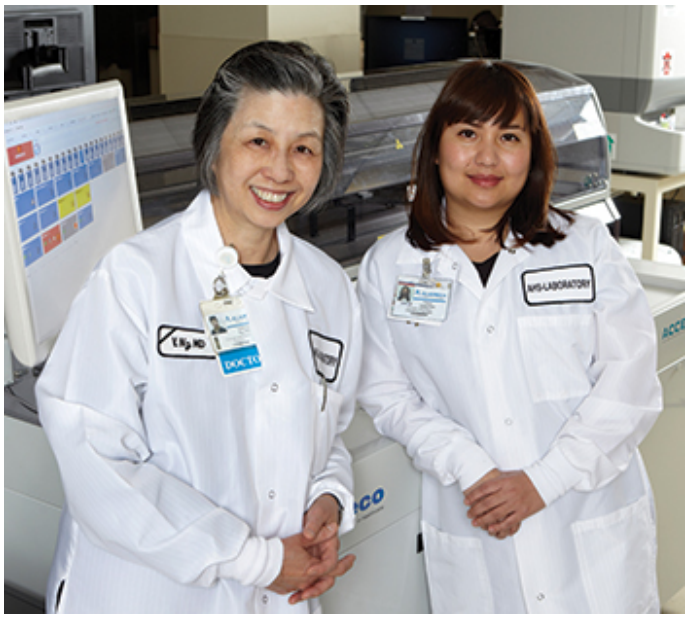
IQCP without agony at the point of care

Anne Paxton

April 2016—For many point-of-care testing coordinators, the prospect of developing Individualized Quality Control Plans is far from enticing. But there has never been much chance that laboratories could opt out of the Centers for Medicare and Medicaid Services' new quality control framework for much of their nonwaived testing.

Even though IQCP is an optional program, says Kerstin Halverson, BA, MS, point-of-care coordinator at Children's Hospitals of Minnesota, the alternative—meeting the minimum QC requirements set by CLIA '88—is often impractical. "I didn't stop to calculate what it would cost to do liquid quality control on all the i-Stat cartridge types every eight hours because the number would have been through the roof," she says.



Dr. Valerie Ng (left) with Highland Hospital laboratory operations manager Feuy Saechao. Dr. Ng's advice for point-of-care coordinators: "Don't overthink risk assessment."

Halverson saw IQCP development as a "necessary evil"—optional, yes, but essential to offset the costs associated with meeting minimum QC requirements. Like many in the laboratory community, she thought that the CMS Equivalent Quality Control program, in place since 2004, was working just fine. But now that the Jan. 1, 2016 deadline for developing IQCPs has passed, she and other POC coordinators qualify as survivors of the new process. And some are saying the switch to IQCP wasn't that bad.

In fact, a few, like Lou Ann Wyer, MS, MT(ASCP), were early adopters of IQCP and the companion EP23 program, known as the "IQCP rulebook," published by the Clinical and Laboratory Standards Institute. EP23 guides users on developing a fishbone diagram for hazard risk assessment, the three phases of testing required by the IQCP (preanalytical, analytical, and postanalytical), and the five areas required: samples, people, reagents, environment, and instruments.

"I was probably one of the very few excited about the release of EP23 from CLSI, and so I preordered it. When it arrived, I jumped right on it and started working up some of the analytes," says Wyer, who is director of laboratory services at Sentara Healthcare in Norfolk, Va. Still, to get all the point-of-care IQCPs completed, "we worked right up to the deadline."

Sentara's clinical specialist for POC testing Shirley Church led a team of point-of-care coordinators through each of the test systems that qualified for an IQCP. "It resulted in doing more than 70 risk assessments for 20 IQCPs within our integrated POC program," Wyer says. "We have multiple hospitals, and a very large POC program, and we had to look at a risk assessment for each facility where POC tests are performed."

