Connectivity and control—pivotal issues at the POC

March 2022—*How can we connect these point-of-care devices? How do we standardize and ensure competency? How do we get the results from at-home testing? How can we integrate point-of-care information into the whole of analytics?*

Just some of the questions those who lead POC testing and make it possible are asking today. They spoke with CAP TODAY *publisher Bob McGonnagle on Jan. 25 in a virtual roundtable on POC instruments and system connectivity. Of the many results generated away from the "traditional diagnostic domain," Quidel's John Zacharia says: "We have a tough decision to make as an ecosystem: choosing how we open the gates to allow some of these 'devices' . . . to be part of our collective domain."*

With McGonnagle and Zacharia to talk about POC testing were Barbara Goldsmith, PhD, FACB, Thomas Jefferson; Kathleen David, MT(ASCP), TriCore; Steve Valorz and Bruce Morgan, Abbott; Daniel Gundler, Siemens Healthineers; Curt Johnson, Orchard; and Becky Clarke, Telcor.

CAP TODAY's guide to bedside glucose testing systems begins here.

Dr. Goldsmith

It seems to me in 2022 we can't talk about point-of-care instrumentation without talking about how it fits in and connects with an entire system of care, which as we know is consolidated. Barbara Goldsmith, what two topics are most top of mind as you think about point-of-care testing and connectivity within your health system?

Barbara Goldsmith, PhD, FACB, director of clinical laboratories and of point of care and quality management, Thomas Jefferson University Hospitals: I joined Jefferson eight years ago and we were three hospitals. We are now 18. Our point-of-care program although large was modest compared with what the expectations are now to support inpatients, outpatients, and our physician office colleagues. When we talk about interfacing and connectivity, that becomes a whole different kettle of fish. We have our program in Center City—Thomas Jefferson University Hospital, Methodist Hospital, which is about a mile away, and Jefferson Hospital for Neuroscience, which is two blocks away. We also support an infusion center and a cancer center here and another one close to one of our other sites, and all of them do point of care. Are we responsible for all of them? Not yet, though I see it coming.

The things I'm interested in are how do we standardize our point-of-care systems, devices, and connectivity? At Center City we have about 5,000 operators who do point-of-care glucose and other tests. How do we make sure everyone's competent? How do we ensure proper training and retraining? When you have that many people, having apps, systems, and a way of monitoring all those folks and where they are in the point-of-care spectrum is important. It's having tools in addition to interfacing that allows us to keep track and implement where appropriate.

Kathleen David, TriCore has a little larger geographic footprint than Thomas Jefferson from what I know, but are you hearing similar themes and concerns?

Kathleen David, MT(ASCP), associate director, near patient testing services, TriCore Reference Laboratories: Absolutely. When a new device comes in, our first question is, Can we interface it? Because we cover most of New Mexico and support hospitals and clinics all over the state, it's essential we have as much centralization of that information—both the devices and results—and in managing the devices and operators as we can. We have about 10,000 operators in our system.

We've started marketing point-of-care services for commercial clients, those who aren't part of our system already, and many of them are interested in interfacing their devices. How do we do that? They're not part of our system, so how do we bring in their admission, discharge, and transfer information? How do we connect with them physically? These are questions we're looking at now. The more you can manage things with your IT systems, the better. Any kind of manual process is waiting for a problem.

In terms of an agreeable solution to these dilemmas, is your cup half full or half empty?
Kathleen David (TriCore): We have good cooperation from our operators and the people who use the devices as well as help from our middleware solution and our Rhodes Group IT partner to connect all of this. I don't know how people do it if they do not have those pieces in place.

Steve Valorz, tell me about the dilemmas people are facing and what the solutions are from Abbott, for POC informatics.
Steve Valorz, global marketing communications manager, Informatics at Abbott's rapid diagnostics division: When we started connecting devices 25 years ago, capturing those results electronically was first and foremost. We wanted to make sure we were able to remove that manual process. As time went on, a lot of other things came into the point-of-care program. Not just managing devices and tests but managing all the operators. Providing tools to improve the way the operators are certified and keep them competent and current so they're not locked out of devices is key to the success of the program. We offer a variety of tools that go beyond collecting data, that manage the entire point-of-care testing program.

