The Path to Painless Point-of-Care Implementation

Moderator

Welcome to our webinar, The Path to Painless Point-of-Care Implementation. This webinar is part of a series developed by POCT University.

POCT is defined as testing at or near the site of patient care. Point-of-care testing (POCT) has been shown to have an immediate impact on patient care and workflow, which can result in operational and economic benefits and increased satisfaction of patients. The benefits of implementing POCT have been well established, but challenges remain. This webinar will provide information on the benefits, implementation, maintenance, and future of POCT.

This webinar is eligible for continuing education credits for physicians, nurses, laboratory professionals and respiratory therapists. This program was supported by Siemens Healthineers. Content was planned and developed by Medavera. There are no additional disclosures for this program. After this webinar, participants will be able to identify benefits of POCT, review currently available POCT methodologies, evaluate the challenges associated with point of care implementation, and determine how to maintain POCT usage in their facility.

To obtain credit for this program, please listen to the webinar in full and click the button below the video for the CME/CE evaluation. Fill in your information on the evaluation page and answer the questions. Upon submission of your evaluation, an e-mail will be sent with your certificate to the e-mail address you provided. If you do not receive your e-mail certificate within a few minutes, please check your junk or spam folders for an e-mail from info@medavera.com.

This presentation will be given by POCT consultant, Dr. Marcia Zucker. Dr. Zucker will discuss the benefits of POCT, current methodologies, selecting an implementation of point of care platforms, maintaining POCT programs, and the future of POCT.

Dr. Marcia Zucker

Thank you.

As you know, today, we're here to talk about point of care testing. And point of care testing has so many aspects that because we don't have six days to do this, we're going to do things at a fairly high level. We're also going to be speaking predominantly of POCT that's being done by medical professionals, whether that's a doctor, a nurse, whomever. But we're not going to be speaking about home testing in detail.

We want to use POCT for a lot of different reasons, but mostly because it really increases the satisfaction of both the patient and the caregiver. The patient doesn't have to worry about getting a call back to find out if their results are good, bad, if their medication or their treatment has to change. The caregiver feels good because they don't have to worry about reaching out to the patient later if they need to make a change in the patient's care. We also get to use finger sticks instead

of venipunctures for our sampling, which in general patients do prefer. When we're doing our testing for infectious diseases, being able to distinguish between viral and bacterial infections means that we can also reduce antibiotic usage when it is unnecessary.

Everybody worries about the cost of point of care because on a per test basis, point of care is generally more expensive than running the same test in a central laboratory. However, the timeliness of care is hard to quantify. How much money have we saved by being able to discuss the test results with the patient right there and then when we get the results for not having to send the patient home and asking them to come back or to call in or to try to call the patient? Those are all costs that are usually overlooked when we're thinking about it. So when you're looking at the cost of point of care, make sure that you are looking on a global scale, not test by test.

And think about where you're doing the point of care. The number of places of actual locations where clinical personnel are doing point of care tests is astronomical. There are just a few that I'm listing on the slides here. What we've got are patient settings, clinic settings, outpatient settings, nursing homes, laboratories, everywhere you can think of where a patient is being treated. We can expect to find POCT and once we get outside of those traditional settings, the doctor's offices, the hospitals we find even more places. What about on a cruise ship? What about in an ambulance? During transport, what about in the helicopter during transport? Think about if you go to a health fair or even a carnival where you'll sometimes see booths set up. We'll test your cholesterol for you. We'll test your glucose. These are all very non-traditional settings. But a professional, someone who has been trained, is doing the testing on a patient and it's all considered point of care laboratory testing.

Not only is point of care being performed in literally hundreds of different settings, we also have an awfully wide range of methodologies. When looking at professional POCT, we're generally speaking about small handheld devices. Some of them are bench top, but most of them are really portable. Most have features that allow the operator to input their ID, to input a patient ID, to have your quality control tracked. Some of them have built-in quality control processes. Some of them have quality control lockout, so if you don't do your QC when required, you cannot do a patient test. They may or may not have connectivity features. There's lots of bells and whistles, lots of features that make both use and compliance much more straightforward. But each system has a different selection of these different features. Some of them, because they have links to the electronic medical record will also allow you to enter manual tests, temperature, blood pressure, whatever your system requires to make it easier to transmit these data to your electronic health records.