Wyer

The laboratory's decision to do separate risk assessments for each analyte in a cartridge-based system is the reason for the large number of IQCPs. In addition to its Accriva Diagnostics Avoximeters and Medtronic Hepcon coagulation analyzers (also subject to IQCPs), Sentara has about 400 Abbott i-Stats. "We analyzed each parameter's performance within a cartridge over time across all devices, identified our laboratories' expectations for quality control performance, and then determined the frequency level of quality control needed based on all data evaluated. In the end," Wyer says, "our QC plans pulled all these elements together and based our QC frequency for the cartridge on the parameter that requires more QC."

Since risk assessment under IQCP must also take into account the number of POC testing locations, a large POC program like Sentara's has special challenges. "With 400 testing locations—including cardiac cath labs, radiology, respiratory, central OR, cardiac OR, emergency departments, ICUs—we determined if there were differences in risks based on the different locations. If there are similarities, you can group them together."

With competencies, for example, there may be good reason to develop separate IQCPs. "For areas new to POC testing or with new procedures, we like to give them a little more personal attention to make sure they're on the right track." With each risk assessment, she says, "we looked at complaints, concerns, errors, variances for all our operators. Within the preanalytical phase, sample collection and handling is always an important factor."

The CLIA default to perform at least two levels of QC each day prior to patient testing can be very difficult and expensive for some systems, Wyer notes. "With instruments that have internal QC, you can perform your liquid QC at a frequency that meets your lab's proven comfort level, but what we're trying to get with IQCP is the 'right' QC. Your risk assessment is going to lead you to the right QC. Sometimes, based on your risk assessment, you might even want to increase the frequency of QC."

Wyer's IQCP analysis of the environment included temperature and humidity, of course, but also surfaces where analyzers are placed. "We asked whether the testing was done on a flat and level surface, without vibration or motion. We also looked at airflow and ventilation—anything that might alter the test results or is done outside the limitations of the manufacturer's instructions."

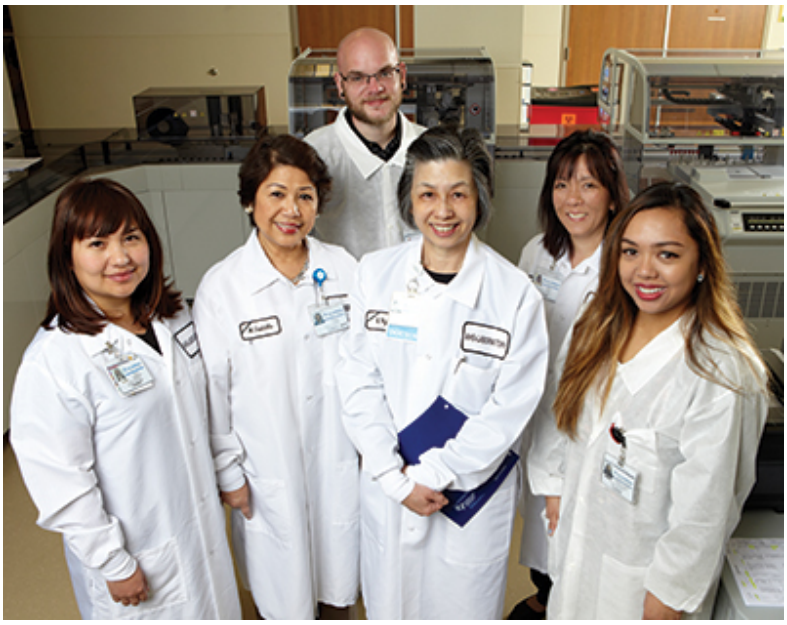
Nothing shocking was discovered, Wyer says. But having an instrument on a flat, level surface without vibration is important, especially for coagulation testing, and developing the IQCP highlighted that, in her view. "These details are used to train employees on the proper use of the instrument, included in competency assessments, and used to troubleshoot if staff have questionable results."

For the postanalytical phase, Wyer says, the focus is getting the correct result to the correct patient's record. This can include verification of interface transmissions and notifications from the operator in the event of a misidentified specimen. "All of this information is included as part of a risk assessment. We can look at the frequency of events, trends, and specific operators."

After the laboratory developed a spreadsheet for each group of like cartridges or test systems, Wyer says, the risk assessment data were plugged in, including a list of policies, procedures, and job aids reviewed; training materials;

investigations and complaints; product recalls; proficiency testing; personnel competency records; and observed errors. “The outcome of these reviews led us to modify the specimen collection and handling sections of our procedures.”

