## Developing and Implementing an Individualized Quality Control Plan

REED: So people should be coming in. Hello, everybody. We're just going to give people a few more minutes to join, not too long. And then we'll go ahead and get started. I did want to let everyone who is attending the session know that we are going to be recording it. So please be advised.

Still got people coming in. I'm going to go ahead and wait until about two minutes after. And then we will go ahead and get started. All right, as we wait for other people to join, I'm just going to go ahead and go over some brief housekeeping. We're going to go ahead and get started today.

My name is Reed. I'm a consultant with Tana Health Services supporting CDC's OneLab Initiative. First of all, I'd like to welcome everyone and thank you for joining us today. We're really excited about this event.

A couple notes before the webinar begins, if you have technical issues at any point during the webinar, please email the onelabtest inbox for support. Harry has just put it in the chat. That's onelabtest@cdc.gov. We put that address in the chat window.

Please do keep an eye on the chat window. We'll be posting links to materials during the webinar. Bear in mind that the chat is for reference only. If you have questions for the test team or for our presenter at any time during the session, please use the Q&A function. You can see the Q&A button if you go down to the bottom of your Zoom window.

We will be holding questions until the end. But we will be reviewing the questions to go over at the end of the presentation and do our very best to answer. If you need closed captioning for this session, you can go down to the bottom of your Zoom window. There are the three dots and the word More. Please click on those dots, select Captions on, and then select Full Transcript.

So we'll start off with the introduction of today's OneLab Test facilitator, who will go over some relevant OneLab Test resources related to today's talk and introduce today's speaker. Today's guest speaker will then provide you with today's presentation. Following the presentation, we'll have a question and answer session, of course, and a brief discussion of upcoming test events. And then we will end with any closing remarks.

And now I'm going to turn it over to our OneLab Test facilitator, Jamie Perniciaro. She's going to share some of our new resources. Jamie is a health education specialist in CDC Training and Workforce Development branch. In addition, she has over 10 years of laboratory experience researching zoonotic diseases. Leveraging her interests in health education and laboratory science, she provides technical assistance to many audiences. Go ahead and take it away, Jamie.

JAMIE PERNICIARO: Thank you, Reed. Hello, everyone. I'm Jamie Perniciaro. And as Reed mentioned, I'll be facilitating today's webinar. Also, Reed will be adding relevant OneLab test resources to the chat.

First off, the Division of Laboratory Systems has created resources to assist laboratory professionals and testers. We identified two resources related to today's presentation. In the chat, you will find links to an individualized quality control plan step-by-step booklet. It can be mailed free to anyone by email request.

You will also find a link to a course titled Introduction to Clinical Laboratory Improvement Amendments of 1988. This course will equip learners with foundational information about CLIA. Topics include the history, importance, and implications for clinical laboratories and facilities that perform testing under regulations. If you have any complications accessing these resources, you may email onelabtest@cdc.gov.

I'm now excited to introduce our presenter today, Dr. James Nichols. Dr. Nichols is a professor of pathology, microbiology, and immunology, medical director of clinical chemistry and point of care testing, and medical director of special testing at Vanderbilt University Medical Center in Nashville, Tennessee. Dr. Nichols is currently the president-elect of the Clinical and Laboratory Standards Institute.

And Dr. Nichols' research interests span evidence-based medicine, information management, laboratory automation, point of care testing, and toxicology. As a federal employee, I do need to say today's slide decks may contain presentation material from panelists who are not affiliated with CDC. Also, presentation content from external panelists may not necessarily reflect CDC's official position on the topics covered. I will now turn it over to Dr. Nichols. Welcome.

JAMES NICHOLS: Great. I'm going to share my slide deck. Give me one second here. There we go. And I'll start presentation mode. Can you see that OK, Jamie?

JAMIE PERNICIARO: Yes, I can.

JAMES NICHOLS: OK, perfect. So I'm going to be discussing developing and implementing an individualized quality control plan. The objectives today are to recognize common sources of laboratory error, identify the CLSI-- that's Clinical Laboratory Standards Institute-- Evaluation Protocol number 23, or EP 23, guideline as a resource for risk management and building an IQCP. That's an Individualized Quality Control Plan.