And those POCTs can be in just about as many medical categories. As a lab test, hematology, kidney disease, critical care testing, blood gases, chemistries, cardiovascular disease, they all have POCT options and all of these test options use a lot of different point of care technologies. Think about going to a laboratory. They have their chemistry analyzers over here. They have their molecular analyzers over there. They have their immunoassays in a third spot, all in different sections of a large hospital laboratory. Well, at point of care for POCT, each of these technologies is somewhere very close to where the patients are, at the point of care, also called near patient. So it's a very different world than what we see in the lab, because everything's available everywhere.

If we want to implement any or all of these point of care tests, it has to be a concerted effort. The point-of-care coordinator (POCC) or someone serving that role generally coordinates everything. The POCC has to wear a lot of hats to do this, but you need somebody who's overseeing it all. The clinician is the one who says we need point of care for this test and they're the ones who have to trust the result so they can treat their patients. And the sales rep is actually a very important part of this because that is your link to understanding what studies have already been done by the manufacturer so you can assess the risks surrounding using point of care with this specific device.

We sort of think we want point of care. How do we go about figuring out what to use, generally speaking? The end user says, “I want point of care.” Sometimes, yes, it's because the sales rep came in and convinced them they want point of care, but more often nowadays it's because they actually feel a need. So they're going to come to the POCC. They're gonna say, “Hey, I really want this to be run point of care.” And at that point, a process needs to begin. That process has to include all sorts of different people to allow you to decide, “Yes, we're going to do this,” analyze the systems, pick one, and then bring it in house and watch to see if it really made the improvements that you hoped for.

So let's talk about this a little more detailed. We know that someone has asked that we implement a specific point of care test. Hopefully this is the end user. When it's a lab-to-end user decision, it’s usually much more difficult than an end user speaking to the lab decision. There's lots of resources to help you.

CLSI has a very nice “How to select a point of care test” guidance in their POC TO9, but you need to think about creating a formal policy in your institution in order to request this test, and that policy needs to include a justification. You know, why do I want it? Because I want to improve outcomes? Is it because I'm not getting my test results fast enough? Is it, you know, medical or resource and operational? There are all sorts of reasons that you might want point of care. So how do we do this justification?

Well, first question is, is this a brand-new test that's not in the institution or do we want to replace a lab test with a POCT? Or do we want to replace a test that we currently use at the point of care with a different manufacturer’s solution? Well, what analytes are we testing? Who's the patient population going to be? Do we think that we're going to improve patient compliance? If you want to change a patient's dose and they're there and you can discuss the test result, it's more likely that they'll change their dose based on your recommendations. Rather than if you just picked up the phone and called them. Do we expect to see cost savings? Is the problem that we just don't have the turnaround time from the lab? The requester really needs to think about this and think about: What is the impact going to be on how we're performing our patient care? Who's gonna be running the tests? Are we going to ask people who are in the emergency room trying to triage all their different patients to run a test are they willing to add testing to their burden? Will we need to change how we do things? If I want to add a test like a troponin to the emergency room, do we want to just say, okay, anyone who comes in now if they say they have chest pain, we'll immediately do a point of care troponin rather than waiting for the doctor to look and make the orders and send the sample to the lab? That's a very common implementation of point of care in the emergency room. But, if people don't realize they need to change their processes, implementing point of care is not going

to help. If I run the test now, but nobody looks at it for an hour, why is that any better than sending a sample off to the lab and getting the answer back in an hour?

And there are a lot of people who are going to be involved in this, not just the people doing the testing, but the people doing the training, the people making the writing, the procedures. The people doing the ordering, people doing storage, people doing inventory control, all these things have to be thought about way early in the process. So, we're going to figure out what is it about the test that makes it clear to us that point of care could be an asset. Remember, not every test needs to be point of care. If you don't care if you get the result today or tomorrow or in an hour, don't implement the point of care. But if we need the result within the next 20 minutes, point of care is a very good option.

