Dodging point-of-care testing potholes in PT, IQCP

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December 2019—For point-of-care testing, perform proficiency testing on only one method or instrument unless your testing procedure says all patient samples must be tested on multiple instruments. And if a single IQCP is written for more than one POC testing location, account for all variations.

These and other tips come from a CAP19 session, "Point-of-care testing pitfalls: what you don't know can hurt you," presented by Deborah A. Perry, MD, medical director of pathology at Methodist Hospital in Omaha, Neb., and Bradley S. Karon, MD, PhD, chair of the Division of Clinical Core Laboratory Services, Department of Laboratory Medicine and Pathology, Mayo Clinic. They used scenarios to illustrate how best to approach PT, the IQCP, and CAP inspections for POC testing. (Part one is published in the November issue.)

PT has unique aspects related to point of care because point-of-care programs tend to employ high numbers of devices, said Dr. Karon, who is also co-director of Mayo's stat labs and point-of-care testing programs. And in 2016 the Centers for Medicare and Medicaid Services said labs are "not allowed to report PT on more than one instrument or method unless that's how all patient results are reported."

"We always say treat and monitor PT like a patient specimen," he said, adding, "It's complicated because there are times when you cannot treat your PT like a patient sample. You certainly can't refer it between labs A and B if they operate under separate CLIA licenses. Even if you confirm all point-of-care INRs over five with plasma, you can't do that for PT if you're crossing a CLIA license—and there is some risk for doing this within a CLIA lab unless the SOP is very clear on what situations require a lab confirmation of POC INR." There are also practical considerations and limitations to confirmatory testing, he added. PT materials designed for whole blood INR may not work well for laboratory methods.

Second of two parts. Last month: Personnel paradox and more: POC pitfalls

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Also tricky, he said, is how laboratories should handle PT for POC programs when they're under the same CLIA certificate as the lab, and when they're not.

With these two issues raised, he introduced this situation: *You are a laboratory director for a stat lab and POC program (operating under the same CLIA number), both doing plasma PT/INR, and your POC program supports several dozen nonwaived whole blood POC INR meters.*

The laboratory director in this situation could avoid sanctions related to performing PT on more than one method by ordering unique whole blood and plasma PT kits, Dr. Karon said. Other options: Order a plasma PT/INR survey and do a comparison between laboratory plasma and whole blood POC INR (alternative assessment for the nonwaived meters) using patient samples, or order a plasma PT/INR survey and use a PT/INR plasma Quality Cross Check product to test each of the nonwaived meters.

"Only perform PT on one method or instrument unless your procedure states that all patient specimens get tested on multiple instruments," he said. "This applies to regulated, nonregulated, and waived analytes." If a lab enrolls in a waived glucose PT survey and a nonwaived plasma/serum glucose PT survey under the same CLIA certificate, the PT products will be different, and that is acceptable. "But if it's the same PT material, you can't test both." This affects labs that have multiple instruments and split lab/POC programs.

In 2017 the CAP accreditation program stopped requiring enrollment in PT for waived whole blood glucose or

waived whole blood INR testing, “in recognition of the fact that we have lots of glucose meters, INR meters, and i-Stats in our institutions, specifically for glucose and INR, and the CMS will only allow you to buy one kit and test it on one glucose meter” per cycle, he said. “If an institution has 500 meters, it wouldn’t make sense to require that laboratory to buy a kit to test one of 500 meters every cycle. It would take 30 years to get through all the meters with PT.”

“But,” he said, “this is where it gets tricky.” Nonwaived glucose is regulated, and CLIA requires that labs be enrolled in PT for regulated analytes. INR is not a regulated analyte, but the Laboratory Accreditation Program requires PT enrollment for nonwaived INR testing. If a laboratory’s POC program is under a separate CLIA certificate and performs nonwaived glucose or INR testing, “even if you have 400 nonwaived point-of-care glucose or INR meters, you still must enroll in a PT survey,” Dr. Karon said. In this case, only report results from one of the instruments/meters per PT event.

A laboratory that uses more than one method for the same test should use the primary instrument for PT. As a general rule, Dr. Karon said, whichever instrument performs the higher test volume is considered primary, but ultimately it’s up to the laboratory director to designate which instruments are primary and which are secondary. “You can cross-check against the primary,” he said. Labs can use the CAP Quality Cross Check programs or develop their own cross-check procedure.

Multiple kits can be ordered under the same CLIA number, but the lab has to ensure it doesn’t run the same PT material on any other instruments before the due date provided on the result form. “That gets risky,” Dr. Karon said, “but some labs will do that as a way to make sure they’re checking their systems without violating PT referral.”

Dr. Karon turned to POC lab inspections and shared the following scenario: *You are inspecting a hospital POC program (or leading a team and have asked a team member to inspect). The POC program has seven sites performing POC testing, five tests/instruments/methods (two nonwaived), and 30 nonwaived testing personnel. During the POC inspection you visit three sites (all doing just waived glucose meter testing), speak with three operators (all nurse managers familiar with POC procedures), and find no deficiencies. Two months later a CMS validation inspection of the POC program goes to the cath lab (a site you did not visit) and finds expired reagents, multiple unqualified testing personnel, and testing staff generally not knowledgeable about procedures. Among other citations, a condition-level citation is given to the lab director for failing to ensure quality system functioning and lack of oversight. What went wrong with your inspection?*

The inspector should have sampled sites in order to observe each of the five POC tests offered, rather than have visited only sites performing waived glucose meter testing, Dr. Karon said.