And we'll learn to appreciate the variety of engineered control processes that manufacturers have built into point of care devices. And I'm going to use point of care as an example. They tend to be simpler than laboratory instrumentation and, because they're simpler, easier to use. I think that we can understand the risks a little bit better, and how to control those risks.

Let's start with the history of clinical laboratory risk management. CLIA 88, when it was published, requires two levels of quality control each day of testing or, if it's a qualitative test, a positive and a negative quality control. Newer laboratory devices, however, offer internal and engineered control processes that make daily liquid QC duplicative and redundant. The Centers for Medicaid and Medicare Services, CMS, implemented equivalent quality control in 2003 as a means of adjusting to all of the newer point of care devices that were coming out on the marketplace.

But that wasn't really scientifically based. So a conference was brought together. And out of that conference, we had a number of experts that proposed and developed EP 23.

This was the first document that introduced industrial and ISO risk management principles into the clinical laboratory. CMS adopted key risk management concepts into the individualized quality control plan concept, and that option for quality control in 2016. At that time, IQCP replaced the 2003 equivalent quality control options.

Now, the IQCP in 2016 gives you two options. The laboratory can continue to run two levels of liquid QC required by CLIA 88 each day of testing. Or the laboratory can develop an IQCP. This IQCP is intended to balance the internal control processes built into that device with external controls. This allows laboratory directors and laboratories to reduce the frequency of external liquid QC to the minimum recommended by the manufacturer, and maximize clinical outcome with available staff resources, and apply cost-effectiveness strategies in the laboratory.

Now, some considerations for developing an individualized quality control plan-- and I took this out of CMS CLIA brochure number 12 you can see at the bottom of this slide. So starting at the top for current or any new test system implemented in the laboratory, are there manufacturer's instructions for control procedures in the package insert or the operator's manual? If not, heading to the right, you have scenario number 3, where there's no control procedure requirements in the manufacturer's instructions. Or it's a laboratory-developed test, and you can select one of two options-- follow CLIA quality control regulations for two controls a day or perform an IQCP.

That has three components-- a risk assessment, a quality control plan, and a quality assessment program. If there are instructions for quality control in the package insert or operator's manual, then you have to ask, is the frequency of the manufacturer's QC instructions less than two levels of external QC each day? If it is, you can continue and select one of those two options-- following daily QC or performing an IQCP. If the frequency is two, then you are required at least two levels of QC each day of testing. That's scenario number 1, always have to follow manufacturer's QC instructions.

Now, many laboratories are accredited by the College of American Pathologists. They similarly have recommendations for laboratories to ask, is my test eligible for an IQCP? And to be eligible, the test must meet both of these criteria. It has to be non-waived.

But I will say, even though it is non-waived, you can benefit, and all laboratories can benefit, from running a risk assessment and developing a quality control plan, even for all of their waive tests. And many of the test systems I'm going to discuss today are CLIA waived. So is it non-waived that employ an internal quality control system, either electronic, procedural, or built-in?

And the exception is really microbiology, media, or reagents used for microbial identification and susceptibility testing. They can implement an IQCP. And are the tests performed in specialties other than anatomic pathology and cytopathology?

The exception is if anatomic pathology and cytopath tests can be assigned to a different CMS subspecialty. It may qualify. And IQCP requirements, as I mentioned, don't apply to waive testing formally by regulations. But laboratories really can benefit from running through the exercise, determining your weaknesses, and coming up with a quality control plan to minimize errors.

So what is an individualized quality control plan, an IQCP? I mentioned it's three components. First step is to do a risk assessment. What comes out of the risk assessment will be a list of hazards or weaknesses in the testing process, as well as how the laboratory is going to address those weaknesses.

That's summarized in a quality control plan. And once the lab implements the quality control plan, you're going to continuously assess the quality. And if continued errors occur, you're going to go back and reassess your risk and modify your quality control plan. So it is a continuous quality improvement process.

Let's talk about, how do we get started? When we talk about risk in the laboratory we have to all realize-- and I think many of us do from the experience that we have working with laboratory tests-- that there is no perfect laboratory device. Otherwise, we'd all be using it. We don't have Star Trek tricorders sitting around that are non-invasive and perfect and test for everything under the sun.

