is released. What you received last month you may not get this month. Overall, it's still problematic, a little shaky.

**Brian, what is the tube situation from your perspective? You depend on supplies just like the laboratories do.**

*Brian Durkin:* We are aware of it and help where we can. The supply chain, inflation, and health economics are strained. Throughout the pandemic, we haven't missed a shipment. Two examples—from our hemostasis business, D-dimer demand, which was standard of care, almost doubled, and on the blood gas side, requests for respiratory cartridges increased exponentially. We were able to meet demand despite challenges in obtaining some key components.

Where products are made is another important factor. We make 95 percent of our products in our U.S. technology centers. We're proud that we're able to meet the higher demand.

*Stan Schofield:* To Brian and his colleagues' credit, we never had a problem with the IL instrument or ACL Top materials we needed. They're one of the vendors we could count on through the crisis.

**Brian, can you comment on autoimmune testing? Where is that business now and where is demand for those tests?**

*Brian Durkin:* The demand has surged. During the pandemic, we saw a sharp decline in the volume of autoimmune tests because people didn't want to go to a hospital and hospital staff were focused on managing COVID. Now we're back to normal or even growth levels in autoimmune testing.

Oftentimes it takes years for clinicians to diagnose an autoimmune disease, but our products make it faster and easier for clinicians to identify whether it's, for example, rheumatoid arthritis or something else, and provide care as fast as possible.

**Stan, is it your experience at NorDx that demand not only for this but other tests is getting back to**

### **normal in the immediate post-crisis?**

*Stan Schofield:* Autoimmune is a growth area, and as more markers are developed and the instrumentation becomes better, using and identifying those markers is a growth area. But it's still only a small percentage of the entire laboratory. For routine work in the laboratory, we're at about 96 percent of where we were in October 2019. The reason is we can't get patients' blood drawn in the outpatient arena and run it. We have capacity, but total volume is still off about four or five percent. Autoimmune remains strong and is growing. But of all the tests we do, autoimmune is only one percent.

### **Is there a testing category, however big or small, that has a percentage that surprised you, either in how it has not resumed or has bounced back strongly?**

*Stan Schofield:* No, not in any major categories. Routine, nonesoteric testing has remained consistent. The demand for next-generation sequencing and oncology markers is expanding to higher panels and more markers. But for autoimmune, allergy, infectious disease, it's all about the same per patient ratios that we've experienced. Tickborne illnesses have always been strong here.

### **Brian, tell us about the situation in Western Europe. We hear about their economies, and they've had a tough year, the dollar is awfully strong. How has that affected the European laboratories in your experience?**



Durkin

*Brian Durkin:* It is similar here—labor shortages, looking for more automation, health care economic challenges. We take the same approach with the same products and same message—we're looking for a long-term solution. Now that I have a global perspective, our strategic plan is similar because the issues are aligned. Inflation is high everywhere, so we're challenged with our value pricing. People push back and say, well, there's inflation. But we have to understand inflation hits manufacturers as well as health care providers. If we agree to invest in high-quality products, the long-term costs will be mitigated, and that's the mutual goal.

### **Stan, are you continuing to see a rise in the use of the new class of drugs for anticoagulation control, or is that a fairly steady but not dramatic increase? I'm talking about the direct oral anticoagulants that are replacing warfarin by and large.**

*Stan Schofield:* Yes. We are busy with that in our special coagulation area. It has been a slow, steady increase the past five years. As those drugs come onto market, we have to adapt and adjust the various specialty factors and tests. We've been fortunate to work with Werfen and IL around many of those assays.

### **Can you comment on that class of tests, Brian?**

*Brian Durkin:* Overall the growth is high. And while traditional prothrombin time testing is declining, our direct oral anticoagulant testing and the specialty testing Stan mentioned continue to grow.

### **Stan, laboratories dodged the worst of it with the suspension of the PAMA cuts for the year, but are there other financial issues you'd like to bring up?**

*Stan Schofield:* All laboratories are going to be stressed this year due to health care system finances. Nursing contract labor is breaking the bank everywhere, and many big health care systems are running seven to 10 digits into the red and it can't be sustained. The lab is going to be impacted financially for capital equipment, operating support, improvements, and staffing. Lab staffing is a problem, but the economics of the parent corporations are deteriorating rapidly. It's something we have to watch for and try to balance out in almost everything we're doing. That has to be a major consideration going forward.

**Brian, do you have a closing comment about finances or anything else?**

*Brian Durkin:* Stan said it well. Health care institutions are stressed every day. From central labs to the point of care, the importance of diagnostics results was validated during the pandemic. So the hospital C-suites understand that we can't shortcut lab quality and they're willing to invest in high-quality products in the central lab and at the point of care.