IQCP worries? Help with what ends and begins

Anne Paxton

July 2015—Technically, it's true: The Centers for Medicare and Medicaid Services' new program, the Individualized Quality Control Plan, is a voluntary, alternative option that clinical laboratories can use to customize their QC plans according to test method, patient population, environment, and personnel competency.

For much of the laboratory community, however, "optional" is the last word association they would make with "IQCP." What many see is an entirely new quality control framework to grapple with every day; a looming cutoff date when the old, reliable system will become extinct; and potentially a major drain on their workday time and energy to cope with unfamiliar concepts of risk assessment.

It's no wonder that, as CMS' Jan. 1, 2016 implementation date nears, some laboratory directors are considering an Ativan prescription. But as a service to CAP-accredited labs—and with the aim of keeping panic at bay—the CAP has marshaled an array of resources to ease laboratories' transition to IQCP. Already available are workbooks, algorithms, templates, lists of frequently asked questions, and other guidance from the CMS, the CAP, the Clinical and Laboratory Standards Institute, and the American Society for Microbiology. Now, the CAP Laboratory Accreditation Program has integrated IQCP requirements into the 2015 edition of the All Common Checklist, which at CAP TODAY press time was scheduled for release at the end of July.

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"For those who are writing individualized plans using IQCP, the Laboratory Accreditation Program wants to provide support, and so we're offering nuts-and-bolts help," says checklist commissioner Gerald A. Hoeltge, MD. "The All Common Checklist will have a brand-new section on IQCP that will itemize all the pieces that must be in place, and you can go to the College's 'Frequently Asked Questions' page for a really clear preview of what you'll need to do."

There's really nothing mandatory about IQCP, Dr. Hoeltge emphasizes. "Labs can continue to do the traditional two controls each day of testing. But we're getting toward the end of the transition period, and more labs are going to be thinking about IQCP and working toward it."

IQCP's downside is undeniable. Establishing an IQCP in a laboratory involves a significant amount of work compared with what was required to implement the Equivalent Quality Control (EQC) program as developed by CLSI, says Adrienne Malta, MT(ASCP), MBA, senior manager of inspection services for the College.

The risk assessment component of the IQCP is new and will require additional work to identify, evaluate, and validate the laboratory's proposed QC plan and frequency of internal and external controls. "Laboratories may have sufficient historical data to use as part of the risk assessment," Malta says, "but there may be some risks that are identified for which the lab has insufficient data, and it will need to gather this data to complete the risk assessment."

Even if a laboratory already has all the necessary data, the process of preparing a detailed risk assessment will be time-consuming. Potentially complicating the picture: instruments that use several different test cartridges. "It is possible that a separate risk assessment and IQCP will be needed for each cartridge type, even if many of the risks are the same for all cartridge types," Malta says.

But there is an upside to IQCP too, she notes. It could save labs money. "Depending on the test and volume of requests, having to revert to traditional QC requirements can significantly increase the amount of external QC materials that must be purchased, particularly if an internal control was used daily and the external control was run only once or twice per month under the EQC guidelines." If the test is a unit device test kit, the laboratory will need to purchase additional test kits over the course of the year to account for having to run daily external QC, further running up costs, Malta adds.

Flexibility is another plus. "The flexibility of an IQCP does allow laboratories the ability to personalize their QC processes and tailor them to the test systems in use," she says. Laboratories may thus find QC options that better fit their risk management objectives.

One of the key differences between the IQCP and past approaches to QC is IQCP's breadth. "The QC processes to date have been focused on the analytical component only—asking 'Does the testing piece work?'" says Deborah A. Perry, MD, chair of the CAP Point-of-Care Testing Committee. "IQCP covers the whole process—the preanalytical and postanalytical as well as the testing process. In the past, from a regulatory standpoint, CMS did not look at the other pieces to the degree they will now."

Dr. Perry

Dr. Perry, too, stresses that IQCP is voluntary. "The CLIA guidelines say to do two levels of QC every day of testing. So if your lab wants to do that instead of an IQCP, that is fully acceptable. Those are your two options as of January 2016."