Any device that we have, any test, can and it absolutely will fail if it's used under the right conditions, what I will say, the wrong conditions. A discussion of risk, therefore, has to start with what can go wrong with the test. Where are the potential for errors and non-conformities?

Lab tests, essentially, are not foolproof. And when a clinician sees a number, they think, oh, the test must have worked, we got a number. That we understand is not necessarily true. So we have to really break apart our processes.

And much of this risk management in the laboratory is common sense. I think from this picture, we would realize if this person starts up this chainsaw in this position, that this is not going to end well. So a bit of what we do with risk management is using and applying our experience and our understanding of laboratory tests in the laboratory.

What is risk mitigation? Typically, we have historically used liquid quality control as a means of detecting and preventing errors, preventing what we call non-conformities or incidents. Liquid controls we realize, in the laboratory, do a very good job at detecting systematic errors that affect every sample in the same way, things like calibration errors, pipetting errors, reagent degradation. That's because the controls are processed in the same manner as the patient sample.

But liquid controls do a very poor job at detecting random errors that affect a single sample, very uniquely, unique from the liquid quality control. Things like hemolysis, lipemia, clots, drug interferences, in a single sample, quality control does a very poor job at detecting those because the quality control is a separate sample. And we have to realize for a lot of our point of care testing devices, for unit use tests, they are a single cartridge, single test strip, a single test at a time.

When we run liquid QC on that test, we've consumed the entire cartridge. And the very next test, the next cartridge may behave a little bit differently. What we have to realize is that the newer devices have built-in electronic controls and onboard chemical and biological controls.

Many of these different devices, as we see them here, have a lot of different mechanisms. Some of them are even non-invasive. I mentioned the transcutaneous bilirubinometers, the breathalyzers. You can't even run quality control on those.

So how do we manage quality on a test like this? There are onboard or analyzer QC that manufacturers have built into devices. They are system checks. We have internal QC. This is internal or laboratory-analyzed surrogate liquid control samples, what we call external QC from an international perspective, ISO perspective. This is our blind proficiency surveys.

But there's this host of all kinds of other quality control processes, either engineered by a manufacturer or enacted by a laboratory to ensure result reliability. What we have to realize is that no single quality control procedure, like two levels of liquid QC each day of testing, it's not going to cover all devices because the devices differ. And newer devices have these built-in electronic controls, onboard chemical biological controls.

So developing a quality control plan, an IQCP, surrounding a laboratory test and testing device, it really requires a partnership between the manufacturer and the laboratory. Some sources of error may be detected automatically by the device and prevented, while others require the laboratory to take some kind of an action, such as analyzing liquid quality control when you receive a new lot of reagents. Because we don't know how those reagents were shipped and what environmental extreme temperatures conditions they may have been exposed to during transit. So it's always a good step to test quality control when they come in to make sure that they are actually viable before we put them on the shelf and start using those reagents for patient testing.

So clear communication of potential sources of error and delineation of the roles of the laboratory and the manufacturer are essential components of risk management, understanding what the manufacturer can detect and prevent and what we have to do in addition to that, as laboratorians. This is summarized in EP 23, the CLSI document, Laboratory Quality Control Based on Risk Management. I had the privilege of being the chair holder for this committee of experts. And EP 23 describes good laboratory practice for developing a quality control plan based on manufacturers' information, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting.

To get started, we essentially take information about the test. What are the medical requirements for the test? What's the total allowable error or medical uncertainty about this test? How is the test going to be utilized, the result, by the clinician? What's the regulatory and accreditation requirements?

Here in the United States, we're under CLIA. But outside of the United States, there may be local, regional types of regulations that require laboratories to perform quality control, do certain things at a certain frequency. Then we have what's in the package insert, the manufacturer's instructions for use. That's the ones that are provided by the manufacturer about the test, its accuracy, its precision, and what we obtain as a laboratory, by maybe picking up the phone, writing an email to our colleagues who are using this test, and asking them, hey, what have you been doing, what have you seen as potentials for error.

