Pressing questions in POC glucose testing

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April 2015—Sometimes major changes to a health care organization's point-of-care testing system come from powerful regulatory agencies in Washington, DC. Or they may arise when a child with diabetes objects to frequent venipuncture. In either kind of case, experts say, pathologists and laboratory professionals must form strong relationships with clinicians and build structural foundations to help them meet these and other demands.

Most pressing is the challenge emanating from the nation's capital. After years of building concerns about the use of blood glucose monitoring systems among critically ill patients, in January 2014 the FDA issued draft guidance on point-of-care glucose meters that calls on device makers to submit data on how the meters perform in different patient populations.

"If you intend to make claims for use of your meter in populations that are particularly vulnerable to potential interferences, you should include patients in surgical and medical intensive care units," the guidance said. "To collect performance data in such populations, each study should include at least 50 patient samples from the surgical ICU and 50 patient samples from the medical ICU."

The draft guidance, available at http://j.mp/fdabgms, has drawn dozens of comments—mostly negative—from physician organizations and other stakeholders concerned about its potential impact. Among those objecting is the CAP.

In an April 16, 2014 letter, CAP president Gene N. Herbek, MD, wrote, "First, we believe that the term 'critically ill' is too vague and should be avoided. We think it is more appropriate, and more scientifically valid, to focus on the specific limitations cited by the manufacturers and the literature, as specific situations in which the meters should not be used for capillary samples, including, among others, severe hypotension, dehydration, shock, hyperglycemic-hyperosmolar state. We agree with, and strongly support, the specific exclusion of blood glucose monitoring devices, under any and all circumstances, for so-called tight glycemic control."

"The second issue," Dr. Herbek added, "is the implication of the FDA draft document on the manufacturers' current intended use package inserts, in that it could result in the immediate removal of BGM devices from acute-care situations. Removing these devices from a variety of hospital settings … will compromise some types of care because of the time delays associated with getting results from the central laboratory."

The FDA has not yet taken action to finalize or otherwise alter its draft guidance.

The agency did issue its first—and at this article's deadline the only—nod to a glucose meter for use among critically ill patients in September 2014, giving the OK to Nova Biomedical's StatStrip Glucose Hospital Meter System. The clearance is valid only when venous, arterial, and neonatal arterial and heelstick whole blood specimens are used.

In his letter, Dr. Herbek noted how the FDA's proposed move to tighten requirements for glucose meters could potentially compromise care. The Centers for Medicare and Medicaid Services then appeared to put flesh on the bones of that worry in November 2014.

The agency's Survey and Certification Group issued a memo to state survey directors warning that using a test outside the FDA's approved or cleared "intended use, limitations or precautions, as indicated in the manufacturer's instructions, is considered 'off-label use.'" That applies, the CMS said, "whether the test is waived or non-waived and it means that the test is considered modified and therefore defaults to a high-complexity test under the Clinical Laboratory Improvement Amendments regulations. This will require all laboratories using the device for an 'off-label use' to meet all applicable CLIA high-complexity requirements."

The agency also instructed surveyors to document off-label use when found, and to issue a written statement of deficiencies that would give cited hospitals no more than a year to come into compliance. That would entail establishing the performance characteristics and meeting the testing personnel requirements to continue using the glucose meter off label. Alternatively, health care organizations could switch to Nova's glucose meter or another POC device FDA-approved for CLIA-waived or moderate-complexity testing in critical-care settings, such as Abbott's i-STAT or Abaxis' Piccolo Xpress panel tests. Laboratory professionals can search the FDA's website for moderately complex testing options at http://j.mp/modcomplex.

Dr. Perry

For now, hospitals and labs may have room to breathe, says Deborah A. Perry, MD, chair of the CAP's Point of Care Testing Committee. She is a pathologist at Methodist Hospital and Children's Hospital and Medical Center in Omaha. As a result of pressure from stakeholders, including the CAP, the CMS in March temporarily withdrew its Survey and Certification memo and reissued it as a draft (http://j.mp/cmsbgm_memo), providing an opportunity for comment. The document clarifies that bedside glucose devices can be used, but they must be validated as a high-complexity test if used in situations not specified in the manufacturer's package insert and thereby regarded as off-label testing.

"The CAP is reviewing the draft and will comment as it continues to work with members and other stakeholders on a rational solution," Dr. Perry says.

