POC testing roundtable: risks, resources, relationships

March 2019—*Infection control and the heavy demands on point-of-care coordinators were among the top concerns that came up in a recent* CAP TODAY *roundtable on point-of-care glucose testing. Publisher Bob McGonnagle spoke with four POC testing experts: Sharon Geaghan, MD, Cynthia Bowman, MD, Steven Cotten, PhD, and Corinne Fantz, PhD. Here is what they told us.*

We have seen many ups and downs in bedside glucose testing. There was at one point a mania for tight glycemic control; more recently, the FDA had concerns about the use of bedside testing devices in critically ill patients. Dr. Geaghan, what is top of mind for you now, and what are your concerns about point-of-care glucose testing and the devices?

Dr. Geaghan

Dr. Geaghan, emerita chief of pathology, Lucile Packard Children's Hospital at Stanford and emerita codirector of Stanford Clinical Laboratories: Two top concerns I have are the infectious risk of point-of-care glucose monitoring and the limitations of conventional glucose monitoring by fingerstick in terms of the quality of diabetes care and outcomes.

Recently, the CDC reported on health-care–associated hepatitis B and C outbreaks reported to the CDC from 2008 to 2017, and before we talk about the numbers it's important to remember that the long incubation period of these hepatitis infections—up to six months—and their typically asymptomatic course mean the outbreaks have likely been greatly underestimated. And reporting to the CDC is not required when state and local health departments are notified of outbreaks.

With that in mind, there was a fairly stunning summary of outbreaks of hepatitis B, which required more than 10,000 at-risk persons to be notified, and hepatitis C, which required more than 100,000 persons to be notified. The vast majority of these exposures were associated with point-of-care testing. The fact that single identified cases are not even included in this report and the breadth of settings—from home to long-term care to dialysis units to dental offices, and so on—make this a public health issue of great import.

Bedside glucose testing systems product guide

The CAP has gone a long way toward improving care by adding four requirements to its accreditation program checklist targeting some of the risks, specifically requiring single-use devices for capillary sticks, handwashing and changing gloves before and after patients, and disinfecting the glucose monitoring devices.

My second concern is the limitations of conventional glucose monitoring, mainly that it's not continuous, there aren't alarms, and very high and very low levels can go unnoted because of intermittent monitoring.

Dr. Cotten, would you like to comment on Dr. Geaghan's points?

Dr. Cotten, assistant professor, Department of Pathology and Laboratory Medicine, University of North Carolina School of Medicine: Decontamination of the device after use is an important aspect of creating an effective point-of-care program, and device manufacturers could probably spend a little more time in creating a device for which decontamination is easily documented. There has been such influence on the accuracy of the glucose measurement that often we forget all the other aspects that go into effective and safe use of the device in a hospital setting.

Dr. Bowman, former laboratory medical director, Baystate Wing Hospital, Palmer, Mass., and Noble Hospital, Westfield, Mass.: I would echo the concern about infection control, but it goes along with being aware of the limitations and the risks associated with these devices, and that's probably the biggest issue. The devices have gotten better, and we now have a different, less intense approach to glycemic control; we no longer aim for tight glycemic control. But even some people on the FDA advisory committee were not fully aware of the limitations of point-of-care glucose devices and that any hospitalized patient in a dynamic state could manifest the conditions that affect glucose meter accuracy.

Stakeholders, operators, and the laboratory need to be fully involved in educating people about this. Many are not aware of all the variables that go into the accuracy or usefulness of the devices. We need a strong verification process to introduce these concepts and test the actual practice of using glucose meters, but we also need to have a strong, comprehensive quality process that involves education and constant monitoring of their use and looks for outliers and possible inaccuracy.

The FDA is trying to waive a lot of these devices and get vendors involved so that they will qualify to have their devices waived for use with capillary samples, but there are still a lot of variables associated with that use, and we have to be respectful of that. That's a great opportunity for the laboratory to be a partner in educating people and assisting in the oversight of glucose meters.

Dr. Fantz, director of medical and scientific affairs, Roche Diagnostics point-of-care: I agree with what has been said. We see customers continuing to struggle with the package insert and being able to educate all the providers using the equipment because there are so many operators in an institution. Getting this information out in a coordinated way is one of the things we've focused on with education and the training materials we provide to customers.

