Full-court collaboration in transition to IQCP

Anne Paxton

September 2015—With the CLIA Individualized Quality Control Plan process geared to unseat the familiar Equivalent Quality Control process on Jan. 1, there seems to be wide agreement that microbiology laboratories will have the biggest adjustment to make to comply with CLIA QC requirements, despite the IQCP being voluntary.

With microbiology laboratories likely to feel the effect of the IQCP process more than some other labs, a CAP/ASM/CLSI working group has provided examples as guides. “We felt it was important that the three organizations speak with one voice,” says Dr. Susan Sharp.

“IQCP will have a more profound effect on clinical microbiology than some other areas of the lab that already run positive and negative controls every day they run tests,” says Susan Sharp, PhD, president-elect of the American Society for Microbiology and a member of the CAP Microbiology Resource Committee.

Janet A. Hindler, MT(ASCP), also a committee member and a senior specialist in clinical microbiology at UCLA Medical Center, says, “We will either be preparing IQCPs or we will revert to following CLIA regulations developed in ’88, despite the fact that for several commonly employed clinical microbiology tests, CMS recognized several decades ago that there were less stringent alternatives for QC of these tests.”

It’s unfortunate that IQCP came on the scene just as the exceptions for using Clinical and Laboratory Standards Institute documents for QC were removed from CMS’ CLIA guidelines, says Nancy Anderson, MMSc, MT(ASCP), chief of the Laboratory Standards Practice Branch at the Centers for Disease Control and Prevention. The CLSI removal was going to happen anyway, but it added to the anxiety of microbiology labs over IQCP. “Many microbiology labs perceived that this removal was because of IQCP, but it really was coincidental,” Anderson says.

She agrees with Dr. Sharp and other microbiology leaders who suggest that microbiology laboratories need to focus to get their IQCPs underway, but that panic does not need to be part of the game plan. “In a way, IQCP will

allow labs to continue to follow the QC processes they've been doing under CLSI, although it will take effort up front to pull together the documentation they need," Anderson says.

To smooth the transition, the three leading groups in microbiology—the CAP, the ASM, and the Clinical and Laboratory Standards Institute—have made a concerted effort to provide webinars, templates, answers to frequently asked questions, detailed examples, and more. "We felt it was important that the three organizations speak with one voice, so the templates and documents have been signed off on by all three," says Dr. Sharp, who is director of the regional microbiology and molecular infectious diseases laboratories for Kaiser Permanente Northwest in Portland, Ore. "We hope microbiology labs will find them very useful." (These examples and templates "are only examples," she emphasizes, and each laboratory's risks and mitigations are likely to be different.)

Thanks to a nine-member CLSI ad hoc working group that has representation from the three organizations, examples of IQCPs have been made available for antimicrobial susceptibility testing systems, commercial identification test systems, and culture media (clinmicro.asm.org). So while microbiology laboratories have work to do in adapting to the new QC program, the CAP/ASM/CLSI working group is providing multiple guideposts to show the way.

In July, the CAP also made available a complete list of all changes in the 2015 edition of the All Common checklist for laboratory accreditation that relate to IQCP, including five new checklist requirements starting with COM.50200, plus a series of changes to the microbiology checklist.

The IQCP option applies to a variety of non-waived microbiology tests, but it may be most useful for testing that has been performed following the CLSI microbiology guidelines for reduced QC testing, including antimicrobial susceptibility testing, commercial identification systems, and culture media. IQCP does not apply to some types of testing for which daily QC is not performed and where the CLIA regulations and the CAP in its microbiology checklist have defined an alternative QC frequency, such as Gram stains with weekly QC.

In general, separate instruments require their own IQCP. For example, a laboratory that uses a MicroScan and a Vitek 2 instrument would require two separate IQCPs since they are different test systems with potentially different risks. Etest and disk diffusion tests also represent unique test systems, so each would require its own IQCP.