The CMS proposal on glucose meters would pose a huge change to current practice, said Sharon M. Geaghan, MD, a member of the CAP's POC Testing Committee, former director of point-of-care testing at Lucile Packard Children's Hospital Stanford, and associate professor of pathology at Stanford University School of Medicine.

"For the vast majority of us, we're on a sinking ship without these devices.... Institutions must either cease point-of-care glucose testing in critical care areas, according to the FDA and CMS, or demonstrate to inspectors a robust performance evaluation in the intended population," she said at a CAP '14 session, "How to Surf the Wave of Point-of-Care Testing Technologies: Strategies for Establishing and Maintaining a Robust Quality System."

"This has really shaken us all in the industry—the vendors and health care professionals," she added.

"However, the FDA's oversight of off-label use is an important protection for patients," she tells CAP TODAY.
Dr. Perry says the regulatory direction outlined in the November 2014 CMS memo directly affects the clinical laboratory in two ways.

"First, use of a blood glucose meter not according to manufacturer's guidelines requires that the laboratory perform a validation study on non-waived blood glucose meters. And second, the test complexity changes and thereby who can perform the test changes accordingly," Dr. Perry says.

"These regulations have led health care facilities to review their current bedside glucose meters, their corresponding package insert and limitations, their current facility use of blood glucose monitors, and revise practices accordingly," she tells CAP TODAY. "One of the biggest challenges to many facilities has been defining the 'critically ill' population, with the second challenge having the appropriately trained personnel available to perform the blood glucose monitoring."

Washington's attempt to give health care organizations wiggle room in how they define what constitutes a critically ill patient for the purposes of glucose meter use is more of a headache than a help, says David S. Bosler, MD. He

also is a member of the POC Testing Committee and is the former medical director of POC testing at Cleveland Clinic.

“What’s happened here is that by just saying ‘critically ill patients’ and not providing any definition of what’s included in that, the FDA and CMS have left open to interpretation how those patient populations will be defined in a health system,” he says. “It could be someone who presents to an emergency room. It could be someone who’s in a code situation who needs advanced care and life support, who’s found pulseless—or it could exclude those things.”

“The more important question is not how you define critically ill, but how you define critical illness for the implementation of glucose testing,” Dr. Bosler says. “Probably the best thing to do is to understand the limitations and define protocols for those limitations, rather than just broadly painting critically ill patients with a big fat brush.”
Dr. Bosler, who now heads Cleveland Clinic’s reference laboratory operations, says there is a danger in applying the critical illness tag too broadly in an effort to comply with Washington’s dictates.

“Lots of laboratories and clinical organizations believe that restricted access to use of glucose meters in these settings will harm patient care,” he says. “The risk is that restricting access does more harm than it does good … potentially delaying diagnosis of hypoglycemia in these patients.”

The FDA and the CMS are not the only ones looking at this thorny question of glucose meter use in critically ill patient populations. The International Federation of Clinical Chemistry and Laboratory Medicine has established a workgroup composed of experts in glucose POC testing and critical care, as well as representatives from POC glucose device makers. The chair of the workgroup, Cynthia Bowman, MD, previously served as chair of the CAP’s POC Testing Committee.

“We know there are a number of technical and operational issues that have been associated with glucose meters,” Dr. Bowman says. “And those issues are potentially more prominent with critical care patients. That’s the very group of patients where you want the most accurate results, and where inaccurate results may have serious consequences. One of our concerns is that, both within the laboratory community and the broader clinical community, there may not be a full appreciation of all the variables or potential errors associated with glucose meters, especially with patients who are in a dynamic clinical state. Some experts believe that glucose meters have too much potential variation and should never be used for these types of patients.”

The IFCC workgroup will advocate a single high performance standard for glucose meters, but address the different ways that users can meet that standard. Dr. Bowman adds that a complete understanding of the issue requires looking beyond the glucose meter itself.

“It’s not just the accuracy of the result, but it’s how the result is used,” she tells CAP TODAY. “So, what is your definition of tight glycemic control, or glycemic control? And, then, what type of insulin-dosing protocol do you use? Those variables may be outside the lab’s control, but they are equally important in terms of what happens to a patient. We need to appreciate that there are variables associated with blood glucose results, but there are also variables associated with how those results will be used.”