Gundler

Dan Gundler, what is Siemens Healthineers doing in this point-of-care dilemma?
Daniel Gundler, national commercial director, North America POC Informatics, Siemens Healthineers: The point-of-care challenges are real—managing many different devices across the network, different facilities, even outside the acute space and in a physician office-type environment. How can we connect those devices? More importantly, how can we help them manage quality control measures and compliance? How do I understand who's using the equipment? How can we help train and certify device operators and guarantee only certified operators have access to the devices?

Our software has helped customers address those challenges. And it's not just our software; it's working with device manufacturers to create smarter devices. Your point-of-care operation is only as good as not just the middleware but the device itself. To get what's called a unidirectional-type interface is to get results only, and that's not enough for point of care. It's working with device manufacturers to create smart devices that will help take advantage of the full spectrum of functionality that our software offers the customer.

Zacharia

John Zacharia from Quidel, how do you see these problems with point of care? And can you comment on the added burden of the staffing issues your customers face?

John Zacharia, senior director, product management and digital health, Quidel: From a bottoms-up standpoint, there are fundamental points of friction we are continuing to chip away at in terms of getting folks connected, resolving operational issues, and adding value to having connected devices. When we talk about it inside of Quidel, there's a headset we use, which is: From a value proposition standpoint, are you providing enough incentive for folks, especially outside the acute environment, to engage in interoperability and connectivity, to fight through the friction of disjointed standards, mixed vendors, and ongoing operational challenges? Inside an acute environment, the knowledge is there, and people see the value and come to the table to engage in this. When you get to the physician office labs, with their new at-home and virtual care models, the knowledge isn't there, so we have an educational challenge.

To your question about staffing challenges, there's no silver lining. If folks have engaged in autodocumentation and unidirectional connectivity, they're going to reap the benefits of that now. If they're staffed out and struggling, unfortunately now's not the best time to consider an integration project. That tree should have been planted five years ago. But the next best time to plant a tree is now.

Curt Johnson, where do you see Orchard in this?
Curt Johnson, chief commercial officer, Orchard Software: Our goal is to blend what Quidel is doing with what Abbott is doing and understand the outside-the-walls-of-the-hospital workflow—the clinics, ERs, cancer centers—and integrate that with what the hospital, the mothership of the organization, needs. That's the challenge.

John brought up one of today's challenges: How do we integrate results from people testing at home? How do we get all the direct-to-consumer information into the system? It will become an expectation. The vendors realize this is an upcoming need within the industry—to get that information integrated. We have to understand the workflows today and organize ourselves to be a benefit to organizations like TriCore, Thomas Jefferson, to the vendors—Quidel, Abbott, Siemens—and eventually to the end-user consumer. That's our goal, and that's where we're headed.

Clarke

Becky Clarke, I'm sure this sounds familiar to you and you're doing a lot of handholding and consulting in the first phone calls you receive from customers and potential customers.
Becky Clarke, executive vice president, point of care, Telcor: We have always tried to be a "handholding" team, and a great example of that started two-plus years ago with COVID where we spent the first year focusing on how we could help our customers from a service perspective. The objective then was implementing new COVID testing, getting devices connected, and getting them interfaced in two different methods, meaning whether they were unsolicited or solicited results, among other things. We accommodate all those workflows in the system but worked with our teams to follow a new process. When quoting we had to ask, How do you want to report these? How are you going to identify these samples? Are we going to need an orders interface to accommodate a solicited workflow? We also created a new internal process to accommodate the urgency of getting testing implemented and results interfaced to the LIS/EHR.

Another example is moving from the inpatient setting and into ambulatory and freestanding EDs, where one of the biggest challenges for point of care is that I can't drive to these places to add a new operator or remove an existing operator or add a QC material or reagents. From a manufacturer and a device perspective, it is critical for us in middleware to be able to transmit operators authorized to do testing and reagents to every new device that comes on the market because you can't travel to these places anymore. People just don't have time.

Bruce Morgan from Abbott, I want to add one more complication to this question, which is seeking CLIA waivers for the testing you offer on your instrumentation. What are your thoughts about CLIA-waived tests and how that will affect the customer and the mix of business and demands on your middleware suppliers?

Bruce Morgan, global product marketing manager, Informatics at Abbott's rapid diagnostics division: As we're moving into this decentralized environment and putting testing in more disparate areas, we're still trying to have control over the testing. A big part of that control is whether the person is competent to perform that testing and what it means to be competent.