We also have to understand information about the health care setting. Who's running the test? Is it in a clinical laboratory under-well controlled temperature and humidity conditions? Or is it out on the floor? Is it in a car somewhere being driven around the city by a visiting nurse, where it's exposed to different temperatures, different conditions, and non-laboratory-trained operators?

We process that information through a risk assessment. Our output, as we mentioned, is a summary of our action plan. Basically, that is our quality control plan. And once we implement that plan, we're going to monitor, assess for continued errors, and continuously improve this process.

So let's get started. We create a process map. We follow the test like we were a specimen, from order to specimen collection, the pre-analytic portion, getting that specimen onto the testing device, the analytic, and the post-analytic. Once an answer is available, how does that result get back to the clinician, and what is the clinical action taken?

So we have to understand pre-analytic processes, outside the control of the laboratory sometimes, analytic processes, as well as post-analytic. As we step through step-wise, the procedure, we want to identify weaknesses in that process. At each step, ask the question, what could go wrong here and have we considered this, then determine a mitigation for those hazards, those weaknesses in our process.

Maybe it's some type of a detection system. Maybe it's additional training of the operator to look for certain aspects of the specimen. And then we summarize those processes and actions in a quality control plan. As we develop our process map, we want to follow the testing process as if we were a sample. And we want to consider pre-analytic, analytic, and post-analytic phases of testing, as well as samples, what can go wrong with the sample, operators, their training, their competency, things like short-staffing.

During the pandemic, these brought up issues that may not have happened when you were better staffed. Reagents, we have to think about shipping, I already mentioned, but storage, expiration dates, and errors in preparation. The laboratory environment itself, is it indoors, or is it being conducted outdoors somewhere, on the street, for instance, by an ambulance driver?

And the measuring system, what can go wrong, electronic failures, device failures, computerization, internal errors? We want to identify-- this is called a herringbone diagram or an Ishikawa diagram where, on the left-hand side, we identify potential hazards that can, on the right-hand side, lead to an incorrect test result. And these are just some of the considerations.

As we talk about point of care testing, this is testing conducted outside of the clinical laboratory. We have to consider dozens of sites, hundreds of devices, and thousands of operators. It's like having too many cooks spoiling the broth. We've heard about that in the kitchen.

The number-- the reason I pick on point of care here is that the number of sites, the number of devices, the volume of operators, plus the amount of testing that we're doing, creates a situation where even rare events could become everyday types of errors. So these are good to start from. I particularly like this.

My distinguished colleague said, nothing is foolproof for a sufficiently talented fool. So think outside the box. Think like an operator who is conducting the test, not like a laboratorian, necessarily. And think about all the different ways that this device might be used or, as mentioned, misused.

Manufacturers, when they're developing a test and they're going for FDA approval, they consider errors and hazards with that device that could lead to patient harm. And they have mitigation steps. And they show these mitigation steps to the FDA during submission.

This is called a use case scenario for that device. They describe a real world example of how one or more people are going to actually interact with that device. When we talk about-- let's take a glucose meter for instance.

We can take that glucose meter to the patient's bedside and do a finger stick and conduct the test at the patient's bedside. Or we can keep that glucose meter stationary in a spare unit on the nursing unit, say maybe a utility closet, and we can go out to the patient, collect the specimen, and bring the specimen to that device. These are two different use case scenarios that have different risks involved.

When I'm at the patient's bedside, if I use the patient's barcode and I scan it, that specimen never leaves the room. But if I take that specimen, collect it, walk it down the hallway to where the device is-- maybe it's even a blood gas analyzer-- I have a risk now of interchanging that specimen, mixing it up with other specimens from other patients that may be in that utility room also being tested.

So I now have a risk of mislabeling. And that risk is higher if I use the device down the hall than it is if I take it to the patient's bedside. These are some of the considerations as you go through a risk assessment that you need to consider.

I come back to just common sense here. I love this advertisement-- or this news article. And this was a headlines in a midtown-- or a mid-America city, where it said, baseball coach loaned Ferraris to teenagers, what could possibly go wrong? And I like that because we all have seen Fast and Furious, and think all the kids have seen it as well. So when you give them very expensive cars and they speed around without a lot of experience driving, of course they're going to crash these cars.