If laboratories have multiple identical devices, they may develop one IQCP for the test system, taking into consideration unique features relating to the testing environment or testing personnel. "If the devices are sitting side by side, chances are the environment and testing personnel are pretty much the same," Anderson says. However, labs must document that each instrument had a separate verification process when it was put into use, and instruments in different locations in a health care facility must each have their own IQCP.

CLIA has not set a minimum QC requirement, but QC cannot be less than that recommended by the manufacturer and must be supported by the risk assessment and QC data. "It could happen that less than daily QC may be sufficient; it would depend on the data the lab has [accumulated] to show what its results have been in the past," Anderson says. Laboratories would need to provide appropriate documentation such as historical records and additional data to support a reduced QC testing schedule. "But obviously labs that have been following CLSI for many years should have the data to show whether problems have been detected when following those guidelines."

Hindler

Providing examples of IQCPs has been a priority of the CAP/ASM/CLSI working group, Hindler says. “CMS has prepared lots of instructions on IQCP. They have a workbook and they have all these brochures, but very few examples. So by providing examples for antimicrobial susceptibility testing QC, QC for microbial identification test systems, and QC of culture media, our working group is trying to make IQCP as painless as possible for clinical microbiologists. We hope the labs will be able to use these examples as guides.”

The working group tackled an antimicrobial susceptibility testing example first, because without an IQCP there, labs will have to perform daily QC, Hindler says, even though there have been minimal problems with QC in AST. For the past 20 years, most labs have been performing weekly QC under CLSI standards, which have now been deleted from CLIA laboratory guidelines.

In the disk diffusion AST example prepared by the CAP, ASM, and CLSI, the content is straightforward: an overview of the test system and its historical quality review; notation of information used to conduct the risk assessment, including summarized in-house data from routine testing and summary of corrected reports and physician complaints; the risk acceptability assignment for each risk factor relating to the specimen, testing personnel, reagents, environment, and test system; and the risk assessment itself, the final quality control plan, and the quality assessment plan.

The risk acceptability assignment portion of the IQCP allows the laboratory to highlight the possible sources of error that most need attention. In the CAP/ASM/CLSI disk diffusion AST example, the types of analytical elements that might have both “probable” frequency of occurrence and “serious” severity of harm to patient (making the risk “not acceptable”) include training, competency, experience, and preparation and use of reagents. Non-acceptable risks relating to the test system include measurement of zones of inhibition, interpretation of zone sizes, application of antimicrobial reporting rules, and transcription errors during laboratory information system entry.

The required risk assessment component of each IQCP is likely to be the most difficult for microbiology laboratory directors, Dr. Sharp tells CAP TODAY. “Most laboratories have not spent a lot of time specifically evaluating risk of harm to patients, and while we have always tracked our errors in microbiology, in IQCP there will be more work.”

For each risk factor identified, the CAP/ASM/CLSI sample IQCP answers the question, “How can the identified risk and source of error be reduced?”—usually with specific monitoring programs or suggested emphases for initial training and competency assessment.

For example, to reduce specimen errors involving colonies on source plates that are more than one day old, the CAP/ASM/CLSI sample IQCP for disk diffusion AST states the laboratory would emphasize organism growth requirements (especially Streptococcus pneumoniae) during initial training and competency assessment. To reduce errors in measurement of zone inhibition, says the sample IQCP risk assessment, the laboratory would emphasize proper measurement of zone sizes using a measuring caliper or metric ruler, adequate lawn of growth and risk of false susceptible results if inadequate, and recognition of plate contamination during initial training and competency assessment. A laboratory can refer to its SOPs for antimicrobial susceptibility testing, training, and competency assessment without having to restate all details in the IQCP.

In the postanalytical arena, to stem errors in results reporting, the example states the supervisor would maintain a summary of incorrect results released and meet with the laboratory director monthly to review the summary; monitor time to reporting AST results; and again, during initial training and competency assessment, emphasize the need for timely reporting of results to guide therapy and identify potential multidrug-resistant organisms that might require patient isolation.