Inspectors “do have to sample,” because it often isn’t possible to visit every testing site, especially with larger programs, he said. “Six months ago, I inspected a site that had point of care at 55 to 60 sites under three different CLIA certificates. I’d still be there if I were going to visit every site.” If an inspector is going to sample, he advises picking higher-volume, higher-risk areas—his favorites are the ED and catheterization lab—and visiting waived and nonwaived testing sites. Some programs get so engaged in their nonwaived regulations they forget about their waived. “It’s rare, but it has happened in my inspections,” Dr. Karon said.

He noted that planning for point-of-care inspections is more difficult than it is for lab inspections because the inspection information packet doesn’t always reveal which tests are performed at which site. “As a point-of-care inspector, I wait until I’m on site to talk to a coordinator.”

A few of Dr. Karon’s tips for inspectors: Ask the POC coordinator to direct you to testing sites, but “don’t let the coordinator select the sites for you. They’ll take you to sites they know are very compliant.” At each site, ask a nurse to run through procedures for the testing performed at that site, “but again, don’t allow the coordinator to bring you the charge nurse who’s a trainer for the test method. The trainer always knows the answers. Talk to the nurses who are doing testing but are not in charge of the platform. Jot down the names of nurses you talk to in order to look up their competency and training materials, especially for nonwaived testing.” Ask what-if questions

from the SOP: When do you need to confirm the INR? What do you do if capillary glucose results are greater than 400 mg/dL? Ask testing personnel to locate the procedure for you.

Visit sites where POC instruments aren't interfaced and data are entered manually. "What we care about is that the results get in the electronic medical record," Dr. Karon said. Typically, he asks to see results in the EMR from the three most recent tests performed at the site.

Observe testing, if possible. "I've had success getting time from the cath lab nurse to walk me through the steps of testing," Dr. Karon said, and he's had the same success in the ED. It's busy but "be patient. Find a nurse to take you to an empty trauma pod and walk you through the test."

"How do you know if a new device for your point-of-care program is eligible for an IQCP?" Dr. Perry asked, in her presentation on individualized QC plans. "First of all, if it's a waived test, you don't need it," she said, advising directors to find waived tests for point of care, if possible, because the requirements are easier. Any nonwaived testing that employs an internal QC system is eligible for an IQCP. "And even if you do your own internal study," the number and frequency of controls tested cannot be less than indicated by the manufacturer's QC instructions, Dr. Perry said. Laboratories that don't write IQCPs for nonwaived instruments are responsible for two levels of QC per day. "In point of care, we know that's a lot of money and a lot of wasted cartridges."

Most laboratorians are familiar with the three-part basics of IQCPs—risk assessment, quality control plan, quality assessment. But point of care has unique considerations. Dr. Perry presented this scenario: *A 200-bed community hospital in California offers POC testing in the ED and ICU, which is performed by nursing staff. EPOC and bedside glucose testing are performed. A CAP on-site inspection cited no deficiencies related to POC testing, but a follow-up CMS validation inspection identified two POC testing-related citations: The technical consultant performing the competency assessment was not qualified, and the risk assessment portion of the IQCP was incomplete.*

The laboratory had written an IQCP for the nonwaived EPOC, but the CMS was concerned because the lab had written only one IQCP for two testing locations—the ED and the ICU. "Each lab with a separate CAP/CLIA number must do its own risk assessment," Dr. Perry said. "If there are multiple sites with the same instrument and device within one CAP/CLIA number, you have a couple of options."

One is to write a single risk assessment but account for all variations. "You're certainly going to have different people performing testing in the OR than in the ED or ICU. The environment will also be different. You can either write different IQCPs for each location," or write one large IQCP, documenting the differences in location and personnel in the risk assessment portion.

The CMS cited the laboratory in the preceding scenario for failing to have all five components of testing in its risk assessment. Risk assessments are "very prescriptive," and must include the preanalytic, analytic, and postanalytic testing phases and the five components of testing: reagent, environment, specimen, test system, and testing personnel. "If you miss even one of the five," Dr. Perry said, "the risk assessment portion will be considered inadequate."

Developing risk assessments for new POC devices poses an additional challenge when "there isn't any equivalent testing in the lab to compare it to," she said. Laboratories can use the data gathered during the test method verification process. "And sometimes you have to use the default QC for a period of 20 to 30 days to collect enough data to implement an IQCP."

Dr. Perry

An IQCP's quality control plan should "define all aspects of everything you're going to do," Dr. Perry said. "So the number of QC, the type of QC, whether it's external or internal, the frequency of your controls, your acceptability criteria. Sometimes in point of care we forget to write whether a test is qual or quant, and what exactly will be acceptable QC. As we know, point of care is often not in the lab," so it's critical to document a plan for monitoring the testing environment and reagents. "Make sure those reagents are in the fridge if they need to be and that the fridge is monitored."

For quality assessment monitoring, the laboratory medical director or a designee should review QC, instrument maintenance, and function check records at least monthly. "Any complaints from clinicians or other health care providers regarding the quality of testing also must be reviewed monthly," she said.

In addition, reevaluate the quality control plan. If there are changes in the environment or with specimen testing, "document those in your IQCP and note the change to your quality control plan."

Quality assessment monitoring "is sometimes not well documented and not well done," Dr. Perry said. The most common IQCP citations— "evaluation of errors relating to all phases of the testing process" and "evaluation of corrective actions taken if problems are identified"—are related to quality assessment monitoring (COM.50600). "If you do those things correctly," she said, "you won't get citations. And, more importantly, the patients will be taken care of right. That's our ultimate goal."

Charna Albert is CAP TODAY associate contributing editor.