“From there, you can easily pull out what you want to include in your QC program, and then set up your quality assessments.” Her QC program has a standard format for the QC plan, which includes a header with the name of the hospital, cartridge type, testing location, and a summary of what the risk assessment showed.



Dr. Ng (center) with her point-of-care testing team. From left: lab operations manager Feuy Saechao, POC testing coordinator Marian Castillo, LIS analyst Jesse Genosick, clinical laboratory scientist Doro Goto, and chemistry specialist Kristine Claire Fernandez.

“We will be including more patient comparison data than in the past. Because our historical QC data proved consistently acceptable with comparable performance of analyzers over time, we were able to implement the use of a subset of analyzers as part of our quality control plan. Using subsets of analyzers requires significantly less QC than when we were following the CLIA default QC.”

How much time did all of this require? “We did not capture the number of hours it took to do this—and probably for good reason,” Wyer says. “It was an incredible exercise, but it identified opportunities to improve our program. I also think it was a good exercise because we’ve done a very thorough job on our risk assessments, and we can justify our QC plans with no problems.” The process became more manageable as the team proceeded, Wyer says.

In the end, she adds, “I think we have a very solid QC plan.”

One of the key decisions for laboratories that develop an IQCP is whether, for some tests, it would be better to opt out, says Valerie Ng, PhD, MD, chair of laboratory medicine and pathology at Highland Hospital in the Alameda Health System, Oakland, Calif. Her own program includes one major inpatient hospital, one psychiatric rehabilitation facility, and one skilled nursing facility. But “we run a very lean and minimal point-of-care program,” she says, since the central laboratory is able to provide results efficiently.

In the emergency department, operating rooms, inpatient units, and critical care, she has i-Stats and cartridge-based tests for electrolytes, blood gases, and activated clotting times. She also has desktop blood gas analyzers in the ED, ICU, and pulmonary function laboratory. After doing a risk assessment for every step of her desktop blood

gas analyzer point-of-care testing, she chose to go with the CLIA requirements for QC rather than an IQCP.

“Blood gas is probably one of our highest-risk tests,” Dr. Ng points out in justification. “Treatments are immediately altered based on blood gas results and that test has to be in perfect control all the time.” The desktop analyzers have multiuse reagent cartridges and “alternative QC” where it’s checked every 30 minutes. “But that’s not good enough because it doesn’t reflect the actual testing of the patient sample. The patient sample is introduced through a different instrument port” than is used for alternative QC. This, she says, is the most common point of test failure (introduction of bubbles, for example) and therefore the greatest risk of an incorrect medical decision and patient harm.

“I wanted the tightest control over that test that I could logically defend, so we went with the CLIA ’88 QC requirement of three levels of external liquid QC, one every eight hours of patient testing. This allowed us to assess personnel competency of sample introduction to the analyzer.”

IQCP is a much needed advance beyond the Equivalent Quality Control program, Dr. Ng believes. “When EQC was developed, there were three options, and they didn’t have much statistical basis, and they also didn’t implement an ongoing process to evaluate if something went wrong. So EQC was a good first step, but it didn’t quite incorporate the whole patient testing process.”

Like any regulatory program written at a point in time, EQC was destined to become outdated. “So the question is how to devise something evergreen that allows us to adapt to new technology, which is moving forward at incredible speed. And the only constant was risk assessment: When you are doing a test, how much harm can happen and where will it occur?”

A risk assessment is a combination of the odds an error will happen and the potential harm to the patient if it does, Dr. Ng notes. “Most POC coordinators pretty much know the testing process and where failures might be. The more complicated piece is going to be figuring out the harm to the patient. To me, that’s a conversation between scientists and the laboratory director to build a bridge between science and clinical care.” For example, “You can be worried about particular results, but then the medical director can say that result may not be used in isolation and would be considered with other results, so it would not be as detrimental” if there were an error.

