The Path to Painless Point-of-Care Implementation: Training, Competency, & Quality Control

Part 1

Moderator

Welcome to today's webinar, Path to Painless Point of Care Implementation: Training, Competency, and Quality Control, brought to you by Point of Care Testing University. This webinar has up to 1. 5 hours of Continuing Education Credit for Physicians, Nurses, Laboratory Professionals, and Respiratory Therapists, divided into three sections.

This educational program was supported by Siemens Healthineers, and content was planned and developed by Medavera.

After this webinar, participants will be able to identify training requirements for point of care testing, review competency assessment elements and implementation, evaluate methods of quality control, and determine how to develop and incorporate an Individualized Quality Control Plan, or IQCP. To obtain credit for this program, please listen to the webinar and click the button below the video for the evaluation.

Fill in your information on the evaluation page and answer the questions. Upon submission of your evaluation, an email will be sent with your certificate to the email address you provided.

Today's presentation will be given by Dr. Marcia Zucker, Point of Care Testing Consultant. In the first section of this webinar, Dr. Zucker will discuss point of care testing and CLIA, as well as point of care testing training. The second portion of the webinar will discuss competency assessments, and the third video will cover quality control and IQCP.

In order to obtain the full 1.5 hours of credit for this program, you must view all three videos.

Welcome, Dr. Zucker.

Dr. Marcia Zucker

Thank you.

Welcome, everyone. Today's presentation is going to focus on the regulatory side of point of care testing. That part being what the CLIA regulations explain to us about what we need to do for training, competency assessment, quality control, and individualized quality control plans.

So let's go back a bit and just say, why do we bother with point of care? And we bother with point of care for very specific advantages that it gives us. We get the result right there at the side of the patient. We can very quickly give the patient advice, give the patient direction, and we can avoid

delays in shipping samples, delays in getting the results, delays in actually contacting the patient to give them appropriate counseling.

For some tests, like the infectious disease tests, it also allows us to improve our antibiotic stewardship in that patient. We're not going to be giving antibiotics when we know we have a confirmed viral infection. Also, patients often prefer to get finger stick testing to venipuncture. And you know, making patients happy is a very big part of making them compliant.

When we're getting a new point of care system, features that are very important to us are quality control, does it have built in control? Is there available external QC? Are there lockouts so that we can be sure that quality control is performed in a timely manner? Can we lock operators out to ensure that only those who are appropriately trained and shown that they are competent will be running tests on our patients?

And then in the background of the actual use is how we're getting the data to the lab information system or the hospital information systems. Will it fit with our middleware in order to transmit the data directly without worrying about typographical errors in transcription? And does the system have memory?

We want to be sure that every test result has a date and time stamp so that we know who's running the test, where they are, when they are, and we don't confuse results between patients. And all of this is under the umbrella of the CLIA regulations.

CLIA regulations apply to absolutely any test that uses a sample taken from a human body. Your saliva, your urine, your blood, whatever. A sample is taken from a human. Any testing done on it is, is regulated via CLIA. Not only is it all encompassing for tests, but it's all encompassing by facility. Any facility is considered a laboratory if they're doing testing on a sample that came from the human body, and they are therefore regulated under the CLIA regulations.

Within CLIA, we have the definition of three different complexities and complexity is defined based on the test itself and the risk profile of that test. So tests that can be considered high risk, require very, very specific knowledge and background, those are our high complexity tests. Oh, for example, examining a biopsy to determine if it's cancerous or not, that's a high complexity test.

Most of our point of care diagnostics are considered moderately complex. Some training is required to use it, but not the high specificity training we have in the high complexity tests. And then least regulated and least complex are the CLIA waived tests. By definition, these are tests that an untrained operator can perform with little to no risk of an erroneous result.

The FDA is the organization that currently defines CLIA complexity for each test. And that's done when the test is initially cleared for market, whether by 510k or PMA, or in some situations, if a manufacturer submits a request for CLIA classification.

Now the complexity defines what CLIA licensure the facility must have. Remember all those, all facilities doing the testing, are laboratories. And each laboratory that is doing testing on human specimens must have CLIA licensure. We can go from the simplest, which is a certificate of waiver, which means that your facility can only do waived tests that you have listed on your license application or can have one for provider performed microscopy procedures.