When the CMS put out the directive warning about the limitations of these devices, it's not only that some hospitals didn't know those limitations existed, but also that they had to be able to develop quality monitoring programs and audit performance so that operators do what you intend them to do after they're trained.

Health systems are becoming enormous and they incorporate not only inpatient testing, but also, as they take over doctors' offices and clinics and other smaller hospitals and networks, bedside glucose testing. And it strikes me that the laboratory is given a heroic challenge in having to deal with so many hundreds or thousands of people who are engaged in bedside glucose testing to guarantee quality control. The same is true of point-of-care vendors. Dr. Fantz, is this much like swimming in an ocean?

Dr. Fantz

Dr. Fantz: Yes, it is. The demands on the point-of-care coordinator today are overwhelming. People in those positions are struggling to get to all of the sites they oversee on a monthly basis to do the auditing. That's why we think that the data analytics and software solutions that companies can provide can help, so they're not in their car traveling from site to site to analyze what's going on and only getting to the sites once a month or every other month. We do think that digital diagnostics and relying on software solutions to help them do their jobs more effectively is going to be a trend that continues.

Dr. Geaghan: I agree. The manual, old-fashioned visit doesn't suffice to the degree that's required.

Dr. Bowman: This is an example of where laboratories or systems need to provide resources for coordinators.

Point-of-care testing doesn't work well unless you have partnerships and clinical advocates. So you need to have a group that understands the issues—and that's not only nurse operators and other operators but also your providers and administrators—so they can support the efforts.

Dr. Fantz, can you tell us where Roche is on its offerings for digital and IT help in solving this point-of-care dilemma?

Dr. Fantz: We have a connectivity system, the Cobas IT 1000 connectivity solution. It is used to do things like manage your operators. It houses QC and also connects devices that run not just Roche devices but also third-party devices. That's just one aspect of it.

We are seeing the point-of-care connectivity piece a bit more broadly than other manufacturers. Everybody has their own solution, but what Roche is doing is investing in digital diagnostics more broadly. Roche is making investments in Viewics, which is a lab optimization tool. There is also a tool called Navify workflow solutions for pathologists to pull in information from other areas, not just pathology but radiology, et cetera, and consolidate reports. Eventually you will see all of that flowing together. The solution that works in one area may bleed over into point of care if it's working for Navify workflow solutions.

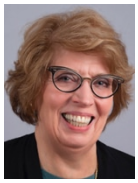
Dr. Cotten, what are you doing at UNC to address the concerns that have been expressed?

Dr. Cotten: I don't direct point-of-care testing at UNC like I did at my previous employer, Ohio State University Wexner Medical Center. I'll speak to this question from the OSU perspective. We took the package insert and intended use very seriously with our glucose devices, and that prompted us to develop a comprehensive management plan of how and where the device was being used and the type of specimens used. We developed criteria that were a decision support tool for the users, and that training eventually was incorporated into computer-based learning that was required by all users, and that worked out very well. It was a long journey from inception to effective deployment of the program, but it turned out to be successful.

We did see in certain populations reduced instances of hypoglycemia. We felt like we were now guiding the user to get the right specimen type for the right population. And they developed quality indicators that were monitored monthly and audited. That's an important component of any point-of-care program; you can't just let the devices go out in the wild and then not have oversight. As others have said, you can't do site visits at all your locations with all end users, so you need some way to effectively audit that data. Ohio State did a good job with that.

At UNC, we're kind of in the same boat. There are point-of-care coordinators who take compliance seriously and work closely to try to round at most locations, as much as possible and at least monthly, and they have QI indicators that are monitored closely by our director who is over point of care. There are the usual struggles and opportunities for improvement.

Dr. Bowman, you said it takes a systematic approach with a lot of commitment not only from nursing but also from clinical advocates. Do you foresee a greater commitment from nurses as these concerns come more to the fore in any institution or health care system?



Dr. Bowman

Dr. Bowman: It will vary but, yes, I do, especially if they understand the risks. This is the age-old conundrum of point-of-care testing: how to balance the lab's interest in technical needs with the operator's interest in clinical needs. Education, quality management, and auditing are extremely important, but there's no substitute for strong

leadership, commitment, and partnership. To me, point of care is a lot about developing good relationships.

Dr. Geaghan, how has the field evolved, and what hopeful signs do you see at Stanford?