How many of the point of care devices do we need? There are point of care devices that can run multiple tests simultaneously. So, if we buy one of those, we need fewer than if we buy one of the more common ones, which can only run a single test at a time. How many tests do we expect to run? Are we only going to run one a week, or are we going to run about 20 a day? All of this is going to be important in figuring out how many devices we need. If we need connectivity. Do we need a new third party interface between our new point of care device and the lab information system? And which of the many bells and whistles that exist in all these different devices are we going to find of value and which do we feel we must have?

Before we even consider a device, let's talk about CLIA complexity. High complexity devices can only be run by very specific individuals. Waived testing can be run by just about everyone, but most of the point of care tests are moderately complex. So, let's talk about those in general. Those are the ones where we're going to be most concerned about what are the QC requirements. Do they have built in QC? Is there external QC? Do we have QC lock out? Who's going to do that? Operators, oversight, the trainings, the competencies, how are we going to do our individualized quality control plan, IQ CP, which we'll talk about in a few moments?

What's the test menu available on the device? Now a lot of devices only do a single test and that may meet your needs. If that's the case, great, but maybe you would prefer to have a device that can run several different tests. Well, if that's the case, how are we going to keep clarity around which tests can be used, where they can be used and what sample types are needed for those tests. Lots of things to think about, and we haven't even made a list of the devices that we're going to evaluate.

Yet when we're looking at bringing in any device. We need to understand who's going to do the testing, who's going to do the purchasing, who's going to do the materials, magic management, who's going to provide the training, who's going to do the inventory management. How are we going to work it? Lot of logistics and you can't expect the operators to be doing all of that. Because it's a lot of work. But if it's not the operators, we're not going to hire individuals just to take care of the troubleshooting and the purchasing and the materials management. How's it going to work in your location?

Now we're ready to think about the specific device that we would like to bring in. We would optimally, it would be great to bring in two or three devices and have the expected operators

to do some testing with them to see how they feel about using this system. Is it easy? Is it hard? Ask the clinicians, “Where have you heard about these devices? What devices have you heard about?” Vendors will help you for sure. Trade shows, of course. But you know, talk to the hospital across the street, talk to the clinic down the road that does pretty much the same sort of stuff that you're doing. What do they have? And do they like it? What are the pros and cons of their device?

Once we decide on two or three devices to evaluate, we're going to need to test for precision, for method comparison, and verification of reportable range. Is there a need for system calibration? What QC do we have to do? I can't stress enough that too many people have vendor representatives do all these studies and then when the test is handed over to the end users after purchase, we discover that the end users find them a lot more difficult to use than the vendor’s reps did. It's not a surprise, but that can affect the quality of the test results and whether or not it's even used.

So now let's move on. We’ve done our testing. We've decided which system we're going to get and now it's time to get it into place. So we need to validate it. Generally, installation is not a big deal for point of care. These little portable devices, there's nothing to install other than the internet, or if you need a charging station. The larger devices will need installation, but that's something that you work with your vendor for. Configuring the system can be a large chunk of your implementation time. If there are lots of different options. If you can have operator lockout, well, there has to be a way to first tell the device what operators are allowed to use the device. If you have QC lockout, you have to have a way to tell the device how frequently QC must be run and when it's run. Possibly we may need to configure it with the ranges that are acceptable, and then we need to schedule how we're going to train everybody to do this. If the device needs to be calibrated, we need to do calibration. And we're going to want to create an IQCP, that individualized quality control plan, so that we're not running two levels of controls every day of patient testing on these unit use devices. A unit use device is a point of care device where you're throwing away the test cartridge right after you use it. The validation studies that you need to do for CLIA, whatever your local requirements are, could be more.

The studies are described really nicely in a CMS brochure. CMS has a bunch of these brochures on their website and I would recommend to anyone who needs to understand the requirements. Take a look at them, because they're written very clearly and really help in terms of defining what we need to do.

Now the first big things we're going to want to do with the device is look at their accuracy and their precision. We don't want to be using a test that is not sufficiently accurate or precise to meet our clinical requirements. So what's the difference? People get confused. If I'm shooting arrows at a bullseye, how close to that bullseye? If I'm running a test and I run the test in parallel with the lab test, really, we would really, really like them to have exactly the same result. They'll usually be off a little bit. But that's how I'm measuring accuracy. Precision on the other hand is, if I use the same device to run a sample 10 different times, how close to each other will those 10 samples be? So, if you look on this slide, the top right, those orange arrows. The tips of the arrows are very very very close. This is a very precise measurement. Every time I run the test, I get a number that's very very close to the last one. But the black arrows are more accurate. The tips of those arrows are pretty far apart in some cases, so the precision is not so great. But they're all right, close to the

bullseye, to truth. And this is something that even when labs change a reagent from one to another, these are the things they need to evaluate. What is the accuracy that I need? OK. And what is the precision that I need for a given test?