So let me give you a case example here. This occurred in an ICU. And we got complaints in the laboratory with our point of care staff. From the ICU, the nursing staff on the unit were seeing sporadically falsely decreased glucose test results. Immediately upon repeating the test on the same meter, it gave significantly what they call clinically sensible values.

We sent our point of care staff out to the ICU, and we had them watch how they were using this device. And what they found was that the nursing staff were taking procedural shortcuts. They were trained to keep the cap on the bottle of glucose testing strips because they're very hygroscopic.

It's humid outside during the summer. Even sometimes in the wintertime, with rain, snow, the humidity can go in mix with the dry chemicals on the test strip and cause issues with the viability of those tests. What we found, though, manufacturers had-- although they had desiccants in the lid, the nursing staff had difficulty getting their fingers, gloved fingers, into the bottle to remove a test strip. The manufacturer had made it very narrow to prevent a lot of air flow back and forth while the bottle was open and the test strips were being taken out.

So instead of keeping them tightly capped, as they were trained, they wanted to speed up and do the test as quickly as possible, get back to their patient. Because that was important, in their mind, the most important point, rather than following step-by-step how they had been trained. And what they were doing, when they opened up a new bottle of test strips, instead of capping it again and taking one strip at a time, they would dump all of the test strips on an absorbent paper on the counter where the testing was taking place.

And sometimes when they finished-- there was a trashcan next to the counter-- they would throw the test strip into the trash can. But sometimes it would make it in the trash can, and other times it landed back on that absorbent paper. So the next nurse who came in to do glucose testing and brought a sample would sometimes pick up a new test strip, other times pick up a used test strip.

And what we found out was that bottles of the test strips were being dumped, and the used test strips were being reused. And I think you can appreciate that there are enzymes on these glucose test strips. And those enzymes would be consumed and chemicals consumed in the first test, and a second test would give clinically much lower test results.

Unfortunately, what we found, even though we trained them and had done studies, that glucose test strips exposed to the air for as little as two hours had been shown to have decreased bias. Strips left on the counter posed this risk for reuse. And what we did was we pulled up several manufacturers of meters.

And some of the meters we noted can error and catch reuse, an already used test strip, preventing a test result from happening. The meter we had, however, did not. And so here's a potential risk that we didn't predict in the first place, and had staff been following policy as expected, probably wouldn't have happened.

So we went back, retrained our staff, but then also really took a hard look the next time we switched to a new meter what meter we were going to pick. We were going to pick a meter where it's going to error rather than give a wrong result. And there are manufacturers out there now that, actually, when you insert a test strip, they can detect damage, abuse to the strip, reuse, used or wetted test strips, scratches, effects from humidity, even temperature.

We also need to figure some meters automatically calibrate based on the lot number of test strips that's being used, while other manufacturers require you to input a calibration code or some type of chip. If you don't change that chip when you switch to a new lot of test strips, you're now introducing a calibration bias. There are meters on the market, as well, that can compensate for hematocrit temperature effects.

Let me talk about pandemic. And this was the first time that we started actually implementing point of care molecular infectious disease testing. These devices have single use cartridges. They minimize the potential for carryover. They're connected, wired or wireless. They test for a variety of different organisms.

Primarily during the pandemic, it was COVID and respiratory, influenza A and B, RSV. Some of these are portable, some are not. They are very simple to operate and require minimum training and education. They are CLIA waived in the United States. In clinic, health care settings, developing countries, emerging markets, military deployment, even disaster relief, they found applications.

But as we were looking what could go wrong with this particular test, we were very concerned because, as a laboratorian, I'm used to our typical molecular laboratory workflow. This is where we separate reagent preparation and storage from specimen preparation steps to amplification steps. And we have a unidirectional workflow so that the amplicons that we do in the last step before detection don't make it back to the areas that we're preparing reagents because that would cross-contaminate, cause false positives. So we were very concerned, even with unit use devices, about the potential for environmental or cross-sample contamination when we implement these, particularly in busy workflows, places like the emergency room or other high-volume types of testing environments.

So sample errors, what can go wrong? We have to be concerned about contamination. And I found some papers by Yarbrough. And what they did was they put a fluorescent powder that they doctored with a bacteriophage. And they watched how handling of specimens, even with gloved hands, was transferring this bacteriophage amongst the different environmental surfaces.