A few sources of error in this IQCP example are dealt with through more direct measures. For instance, for risks associated with the level of experience of testing personnel, supervisors would review AST reports generated by new employees prior to release for the first two months of their employment. For proficiency testing risks, all staff would read and sign off on PT sample critiques. For AST media sterility risks, the staff member inoculating AST

plates is responsible for examining the plates for contamination prior to inoculation.

The QC plan follows the risk assessment. It briefly summarizes the timing and frequency of QC tests to be performed and other QC activities the laboratory needs to perform as part of its plan to ensure the accuracy and reliability of testing. Last, the quality assessment plan outlines the ongoing monitoring that will be conducted. This particular IQCP example specifies that the supervisor and/or section head would conduct ongoing monitoring for effectiveness of the QC plan, including:

- examining and addressing as needed in a new risk assessment the reasons for QC failures, PT failures, and patient isolate reporting errors;
- daily review of patient results for reporting errors and clinician complaints with corrective action and revised QC plan as needed;
- monthly review of QC results by supervisor or section head, with appropriate corrective action;
- monthly review of length of time from specimen collection to AST result reporting to determine incidence of reports delayed beyond five days;
- monthly review of all equipment maintenance/monitoring logs according to standard laboratory protocols;
- regular training and competency assessment according to standard laboratory protocols; and
- continual participation in the institution's quality program that addresses specimen handling and erroneous specimen labeling.

The CAP/ASM/CLSI sample IQCP for disk diffusion AST employs a table format. But the table format is not required. In a separate example, an IQCP prepared for a Vitek-2 commercial susceptibility system, the laboratory chose to use more of an Excel spreadsheet format rather than a table. "CMS does not state how you have to do it," Dr. Sharp says. "Only that you have to include all the required elements of an IQCP."

Another optional tool is a fishbone diagram, which can be a helpful tool for analysis. Dr. Sharp showed, in an ASM annual meeting session in May, how it can be used to look at the five required components to be addressed in the IQCP risk assessment—specimen, environment, testing personnel, reagents, and test system, with "test results" optionally listed separately from test system—to determine what the risk factors are.

"Once you get those risks identified in the fishbone, you can include them in a risk assessment table," she says. That will mean listing, in each instance, the possible severity of harm to the patient and the frequency of occurrence of the risk/error, and the measures to be used to control or mitigate these risks. "One may also choose to include in this table where relevant documentation can be found."

Other key IQCP issues are left to the discretion of the laboratory director, who has the ultimate responsibility to review, sign, and date the IQCP. For example, if both acceptable and non-acceptable risks are listed in the risk assessment, the laboratory director may decide only to address non-acceptable risks in the quality control plan.

Specifically in susceptibility testing, the CMS says it is not prescriptive on whether the "specimen" to be evaluated in the risk assessment is the primary clinical specimen or the organism isolated in culture. It's up to the laboratory director. In addition, the CMS does not specify whether a separate IQCP is needed for both AST and identification components on a commercial automated ID-AST system. Again, the laboratory director chooses.

Munro

Some laboratories, though not all, are using streamlined QC for identification of organisms on commercial systems, such as an automated instrument or an ID strip, and will need to prepare an IQCP for those test systems as well, says Susan Munro, MT(ASCP), a microbiology consultant on susceptibility testing and chair of the IQCP ad hoc working group. The CAP/ASM/CLSI working group recently posted an example of an IQCP that parallels the CLSI M50 document for streamlined QC of identification tests, Hindler says. “This will show labs how to create an IQCP for that, so they don’t have to go back to doing positive and negative controls for each substrate.”

The three organizations also completed an example of a third type of microbiology IQCP: one for culture media. Dr. Sharp provides an example for using Remel commercially prepared CLSI-exempt media that include blood agar, MacConkey agar, Brucella agar, IMA, LIM broth, and Selenite broth, among several others.