We usually use a correlation analysis to determine accuracy. On the X axis, we put our current standard test result. On the Y axis, we put our new test result. And everyone says that you have to see a slope of one, an intercept of 0, and an R-squared of 0.99. Well, guess what? No, that's not true, because not all tests are standardized. And if you have a test that's not standardized? Like the TnI? Depending on the system you use, you're going to see differences in the actual numbers presented by the two different systems.

Even though the test intercept isn't the same now in these two graphs, every line is showing perfect correlation. R-squared is 1.000000. But on the left, we're looking at perfect correlations, but with different slopes. And on the right. It's perfect. Correlations with different intercepts, but with a slope of one. So when you have your comparison data, depending on the test you're running, don't get hung up on how close the numbers are to each other. You want to look at the population. Do they correlate? If they correlate, you may think about what you're using as your clinical targets and how they may need to be altered for using your new device.

Another way to look at this is to look at clinical accuracy. Clinical equivalence is really really useful for non-standardized assays. If we have two point of care tests, point of care one, point of care two, and we compare them to our standard. We look at our slope, we look at our intercept, we look at our R. In this particular example on the left here, you can see the R's are both pretty similar. They're not different enough to cause concern. But the slopes are very different, and the intercepts are very different. So, which one is more accurate? Well, now we do our clinical evaluation on the right-hand side. For this particular test, our clinically critical range is 0 to 0.5 and our cutoff is 0.2 in the lab. That's using our lab result, our reference. Well, if we look at our point of care tests, both point of care one and point of care two give very similar results to each other. But the numbers are very different from the reference. So, in this case, our choice between point of care one and point of care two would not be based on comparison to reference. It would most likely be based on what are the values that we feel most comfortable using. So, point of care two for example, the If the reference is 0.2 at our clinical decision point, and with point of care two, the result is really, really low 0.01. It is likely that we're not going to have very good distinguishing. It will not be easy to distinguish between above and below cut off because cutoff is too close to 0. But point of care one maybe we can because it's 0.1. Now that would all depend on the limit of blank and the limit of detection, limit of quantitation. But the concept is clear. Just because the correlations are one way, the clinical equivalents can be very different when we have a qualitative test.

It is this clinical evaluation that we have to use. Because when we just have two results, positive and negative, how are we going to compare them? So, what again we do is we run the test versus our reference, what we call truth. A true positive is going to be positive with the new system and the old system. A true negative is going to be negative with the new system and the old system. Most of the time you will find some false negatives. So, the new system is negative, while the old reference is positive, and you'll see some false positives. The new system is positive while the reference is negative, and from that we have a two by two matrix of true positive, false positive,

false negative, true negative. We can calculate the sensitivity and the specificity, the positive predictive value, the negative predictive value, all of which are numbers that we want to see. I mean, we would love to see positive predictive values, you know way, way up in the 90 something percents. Same thing with our negative predictive values. The closer the two systems are in clinical agreement. We're going to see, you know, great concordance. The true positive plus true negative over the total number of samples is going to be very, very high, very close to one.

One of the other pieces we must do when we're doing our validation is looking at our reference interval. Our reference interval is our normal range when we run the test in a quote “normal” population. Where do we expect our numbers to fall? Usually, we pick the 99th percentile for that. That means that if we go our mean ±3 SD. Our reference interval, our normal range is that 3 SD range.

We also need to talk about the reportable range. Our normal range may end may be from zero to 10. But the test may give us values up to 1000. When we're looking at our reference range we have to be looking at actual samples from people. When we're looking at our reportable range, we can use patient samples, but we also will use controls and calibrators because it's very hard to get samples at the extremes of the reportable range of the device. And we'll take these samples and say, okay we can get accurate values in this test that reports out on the device from zero to 1000. We can show accuracy from zero to 700. In that case, you have to let your end users know anything greater than 700 should only be reported as greater than 700. Clinically, it may not be a meaningful value. Probably won't make a difference, but that's what we need to do.