And they asked, how much of this is actually getting in and cross-contaminating between samples? You can see pipettes were contaminated, other types of surfaces. But despite spread of this fluorescent powder, they had very few amplifications, less than 1%, cross-contamination or false positives.

So as we put these out, we taught staff, handle one specimen at a time. You're testing one specimen. So as you open it, as you transfer the viral transport media into the cartridge, close the cartridge, reseal the sample, clean the surfaces after you're done, change your gloves between each specimen as extra mitigation steps. What we found was that very minimal cross-reactions or cross-reactivity and false positives in those areas that followed those steps.

People that got sloppy, we saw environmental contamination. And what we did is place an environmental control as an added step weekly, when we initially put these on the floors, to have justice swab, wet it with viral transport media, and swipe the surfaces that are touched-- the keypad, the door handles, the countertops, the top of the device, and test it like a patient sample. And keep track of this as to how many of these or what frequency we saw of positivity rates. And we noted very low positivity rates. And eventually, after the first several weeks of this, in those areas that had very low false positives, we ended up backing away from weekly to bi-weekly and eventually monthly, as just a sort of check.

Volumes we have to be concerned about. Some devices require a calibrated amount of sample to be pipetted. Others, if you don't get an adequate amount of sample in there, you could get a false negative. Some glucose meters, for instance, will automatically trigger and start the test timing once they sense that enough volume has been added. The question really becomes, if you don't add enough at the beginning, do you have time to go back and re-fingerstick that patient, or do you have to start all over again?

And what about operator errors? We want to make sure that operators are trained competent to do the test before they actually start testing. So many of our devices have operator lockouts.

These function through a number code, a name or barcoded ID on the operator. And the database within the device has a list of operators that are trained and competent. They are linked with training dates, so they will automatically expire after one year and require the operator to go back through recertifications.

Devices do also have quality control lockouts. They require periodic quality control. So if you require, as a laboratory, weekly or monthly QC on the reagents, you can program that into the devices. And it will lock up, will not do patient testing if quality control has not been done and is successful at the required dates.

What about patient identification? This is the most important because we can mix up patients. And you can have incorrect entry, a patient identification, which then charts the results to the wrong patient's medical record. This can lead to inappropriate medical decisions, treatment, improper billing, and compliance issues. Wristbands can really improve this, barcoded wristbands. Many of us are using those.

But despite being barcoded, you can admit patients with another institution's barcodes. You can have outdated account numbers. And you can even put the wrong patient's barcode on that wrist, particularly when you're looking at operating room testing, where patients, basically, they take the wristband off so that they have IV access. On an outpatient setting, we don't have barcodes. So how is that information being put into the device?

So I mentioned, there are a residual risk of error, even with barcoded ID bands. Fortunately, manufacturers have now what's called positive patient ID. This works from the admissions discharge transfer information on the patient or from their appointment scheduling, where, when you input the patient's ID number, it will pop up and ask for a second form of identification, a confirmation, like birth date, to cross with that information.

When we implemented positive patient ID, our error rates dropped from about 62 errors a month in the emergency department to less than three. And those three were on patients that were unregistered. In other words, they tested them as traumas coming through, and we didn't have them registered. So once we changed that process, started registering patients earlier, we then had much lower rates and were able to reduce those to practically 0.

Expired reagents-- the CDC, the FDA also indicate to check and record expiration dates of reagents and kits and discard any reagents that have expired. Many devices, our molecular devices and that, are barcoded reagents. And they understand the expiration date when you put that cartridge into the test. Some do, some do not. And if we're doing something like a glucose meter or a control vial, when you open those, there is premature expiration of those manufacturer imprinted dates.

Oftentimes, those manufacturer imprinted dates are a year out or two from manufacture. But if I pop the top off of this vial, humidity, and that is going to affect lifetime. And so they will prematurely expire 30, 60, 90 days after opening. That requires the operator to cross out the manufacturer's expiration date and redate it with an open date so that we know the date it's been opened, and we know when it's going to expire, and discard those before we use expired reagents.