How do we control home testing? How do we validate whether that data is good? And then there is pulling that data together, whether it's for reporting to state health care agencies, ultimately to the CDC and other governance, or back into your health care provider. As providers of connectivity solutions, we need to think about not only the volume of operators but also the environments in which those operators live outside the walls of the hospital, and how we are going to verify and write protocols, have procedures in place, and implement and enforce moderately complex testing and review whether someone has passed for CLIA-certified or CLIA-waived testing.

Barbara Goldsmith, talk about CLIA-waived testing. It sounds like a wonderful solution, but I think it's probably a double-edged sword when we finish with it.

Dr. Goldsmith (Thomas Jefferson): Before I talk about CLIA waived, I want to mention how flexible you have to be, which we learned with COVID. COVID opened our eyes and accelerated the path toward point of care. We have multiple methods for COVID testing—a combination of point of care, PCR, NAAT—to accommodate and help our clinical colleagues in the ED and with preadmission testing. That flexibility and being able to respond quickly is key to being able to do this.

In the hospital, in the inpatient and ED settings, we treat CLIA waived almost like moderately complex. With training, documentation, competency assessment, all of those things, we've developed e-learning modules, which we require those who do point-of-care testing to take, depending on what they're doing. So even though it's CLIA waived, on the hospital side we treat it as if it's not CLIA waived.

Valorz

Steve Valorz, in view of these challenges, is demand for middleware connectivity skyrocketing?

Steve Valorz (Abbott): The use of connectivity at the point of care is definitely greater now than it was years ago. Every hospital probably has a system in place in some way, shape, or form that's connecting at least their glucose meters. The need to connect those other devices at the point of care, beyond glucose testing, is becoming greater for customers.

Can you comment on that, Curt Johnson? You're seeing an increasing call for helping customers get things connected.

Curt Johnson (Orchard): Two years ago not one of us would have thought about lab equipment in a nursing home and the need to interface that equipment. The urgency for interfacing analyzers and devices is skyrocketing. Every nursing home that was asked to do testing would love to have connectivity to their mothership, EHR, and main lab. But this connectivity is not always happening because of the ROI. Is it worth it? Who will manage it? Some may have completed integration; others have looked for partners. Large integrated delivery networks that have a lot of equipment outside the hospital are still looking for connectivity—it's not a priority over COVID, but it's out there.

Two years ago no one would have thought about a bunch of mobile labs around the city with COVID analyzers and

the need to connect those devices to an EHR or main lab. As more molecular testing comes into the point-of-care world and the breadth of menus gets wider and testing gets closer to customers, we're going to need broader and easier connectivity.

When we're in the hospital environment, particularly the large integrated delivery network environment, you have a lot of interfaces when you're in clinics and offices and with device people. Becky Clarke, talk about how difficult that is to sort out and solve.

Becky Clarke (Telcor): Once you've done one HL7 interface, you've done just one HL7 interface. Even with Epic, Cerner, and Meditech, their HL7 interfaces are not the same. Each customer can be different even with the exact same LIS/EHR version. How much demographic information do I need to send a solicited result? What do I need for patient identification on the meters? Medical record numbers, account numbers, contact serial numbers, employee IDs are all used to identify samples. How do we want to identify those samples? It is complex because you could have a combination of any of those within an organization. And as IDNs acquire new hospitals, they aren't all on the enterprise version of an LIS/EHR. You have to accommodate every one of those interfaces simultaneously.

Dan Gundler, would it be desirable from your perspective to achieve a universal patient identifier in the U.S.? It's been debated for years.

Dan Gundler (Siemens Healthineers): If our government could help our customers and hospitals standardize it and have one source of patient knowledge—the electronic medical record, the one source that speaks to everything—it would make our lives a lot easier.

David

Kathleen David, what comments do you have as it relates to TriCore?

Kathleen David (TriCore): I'd like to talk about interfacing. There seems to be a melding of what was traditionally point of care—glucose meters and urine dipsticks—and what is happening now. We have CBC analyzers at point of care. You can argue whether it's a point-of-care device, but we are managing devices I had never thought would be under our department. The other piece is there are point-of-care devices that are being managed in the laboratory with solicited traditional lab orders but that we're managing with our point-of-care middleware because there are multiples of them and it's easier to do it that way. There's a lot of bleeding from one into the other, which complicates things when you do figure out how you're going to connect everything and get your results into their final place.

John Zacharia, does this sound familiar to you as a dilemma? I ask because so many point-of-care devices live in places most of us wouldn't call the point of care.