Dr. Bowman recently joined Baystate Health System as laboratory medical director at Baystate Wing Hospital in Palmer, Mass., and at Noble Hospital in Westfield, Mass. She says the Baystate point-of-care testing staff is engaging with critical-care sites to survey how critical-care patients are defined, and how glycemic and insulin protocols are being used.

“We have to be engaging in these conversations,” she says. “We need to understand how our clinical peers are using glucose meters, whether they understand the potential limitations in different situations, how frequently they are measuring glucose levels, what glucose targets they use, and how they respond to those targets. If we do not know all this information, we are not working with a complete picture in a coordinated situation.”

Dr. Perry has been involved in the effort at Methodist and Children's hospitals to respond to the developing situation over blood glucose testing.

"We recently had a meeting with our representatives from intensive care, the emergency department, surgery, and so forth to work on our definition of what a critically ill patient is," she says.

While this specific circumstance is unusual, this kind of collaboration grows out of an underlying effort to make the process of evaluating POC test requests one that is multidisciplinary and evidence based.

"You need to make certain you have the right people at the table," Dr. Perry says. "If you have the right people and then you interact with them, you'll come to a good result."

An example of a good POC testing outcome, in Dr. Perry's view, started with a patient.

"We had one child at Children's who really got tired of getting a venipuncture," she said in the POC session at CAP '14. "He commented, 'I poke my finger every day for my glucose three or four times, and now when I come here for my hemoglobin A1c I have to do a venipuncture. How come?' And you know, kids are smart. Being at a pediatric hospital, it's amazing. They know about blood and blood draws. So we did something to address that."

Clinicians had a concern too—to have the A1c results while their patients were still in the clinic. The first plan was to have children get drawn at the phlebotomy outpatient area before going to the clinic. But that was not a foolproof solution because results did not always get to the physician's office in time, and sometimes patients needed other laboratory work, which meant a second trip to the phlebotomist in the same day.

To address the issue, they brought in a POC testing device for A1c, first to the central lab "to make sure that analytically it was good and to make sure that it was easy to use, easy to perform," Dr. Perry said. "We found that it met all those criteria." The next step was to put the same point-of-care device into the endocrinology clinic and train a select few endocrinology nurses.

"Now the kids could either have it done in the central lab, if they had other laboratory tests done, or in the clinic," and having it in the clinic solved the problem, she said. "What happens is the kids can get a point-of-care test for the hemoglobin A1c, the result is back while the child is in the clinic, and the doctors can look at them and say, 'You know what, your A1c is 10, Johnny. Quit eating so much pizza, drinking so much pop. You're not in compliance.' As opposed to calling him three or four days later."

Patients and clinicians were happy with the change, and the lab was satisfied with the accuracy of the device. But harder outcomes, such as whether patients' A1c or overall diabetes is better controlled, or whether their hospital admission rates have dropped, are yet to come, Dr. Perry said. She and her colleagues are working to evaluate that now. The medical literature on the outcomes correlated with POC testing is fairly sparse, she noted, and she urged measuring outcomes as a routine part of evaluating the success or failure of a proposed POC test.

"If you're bringing a new point-of-care test online, go all the way from drawing the blood and performing the test to the outcome and looking at what you're going to see," she said. "Did this change the process of the patient experience? Did we get somebody through the ED faster? Did we get someone through radiology faster because now we have a bedside creatinine test that they can do right before their scan rather than going to the lab, getting a creatinine, waiting for that?"

In his CAP '14 talk, Dr. Bosler detailed the Cleveland Clinic's Point of Care Compliance Council. When he became medical director of POC testing in 2009, the council was active in the health system's main campus. He and his colleagues expanded oversight to Cleveland Clinic's eight regional hospitals in Northeast Ohio, as well as its outpatient clinics. The idea is to have a central, multidisciplinary body that assesses requests for new POC tests according to established criteria.

"There's a lot of baggage that comes with point-of-care testing, but at its base it's not either all positive or all negative," Dr. Bosler said. "Each new opportunity for point-of-care testing requires assessment of the individual

application in order to determine whether it is bringing value to the end goal, which is to improve patient care."

