POC glucose: views on volume, critical care, ACOs

April 2018—*Test volume, limitations on devices used in critical care, consolidation, and population health is what* CAP TODAY *asked about when it spoke in March with the makers of three bedside glucose testing systems. Their systems and those of two other companies are profiled here.*

"The customers are more aware than ever of the limitations that are in the package inserts from the glucose manufacturers," says Corinne Fantz, PhD, director of medical and scientific affairs for point-of-care testing, Roche Diagnostics. But she and Kevin Peacock, clinical marketing manager, HemoCue America, say there is still confusion. Here is more of what they and others told senior editor Amy Carpenter Aquino.

How has the decline in reimbursement coupled with a retreat from tight glycemic control affected test volume for patients at the bedside?

Courtney Sweeney, group marketing manager for point-of-care testing, Roche Diagnostics: Yes, the hospital blood glucose market growth has slowed down, likely due to the overall financial pressures in the industry. Hospitals are looking for the most effective ways to manage costs but also optimize patient outcomes. We do see that point-of-care blood glucose testing remains a critical part of patient care in health systems.

The other general trend is toward outpatient versus inpatient care, and this is attributable to many variables that could drive this, including declining reimbursement, hospital incentives to do interventions that impact outcomes, as well as modifying tight glycemic control protocols.

Jeffrey A. DuBois, PhD, MBA, MS, vice president, medical and scientific affairs, Nova Biomedical: I don't think people are abandoning glycemic management protocols. They have modified them slightly, so they're not as stringent. Some institutions have made adjustments to the cutoff levels. That is not a retreat from glycemic management; that's just refining the treatment protocol. Where hypoglycemia may have been defined at 75 mg/dL and below, some institutions now have moved the hypoglycemia threshold to 100 mg/dL and below. And there are some people who still want to be aggressive and have the glycemic range between 70 to 110. Many of the institutions have moved the range so that it's above 100, and it's referred to as safe and effective glycemic management.

If you're focusing on total glycemic control for cardiothoracic surgical patients, it depends on the institution. With the increasing number of diabetic patients admitted to the hospital, the demand for monitoring patients at the bedside has not come down. It's increasing.

I'm not aware of any decline in reimbursement having an effect on bedside glucose testing. We are seeing an increase in bedside glucose testing.

How are your customers adapting to the limitations on glucose devices for critical care applications?

Kevin Peacock, clinical marketing manager, HemoCue America: I think we could all hear the collective sigh of relief from the industry, since the 2016 FDA guidance related to strip meter accuracy was not nearly as restrictive as some predicted. Frankly, many customers are still very confused and are uncertain as to what devices are appropriate to use with which patients. HemoCue, having accuracy levels more associated with central lab results, will continue to be well positioned should the bar be raised even further.

Corinne Fantz, PhD, director of medical and scientific affairs for POC testing, Roche: Generally, the customers are more aware than ever of the limitations in the package inserts from the glucose manufacturers. What we've seen is that they're dedicated to determining the best testing approach for their specific population by first defining the right patient and the right sample in order to achieve high-quality glucose results. We recently sponsored a

webinar for customers that allowed the different integrated hospital networks to share their approaches, best practices, and lessons learned while undergoing changes in the systems that had them, or trying to adapt what they were doing to the new limitations with these meters in critical care settings. They said they have to have the right people at the table and understand what the issues are in their particular setting and what's relevant to physicians, the nursing group, and the laboratory. There needs to be solid communication at all phases with the project. The laboratory directors are the bridge between the point-of-care and hospital medical staff responsible for the testing. Being more collaborative works, rather than the laboratory directing or being an authoritarian type to the clinical staff. You need manufacturers, the clinical staff, and the laboratory all working in a collaborative environment.

All glucose meters have limitations and no meter currently is approved for use with capillary samples in that critically ill population. There is some confusion around that still.