John Zacharia (Quidel): The trend seems to be moving away from centralization, which is why point of care existed in the first place, to bring velocity of insight to where it's needed most. We need to embrace that and continue to support the extension of this network of insight that we're creating with the devices, data sources, and data assets available to us.

We started this discussion around CLIA waivers as an example of challenges to data quality and sample fidelity coming into the data set. We're already leapfrogging that with at-home diagnostics and self-interpreted test results. Millions of test results are being generated outside of what is considered the traditional diagnostic domain. The question Quidel has, as well as Abbott and Siemens: Do we embrace those results and the value they bring to our collective data asset? Do we introduce controls to sanitize, normalize, challenge, and validate that data at the cost of width of the data set? Or do we ignore it entirely? To a certain extent the latter is happening. We have a tough decision to make as an ecosystem: choosing how we open the gates to allow some of these "devices"—in

quotes because a lot of them are not necessarily viewed as devices—to be part of our collective domain.

Given the vast data points a manufacturer like a Quidel, an Abbott, or a Siemens enjoys, is there opportunity to share that more widely for the purpose of improving the health care system? For example, sharing it more generally with your customers. Is that a thought you've had?
John Zacharia (Quidel): Had and acted on. There are two orientations to this. Speaking for myself, vendors have an obligation to be as agnostic as possible. The envelope of your obligation begins and ends at your device; enabling third parties, other vendors, and ultimately your patients and users to access and benefit from that data is mandate now. It's the steering wheel in the car. You wouldn't bring anything to market unless it had that capability. We need to reduce the friction as much as possible to ensure it's taken advantage of.

Morgan

Bruce Morgan, can you comment on this same question?
Bruce Morgan (Abbott): The pandemic has accelerated the concept of reporting and making data actionable. We need to understand the trends the data is showing us, where it's coming from, and the volume in which it's coming. It's incumbent on Abbott and like vendors of data-management solutions to grow with that trend. Our job is to make sure not only that we're moving this data and making it possible for you to manage and have some compliance with and governance over these systems, but also to help you pull the data back to validate it, put it in an actionable format, and share it where you need to share it.

Kathleen David, TriCore has made investments in analytics and IT consulting companies. Did some of that spill over into your activities and point-of-care testing?
Kathleen David (TriCore): Absolutely. This is a huge amount of data, especially if we're going to add home information. What do we do with that data and how do we present it to those who need it? For instance, the providers: How do we present it to providers so they don't have a waterfall of information that doesn't really mean anything?

TriCore, with our Rhodes Group clinical innovations department, is looking into how we can gather the data and highlight and pinpoint areas where action needs to be taken. You've got five days' worth of information on a diabetic patient. Are there any areas of concern? Does that physician need to contact the patient and do something about it? That will be the way TriCore goes—as opposed to giving you results, we want to give you actionable clinical information. How can we integrate point-of-care information, which hasn't traditionally been folded into laboratory results, especially outside the hospital, into the whole of the analytics?

Barbara Goldsmith, it sounds wonderful to have rivers of data pour into the system, but how does it work in practical terms and how is it interpretable for the people who have to make decisions?
Dr. Goldsmith (Thomas Jefferson): You're going to have mountains of data, and we need to distill it so a physician, a physician assistant, or somebody who is assigned to take care of the patient gets it in time to do something with it and document what they did with it. If a patient with diabetes is not stable and you get many data points during a 24-, 48-, 72-hour period, who does the data go to, what is done, and how quickly? Those pieces, certainly from a non-inpatient point of view, are challenging. I don't think we're there yet.

Johnson

Curt Johnson, we all want data that means something to the patient, and timeliness is almost everything in health care and yet there's a big gap, particularly in an era of such staffing crises. Capital budgets themselves are not moon-shot-type activities. What's your reaction to this discussion?

Curt Johnson (Orchard): There will always be a gap because technology and advancement move so fast and other areas do not move at the same speed. There are two parts to data integration. You have to be able to gather all the data and, even if you're in one system, have a master patient ID. You need to be able to integrate the data in different ways, depending on what you're trying to accomplish. If you can marry laboratory results—microbiology results, for example—with pharmaceuticals being ordered, you could begin to bend the curve of costs within a hospital system.

As we move from a fee-for-service industry to outcomes-based reimbursements, Medicare Advantage type, that point-of-care data combined with blood pressures and the whole health of the patient becomes critical not only to improving their health but also to bending the cost curves. The lab is one piece. You've got to integrate the lab with pharmacy, with claims data, and the whole view of the patient. When we get there, you will see positive changes in our health care, and the laboratory should be leading that, not following.

