## **NEWEST FIRST**

Marissa Chupp: Anyone here using Nova Glucose meters? How did you define critically ill?

Linda Danis: Thank you Lou Ann

Monica Ianosi-Irimie: Thanks! We are looking into that.

Jeanne Mumford: Monica: we use a program called MTS that has learning modules for each PPM performed. Our quizzes are filled with questions to test their knowledge on how to perform the test, interpret results and prepare specimens if necessary. We manage completion every 6 months.

William Donohue: Diagnostic error is associated with a majority of malpractice settlements. I wonder if folks are getting legal affairs departments to sign-off on their IQCPs? Clearly, with the expanded discretion in developing individualized QC programs under IQCP, there is increased responsibility and liability.

Lou Ann Wyer: Linda Danis-Yes. Come back to the virtual environment anytime until May 15, and then the materials, including Q&A transcript, will move to the AACC web site. Participants will be notified of the migration by email.

Nicolle Ellious: Thank you all! This was very helpful in all areas! :)

Marcia Zucker: thanks!

Peggy Mann: thanks Marcia! I'm sure you are a very reassuring presence to calm folks down in this regard.

Marcia Zucker: Hi Peggy- yes, folks are definitely still very nervous- I have given and attended several talks on what to expect at the first inspection.

Kimberly Skala: RE: Hear what's not being said-I found that if I wanted to truly learn what the workarounds are for nursing, you have to make them comfortable in telling you why they don't follow policy as written. They don't want to say out loud that they don't follow policy but by working with them and without the fear of reprisal, they will help you understand how to improve patient safety if you really listen.

Peggy Mann: Marsha are you still here? If so, are you seeing folks going back to their 'January 1 2016' IQCPs to 'rethink' before their accreditation survey is due? Just wondered ;-) Monica Ianosi-Irimie: Jeanne, Can you shed some light on how you maintain compliance in your PPM programs?

Jane Tansiongco: Thank you, Dr. Nichols.

Jeanne Mumford: Peggy: thank you. We are constantly changing and growing as each day passes

Lou Ann Wyer: Linda--I am getting that answer for you.

Shana Nowelani Gaug: @ Dr. Nichols- As you mentioned that analyzers are cleaned after each patient when the analyzers are brought to the bedside, what is done when samples are brought to the analyzers? E.g. does your staff clean & disinfect after each use?

Peggy Mann: Jeanne: I admit, I had to really focus on 'not hearing Peggy Mann' filing in the blanks! Listening is perhaps 'an art form'? However, your mgmt. approach of 'visiting monthly' to get to know POC Operators/local site management IMO supports teaching the POCCs to take the time to 'listen for what they are not saying'. I'm very impressed with your program as you outlined it in your talk, kudos Jeanne

Linda Danis: Will we be able to access a transcript of the Q/A session?

Kimberly Skala: Aloha Shana!

Lisa Dunay: Thanks, Jim. I can see where things could get real challenging when different units are sharing devices! Whew!

James Nichols: Jane, negative patient samples can be used to validate low levels or negative values at the detection limit for troponin if samples are not available from the manufacturer.

James Nichols: Lisa - continuation, those units that share testing and devices can be helped by interacting with both nursing units and making both areas equally responsible or alternating responsibilities for instance.

Jane Tansiongco: Dr. Nichols- what can we use to validate the lower level or negative value of an i-STAT analyte (e.g. troponin) when no cal-ver material is available from the manufacturer?

Jeanne Mumford: Peggy; that's a good thought, listening to what they are not saying.

Shana Nowelani Gaug: Peggy-thanks for sharing that tip! Aloha Kim!

Lou Ann Wyer: Peggy/Kim---great tip!!

Jeanne Mumford: Peggy: thanks for the encouragement!

Kimberly Skala: No apologies needed Peggy Mann. You communicated it clearly!

James Nichols: Lisa, yes certain groups, like the ED staff, have unique issues that other staff do not. Those needs should be addressed in the training and management follow-up at those locations. Places which share POCT, in other words, staff from two nursing units sharing the same device and test location have more issues with documentation, QC, and follow up as neither claims responsibility for other unit.

Peggy Mann: Sorry to Kim Skala if I misrepresented her 'communication tip'!

Peggy Mann: Jeanne: I heard a Kim Skala, Chicago area POCC at the time, presentation and one of the communication facilitator tips she had was: 'listen to what they are not saying' - - has saved the day for me so many times in 'listening' to 'read backs' from POC operators...just a thought.