However, IQCP is likely to draw far more participants than other forms of compliance with QC requirements. "Most will follow IQCP for at least some of their testing," says Dr. Perry, director of pathology at Children's Hospital and Medical Center in Omaha, Neb. "Two levels of QC per day is a lot of quality control with point-of-care type testing. So I think in that world and in microbiology, for microbe identification and susceptibility testing, people will be highly likely to develop an IQCP."

Some tests are eligible for IQCP and some are not. "The first thing labs have to do is make sure the tests they're considering for IQCP are eligible," Dr. Perry says. As helpful resources, she points to the eligibility criteria published by the CMS and the CAP as well as a one-page algorithm worksheet the CAP has drawn up (see page 78 for list of resources).

From the point of view of the CAP accreditation program, IQCP has special significance because CMS regulations on IQCP actually have two parts, Dr. Hoeltge says. “The option to customize one’s own QC system is one, but the other is the elimination of the EQC alternative.” The CAP never embraced CLSI’s EQC as it was developed, but a number of checklist requirements were based on the EQC model, he explains. For example, some checklists have a requirement for non-waived testing that allows an accredited laboratory to use electronic, procedural, or built-in controls to meet the daily QC requirement. “That kind of formulaic checklist language is going to disappear Jan. 1 because EQC disappears Jan. 1.”

After that date, the CAP will limit the eligibility for use of an IQCP to testing that meets both of the following criteria: 1) nonwaived tests that employ an internal (electronic/procedural/built-in) QC system (except that microbiology laboratories may implement an IQCP for media and reagents used for microbial identification and susceptibility testing as defined in the checklist); and 2) tests performed in specialties other than anatomic pathology and cytopathology (unless such a test can be assigned to a different CMS subspecialty—for example, FISH testing, which may be classified as either histopathology or cytogenetics).

Labs can continue to make use of the built-in controls if they want, Dr. Hoeltge adds, but they’ll need to craft their own IQCP to do it and be accredited. “That’s a really key aspect of what the College is doing to prepare,” he says. “It’s not just that the Laboratory Accreditation Program is there to help labs write an IQCP. Labs have to know that some of the familiar things in the checklist that we’ve been using and counting on are going to disappear Jan. 1.”

Beginning this summer, the 2015 edition of the checklist does put restrictions on what labs can do with regard to the IQCP. “No. 1, it only applies to nonwaived testing. And No. 2, it can only be done in those states that permit it,” Dr. Hoeltge says. (The state of California recently approved the use of IQCP. Kentucky and New Jersey are not allowing it, according to CAP checklist editor Lyn Wielgos, MT(ASCP).) “This means that those laboratories must follow the default CLIA regulations for quality control at a minimum [two levels of external controls per day of patient testing, or more frequently for some types of testing, such as coagulation and blood gas testing] or more stringent regulations if defined by the state,” Dr. Hoeltge adds.

The third restriction on the IQCP is that anatomic pathology and cytology are excluded, Dr. Hoeltge says. No. 4 is that the IQCP must be used on devices with an internal control process, or in microbiology testing. “For this first foray into IQCP and accreditation requirements, the Laboratory Accreditation Program supported the two areas of microbiology and point-of-care testing. That’s what most labs are interested in right now. In the future,” Dr. Hoeltge says, “we may have checklist requirements that will apply to a broader range of tests.”

No specific IQCP format will be required to meet CAP checklist requirements. Laboratories will be allowed to develop their own model or use other resources, such as CLSI guideline EP23-A, the CMS guidance, manufacturer protocols, or other commercially available products. Laboratories will, however, need to complete CAP forms that list and summarize their IQCP plans for inspector use during an on-site inspection. The CAP is also working collaboratively with the ASM and the CLSI to produce templates for developing an IQCP for microbiology.

One other important feature of the checklist requirements is that the accreditation program will not require laboratories to validate their IQCPs. “The reason is that you’re basing your QC on a personal assessment of risk that’s altogether different from compliance with external requirements. So you’re not going to have to validate your IQCP plan. The accreditation program will simply expect labs that chose to write an IQCP to do it well,” Dr. Hoeltge says. That’s also why the College has been diligently offering guidance and alerts so that laboratories will have access to expert tools when preparing their IQCPs.