This was a source of error, obviously. And it's a continued problem. I'm constantly talking to our manufacturers to prevent this type of problem. But when you go out onto the floors and you find undated test strip vials, what do you do with those? You can only throw them away because you don't have any idea when they were open. This institution actually stored them up, took a picture of six months, and showed the staff exactly how much wastage they were causing because of premature expiration and not following through.

Fortunately, newer manufacturers, newer reagents, what they are looking at is serialized vials and test strips, individually packaged tests, as well as serialization in multi-test packaging, where the first time that that barcode is read, that data management system understands this was opened on this date. And as you use that, test strips from that vial, if it goes beyond the open expiration date, it will flag, warn, and not allow patient testing. These are newer control mitigation steps that are available. And I think it's a rather novel solution to an engineering issue.

I will mention that, in the revised CAP Molecular Point of Care Checklist questions, there is specifically questions about monitoring. And at the very top of this, POC 08675-- the laboratory monitors for the presence of false positive results due to nucleic acid contamination for all molecular microbiology tests, including point of care and laboratory testing.

So I want to summarize and end my talk by stating, where is the risk in our process? A lot of this is common sense. And we know this painter is not going to end well as he moves with his ladder position this way. A lot of what we do is common sense.

There are resources out there to help you talk through certain error processes and how they were handled in the laboratory. This was a discussion in the Clinical Chemistry [INAUDIBLE] series that I wrote with Carol Roush, a good colleague friend of mine. And it focused on errors in the chemistry laboratory.

But it included point of care devices as well. And there was a discussion of real world errors and what can be done to detect and prevent errors. I will mention, and I'm very proud, that EP 23 second edition has just been published a couple of weeks ago. These are some of the changes that you can expect. Version 2 aligns EP 23 better with ISO 22367 and ISO 14971.

It incorporates detectability in the risk assessment. And we replaced the glucose concentration measurement example with real world examples of quality control plans for non-instrumented single use devices, instrumented single use devices, and exempt microbiological media. And we updated the references as well.

So in summary, there's many sources of laboratory error. Risk management assesses the workflow for weaknesses and allows labs to take action before errors occur. Our IQCPs are more than reducing the frequency of QC. In fact, some mitigation steps may say you need to do more QC. IQCPs provide us with the opportunity to interact with clinical departments on a shared quality improvement project.

And they improve our workflow and operational efficiency. Most importantly, IQCPs justify why we're doing what we're doing, not just because we're meeting regulations, but we are doing QC at this frequency because it's mitigating X, Y, and Z errors. So it's beyond just meeting regulations.

So at this point, I'll turn it back over to Jamie. And I want to thank you for your attention. And I think we will answer some questions.

JAMIE PERNICIARO: Thank you, Dr. Nichols. Yes, we will take a few minutes to answer as many questions as possible. If we do not get to your question today, we will do our best to respond via email to those who provided their registration name. If you have questions after today, please feel free to email the OneLab Test inbox at onelabtest@cdc.gov.

It just put it in the chat as well. So we will go to our first question. The first question, it was earlier in the presentation. Why do we need an IQCP? For instance, as per CLIA 88, two levels of quality control should be run per 24 hours for analytics. That's for Dr. Nichols.

JAMES NICHOLS: Sure. So you have an option now. Before IQCPs, everyone had to run two levels of QC every day of testing. But I'll give you an example. Let's talk about fetal Fibronectin. This is a test for preterm labor. Each of those test cartridges cost over $100. And if we have to run two levels of QC each day of testing, we're running $200, let's say, worth of tests that we can't bill for.

So the laboratory, despite maybe only getting one sample a day, is running a lot of QC. But on every one of those cartridges, there is a built-in positive and negative control. So why do we have to run an external QC, consume this reagent, spend time running it from the staff, as well as having to document that and maybe troubleshoot if there are issues?

That's extra added effort that we're not getting bang for the buck for. So this would be one of the reasons why. If you have a test that has a lot of internal processes, why are you running external QC? And what frequency should you run external QC? That's when an IQCP is going to help you. I hope that helps.

JAMIE PERNICIARO: Thank you. And we have about four more questions. We'll see what we can get to you. Thanks. Next question, is there a specific frequency for repeating the risk assessment and realigning the IQCP? Dr. Nichols.