So, we've done all this work, we've put our system in place but the maintenance is where we get into trouble because the clinical personnel really don't want any part of this piece. We have competencies. We're going to train everybody on how to run a test and now at six month intervals in the first year and then annually thereafter, we need to do something to determine if the end user has maintained their ability to perform the testing.

And competency actually has six different pieces, according to CLIA. You have to have direct observation of routine patient testing. We have to see if the person can monitor recording and reporting of test results. Can the person review quality control records? Proficiency testing? We need to watch the person perform maintenance or any function tests that are necessary. We have to see if they can assess if the test is performing properly. And do they have problem solving skills? What do they do if they get an error message? And those six elements are for any non-waived test system. Now they don't all have to be done at once. Frequently people will have job fair type things where they assess competency on a single point of care device by every end user. It's a lot of work. You can do it over time. You know, every year, competency must be assessed, but it can be across that year that you're doing the assessment. So that it doesn't have to interfere with their daily routine work.

Little glitch to all this is that in order to assess someone's competency, the assessor must qualify as a technical consultant under CLIA. Which means at least a bachelor's degree and either two years of laboratory training or two years of experience doing non-waived testing. That includes nurses. So yeah, the nurse, the head nurse on the floor, can assess all of the nurses on her floor. The lab director has to delegate in writing who is going to be doing the competency assessments.

So have a list of who can do competency assessments for each device and make sure that the lab director signs off on that. You cannot just have peers assessing each other's competency if they do not meet the technical consultant qualifications. And then you have to think who's going to assess the technical consultant to be sure that they can do the assessment of the end users well. We want that assessment. Usually it's the lab director or a designee who's doing it. And they have to show that they have the ability to troubleshoot the test system, to ensure that the quality policy is being followed. They can figure out who needs additional training. And they're committed to getting all the competency assessments done when the competency assessments need to be done.

Make certain that everything is in writing. You can't say, well, we've been watching this person perform the testing over the course of the year and their competency is great and their competency assessment has been completed if you don't have something in writing showing that each of the six elements has been observed.

The other painful procedure for the end user is QC. From an end user's perspective, QC is time away from the patient. But in the CLIA regulations, we're saying that QC is a procedure that's going to immediately pick up on errors because of system failure, adverse environmental conditions, operator performance, and will be able to look at the performance of the device over time. And it's the lab's responsibility to decide how much QC has to be run when. There is a default. The default is that every test must have two levels of QC run every day of patient testing. But, with POCT, every time we run QC, we're actually using a different device than when we're running the patient samples because each device is thrown away right after the samples run. And things like, if one cartridge is bad, will the QC pick that up? Hopefully nothing like that would happen, but no, traditional QC wouldn't tell us if a single cartridge was bad. It would tell us if the box was bad. We know that point of care QC is often run very, very differently from patient testing. So even the process itself is not really useful when we're using external surrogate sample QC.

And so we have an option, we can use a risk assessment in order to define how often we're going to run traditional QC samples. That's our individualized quality control plan, IQCP. And if we're not going to run two levels of control every day of patient testing, the IQCP is the only alternative that is CMS approved. It has three parts. There's the risk assessment. There's the quality control plan. And then there's the quality assessment. The risk assessment is the piece that has the most parts to it. We're going to look at what exists, we're going to say, OK, we can use our external LQC, but there's also onboard QC for this device and electronic QC. So the lab and the operators are going to work together to figure out how we can mix and match all of these different QCs to create our IQCP. And that's done through this risk assessment.