James Nichols: Tawny, for the iSTAT IQCP, 3 levels of liquid QC, for each cartridge type (because those are different lots). We do take into consideration storage, and all cartridges are stored refrigerated until use, so both room temp and refrigerated temp monitoring (as well as concerns when cartridges are taken out on flights for conditions out in the environment) we've recommended continuous thermometers

Kimberly Skala: Thank you all!

Peggy Mann: Jeanne: I hear your pain on the lot #s in use at any given time (scary and time consuming for the POCC!) Good luck wresting that beast! Working with ambulatory management to pressure THEM to narrow down where folks are allowed to order helped our ambulatory finances as much as it did POCT...never say never - I know you can pull this off!

James Nichols: Jennifer, an IQCP is not required by CMS for CLIA waived tests

James Nichols: JoAnne, we wrote an IQCP for the device and test analytes conducted on that device, with consideration for unique site specific factors and staffing. We did not write a separate IQCP for each test cartridge, since many of the cartridges share same analytes. But if one unit had more frequent hemolysis for instance, we addressed that issue for potassium tests in the IQCP

Jeanne Mumford: Lou Ann: Nurse teach back methods have worked for us when we have units that are making the same mistakes over and over. We give the instructions to the testing personnel and have them talk us through what they are doing as they are doing it. At this time, we allow the testing personnel to use their own words and interpretation of what we taught them

James Nichols: Kimberly, for a new test our finance department will develop a business plan along with comparisons for best options - purchase or lease, which includes patient outcome and other considerations. The vendors work with finance to meet the request for proposal sent out from finance.

Shana Nowelani Gaug: Dr. Nichols-despite IQCP being geared for nonwaived devices, has your team also completed any for waived devices, like the glucometer?

Jeanne Mumford: Nancy Lawson: sorry, missed part of your question. When we do monitor, we use a min max thermometer and a paper logs.

Jeanne Mumford: Nancy Lawson: we do not monitor RT for glucose testing. However, we do monitor for some other POCT.

James Nichols: Lou Ann, for a multi-analyte device, one IQCP for the device that covers all tests should be sufficient. However, your IQCP should take into account different locations and staffing at different locations - or at least be modified for those locations that may have different conditions, frequent staff turnover for instance

Wallace White: Jim: Thank you.

Kimberly Skala: Dr. Nichols- Do you feel the risk assessment and risk management based QC approach will have a broader scope in main lab in the future?

Nancy Nelson: Jeanne, do you have thermometers at every location in your hospital that has a POCT glucose meter? How do you handle room temperature readings?

Peggy Mann: Dr. Nichols: thank you for that excellent point! I've been 'pushing' for the nursing side to set up focus groups (at least through 'journal club'/CCAPS/Magnet councils) to do education on 'communication' and the importance of intra and interdepartmental communication. Sure help a lot more than 'just' with IQCPs ;-) Thank you, Peggy

James Nichols: Wallace, regarding the air exposure leading to test biases on glucose strips, we emphasized through training, proper technique. This was reinforced by POC staff during nursing unit rounds where issues are tracked and feedback given to the managers on those units. If bottles found open, then the issue noted and communicated with management team. This constant reinforcement helps.

Jeanne Mumford: Kimberly Skala: good luck with your Lean goals. I'd be interested to hear from you and your success in the future.

Lou Ann Wyer: Dr Nichols: can you speak to how the inspectors are viewing the IQCPs and any suggestions we can take away from their recommendations?

Jeanne Mumford: Peggy: that is a loaded question! We have a mixture of units who purchase directly from central, some supplies come from an offsite warehouse, some units have supplies delivered by our POCC's...this is one of my personal goals for the year to learn who orders what from where and when. We are constantly hit with lot #s that aren't in the system for our interfaced devices

Kimberly Skala: Thank you Jeanne. We're hoping to help with LEAN and workflow analysis services for POC to help in these areas.

Lisa Dunay: Hi Jim, Have you found over time that certain groups of POCT device users face challenges in performing QC and if yes, are there specific interventional actions that can resolve these challenges?

Shana Nowelani Gaug: Mahalo Dr. Zucker!

Marcia Zucker: (Continuation of last reply) POC menu. If required, there should be a way to trace when a result is acted on, or you could ask the operators- if an MD ordered the test, it is run immediately, when does the MD look at the result and alter patient treatment

James Nichols: Janina, for monthly QC you should consider location, storage of reagents, number of devices, number of different types of cartridges and number of lots in use. For the example that I used with Life Flight, despite using the same lot of cartridges, because the cartridges are divided to different locations and stored under separate conditions, we run QC at each location with representative iSTATs.