Steve Valorz, would you agree that this integration with other cost inputs, pharmacy, et al., will be a critical part of success down the road?

Steve Valorz (Abbott): It has to go in that direction. We're talking about data from the point-of-care perspective, but there are mountains of data elsewhere within the four walls of hospitals and clinics that have to be integrated. That could include insulin-dosing tools, continuous glucose monitoring systems. The data needs to be integrated somehow, some way, and by someone because the data collected is equally important whether in the hospital, doctor's office, or at home.

Becky Clarke, do you speak about these things internally and with customers as you seek to improve the total value chain?

Becky Clarke (Telcor): Absolutely. The piece we are missing, particularly as testing has moved outside the walls of a laboratory, is, Who is the ordering provider? The ordering provider is critical in data integration for reporting and billing. When it comes to point-of-care testing without orders, we don't always know who the ordering provider is and that makes it difficult to put the results in the appropriate provider queues. EHRs have queues for an ordering physician to look at and say, these are the results that got generated yesterday for my patients.

Barbara Goldsmith, clinicians have a lot in their queues and it often goes neglected for an excessive period. Am I right?

Dr. Goldsmith (Thomas Jefferson): You're right. It also goes hand in hand with appropriate test utilization. Because we're ordering panels for a lot of tests and maybe looking for one or two things that stand out, sometimes there's information overload. It would be helpful if good algorithms could be written so those tons of results are distilled into something that correlates with a patient's diagnosis or potential diagnosis and flagged so you go right to it and do something about it.

Kathleen David, can you speak about algorithms at the front end to optimize test ordering and utilization?

Kathleen David (TriCore): One of the things TriCore is looking at for a clinician is, What are you looking for? And here are our suggestions for the testing you should order to decide on your differential diagnosis. It would be helpful to have more of that information. It's similar to what happens when someone wants additional point-of-care

testing. As opposed to saying, “I want a device X,” say, “I want to test for whatever; this is the outcome I want.” And then we in point of care in the laboratory can say, “This is probably the device you want to use for that.” Or, “Here are two or three devices that will do that testing. Which one will work for you?”

Dr. Goldsmith (Thomas Jefferson): Our ED came to us and said they are taking care of a large homeless population in Philadelphia, and once the patients are treated, they’re discharged to what they’re calling a COVID hotel. I don’t know if algorithms would help streamline which patients go where—are they inpatients or can they be discharged by doing flu testing, COVID testing, et cetera?—but it’s certainly another application of needing rapid tests versus possibly non-rapid or PCR tests. And there are other examples where it’s used for triaging and needs to be done quickly with good results because big decisions are made. We have found that we’ve helped our clinicians immensely by being able to implement some of these tests right away so they can properly disposition their patients.

Would anyone like to make an additional comment before we wrap up our discussion?
Becky Clarke (Telcor): It’s important for the middleware providers to work closely with the device manufacturers. In the recent past I’ve seen more sophisticated devices and more coordination between the device manufacturers on middleware and IT requirements for their devices. That collaboration has improved things greatly in the past five years, and we look forward to the next generation of devices.

Steve Valorz (Abbott): Testing will go to retail pharmacies, sporting events, concert venues, and it’s not going to be just COVID. We’re going to see a need for solutions for a wider range of tests from flu to coag and others. Connectivity vendors will have to be more flexible and adaptable. We’re getting away from network-based ways to gather and move data, and we’re going to have to start using Wi-Fi and cellular networks. That’s where the trend is heading in terms of the ability to capture results. Testing is not just at the bedside. It’s not near patient, it’s on the patient.

Bruce Morgan (Abbott): It’s not just where we’re collecting the data; it’s the context around the additional data. We’re good at saying, This is a glucose result. Well, a glucose value of 110 does not mean anything without context. Have you been exercising? What have you been eating? When was the last time you took insulin? For COVID testing, when were you exposed? Do you have symptoms? It’s the additional data, and as we get farther away from traditional testing sites and into places like sports venues, pharmacies, mobile testing clinics, and community outreach testing programs, it will be the context in which that testing is done that makes it actionable when it gets back to physicians, physicians’ assistants, anyone who is helping with those patients. As an industry, we need to figure out how we make the data actionable with the context necessary to do so.