It’s true that the kind of risk assessment the IQCP will require is a lot of work. However, Dr. Hoeltge doesn’t view risk assessment as something new or overly challenging. “Risk assessment isn’t difficult. There’s a method to it, and one works through it step by step and comes up with a picture of those variables that are most important and determines how to manage those variables. It’s not something labs haven’t been doing for a long time. Every lab accredited by the College has the expertise to do a risk assessment if they choose to. But now that risk assessment will have a structure and a table behind it.”

“The better question is: Is it worth it?” he says. “And it surely can be, especially when one has multiple devices that are doing the same tests. So the investment in the time and effort at this point can pay long-term dividends for labs.”

Dr. Hoeltge thinks labs are well advanced down the path to IQCP. “Some are going to put it off awhile, but I do believe that most medium and large labs will find that IQCP will help them.” Small labs that are doing a lot of point of care on identical devices or having identical test methods going on in multiple parts of the hospital will also find IQCP useful, he says. “This would be especially true in microbiology. It’s a lot of extra work to do QC on each batch of media or each time you’re doing a test for antimicrobial susceptibility testing. And there are good ways to do that through an IQCP. So most every microbiology lab will want to look into IQCP for media QC and for AST QC.”

The IQCP arose from a sense that the old EQC program was inadequate, says Christopher Lehman, MD, a member of the CAP Standards and Checklists committees. The EQC rules were published in 2003 in response to manufacturers who felt the QC requirements under CLIA were too stringent for their instruments that had some level of internal QC. “But the EQC rules were pretty roundly criticized, because the algorithm they had created really had no statistical basis to support it.” The EP23 standard for assessing risk from a patient point of view was a partial way of addressing that critique, and the CMS gave its approval to the EP23 document, but it set a date on which EQC would sunset: Jan. 1, 2016.

Dr. Lehman

Dr. Lehman, medical director of clinical laboratories at the University of Utah, was part of the workgroup that developed the plan for how to implement IQCP for CAP members. “The reason why I and other members of the Checklists Committee supported the concept of beginning with internal QC is because that’s where EQC originated,” Dr. Lehman says. So the checklist standards are restricted to assays or instruments that have internal QC.

“From my perspective, we have three points of view for approaching this,” he says. “One, we want to make sure we’re protecting patients. Second, we’re protecting laboratory directors under CLIA rules. And third, we have to have a way of inspecting this. Since nobody has experience with evaluating IQCP plans, we felt we have to have a basis, and starting with assays that had some kind of internal QC running was a good place to start.”

Since IQCP does not apply to waived testing, “if they’re running moderate-complexity testing with internal controls, then any laboratory could do this,” Dr. Lehman says. And, he argues, there are not only patient care benefits to adopting IQCP but also economic incentives.

“QC materials tend to be expensive, and it takes time and effort and personnel to monitor QC. The more you run, the more you have to monitor. So certainly money is one incentive. Labs are trying to find ways to be cost-effective, and you cannot dip below the manufacturers’ requirements for QC, but in some circumstances the CLIA requirement will be greater than what the manufacturer recommends, so with IQCP you can save money and still provide quality care.”

There has been a lot of progress in clarifying and fleshing out the “how-to” of IQCP in the past several months, Dr. Lehman says. “When we were designing the checklist requirements and forms and guidebooks, the only thing out at that time was the basic brochure that CMS had published. It had no real details about how to do this. Now there are workbooks people can use for free, and many companies have come out with plans that people can follow for their instrumentation.” The CAP allows people to use other plans as long as they review the plan and the laboratory

director is confident the plan is appropriate.

So even small laboratories should not be intimidated by IQCP, he believes. “Any labs that are already practicing Lean principles will recognize this and see that it is not really anything new. Doing a risk assessment is really evaluating a process, so labs that have implemented Lean or Toyota processes will be familiar with this. With so many proposed plans coming out, I suspect that labs will take a look and will say ‘I can do that.’”

There may be some confusion about what the CAP is going to require, he notes. But a glance at the CAP “Frequently Asked Questions” document should set labs’ minds at rest that the CAP is restricting the checklist changes to only those tests that have internal controls and certain microbiology tests.