Jeanne Mumford: Kimberly Skala: I would think that your vendors could help in this process. I think they can help you analyze the usage of the POCT and give you quotes based on your program, maybe that could help decrease costs for you. We are looking at global/enterprise usage for our POCT to help drive down our costs at Hopkins

Marcia Zucker: For test utilization, I think that there are 2 clear statistics to define Shana. The first is the frequency that the test is used- if it is rarely used, is there a reason to keep it? The next is the number of users of the test. I think that many tests are simply in place because one doc believes it important (for example Myo for AMI), these tests should be scrutinized and often removed from the menu.

Lou Ann Wyer: For Jeanne: Do you have any examples when the nurse teach back or feedback method was successful for you when working with your testing personnel?

Peggy Mann: For Jeanne Mumford: are the POC kit/reagent costs coming out of site budgets (meaning the lab is not providing POC materials for ambulatory, surely, but does the lab pay for inpatient POC reagents?)

Jennifer Sapp: Thank you Jeanne!

James Nichols: Peggy, Risk assessment was an eye opener for all involved. Many errors can be avoided and corrected by better communication. If anything the Risk assessment process opened channels of communication by getting everyone involved on the same project and working together to solve the issues uncovered.

Jeanne Mumford: Jennifer Sapp: it is correct that IQCP is not required for waived testing. However, consider the benefits of the Risk Analysis when deciding whether or not to use IQCP for future waived tests in your program. I suspect that IQCP is going to be playing a bigger role in all of our POCT programs in the future. :)

Tawny Arensmeyer: Dr. Nichols- Regarding the iSTAT IQCP. You indicate 3 levels liquid QC, each cartridge type, on 1 iSTAT at each site. Do you take into consideration the storage site - QC each cartridge stored refrigerated and each cartridge stored room temp?

Kimberly Skala: Thank you Jeanne. Do you think there are ways that vendors can help in this process or is it strictly internal?

Marcia Zucker: I have heard folk say that this was planned, but no one has said to me that it was completed. When determining their training deficiencies a lot of POCC have said that the issues were across platforms, not just for the platform which was the focus of the IQCP

Shana Nowelani Gaug: Thank you Dr. Nichols.

Jeanne Mumford: Kimberly Skala: we do require a signature from the finance manager from each unit that requests new tests on our form. I think to answer your question, yes, we do require that the site/unit give us detailed accounts of how the lab is not meeting their needs and to that effect we'll evaluate the cost of the POCT with them to see if its addition is justified.

James Nichols: Nelda, It is good lab practice to perform initial validation studies on a new methodology being introduced to your lab to do multiple replicates of samples for AMR validation, since this will give you method performance and precision. But after implementation, a single replicate should be fine for AMR validation, particularly if you are performing on multiple analyzers.

Shana Nowelani Gaug: @ Dr. Zucker, my pleasure-What would you recommend to evaluate existing POCT test utilization?

Jennifer Sapp: Is it correct that IQCP is not required for waived testing??

JoAnne Palmer: Dr Nichols - Did you write up an IQCP for each individual test cartridge or for the device itself?

Peggy Mann: For Dr. Zucker: thank you. Next question: have you seen competency assessments get spiffed up due to IQCP work in nonwaived - meaning when folks are writing down in their Plan 'retraining' to take place, they go back and 'work on' improving their training plans? Just wondered, thanks, Peggy

James Nichols: OK, continuing from previous, we have each management team rotate responsibility for correlations of GEMs against i-stats, but we don't correlate every analyzer every 6 months. So, one event will have adult do the correlations, next peds, next event may be core lab, since we all share same methodologies and cartridge types.

Kimberly Skala: Great presentations. My question is for Ms. Mumford and Dr. Nichols. At your sites, do you require a business case (financial justification) as part of your new test request process? And if so, did you ask the vendor for help with this in any way?

Marcia Zucker: ABSOLUTELY Peggy- I only see electronic systems in the very tiny or very large hospital systems. The mid-range (which in my experience is still the majority) cannot get the financial support to implement better, less paper, systems.

James Nichols: Shana, with regards to IQCP for iSTATs, our risk assessment has us performing 6 month correlations, but we do not do this on every analyzer at every location every 6 months. Instead we have 4 different management teams involved with blood gases, our core lab GEMs, our POC GEMs, adult respiratory GEMs and peds respiratory and our peds i-stats for neo transport. See continuation

Lou Ann Wyer: For Jim Nichols: With multi-analyte devices, like a blood gas analyzer testing a basic metabolic panel, do I need a separate IQCP for each test or can I develop just one IQCP to cover the analyzer and all it tests?