It's a tongue twister, but these are procedures such as testing that a doctor uses a microscope to examine a specimen from a patient. And they are not waived tests, but they're not quite up to the level of moderate complexity. They are provider performed microscopy procedures.

Then there's the certificate of compliance, where you are inspected by CMS, the Centers for Medicare and Medicaid Services, and the Certificate of Accreditation, which is where you are inspected by accrediting agencies such as CAP, Joint Commission, COLA, or several others. And in either case, all complexities of testing could be done under that licensure.

Now, one caveat to this licensure is you must be aware of your state regulations because not all states recognize all waived tests that are waived by the federal government.

And the training required for each of these complexities is very different. Now, everyone needs some sort of training, you would think, whether they be the operators, the providers, the clinicians, the supervisors who oversee the entire point of care program. Maybe it's the laboratory folk. But according to the CLIA regulations, what training is needed is very specific. In your facility, it is likely that you will have many nurses who will object to formal training because they've been doing point of care testing forever.

Despite that, there are unique qualities to each test that really do to make it important that everyone to get training, Lab folk may think they don't need training because point of care tests are much simpler to do than laboratory tests. Again, the unique qualities of the different tests lead to the need for formal training.

And this can be anything from the simple thing of preparing the patient and collecting the sample to the very complex parts of instrument maintenance, knowing how the results have to be interpreted, knowing how to do the QC. So training is not just take the sample, put it on the device, go away. It involves everything from the thought that “I would like to see the result of a specific test”, to the review of that test result in the hospital information system or the laboratory information system.

When defining what training each of your operators are going to get, we're going to look at the regulations by complexity. Now, for moderate complexity testing, which, again, is most point of care tests, you need to have a high school diploma or equivalent in order to run the test. In certain states, you need a lot more than that.

Some states require a four-year degree in order to run a point of care test. Other states require state specific licensure. When defining who in your facility is going to run the different point of care tests, it is critical that you verify your state requirements for that testing before wasting everybody's time training individuals that the state will not allow to do the testing in your facility.

When we're talking about waived testing, again, waived tests are supposed to be so simple to use that an untrained operator can perform it with minimal risk of an erroneous result. That means that if you're going to be running a waived test, you need to be able to read and understand the manufacturer's directions and follow them.

Many years ago, when there was a large study of laboratories with certificates of waiver, it was found that the deficiency most often noted in those laboratories is that the operators were not

following manufacturer's directions. Sounds really simple, but that's the key for waived technologies.

For moderate complexity testing, we need to do a bit more. We need to train our personnel. We need to be sure they have the appropriate experience for doing the testing. And then we have to verify that the training took; that they weren't just sitting there shaking their heads when you were doing the training, but they actually know what they're doing. To do that, we're going to assess their competency. And that competency assessment gets a little complicated. We'll get to that in a moment.

Part of our training has to be to be sure that anyone who's going to be running the test understands all of the policies and procedures surrounding that testing, and that they're capable of doing the testing, performing and documenting quality control, and that they can perform proficiency testing. Proficiency testing is supposed to be performed by operators. The ones that normally run the test are supposed to be doing your proficiency testing. And they also have to be able to maintain the equipment.

All of these should be a part of your training program and that training can be performed by anybody. Places frequently have the manufacturer come in when they have a new device and have the vendors actually doing the training. More frequently, the vendors come in and do what's referred to as a 'train the trainer', so the vendor walks in, they train some of your operators, many possibly, but they mostly train the people who will be your in-house specialists on this given test, and they will be doing the training of the other trainers or of the other operators. You could even have a self-training program. There are systems that have learning modules online. We can use that as a part of our training. There's lots of different things you can do as long as you can be sure that your operators are being trained and that that training is relevant.

So, if a laboratorian walks onto the floor and says, "Here's how you run the test," do they understand all the little nuances? Things like, don't put a drop of blood on the countertop, or be careful if you're using a capillary. Maybe you do want to have clinical personnel training other clinical personnel because they have a different way that they relate to the testing, more similar to what the actual operators understand.