Accreditation program inspectors may or may not be implementing IQCP in their own labs, and there could be a lag period during which they are not as familiar with IQCP and how it is integrated into the checklist. But to bring them up to speed, the CAP will have instructional offerings, a free webinar, and training to go along with the revised checklist, Dr. Lehman says.

“I think everyone can go through their testing, create risk diagrams saying where are the various points they need to evaluate risks, and follow whatever plan they choose. I don’t think that will be a problem. It will come down to reviewing the QC records they may have been doing under EQC and evaluating how often they need to run QC.” Again, he stresses, while the laboratory may never do less QC than what the manufacturer recommends, “they may be able to do less than what CLIA recommends or CLIA requires currently.”

Lab directors will need to determine the appropriate amount of QC based on their history of running QC and evaluating what their rates of failures are for each individual instrument or test, Dr. Lehman says.

The volume of testing and the test’s impact on clinical care are critical questions. “Are you doing 100 tests a day or two a week, and how quickly will physicians act on the results? Those questions may determine whether you want to go with a more frequent QC or you’re comfortable with less.”

“The reality is that’s something that should occur anyway. When you’re creating a QC plan, you should be looking at your tests and saying in some cases, ‘This is a critical test; physicians will be acting on it immediately and we run a lot of these. So we want to run QC more frequently.’ Or, you’ll want to decide which tests seem to be more stable, which are less stable.” If you have concerns about a test or the instrument or assay has the chance of not functioning correctly, Dr. Lehman says, “ideally you would also be running QC more frequently, because it will be one way to assess whether the assay is running properly.”

To his knowledge, there are no good statistical models that tell laboratories exactly how often they should run QC. “But I think the principles that are in the EQC document still apply, in terms of helping laboratory directors assess risk.” All laboratory directors do risk management in their heads, he says. They just haven’t formalized it into a set process. “I think IQCP is just formalizing it, and when you formalize things, you’re having to use tools you may not have used before. But it really shouldn’t scare people.”

He agrees that the IQCP represents a significant change. “But if you look through the workbook that CMS just put out, the concepts and the questions it runs you through are ones we should have been thinking about anyway, and many institutions have incorporated them into their standard procedures. A lot has been done. People have thought about risk and have incorporated it into how they collect specimens and manage training. So I think the change is taking all that information we’ve probably already been doing and putting it into a more structured format. Then we can kind of justify it.”

The IQCP’s impact on microbiology will be substantial, says CAP committee members who have been involved in the IQCP. “The microbiology changes came late last year and they are huge because they relate to microbiology labs’ media and susceptibility testing,” Dr. Perry says. “To now have to do two levels of QC every day for that piece of the microbiology world is a huge amount of work and expense. I think people in labs are willing to do additional work if it has an impact on patient care, but nobody really sees that in the microbiology section it would positively

change anything."

Returning to two levels of QC daily will be hard, agrees Denise K. Driscoll, MS, MT(ASCP), CAP director for laboratory accreditation and regulatory affairs. "Microbiology labs just haven't done that in decades, so to them, IQCP doesn't feel very voluntary." The reason this is happening, she explains, is that the CMS removed mention of CLSI documents from its interpretive guidelines for quality control, because government agencies cannot make private guidelines regulatory in effect unless those guidelines are available for free. "But those documents were ones that microbiologists had been going by for years to adequately define their QC. So now microbiologists feel blindsided, and they feel like they're being forced to do IQCP in order to get back where they were," Driscoll says.

"That's why the College, including our Microbiology Resource Committee and the CAP checklist group, worked with ASM and CLSI to produce sample guidelines the labs could use in lieu of the purchasable CLSI documents," she adds.

The IQCP has been a long time coming, says Susan Sharp, PhD, director of regional microbiology and molecular infectious disease laboratories for Kaiser Permanente in Portland, Ore., and a member of the CAP Microbiology Resource Committee. "We've been using EQC for many years, which has worked well for the clinical microbiology laboratory. CMS worked together with the CLSI to come up with the EP23 document, and from that document, CMS came up with IQCP. IQCP is not exactly like EP23, but it has some of the same principles in it, and it is based upon risk assessment."