The laboratory’s decision on the proper number of IQCPs should depend on the location of the POC test and who staffs that location, Dr. Ng says. “The number of operators is not really that critical. For example, if I look at my program in the ED, it’s going to be RNs running it, and I know their level of training and skill and competence. But if I look in the OR and I might have an anesthesiologist running the test, there I need to focus on a different culture.”

IQCP’s incorporation of the preanalytical and postanalytical phases in QC is of benefit in such a situation, she adds. “Unfortunately, in the usual physician’s day, they assume that any number from any lab device is a correct number, so it’s up to us to teach them, if they’re running the test, all of the pre- and postanalytical factors because those are the major sources of error.”

She contrasts this task with what is needed to train pharmacists to operate a point-of-care INR, another test system for which she has created an IQCP. “The INR is a single device run only by doctoral-level pharmacists who run the coagulation clinic, and pharmacists by nature are extraordinarily precise and detail obsessed.” So the level of risk and training needed for that testing environment is different.

For the hazards identification that is central to IQCP risk assessment, Dr. Ng has found observation to be a big eye opener. Her laboratory wanted to see how operators did their QC on the preanalytical side. “The first thing we observed is that they were not mixing the QC adequately; they weren’t rolling it or doing the end-over-end rotational mixing procedure,” she said last July in an IQCP webinar sponsored by Bio-Rad Laboratories.

“And we had observed on occasion they were doing the same inadequate mixing with the patient specimen. When they ran the QC, some folks would walk away from the instrument without even reviewing the results, an absolute no-no. And if they did stick around to review results, they weren’t using the current applicable QC acceptable

range. They were reviewing against the manufacturer's insert and not against the revised and customized acceptable range. So that was worrisome." These were important competency issues to be addressed with recommended actions in an IQCP.

In the Bay Area, where her hospital is located, environment can play an important role in the risk assessment for preanalytical factors, Dr. Ng notes. "Because we're in a temperate zone, we typically don't have air conditioning. So twice a year, when it gets into the 90s, we often have to relocate our point-of-care supplies to an area with controlled temperature in the acceptable range or we have to throw them out because their storage has exceeded manufacturer's requirements."

Refrigeration, too, can pose unexpected risks. "You have a certain window of 2°–8°C, and if you exceed that, then the manufacturer doesn't stand behind the product." But that temperature can be interfered with if an operator keeps a refrigerator door open for an extended period. So her laboratory installed refrigerators with sliding glass doors that let people look first and decide which supplies to select before opening the door.

In another instance, there was discussion of how to monitor room temperature. "I said you need to monitor right where you keep the supplies. In one case we were keeping supplies in a drawer right under the ice machine, which was putting out heat from the bottom and exceeding the manufacturer's recommended storage requirements."

One IQCP is enough to cover all analytes in a particular cartridge's array of analytes, in Dr. Ng's view. "The QC challenge is that when you use a single cartridge, you've destroyed it, so there's no way of running QC on that cartridge at the same time you're running a patient sample. The way around that is the manufacturer's claim that they are making these cartridges to Six Sigma specifications, meaning that a cartridge would fail only three out of a million instances."

For your IQCP, "If you look at your historical experience with the test system and show they have been very, very stable, that would support the manufacturer's claim of production to Six Sigma specifications. And that's how your IQCP would justify a reduced frequency of QC to that mandated under the original CLIA regulations."

However, she says, different IQCPs are needed for each location or environment where testing is done. "That's because whether your device is in ambulatory care, the ED, critical care, or the OR, the type of personnel running testing in each of those environments is likely to be different," as is the risk. Environmental factors such as air conditioning or no air conditioning must also be considered in the choice of a separate IQCP.

Nevertheless, she advises POC coordinators: "Don't overthink risk assessment." Often, Dr. Ng says, scientists can sit down and think of a million ways a test could go wrong. "But then I redirect the scientist to say historically what has gone wrong—and that's what we should focus on."

There are basic initial questions to ask in deciding whether a point-of-care test is a good candidate for an IQCP, says Deborah Perry, MD, medical director of the Department of Pathology at Children's Hospital and Medical Center in Omaha, Neb. "For waived testing, you do not need to do an IQCP, but if it is a nonwaived test, then you look and decide whether, first, it is eligible, and second, if it's something you want to do in your laboratory. So that's kind of the first triage on it."