The central question, he said, is whether the benefits of a POC test outweigh the risks. That involves looking at the clinical application, the perceived value to patient care, the anticipated volume, the number of users and their credentials, the number of sites, and the setting of the testing. Other factors to evaluate are the differential in quality of the POC test method versus the central laboratory, the CLIA status, and the costs.

Clinicians frequently misunderstand the financials associated with bringing in a new POC test, Dr. Bosler tells CAP TODAY.

"They might, for example, look at the cost of test strips and compare it with the charge-master price for a given test and say, 'Look, it's so much cheaper.' But when comparing the full cost of the point-of-care test to the full cost of the automated line, it is really difficult to make the case that the POC test is cheaper on a test-by-test basis, unless you can make the case that having the result earlier will make a difference in patient outcome or efficiency," he says.

"Point-of-care testing quality management also can be complex, if you have high volume, and a high number of instruments, and a broad number of users that you need to manage centrally with a quality coordinator. And if you don't have interfacing capabilities, that drives a lot of manual processes. The clinical team may not be thinking about those efforts and costs."

This is just one area that is regularly elucidated through the systematic process of evaluating POC test requests through the Cleveland Clinic council, Dr. Bosler said in his talk. But that exchange of perspectives will not occur if the laboratory alone is making the call.

"This really should not be done as the laboratory making decisions in a vacuum," he said. "We need to have a cross-functional team because to impact a system of care, the decision process must involve cross-functional representation of the system."

At the Cleveland Clinic, that means representatives from quality and patient safety, pathology and laboratory medicine, inpatient and outpatient nursing directors, and more. There are two reasons why that inclusive approach is essential, Dr. Bosler explained.

"One is that cross-functional representation provides better input to start with; it yields better decision-making. And secondly, cross-functional input, once those decisions are made, really helps to drive the execution and compliance with those decisions…. An important concept is that engaged leaders will be a powerful ally in alignment of priorities, resources, and compliance efforts."

As an example of the process in action, Dr. Bosler told of rheumatology's seeking to use synovial fluid crystal analysis at the point of care. This was a high-risk setting, the council judged, because it was at multiple sites, with low volume, performed by physicians who may be less likely to comply with policies and procedures, and highly complex, and it involved a manual method with manual resulting.

The council approved the POC testing program, but not before designing a compliance program and coming to terms with the rheumatologists in a detailed service level agreement. The document spelled out what would be done by laboratory medicine, and what would be the responsibilities of the rheumatology department and its testing staff with regard to documentation, competency and proficiency requirements, inspections, maintenance, and reporting. The council held the lever of withdrawing its authorization for the POC program if the rheumatologists didn't follow through on the agreement.

"This is a tool that we can use to provide both role clarity—so it's very, very clear from this document what the responsibilities of the rheumatologist and the rheumatology department are—but then also accountability, because we can point back to it and say this is what we agreed you would be doing," Dr. Bosler said. "So if either party is sort of lapsing on this, we can draw back to the document."

In addition to evaluating POC testing's quality outcomes and taking a collaborative approach to assessing new POC test requests, it is essential to ensure that POC testing is done in a way that minimizes the risk of disease transmission, said Stanford's Dr. Geaghan. She discussed several hepatitis B and C outbreaks that have been traced to POC glucose meters and related equipment, and outlined steps hospitals can take to improve patient safety.

Only single-use lancet devices should be used, she said, and meters must be disinfected after every use. According to the CDC, the POC glucose meter should be restricted to a single patient, if possible. Meters should be properly stored to eliminate their inadvertent use for other patients. Nurses and other health professionals administering the tests should change their gloves and wash their hands between each testing event, and single-use packaging of glucose test strips also should be considered.

"It's our responsibility to protect our patients and use best practices," Dr. Geaghan said.

The best single action hospitals and clinics and other facilities can take, in her view, is to do an unannounced observational audit.

The goal of patient safety and many others in POC testing can best be achieved through a collaborative process, Dr. Bosler says. He brings this story back to where it began with the federal government's impending regulations on glucose meter use among critically ill patients.

"It's the process of building relationships that over time helps you," he says. "Just the process of defining a critically ill patient is a primary example that requires a multidisciplinary approach. And it's easier to have those conversations because of the infrastructure that's been set up, and the communications that were set up, through our point-of-care council. Not necessarily that all the people who would be involved are attending regularly, but there's a network of interested parties to start with."

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