Dr. Sharp worked with another member of the CAP Microbiology Resource Committee, Janet Hindler, MT(ASCP), a senior specialist in clinical microbiology at UCLA Medical Center, and other colleagues to develop materials to guide microbiology laboratories in IQCP. But Dr. Sharp herself says she did not become aware of IQCP until about a year ago. "CMS gave us two years' notice, but I don't think all the information made its way down to the clinical microbiology directors. As a matter of fact, it first came to me through my compliance people here at Kaiser last year."

Dr. Sharp

The IQCP is going to affect microbiology much more than some other parts of the laboratory. "In some areas like hematology and chemistry, they run controls every day on many tests, which is what you must do for CMS default QC. In microbiology, we've been using EQC for the last decade or more, where you don't have to do QC every day you perform the test."

That will end Jan. 1, leaving microbiology laboratories with the choice between IQCP and the daily QC option. "That's not much of a choice as we can't possibly do daily QC on our susceptibility testing or some of our molecular testing. So it's a pretty drastic change." Dr. Sharp points out that point-of-care testing has some of the same issues that microbiology has because oftentimes in the POC area QC is also not performed daily.

The CAP's approach—coming out with preliminary general checklist items in the All Common section on IQCP—is helpful, Dr. Sharp says, as is the joint effort involving the CLSI, ASM, and CAP in production of guidelines, templates, and examples for susceptibility testing. Just reading the CMS' information, she says, "It's difficult to understand the requirements. It took me several weeks of reading the materials to get my head around what we were supposed to be doing. CMS is being very nonprescriptive in how they ask people to go about developing an IQCP. You can really approach it in any way, shape, or form—as long as you cover all the required areas."

On the other hand, a nonprescriptive approach has disadvantages, she adds. "It leaves a lot to the discretion of

individual laboratories, and that's why we felt it was important for the three microbiology organizations to work together and speak with one voice to come up with some guidance to help clinical microbiology laboratories."

There are tricky parts to risk assessment, Dr. Sharp notes. "We can all look back at our own data to determine the frequency of occurrence of error in our laboratories. But to try to determine what impact errors might have had on a patient is difficult. Depending on the results that might be in error, there could be no effect at all on the patient or it could be very significant; it's difficult for the laboratory to determine," she says.

In the laboratory world outside microbiology, Dr. Perry is not sure most people will understand much about IQCP until they start developing their own plans. Nurses, in particular, are just now hearing the term "Individualized Quality Control Plan." "But there's not a lot of understanding yet. To a degree, they will need to be involved in developing an IQCP because they are testing personnel."

The most significant work of transitioning to IQCP will be at the front end, Dr. Perry says. "We have the materials and we're already doing most of the procedures. The processes for nurses and other non-laboratory personnel at the testing sites probably won't change significantly. But to document the procedures, to write up the plan, to get people involved and understanding—that's going to be the big part. It's all so new."

The general understanding of risk assessment is fairly basic, Dr. Perry says. "I think a lot of people are pretty green on it. They haven't really thought about lab testing and risk assessment in this way, even though we all know there's always risk." The EP23 and CLSI documents on risk are good resources, she adds. "But they're not something most people have read yet."

The CMS, vendors, and professional groups have already produced numerous guidebooks and webinars. "AACC has one of the really good documents, and CMS, along with the Centers for Disease Control, issued a step-by-step guide that is really helpful. So there are quite a few resources," Dr. Perry says. She herself will lead a complimentary CAP webinar in August that will walk Laboratory Accreditation Program participants through development of an IQCP plan.

Dr. Perry advises a strong upfront effort in implementing IQCP. "Use all the resources available and develop a good team to get your first one developed. Because after you've done it once, hopefully the ones that follow won't be quite as big a challenge."

It's understandable that labs feel trepidation in contemplating the shift to IQCP, Dr. Hoeltge says. "Up to this point, labs were told how to do their QC, what frequency it was, and where they had to go to get the materials. And although those are still valid resources and practices, to have the option to shape QC in your own laboratory environment is a big deal. That's a gift. But it's not one that comes without strings. IQCP requires a lab to conduct QC thoughtfully and with a level of appreciation for proper risk assessment."

Anne Paxton is a writer in Seattle.