Personnel paradox and more: POC pitfalls

Charna Albert

November 2019—Point-of-care testing makes up only about 10 percent of all laboratory testing but the aggravation factor and number of people involved far exceeds that, said Deborah A. Perry, MD, medical director of pathology at Methodist Hospital in Omaha, Neb., speaking at CAP19 and calling POC testing "a whole different world."

In a session titled "Point-of-care testing pitfalls: what you don't know can hurt you," Dr. Perry and Brad S. Karon, MD, PhD, professor of laboratory medicine and pathology and co-director of the point-of-care program at Mayo Clinic, used scenarios to illustrate point-of-care testing risks and how to mitigate them.

"Initially, people kind of let the point-of-care side of the world go to the medical technologists, and the laboratory medical directors hoped we wouldn't have to worry about it too much," said Dr. Perry. "But as we have watched the point-of-care testing volume and test mix grow, and have undergone on-site inspections, we now know that as the medical director it's your responsibility to make sure it's done right."

"We're here to tell you some of the frightful things that have happened to us in point of care, and hopefully help you avoid those," Dr. Perry added.

Here is scenario No. 1: *Nursing performs competency assessment for POC on career day, where competency is assessed for both waived and moderate-complexity testing. Some nurse educators performing competency have four-year degrees with less than one year of experience in POC, while others have associate's degrees in nursing but many years of experience in POC. Some of the nurses being assessed work in different buildings under different CLIA numbers.*

In a CAP inspection, the laboratory in this scenario would be cited for having nonqualified technical consultants sign off on competency assessments for its nonwaived testing and for completing competency assessments at a site other than where lab testing is actually performed, Dr. Karon said. For nonwaived testing, competency assessments must be done "at the site where the test is performed at each CAP and CLIA number," he said.

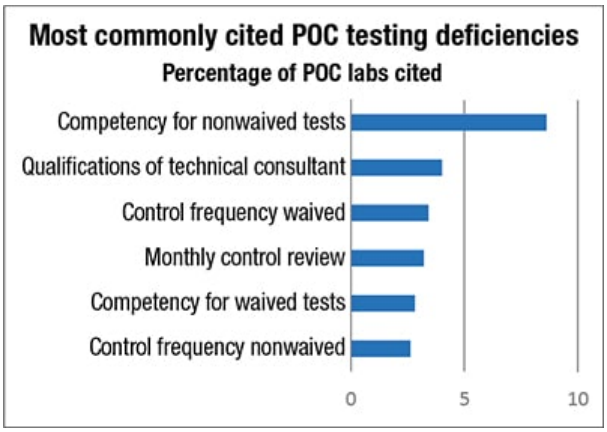
"I've directed Mayo's program for 15 years, and our nurses are perfectly understanding when we need to follow them around to all three clinics where they perform nonwaived anticoagulation testing to assess their competency," Dr. Karon said, with a touch of humor.

Competency assessment is the No. 1 citation year after year, in the Laboratory Accreditation Program as a whole and in POC testing specifically, "and explaining why this has to be done can be difficult for point-of-care directors," he said.

In point-of-care testing, the second most cited deficiency is for nonqualified technical consultants signing off on competency assessments for moderate-complexity testing.

Under CLIA rules, personnel performing and signing off on competency assessments for high-complexity testing must meet technical supervisor (often known as section or medical director) or general supervisor requirements. Technical supervisor requirements can be fulfilled with a doctoral, master's, or bachelor's degree in clinical laboratory, biological, chemical, or physical science and one year of training and experience in high-complexity testing. General supervisor requirements can be fulfilled with an associate's degree in an approved science and two years' experience in high-complexity testing in that area, such as microbiology, chemistry, or transfusion medicine.

For moderate-complexity testing, on the other hand, "the role of general supervisor does not exist; therefore, only a technical consultant or the CLIA medical director can perform and sign off on competency. Technical consultants must have at minimum a four-year degree and two years' experience" or a doctoral or master's degree and one year's experience, Dr. Karon said.



"This is obviously somewhat of a paradox. High-complexity testing is high complexity; it's supposed to be more complex. But our general supervisors with associate's degrees can sign off on competency" for high-complexity testing, he said.

At the point of care, "many larger hospital-based programs do both waived and moderate-complexity testing," Dr. Karon said. "In our practice, almost all our point-of-care coordinators have associate's degrees and do not qualify as technical consultants." If the laboratory medical director or someone else meeting technical consultant requirements doesn't sign off on competency, "we have unqualified people overseeing competency for moderate-complexity point of care. Full disclosure," he added, "three or four years ago, our program at Mayo Clinic did get cited for a nonqualified person performing competency assessment. It happened to me, and therefore I'm sharing my wisdom with all of you."