Every facility is different. Everybody wants to think about it. You just have to be sure that before anyone is approved to perform point of care testing, they have their training and their initial competency assessment. That includes not only for a new system, but for any changes in the system. Maybe we've been using a test for a year or so and realize that if we change the way we do things just a little bit, it will actually be better because it will not be as intrusive on the clinical personnel.

Okay, fine. We can make a change, but then we have to retrain everyone who's going to be doing the testing and do another competency assessment to be sure they got it. Then they can go and move forward and perform the point of care test.

Part 2

Moderator

For the second section of our program, Dr. Zucker will discuss competency assessment. For additional information on continuing education credits available for this program, please make sure you view the first video.

Dr. Marcia Zucker

I keep saying competency, competency, competency. Well, what's competency? Competency is the ability of a person to take what they've learned and use it correctly.

It's pretty straightforward. You've been trained. Can you follow the training and do things the correct way?

Well, who's going to say if I can do a test the right way or not? That person is my competency assessor. But the assessor can't just be the person who I work next to every day. It has to be somebody who, number one, qualifies as a technical consultant under CLIA, which means they have a bachelor's degree, and either two years of lab training or two years of experience with non-waived point of care testing. Could be a nurse. But number two, they must be delegated in writing by the laboratory director. If you want everybody on the floor to be able to assess each other's competency, you've got to make sure each and every one of them is qualified as a technical consultant. You've got to make sure each and every one of them is delegated the authority by the lab director, the person who holds the CLIA license. That's not likely going to be a very large number of people, but they are the ones who can assess others competency. Their competency as an assessor must be documented based on their knowledge of troubleshooting the system, verifying compliance with quality policy, making sure competency assessments will be done in a timely manner and overarching all of that, assessing new training needs.

Anyone who is going to be performing any sort of testing must have a competency assessment for the testing they will be performing. And that assessment has to occur right after they're trained, or shortly after they're trained, just to be sure that they took up what you trained them on semiannually for the first year of testing and annually every year thereafter. So, if you're going to make a change in your policy, it usually makes sense to do it towards the end of a competency year, if you have such a thing in your facility. If you have a rolling competency schedule, it doesn't really matter when you bring in something new, but it just allows you to minimize the number of repetitions of your competency assessments, depending on how large your staff is.

And the reason you want to sort of minimize it is because there are six elements that must be assessed each year in the competency assessment. We have direct observation of performance. recording and reporting of test results, review of QC and proficiency testing results, direct observation of maintenance, assessment of test performance, this isn't just watching it being performed but making sure they get the right answer, and assessment of problem-solving skills.

So that can be a lot when we're watching or doing our direct observation. You know, you're walking around the floors while people are doing testing. You're seeing that they are handling their specimens properly, preparing the patients properly, running the test properly, and then, recording the results. Do the results get automatically transferred by the, to the EMR? Great. If they're not automatic, are they being transcribed properly? Absolutely.

Do the testers know when they see a critical value what they're supposed to do? The direct observation actually applies to multiple tests on a single system if there are differences in the way you do the test. There are systems that can use purple top tubes and green top tubes and finger stick samples. Well, if we have three different types of samples that can be used on the same system, direct observation of routine patient test performance includes watching people select the appropriate sample type for which to do testing.

Do they know what to do if your QC is out of range? I've observed people running QC and then going on to do patient samples and not noting that the QC was outside of the acceptable range, and that therefore, no patient testing should be done. Now if your system has lockout, great, that can't happen. But many systems do not have lockout based on the test result, just that you actually said I was running a QC sample. And with those systems you want to be certain that each operator knows not to run a patient sample until the QC is in range.

Does everybody know how to do QC? Does everybody know when they should be doing QC? When they should be doing electronic QC? That after each patient sample they should be cleaning and disinfecting the system? That's routine maintenance they need to know.

To be sure that our operators are getting the right result, we want to do testing of known samples, blinded samples. And we're going to come back to this in a couple of slides, because there's lots of options for a blind sample. And then the assessment of problem-solving skills is something that can even be done as a paper and pencil exercise. Do you know when you should be repeating a test? Do you know how to tell when you did something that might not have been right?