“We’ve been following the CLSI [NCCLS] M22 document since the 1980s for media that have been given exempt status,” Hindler says. “That means the lab doesn’t have to re-check that media with microorganisms to make sure the media will support growth, because as long as the manufacturer fulfills certain criteria and tells the labs it has done all the quality checks, it’s acceptable for the lab not to have to redo all of that.”

“There are several types of media that, when they are received in the lab, require only a visual inspection checklist and for which you do not need to do performance testing,” Munro says. “The IQCP example that the CAP/ASM/CLSI workgroup prepared has addressed this.”

In its sheet of frequently asked questions, the CMS confirms that visual quality checks of CLSI-exempt media, as documented by the laboratory, are considered acceptable in-house data, and the lab may also include manufacturers’ quality certificates as part of the information considered in its risk assessment.

CLIA does not require that a single tool or mechanism be used to document the risk assessment and QC plan, Anderson emphasizes. “When inspectors come to the lab, they will look at whether a risk assessment was done to determine where there might be potential failures or sources of errors, and whether the risk assessment covers the entire testing process. They will be looking to make sure you have looked at all the five components listed—specimen, environment, testing personnel, reagents, test system—and have considered things that might go wrong in the laboratory.” These won’t be identical for every laboratory setting, she says. “Then they will look for a QC plan that incorporates the results of the risk assessment in a written document describing how the lab is going to reduce or mitigate those risks. The format or structure for that QC plan can be done in different ways.”

Anderson

Laboratories will find several tools available to use to develop their own mechanism to prepare a risk assessment, Anderson says. The joint CDC/CMS workbook is one such tool. “It doesn’t include any tables that specifically quantify risks that the laboratory identifies, but it has the questions that should be asked for the laboratory director to determine which risks need to be addressed in the QC plan.”

The quality assessment phase of the process should be close to what labs already do, Anderson notes. “CLIA is not prescriptive in how laboratories should capture the information or monitor their IQCPs. Inspectors will rely on the fact that the lab director has signed off on the QC plan and that there are no problems or failures showing up through the quality assessment process that can be attributed to the IQCP.” If IQCP-related issues are identified, Anderson says, the laboratory should go back and reevaluate its risk assessment and QC plan, then make changes as needed to address them. The laboratory director should then re-sign and date the revised QC plan.

“Everybody’s risks will be different, and these templates are just examples,” Dr. Sharp notes. “But we have now published the templates in both PDF and Word formats. This way they can be modified to suit each individual laboratory.”

She predicts that the transition of microbiology labs to IQCP will prove manageable. “Risk assessment is kind of new to us, but you’re going to get really familiar with it,” she told her ASM audience. “And you’ll find that a lot of the IQCP information on your test systems, getting test results from the LIS to the hospital information system, your training, your personnel, will be the same from one test system to another.”

As further assistance, the CLSI is offering two webinars on AST IQCP that Munro believes will show the positive things that could come out of IQCP. “Results reported on patients’ isolates may not always be accurate, even when results from testing routine quality control strains are ‘in control,’” Munro points out. “The November webinar on AST IQCP does not focus on frequency of QC testing but is about how a risk assessment process can reveal an unexpected way to improve patient care.”

Titled “Finding Value in Your AST IQCP: Improving Accuracy and Timeliness of AST Reports,” the CLSI webinar will be offered Nov. 19 (1 PM–2 PM EST). It will focus on developing a plan that includes work aids to minimize errors in reporting AST results, and for reporting preliminary and final results in a timely manner, with emphasis on the results most likely to have an impact on patient management.

Eventually, the IQCP will show its value, Munro believes. “The educational component is going to require time even before microbiology labs can develop an IQCP process, and many labs do feel blindsided by all these new requirements. It’s a little overwhelming for them. The first one or two IQCPs they do are going to be difficult. However, I think most labs will find the benefits outweigh the disadvantages.”

[hr]

Anne Paxton is a writer in Seattle.