Dr. Perry

In her laboratory, some of the tests that were good candidates for an IQCP were Cepheid's Gene Xpert influenza

A/B, MRSA, pertussis, and enterovirus testing, along with serum β-hCG and rapid HIV-1/2 tests. Another large area was point-of-care blood gases and chemistry. All told, “we ended up doing IQCPs for about 20 tests or test systems,” probably an average number for laboratories their size, says Dr. Perry, who is the former chair and now an advisor to the CAP Point-of-Care Testing Committee. “I would say most of our nonwaived tests that were eligible for IQCP did end up getting an IQCP.”

Once the selections were made, IQCP development began. Dr. Perry is also a pathologist at the nearby Nebraska Methodist Hospital, and “when we were developing IQCPs, we had a team from both the children’s and adults’ facilities to try to help us all learn how to do it.”

“We started in the fall of last year with a team of technologists from three different laboratories that we direct, and met for an hour or two every other week until we got them done in December. It was a big time commitment in the fall, so for a couple of months it was pretty intense.”
The team listed all the tests at each hospital that it thought would be eligible, then assigned people to them. “Next, we came up with a template we thought would work for all three labs for risk assessment, a QC plan, and quality assurance, and we came up with forms each of the labs could use to help us have consistency.”

No test system was especially difficult to manage, Dr. Perry says. “The most difficult was the first one, because the whole process was something none of us had ever done.” The test systems with the most operators were the Alere Epoc Blood Analysis Systems and the i-Stats. “One test system is located in each of the three hospitals; they have the most end users and most locations, and we needed to get those operators up to speed.”

For some locations, that meant involving the testing personnel—the nurses on each unit, for example—at the front end for the risk assessment. “We had to educate them about what we were even talking about first. We showed them why we need IQCP and why we needed their input, so then they’d know the plan at the back end.”

That IQCP addresses the preanalytical, analytical, and postanalytical is, for her, the high point. “So while honestly, it’s a lot of work to do an IQCP, that’s been the piece that’s been most worthwhile,” Dr. Perry says.

Analyzing the environment, for example, can frequently reveal important differences among testing locations, and each location where a POC nonwaived test is done needs an IQCP. “The environment was a little different at each place, whether they were doing testing at the bedside or collecting the blood and going to a storeroom to do it. We had to make sure people knew whether a kit could be refrigerated or could be at room temperature, whether they were storing the test, where they were performing the test—making sure they weren’t doing it, say, beside the sink and having water spill into the kits.”

The two major risks to be taken into account for the POC preanalytical phase are patient identification and collection, she notes. “As to the postanalytical phase, probably the biggest risk is just making sure the results get entered into the medical record.”

“And the other thing we like to do is make sure the clinical feedback and clinical impact are right. So the caregivers see the results, they make sense, they act on the results. Those would be a couple of things we watch on the back end.”

She has found the vendors to be helpful in writing IQCPs. “Many times they provided whatever data they had in manufacturing the test and reviewed their testing requirements, helping us to ensure compliance. They are cognizant of what we’re needing to go through. In fact, many vendors provided IQCP templates or models as early as last summer, and that did give us a starting point.”

The main cost of IQCP is the people, Dr. Perry says. “Gathering together the testing personnel as well as the laboratory staff to write the IQCPs and keep doing assessments going forward—the personnel cost can be a lot. One of our hospital executives said, ‘Is this going to save us any money?’ and the answer was no; this is a quality issue and absolutely a regulatory issue. You do this or you do the default QC. And if you did default QC on every one of our nonwaived POC tests, that would be very costly.”

People are getting over the hump and ironing out the difficulties, Dr. Perry says. “I saw a lot of anxiety and nervousness in the fall and early winter when people were trying to figure out how to do this. But for most people I’ve talked to, once they did one or two IQCPs, they kind of got it and the angst has significantly decreased.” In the process, she thinks they are realizing that one positive thing about IQCP, for the labs and for hospital personnel, is the addition of pre- and postanalytical phases to QC. “This is an improvement over simply analytical QC.”
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