Do you know what to do when that happens? Do we repeat the test? Do we call the point of care coordinator? Do we sit down and cry? You've got to know how to react to all of these things.

Lots of places have competency fairs, so you have a day, a week, a month, however long it takes for your institution to get all these competency elements done. Another way to do it is to actually just do it across the course of a year. We have operators who ran the PT this year, so we can check off that piece of competency for them.

We have operators who called in because something happened, and the device wasn't working. Hey, we can check them off on that aspect of their competency because they recognize that the device wasn't working, and they knew what to do about it. All those things are great as long as within the year, we've assessed all six elements and documented it.

If it's not written down, it never happened.

Part 3

Moderator

For the third section of our program, Dr. Zucker will discuss quality control. For additional information on continuing education credits, please make sure you view the first video. For the full 1.5 credit hours available, please ensure that you view all three videos in this program.

Dr. Marcia Zucker

All of this is leading us to the big painful portion of point of care, which is getting clinically minded individuals to perform quality control on a schedule.

And CLIA is really, really, specific on what the quality control should do. QC is a process. Understand it's a process. It's not necessarily a given sample. Our process has to immediately detect errors due to the test system failure, the operator messing up, or the fact that we're doing it in the desert when it's 100 degrees in the shade and there's zero humidity and that's way outside the specs for our point of care, and It needs to be able to monitor over time the accuracy and precision of your test performance.

But who defines what that process is going to be? And again, CLIA tells us, the laboratory. Now understand the laboratory is any facility running a test. But it's really whoever has oversight of your point of care program, which is likely a laboratory, has to be the ones to establish the number, type, frequency of testing control materials. That's where the process will come from. The problem with point of care is that the process, the traditional process, doesn't always apply. Back when there was no such thing as point of care, you'd be in the laboratory and you'd stick some QC samples just anywhere in the sequence of your patient samples on your automated chemistry device, and you knew that the same techniques reagents, everything was identical.

That was great, but if you're using point of care, most of the time we're using a unit use device. That means that each and every sample is being tested on possibly a different reagent. If I've got 20 strips in a bottle, what's to tell me that all 20 strips are going to be the same? If I QC one strip, it doesn't tell me the next strip is definitely good. We've got to worry about that a little bit.

There's also a problem that a lot of QC for point of care is not run the way that operators run patient samples. That's also distressing, but it's because a lot of point of care is run on whole blood and whole blood doesn't dry down well to do QC. The way we get around this is by developing our QC processes based on risk. We use risk assessment to define what is the risk and we use those risks to help us get buy in from the people who have to do the QC testing.

When we're doing all of this on a risk basis, we can define the frequency of testing based on individual location. So, if you're in a clinic that is doing 50 tests a day of the same test, such as a PT/INR. We do 50 tests a day. We know what we're doing. We recognize when the test doesn't look quite right. And doing an extra test two samples a day really is not going to improve patient care because we know what we're doing.

But then we have the sites like the physician's office labs that we're overseeing, and they may be doing a test a week, maybe two tests a week. And they may forget that the third step in performing this test was to turn around three times and touch their nose with their left forefinger, but if you don't do that, you get the wrong result. Well, those people may need to get to do QC every day of patient testing, because that will remind them that they had to turn around three times and touch their nose with their left forefinger to get the right result.

We want to optimize the frequency of QC testing based on the risk to patient care. Pretty straightforward. It's what we all want to see, and we get the advantage that the operators aren't going to grumble as much if they see that the reason they're doing this extra testing that has nothing to do with their patient care is because it reduces the risk to their patients.

We have a starting place. According to the CLIA regulations, unless you have a CMS approved alternate methodology, which is IQCP, QC is required at least once each day that patient samples are tested. Hematology and blood gases more often. And for quantitative procedures, that has to be two controls of different concentrations. And for qualitative procedures, that must be a negative and a positive control.