Jeanne Mumford: Lisa: I would choose to standardize IT first. We are working on adding all of our 5 hospitals to one middleware product at the same time that our IT folks are implementing their LIS and of course EPIC is rolling out in stages (to be completed July 1, 2016!!!! the end is near!!!)

Marcia Zucker: Shana- First thanks personally for your recommendations for my kids- they had a blast. In answer to your question-The determination of immediacy should really be made when the POC test is originally requested to be added. The requestor should be able to justify the need for immediacy. Lacking that, I would think that the POCT committee would be able to make the determination.

Peggy Mann: For Marcia Zucker: as you go around and meet up with POCC groups, do you get a sense that there are still quite a few of us who must rely on using 'paper' to document competency assessments? Thank you, Peggy

Lou Ann Wyer: Jeanne--can you speak to Peggy Mann's question?

Lou Ann Wyer: Dr Nichols--can you address the question from Shana?

James Nichols: Brenda, for i-stats we noted that 3 of the QC levels packaged in the 5 level linearity set were the same materials. So, if you pick the highest and lowest levels and one in the middle, you are covering your linearity and verifying AMR with each QC event.

Wallace White: Hi James. I should have been more specific. What did you do about the potential for prolonged air exposure leading to negative bias? Thanks.

Jeanne Mumford: Peggy: Yes, we are performing rapid/manual tests and we do use the enter/edit function in EPIC for these tests. Thank you.

Marcia Zucker: Lou Ann- I think it best to work with the clinicians who are using the test results. While the MDs might be good to include from a political view, it is often the RN's or the RT's actually acting on the test results. The educators should be a part of the development of training and competency assessments.

Jeanne Mumford: Lou Ann: You should meet with your testing personnel at least monthly. I recommend reaching out on a monthly basis to start and consider adding more frequent visits for those sites that may need more time.

James Nichols: Wallace, We did a lot more than just retrain the staff regarding glucose strips being dumped on the counter. We investigated the meter we were using and several others available on the market and found that some will allow retesting and reapplication of blood, generating an incorrect result, while others ill error. So, at next opportunity we switched meters to a model that errored to prevent this

Lou Ann Wyer: Marcia--Shana is asking a great question. Thanks for your response to Shana in Hawaii!!

Janina Resurreccion: For the monthly QC on iSTAT, do you run monthly QC on all iSTAT instruments or on one device only considering only one lot # is in use?

Shana Nowelani Gaug: Aloha Marcia. Who determines if POC results are acted upon immediately? Is that reviewed through Medical Exec Committee, physician groups, POCT committee? All three?

Peggy Mann: Question please for Dr. NIchols: would you agree that in pushing through Risk Assessments, 'the lab side' learned as much as 'the operator side' on errors they overlooked which 'could be corrected' by adding an improved process? Thank you, Peggy

Lou Ann Wyer: Marcia--what types of clinicians do you find to be the best to work with on the risk assessments? RNs, MDs, Educators?

Lisa Dunay: Hi, This question is for Jeanne: You mentioned at the end of your presentation that future goals include greater standardization (IT platforms, EHR, etc.) If you had to prioritize and choose one of these areas to accomplish first, which area would it be and why?

Nelda Griffin: currently I am running 3 different levels of linearity on my iSTAT every 6 months. Is it good (or necessary to run them in duplicate or triplicates. If so, what regulation does this satisfy?

Shana Nowelani Gaug: Dr. Nichols-in regards to IQCP with iSTATS, did your risk assessment also lead your team to perform patient correlations for the larger benchtop blood gas analyzers (eg. ABL90's and Rapidpoint 500) monthly during cartridge changes in addition to 6 month correlations?

Peggy Mann: Enjoyed all three talks, thank you speakers! My question is for Ms. Mumford: are you performing rapids as manual tests and if so, are you using enter/edit in your EMR to document patient results? If not, are you using a molecular platform in ambulatories which is interfaced? Thanks a bunch, Peggy

Lou Ann Wyer: Dr Nichols--can you address Wallace Whites question to get us started?

Lou Ann Wyer: I'm pleased to be joined by our Session 1 speakers, Jeanne Mumford, Jim Nichols, and Marcia Zucker.

While we're waiting for the audience to filter in and get their questions together, I have a question to get us started.

For Jeanne Mumford: How often should I meet with my testing personnel?

Wallace White: Dr. Nichols, what did your group do to address the glucose strips potentially being dumped on the counter? Just re-training or anything else? Thanks for a very good talk. Lou Ann Wyer: Welcome to the day's first Q&A! I will be moderating this Q&A session for you and we will be starting shortly.

Brenda Suh-Lailam: In performing your three levels of qc is this verifying your AMR on the iSTATS?