On the other hand, hope may be on the horizon when it comes to the personnel paradox, said Dr. Karon, who is also a member of the Clinical Laboratory Improvement Advisory Committee. The CMS recently solicited public comment on personnel requirements, and a CLIAC working group was formed to make recommendations on a number of personnel issues related to CLIA. Though the timeline is uncertain, he said, the CMS could in the future standardize personnel requirements for technical consultant and general supervisor. (A summary report of the April 2019 CLIAC meeting is available at www.cdc.gov/cliac.)

Dr. Karon laid out five general rules for preventing competency assessment-related citations:

- Ensure assessments do not exceed one year for waived and nonwaived testing.
- Ensure new staff who perform nonwaived testing are assessed semiannually the first year of testing.
- Ensure POC test systems are defined and all six elements of competency are used for each nonwaived test system. Competency assessment must evaluate the six elements defined by CLIA for each test system, including direct observation of test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, direct observation of instrument maintenance and function checks, employee analysis of PT or blind sample, and evaluation of problem-solving skills. For waived testing, laboratories can select from the elements.
- Ensure it is clear which element was used when documenting competency

assessment.

- Ensure qualified individuals are assessing competency.

Scenario No. 2: Your human resources group insists on maintaining records for point-of-care nursing and respiratory therapy testing personnel, including diplomas, transcripts, and primary source verification, centralized in the HR department. You're concerned this could be a problem for you in your upcoming CAP inspection.

"What documents are required for your CAP point-of-care inspector?" Dr. Karon asked session attendees.

Dr. Karon

When audience response was mixed, he explained that for CAP inspection all that's needed is evidence that an institution's primary source verification system (PSV) is effective. "I inspected large point-of-care programs that decided it's easier to keep transcripts in the lab office," he said. "You can choose to do that, but because CMS now allows primary source verification, the CAP accreditation program also says you can use PSV; you just have to prove it's effective."

At Mayo Clinic, more than 850 personnel perform nonwaived POC testing. If the CMS and the CAP accreditation program didn't accept primary source verification for proof of diploma, "our coordinators would do nothing but bug people about their transcripts," Dr. Karon said.

The CAP has tools to help laboratories keep track of POC testing personnel, including the laboratory personnel evaluation roster, a worksheet labs submit as part of the accreditation process. At Mayo Clinic, where the point-of-care program operates under its own CLIA certificate, Dr. Karon said, "all 850 of our nonwaived testing personnel are included on the roster, so we and CAP can figure out who is this person, what role do they have, are they a technical consultant, or are they just a tester? And how did we verify that they qualified? Did we ping their PSV and it worked? Did we ping their PSV and it didn't work so we got a copy of their transcript on file?"

Where PSV does tend to fail is in verifying the educational credentials of personnel trained outside the U.S., a potential risk Dr. Karon outlined in the third scenario.

Scenario No. 3: You are inspecting a POC testing program. In this program, the nurse performing nonwaived testing has a translated transcript showing an international bachelor's in nursing degree, but few credits in chemistry, biology, or physics. The transcript is translated into English and shows a terminal nursing degree issued from another country, but no equivalency evaluation from a nationally approved agency.

Inspectors in this situation, Dr. Karon said, would have to cite the program, since there is no evidence the nurse's international nursing degree is equivalent to a bachelor's in nursing degree obtained in the United States.

GEN.54400 Personnel Records says if a diploma or PSV report does not specify one of the required areas of study or is for training obtained outside the U.S., there must be records showing that qualifications are met using other acceptable means—transcripts, equivalency evaluation. And the training and qualifications of all personnel trained outside the U.S. must be evaluated by a recognized organization to determine equivalency to an education obtained in the U.S., with records of the evaluation available in the personnel file. "You can't just translate your degree," Dr. Karon said. "That's why at Mayo Clinic we still have to bug about 100 of our nonwaived testing personnel for their diplomas and transcripts."

This is where we air a little dirty laundry," Dr. Perry said midway through the session, launching into a "scenario which shows you that as laboratory medical directors, if we don't pay attention to point-of-care testing, we can get into trouble."

At a pediatric hospital, nursing staff were performing thromboelastogram (TEG) testing in the PICU, Dr. Perry said. "We in the lab agreed to let them do it. The nurses in the PICU were trained how to draw the blood and perform the TEG testing, and the PICU physician, who had done TEG testing where he trained, was going to do the analytical interpretation."