That's where we're starting from. If we want to do that, great. We don't have to do an IQCP. If we want to do anything other than that daily two-level testing, we need to do an IQCP, which is an Individualized Quality Control Plan. That has three basic parts. There's the risk assessment, the quality control plan, and the quality assessment.

The risk assessment is the piece that is most difficult to do, but the most valuable of all of them. Because when we're doing that risk assessment, we're taking information from the manufacturer, from the lab, and from the end user, to figure out how to move forward. Now, the manufacturers will likely have a template you can use, and they often have specific recommendations on when you should do external QC, but even more importantly, they can answer questions about what mitigations they already have built into the system. CLIA requires that the lab establish this process, remember, so you cannot just take the IQCP template from the manufacturer and implement it. You do have to do the additional work.

When we're doing our risk assessment, we're looking at pre-analytic, analytic and post-analytic risks, and we must. And in that assessment, we're also looking at the device, at the operator, at the environment, at the specimen, all sorts of stuff gets brought into this.

But we also need help from the clinician because they're the ones who know, “How wrong is clinically wrong?” What do we need to know to identify a result that looks like it might be wrong? Because part of our quality plan is going to be when do I see a result and reflexively repeat it? Because that's part of quality, right? How can the risk of forgetting that I have to turn around three times and touch my nose with my left forefinger be mitigated? How do I know that for these tests I use a purple top and for those tests I use a green top? Let's find a way to mitigate the risk of getting the wrong sample. But the clinicians are the ones who are going to be able to help and QC may not be the answer.

Running QC more often isn't going to tell you if you should use a purple top or green top tube. Training might. Putting tape on the box in the color of the tube that you need might. But not QC.

QC only looks to the analytic risk, not the pre or the post. And CLIA wants that analytic risk to have QC that detects immediate failures due to the system, the environment, or the operator, and that monitors accuracy and precision of test performance over time.

Well, you know, if we're looking at external liquid QC, which is basically surrogate sample testing. Presumably we are evaluating the instrument, the reagent, and the operator. Except if we're not running it the same way that we run patient samples, maybe we're not really investigating the operator. And it really doesn't necessarily give us accuracy over time or precision over time. Maybe for those two pieces of accuracy and precision over time, we should think more in terms of our six month precision studies or our six month comparisons between different devices, which are also required.

A lot of systems have electronic QC. Sometimes it's a dry cartridge, which you put into the device, and it gives you an endpoint. Sometimes it's built into the system. That's something that checks a large number of components of the instrument for sure, but it's definitely not going to give you any information about the reagent or the operator performance, because clearly running electronic QC is nothing like running a patient test.

Accuracy and precision over time? Well, yeah, if you get the same result over time, we will say that the instrument itself is probably pretty accurate or precise over time, but it doesn't tell us about the reagent.

Now, on board QC usually is used to reference internal reagent controls. On your cartridge there are controls, or on your test strip there are controls, or if you're thinking about lateral flow tests you always have a control line on them. Those are on board QC and those will tell us if the test system fails. It's going to tell us if the reagent was left in front of somebody's air conditioner or on top of somebody's radiator, which are both environmental conditions that would probably destroy the test, which is great. Whether or not they help us with operator performance and accuracy and precision all depends on the system. And that's information you get from the manufacturer.

Most commonly, manufacturers will tell you we should have electronic QC on a daily basis and liquid QC on a monthly basis. And these are recommendations that they've based on their reagent stability. You need to figure out, does this work for you? If you think it makes sense, based on your IQCP, based on your evaluation of the analytical risks, then you need to look to validate it locally.

How do you do that? There are lots of things. You could run liquid QC, every day for two weeks and say, “See, that shows that the electronic QC and the liquid QC match on a weekly basis. So then maybe I'll run it every two weeks for the next six months. And then maybe I'll run it every six months for two years.”

Whatever you decide is the right way to give you enough data that you feel confident that using your electronic, or your built-in, or your alternative QC of any type will meet your needs and the CLIA requirements for what QC is supposed to do.