Dr. DuBois (Nova): Our customers are adapting with a focus on patient safety, while conforming to StatStrip labeling requirements. When using the system to measure glucose on critically ill patients, StatStrip and StatStrip Xpress2 are cleared for use with arterial, venous, neonatal heel stick, and neonatal arterial specimens. The standard of care in most glycemic management protocols we've seen, for patient safety reasons, focuses on having either an arterial or a venous whole blood glucose measurement. StatStrip demonstrated no known clinically significant interferences that could cause erroneous glucose results contributing to patient adverse events.

Not all bedside glucose monitoring systems are created equal. Other devices in the marketplace have limitations and issues that have been addressed in the peer-reviewed literature and in device package inserts.

How has system consolidation—including established system clinics, ERs, and acquired physician practices—affected POC glucose testing for ambulatory patient testing?

Peacock (HemoCue): We see system consolidation as an advantage for the health systems and the patients they serve. Laboratory professionals have a greater understanding of point-of-care testing, including regulatory risks, compliance requirements, and testing limitations. As ambulatory sites integrate with hospital systems, lab supervision plays more of a role, even in waived clinics. Laboratorians get the science behind precision and accuracy. They get why our capillary sample is so different from strip meters.

Dr. DuBois (Nova): What is of interest is to have consistency in glucose measurement from home to clinic to hospital and back to home. One of the issues care providers are discussing is that they want uniformity in their glucose measurements so there's consistency in their care path and mode of treating the patients. When we discuss this with European colleagues, what's important is the alignment of the glucose meter method with a definitive method. If you read carefully the FDA Oct. 11, 2016 guidance for bedside glucose monitoring systems, they must show alignment to a definitive method. Not all of the glucose meters on the market have demonstrated, through FDA submission, alignment to definitive methods. They were approved prior to the guidance. They're still in the market. Nova StatStrip was not only cleared under FDA for use in the hospitals, including critically ill patient care settings, but also for use in the home. Now you have a product that can go home to clinic to hospital to clinic to home, and there's uniformity in glucose measurement.

Sweeney (Roche): Generally, we do see growth in the ambulatory environment. Consolidation may be driving a connected and standardized approach across the health system, which allows for better data management as well as point-of-care oversight.

How does glucose testing and the management of patients with diabetes fit into the concern laboratories have now for population health and accountable care organizations?

Peacock (HemoCue): As medicine becomes less centralized and more personal, there's not a one-size-fits-all

blueprint for patient care. For instance, a considerable part of our population cannot be diagnosed or effectively monitored with HbA1c alone. Plasma blood glucose continues to be reliable in effectively diagnosing and managing our growing diabetic population.

Dr. Fantz (Roche): What we see is that accountable care organizations are being incentivized to develop health care delivery models that impact the patient population as a whole. This includes preventive, chronic or outpatient care, and acute care, or the hospitalized inpatient groups. They have interventions that are being implemented to improve glycemic control and other outcomes. Glucose testing and managing diabetic patients are essential parts of these interventions. For example, they are expanding point-of-care data management solutions to the outpatient environment. That helps the providers capture and report on outcomes they could not previously capture and report, and those data are helpful for achieving their goals and targets.

Dr. DuBois (Nova): It is probably best addressed by looking at the numbers. When ISO 15197:2003 was published and accepted as the guidance for the FDA prior to Oct. 11, 2016, that guidance permitted five percent of results—below 75 mg, an absolute difference of 15 mg—and above 75 mg, plus or minus 20 percent. If that only has to occur 95 percent of the time, then that poses a significant public health risk. When you look at the number of glucose tests performed on these devices globally, we're in the neighborhood of 5.6 billion tests. If you multiply that by five percent that are allowed to be acceptable outliers, that means there is the risk of 310 million erroneous glucose results published off these devices that could affect patient care. If there is a device that meets both criteria and they're held to [accuracy] 98 or 99 percent of the time, then that risk has gone down significantly, especially if it agrees with a definitive method.[hr]