We must make sure we have the clinicians involved here. We want to look at risks that are because samples are collected wrong. We want to look at risks that are because the device gave you the wrong result and how can we look at a patient and decide, you know, this result might not be right? Now mitigating these risks, other than the device itself giving the wrong result, all involve training more than they involve QC testing. And that becomes a part of your IQCP. We can mitigate these risks by changing the way that we train personnel. Make sure the clinicians are the ones who are giving us input for mitigating a lot of these risks and for identifying them. It's the clinician who knows

how wrong is clinically wrong. If I have a diabetic patient whose glucose is 300 mg/dL but the result that I see on my device is 400 mg/dL is that going to be a big deal? Probably not. We're going to treat them the same way. But that same patient, if one device says that they're glucose is 140 mg/dL and the other says that their glucose is 50 mg/dL, that is a clinically significant error. And what do I need to do to make sure this doesn't happen? And as we're doing our risk assessment again, we're going to go through those. Will these mitigations detect test system failure? Will they detect if we're doing our tests in 120° weather in the sun? Will they detect if the operator is doing things wrong? Because that's what your quality control process is supposed to do, and the liquid QC may not be the best way to detect all of these things. Remember, our operators are trained in patient care. They don't know laboratory testing. They don't necessarily question the results. If they get a result, they may act on it with out realizing that they really need to look at the result in light of patient presentation. They're really not going to want to spend the time to do the QC or to do proficiency testing, both of which they need to do. If we work with the clinicians to be sure that the operators can understand the number could be wrong, think about it, and now let's decide if we get a number that we're not happy with, do we repeat the test? Do we ask the patient questions? You know, maybe it's a urinalysis and the patient didn't collect the sample properly. And then the clinicians can also come back to the lab and say, you know what, if we changed the process we used to run this test in such and such a way the operator errors would go down. Let's make everybody a part of the process. The more the clinicians participate, the less they will resent having to do things other than patient care, and everybody can agree that quality test results lead to improved patient care.

IQCP is not a one time deal. We do our risk assessment, we create our quality control plan, and then we do our quality assessment. We watch and say, okay, how's it going? Are we seeing improvements or a decline in the quality of the testing being done? We should see, optimally, improved patient outcomes, We have our routine routine frequency for reviewing our plan. Maybe annually, we're gonna take a look and say hey, “We did this IQCP. Is it working for us? Or do we need to do more QC in this one location because they don't really understand what they're doing, or less in this other location because they really do know what they're doing?” And then we're going to revise the plan to reduce and mitigate any risks, new risks that we have identified. And of course, every time we change anything, it all has to be documented.

So where is this all going to lead? Well, think about it. Nowadays we start seeing we have all these wearable devices, lots of lab on the chip technology, lots of DNA testing. Molecular PCR has come to the point of care. People working on sepsis, on stroke markers, epidemic and pandemic testing. I mean COVID brought a lot of this testing home or to clinics and doctor's offices where we just don't have the laboratory background. But now we're doing much more complex laboratory testing. Because there was just so much that needed to be done.

We've started with our clinicians saying, hey, you know, it would be really nice to get a point of care test. Then we brought in everybody. We brought in the lab. We brought in the vendors, we spoke to the folks in purchasing, in information technology, we spoke to the folks that run the clinics. And we spoke to the folks who were going to do the testing and together we created a system that is going to move us forward and improve patient care. It's this partnering for implementation and maintenance that leads to the success of point of care programs. Thank you.

Moderator

Thank you very much. That was amazing. In listening to all of that, I have a couple of questions. You said something earlier in the presentation about how things should be going from the end user to the lab and decision should not be coming from the lab and going to the end user. And you said sometimes there could be problems with that. What kind of problems would those be if it went the other way?

Dr. Marcia Zucker

Well, what you see very often I see it all the time with coagulation testing. The lab wants to standardize all their testing to a single platform and the physicians, the doctors, whoever the end user is have been trained and have been using one of the other systems that are out there since they were in school. You can't just walk in and say, “OK, you're switching. Period. The end. Here you go,” because the numbers are different and if they get different numbers, you're going to have a riot on your hand. It can get pretty strange and especially because clinicians don't like to know that they have to change their numbers.

Moderator

That actually leads directly to my next question.

You also mentioned that sometimes things could get implemented and then not used because the end user wasn't expecting certain things like maybe the numbers to change. Is that frequent?

Dr. Marcia Zucker

It depends on the test. I mean, you're not going to find it with a glucose or a sodium. But with things like troponin and coagulation, these are non-standardized tests. If you go from one lab to the next lab to the next lab, you get different numbers, so it's not a surprise that when you go from a lab to a point of care. You're going to get different numbers.

Moderator

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