And when the manufacturers give you their recommendations, they should be able to help you with how does their on-board QC help you determine system failure and adverse environment, lousy operator performance, accuracy and precision over time. Is it on every test? Is it on every week? You

know, some manufacturers will tell you, you don't need an IQCP and you don't need to run QC. And those are the ones you have to say, well, I need this in writing. Because there are systems out there that CMS has deemed their onboard QC to be equivalent to running external QC. And if this is the case, they'll have it in writing from CMS. But you don't want to take that based on somebody's statement, it has to be in writing so when someone comes in to inspect your facility, you can show it to them.

Now, some tests just don't have any QC available, so it's your responsibility to develop something that you feel will serve the function of QC on that system. Maybe it's LQC that you could get from somebody else. You know, it's built for a different system, but it works on the one you're using. You'll have to develop your own ranges for it, but you could use that. You could use blind samples or leftover samples. Some places use delta checks, so you're running duplicates and looking at the difference between your duplicates. Maybe you're just doing it with a comparison to the lab. Some places look at population statistics as a supplement to other QC testing.

There's also, you know, every six months we're going to be doing precision studies. That's going to be part of your quality program. Right? Your IQCP will include scheduled precision studies, scheduled comparisons with the lab or with other devices. Those all become a part of your alternative QC and therefore are in your IQCP.

I keep saying blind samples, and I know that can be confusing, but blind samples are really anything that you know what the results are supposed to be. You could use QC samples, proficiency samples, that the results have already been reported to your proficiency provider. Okay, very important. You can't use proficiency samples until those results are reported for that challenge. You can use calibration verification samples, or de-identified patient samples. The key is that a non-operator labels them A, B, C, D, E, and then the operators test them just like any other patient sample. And you can then judge, did they get the right answer? There's your assessment of whether they know how to run the test. That's part of your competency. It can also work for QC. It can also work as proficiency testing if PT is not commercially available. And it can work if you're investigating a proficiency testing failure or trending in your proficiency results, which is part of what you need to do when you're doing proficiency testing. So, very useful.

Now we've done that risk assessment, we've figured out that we can make changes to the way that we do our competency, or our QC, or our training, in a way that will minimize disruptions to clinical care. We've looked at every step of the process and we've included all of our clinicians with the laboratorians, and we've developed our training and our competency assessment and our QC requirements so we can actually show you how this reduces the risk of erroneous results and increases the quality of patient treatment.

And that's important because now the operators are not going to resent the QC or proficiency testing. They're going to understand the importance of these surrogate sample tests, so they'll be more cooperative because they were a part of developing the processes and the plans. It also encourages them to let the lab know when something isn't working right, when we need to change the process again, because IQCP is a continuous process. We define how we're going to do things. Then we see what works and what doesn't work. That's our quality assessment. Then we're going to update our risk assessment because what didn't work needs to be changed. Revise our quality

control plan, and then go back and check if that works. Because each time we do this, we get a system that's less onerous to the end users, and actually is compliant.

The more everybody's involved, the less people will complain, and the fewer unmitigated risks will exist in your procedures. When we look at all the things we can be doing and we work together, we make a compliant IQCT program.

Thank you.

Q&A

Moderator: Thank you, Dr. Zucker. I've got just a couple of questions for you.

How often does it happen that you see discrepancies between manufacturer and local QC? Is that common?

Dr. Marcia Zucker: Well, generally, it depends on exactly where we're looking. There are areas of the country where it's very difficult, like in New York state. I'm not sure how well New York state has accepted the concept of IQCP.

I just don't know. But they're usually the ones that say, no, I don't care what the manufacturer said, you still can't do it. Most places, they really just want to do the minimum they have to for QC and so they will follow with the manufacturers directions because that is the minimum that they have to do.

Moderator: You mentioned having nurses or clinicians doing training in competency assessment, particularly when they're the end users. Do you get better QC when you do that versus having lab doing competency and training?

Dr. Marcia Zucker: You get better acceptance of the need because it's no longer the lab coming in and the lab doesn't realize that you're over your head trying to take care of your patients and have no time to do all this. Instead, it is people who understand that you have no time to do all this explaining to you why you need to do it and giving you an answer beyond the fact that JCAHO will close us down if you don't.

Moderator: Thank you again, Dr. Zucker.

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