At the time, the laboratory didn't have a designated point-of-care coordinator. "But somebody in the lab was put in charge of training the nursing staff on performing the testing, which was a bit of a challenge," she said. Nurses in the PICU performed about 150 TEG tests per year.

No issues with test performance had been reported to the central laboratory, so the laboratory medical director didn't realize anything was awry until CAP inspection. "Lo and behold," said Dr. Perry, "21 of our 23 phase two deficiencies were related to TEG. This was a big wake-up call to the laboratory and hospital and everyone else."

Dr. Perry polled session attendees about what they would do in that situation, given the following options: meet with the PICU director to review the deficiencies and come up with a new plan; cease TEG testing in the PICU; or cry, scream, and yell.

"There's more than one right answer on this one," she said. "Cry, scream, yell, and swear happened initially," before the laboratory medical director, PICU director, and hospital administration made the call to cease TEG testing in the PICU.

Dr. Perry

"Obviously, our PICU physicians were not happy with this decision," she said. "But the decision was made partly because we didn't think we could take care of fixing all of the problems with the instrument in a timely manner to provide accurate testing. Literally, we pulled TEG out of the PICU, put it on a cart, and put it in a box in the laboratory and buried it." The response to the CAP: testing no longer performed.

Of course, the laboratory still needed to determine a new approach to providing TEG testing. For a year and a half, it sent samples to another laboratory in the city. "That was not a great answer in that TEG is a real-time whole blood test so you like to do it right away," Dr. Perry said. Second, transporting samples from the pediatric hospital to the other hospital and receiving results back was taking two to three hours, and "of course the PICU wanted it back in about two minutes."

The laboratory began to discuss moving testing to the pediatric hospital's central laboratory. "This brought up a whole lot of questions, not just related to TEG," Dr. Perry said. For example, "What should we do in the lab so this never happens again?"

For one, the laboratory medical director was able to justify a full-time point-of-care coordinator position to hospital administration. "If you don't have a point-of-care coordinator, life as a laboratory medical director is a real challenge."

Other valuable lessons? Before beginning a new point-of-care test, "we actually have to go to the PICU or the OR or the ED and make sure testing personnel are trained, stay competent, and do proficiency testing."

“This is a reminder to all of us who are laboratory medical directors,” she said, that if there is a problem with point of care, “it’s not just the coordinator who’s going to get dinged. It’s us. We need to pay attention too.”

The TEG instrument, Dr. Perry said, is now located in the central laboratory of the pediatric hospital. PICU personnel draw the blood samples, which are then transported to the central lab where laboratory medical technologists perform the testing and enter the results so PICU physicians can see and interpret them. TEG testing is now billed for, “which we found out actually hadn’t been happening.” Three years later, “patient care is back in a good place.”

Scenario No. 4: A 300-bed community hospital with 20 operating rooms has one Hemochron for ACT in two ORs, one EPOC, and six blood glucose meters.

“A new CV surgeon arrives in town, who’s kind of a bit of a cowboy, Dr. Perry said. “He says he wants an additional Hemochron, as well as two EPOCs for the PACU and the cardiac care unit, ‘in the OR when I start tomorrow.’”

Dr. Perry asked session attendees if in this situation they would simply order the new devices and install them, meet with the OR and cardiac team leaders to develop an implementation plan, or pull the POC devices from where they are and move them to where the surgeon directs.

“As laboratorians, we get requests for all sorts of things,” Dr. Perry said. “Many times, we can fix the problem with what we already have. And other times we need to change things, but it involves workflow and people.”

Handling the new surgeon’s request correctly, she said, would require meeting with the OR cardiac team and asking questions: “First we need to know, how many cases are you going to be doing? Will all cardiac cases require point-of-care testing? If so, which ones? Do you just need the coag piece, the Hemochrons? Do you need glucose tests? Do you need EPOCs? Who’s going to do the testing? Many times it’s the perfusionists, but it could also be the nurses. Who’s going to purchase the instruments? Sometimes it’s the OR that purchases them, and sometimes it’s the lab.”

Once new equipment is implemented, it’s the responsibility of the point-of-care coordinator to provide training and draft a procedure, determine the IT interfacing, and verify billing. “As those who run point-of-care programs all know, most people who do the testing have no idea of the reporting side, the billing side, and the ordering side. All they know is they have a device and they want to put a drop of blood and get a number. So it’s our job to make sure all the rest of the elements are done,” she said.

Charna Albert is CAP TODAY associate contributing editor.