Dr. Geaghan: More than 10 years ago, I went to a pediatric patient's room because I was offered the chance to see what an artificial pancreas looks like and how it works, and now it is a reality. It's about software and integration in a device system that doesn't need organs or synthetic tissue but is a safe and effective way to integrate the so-called first hybrid close-looped system, which was approved a couple of years ago.

And this field continues to evolve. To me, that's the most exciting future for this field: to integrate the monitoring, which should be automatic and 24/7, and then adjust basal insulin doses in the patient based on their innate close-looped system. The FDA has been committed to making sure these device systems are safe and effective and has developed guidance for these applications. This could be the future and eliminate fingerstick monitoring someday. But for countries and patients that don't have access to this, we have to have a parallel track of improving the conventional diabetes blood glucose monitoring.

Inpatients tend to be sicker than ever before, and with the enormous problem of diabetes in the population, the solutions you're suggesting for the future will play an important role in health care.

Dr. Bowman: But it's actually the nondiabetic population that may be more at risk from dysglycemia or conditions with hypoglycemia, hyperglycemia, and glycemic variability or swings in glucose levels. Dysglycemia may actually reflect a person's clinical severity and put sick patients at more risk. And there's literature that shows that diabetics who are used to the swings may do better, whereas a nondiabetic patient may be more at risk from dysglycemia since they are not conditioned to the swings. So we need to educate people that we're not dealing just with diabetes. We're dealing with dysglycemia, and that means that everybody may be at risk.

Labs have tight budgets and a shortage of qualified technologists, which would include point-of-care coordinators. Some systems have had to put in extra appropriations for laboratory personnel just to hold the cohort in place that they need to serve their patients. Dr. Fantz, have these laboratory labor issues and point-of-care coordinating issues affected point-of-care activities as you see them from your perch at Roche, and if so how?

Dr. Fantz: They absolutely do. We're being asked to develop software solutions that can help manage larger numbers of patients. We're also seeing from a regulatory standpoint a loosening of the guidelines to allow more people to do point-of-care testing. People who haven't been trained in laboratory medicine are now becoming experts in their own areas for their institutions for point of care. We're seeing more test development challenges because concepts that may be intuitive to point-of-care coordinators are challenging to others who have not been traditional users of point-of-care testing, such as troubleshooting, quality control, and operator lockout.

Dr. Cotten, how does the labor problem affect point-of-care testing?

Dr. Cotten: This speaks to the question of where we see point of care going in general. There is a push toward point of care because on paper workflows can be designed around a point-of-care test and on paper there is gained efficiency and cost avoidance, whether it's OR time or triaging. But the cost or the consequence of that is, as has been said, you're pushing the end user to a person who is not a laboratorian to do the testing.

Dr. Cotten

If you ask nurses whether they want to run more point-of-care tests, for most the answer is probably going to be no. Yet the trend administratively seems to be developing workflows, whether in a particular unit or in entire buildings, that are based around decentralized point-of-care testing.

I don't know if point-of-care testing is going to solve the labor problem; I think it's just going to create a different type of labor problem.

Dr. Bowman: Sometimes you think you're going to have a savings, but when you look at the monitoring costs and at the clinical workflow, it's not as big a savings as expected, and it may be more of a burden. So labs have to work with sites to be able to provide the best service they can. But you have to be aware constantly of clinical process and everything that's involved and, of course, there is the adage: If you have a bad process and you add point-of-care testing, all you have is point-of-care testing and a bad process.

So if you're thinking about adding point-of-care testing or using it as an adjunct, you have to open up the entire process and you have to get all your stakeholders invested and get the different perspectives. I'm sure we could all give examples of how you introduced a point-of-care test and it just wouldn't work. And when you looked at it, you saw there was an unworkable clinical process and it was never going to work in that context. In the right setting with the right process, it's wonderful, and it does add to efficiency and better quality. If you don't think that out, you could have a bigger problem on your hands.

Dr. Geaghan: I am a fan of the secret-shopper technique. If one has a resident, or whatever the level individual you can put on this, it's extremely helpful to see what people are doing out on the floor when they are not being watched in terms of ensuring patient safety in this point-of-care testing arena.

Eliminating the need for fingerstick blood testing for people with diabetes is now a reality with some of the new technologies the FDA has authorized, and that, to me, is the most exciting solution. As currently implemented, fingerstick blood testing continues to pose risk for patients as we see from the literature. In that sense, we still have a lot of work to do out there.

HemoCue America was unable to provide information for the product guide in time for publication.