JAMES NICHOLS: I would say need to relook at your risk assessment and reassess your risk whenever you see an increase in errors, or a particular error starts to pop up. Short of that, I would at least look at them every year to make sure that what you have stated at the beginning is still being done and is still valid.

JAMIE PERNICIARO: OK, thanks. And then there's a comment for concern-- what is the probability that point of care tester people will change gloves between testing?

JAMES NICHOLS: Well, it depends on the speed of the test. But if you've got a test that is taking 20 minutes, say in a molecular point of care device, they don't want to be walking around with contaminated fingers. It's more than likely they're going to change their gloves after they apply that first specimen.

JAMIE PERNICIARO: Thanks. And next question, any comments on the LIS errors where results are entered manually, not through HL7? Example-- MVP vaginal panel or yeast, BV agents, and [INAUDIBLE] run on the same cartridge or [INAUDIBLE].

JAMES NICHOLS: Sure, I can comment. You kind of have to look at your staff. But if you're manually entering results, there are some studies out there that indicate that manual processes can have errors upwards of 1% to 5%, just by typos and other issues. Staff are-- you're short staffed. They're stressed. They're working longer hours. They're seeing more patients. And they're not taking the time. They're thinking about other things. And I think manual processes are going to have higher percentages of errors.

JAMIE PERNICIARO: Thanks. Next question-- with the references for waived point of care testing in this IQCP presentation, is there an intention in the future to require IQCP for waived point of care testing?

JAMES NICHOLS: I can't say. I'm not a government employee so-- or that it would move that way from CMS. But certainly, I think the most, I think, highest risk test were those moderate complexity out there, the ACT coag testing, the blood gas testing. These you can apply in IQCP. And as I mentioned with this presentation, anyone can really benefit, even our waived test, from running a risk assessment.

JAMIE PERNICIARO: Thank you. And last question, for the I-stat, does the IQCP apply to the device or to the cartridges?

JAMES NICHOLS: It actually applies-- an IQCP applies to an individual test. So while the cartridge is in the same device and you may have multiple tests on one cartridge, you really have to consider that each of those tests have different risks. Take, for instance, hemolysis. If you have a unit, nursing unit, that has higher hemolysis rates, they have higher risk of error with the potassium results, versus if you have a cartridge that doesn't have potassium on it.

So that's the reason to look at the test level and also the location level of where you are actually doing the testing and incorporate that within your IQCP. You can have one IQCP that covers I-stat and covers all the different tests in your cartridge menu. But you have to also incorporate into that where the testing is occurring because you might have higher rates in a pediatric emergency room or in a NICU than you would in a general medical unit.

JAMIE PERNICIARO: That makes sense. Thank you. We want to thank Dr. Nichols, again, for joining us and giving this fantastic presentation. If you're not a test member and would like to be, you can create an account on the OneLab Reach website. The link is in the chat, and you may opt in to test membership.

And now I want to highlight a few upcoming OneLab events. The next OneLab Test event, titled Personal Protective Equipment for Point of Care Testing Sites, will be held October 31 at 12:00 PM Eastern. Time please keep an eye on your inbox and on the Test home page for updates on the registration opening.

In the month of September, OneLab Network will have two events, one webinar titled CMS Proficiency Testing, Final Rule CMS 335F, will be held on September 7 at 12:00 PM Eastern time, followed by another webinar on September 26 titled How to Plan for Possible Burkholderia Pseudomallei Exposure and Cases, at 12:00 PM Eastern time. Each webinar will be one hour long and will be recorded for those who are unable to attend. Two links are in the chat to register for these OneLab Network events.

In the month of October, we will be hosting the OneLab Summit, which is a three-day virtual learning event from October 3 through 5. It is created for laboratory professionals. Attendees will improve their skills through hands-on technologies, learning, and development tools, and practices, glean insights from the laboratory community's success and resilience, also collaborate and connect with CDC and laboratory education and training peers. We will post the registration link on the OneLab Reach website on September 1.

As a reminder, the slides from this presentation with links will be posted to the OneLab test home page. For those who are test members, you should also receive an email with these links. Thanks, and I hope you have a great rest of the day.