Article:
Robert F. Moran
Point-of-Care vs Central Lab "Discrepancies": Getting the Message Across.
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Guest:
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Randye Kaye: Hello, and welcome to this edition of "JALM Talk" from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. I'm your host, Randye Kaye.

Point of care, or POC, testing allows for rapid turnaround times for specific analytes with minimal sample manipulation close to the patient's bedside. However, when patient samples are also sent to the central laboratory for analysis of the same analytes, differences in the results between POC in the lab may be observed.

For clinical laboratorians, this is a well-known phenomenon, but for medical personnel carrying out point of care testing, it's not well understood. So how do you explain to everyone involved the reasons for these differences, or come up with a plan to make sure that both the point of care testing result and the central laboratory result are indeed correct.

A Technical Tips article entitled "Point-of-Care vs Central Lab 'Discrepancies': Getting the Message Across" published in the March 2017 issue of JALM, discusses one way of managing everyone's expectations in a three-step process: manage it, quantify it, make it right. The author of this article is Dr. Robert Moran, Associate Professor of Physics and Chemistry at Wentworth Institute of Technology in Boston and he's our guest for today's podcast. Welcome, Dr. Moran.

Dr. Robert Moran: Well, thank you very much, Randye. I appreciate the kind introduction.

Randye Kaye: What are some of the key reasons for differences in reporting values of any particular, analyte including clerical error?

Dr. Robert Moran: The key reasons really boil down to what have been traditionally issues with result discrepancy, and that is sample handling as well as the variation amongst various instruments making the measurement, not that they're inaccurate but there is a distribution, of course, of individual

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measurement values. And I think the biggest of all these typically is related somehow to sample manipulation.

Randye Kaye: So there is some reason, when there is a demonstrable difference in the reportable values, how does this get reconciled?

Dr. Robert Moran: It's rather depends on particulars of the circumstance. You need to identify where the issue is. For example when you're talking a particular measurand such as hemoglobin generally speaking, the hematology lab knows how to mix a simple very well routinely. In a care unit, this may not be such an automatic thing. And it's amazing how rapidly a sample can separate cells, depending on how the syringe is placed: tilting it, laying it flat, whatever. It may not be noticed especially since other measurands are exactly as expected.

So the key here is to begin to really forensically approach the whole problem. I think that in terms of reconciling it, it first has to be observed and the ball taken, as it were, by someone in the laboratory whoever gets that complaint in the laboratory first would need to address it internally and then start an exploration immediately. I think the key thing here is when the laboratory hears about it, even if it's informal, you need to jump on it immediately and essentially take control before there's any finger-pointing sessions or anything like that, and to investigate it, hopefully through people in the care units that the individual people in the laboratory know and are acquainted with personally as well as professionally.

That will eliminate a lot of issues, I think, just having that personal rapport established ahead of time before there's any particular problem that crops up. One of the things that does seem to develop in the point of care versus laboratory environment, sometimes of course the point of care is under the control or oversight of the laboratory. However, that's not always the case and that's really where the issues become quite obvious because things tend to get out of control before the lab finds out about it. And that's why I suggest keeping your ears tuned to the issues. And that's done really by having this good personal relationship with folks in the care unit, especially point of care, critical care testing, intensive care, anesthesiology, whatever, to make sure that they know that they can come to you informally at first, or formally, without having to run through any of the bureaucracy that frequently plagues the larger institutions.

Randye Kaye: That makes sense. So this is all part of "manage it" which is like be aware of it and have the relationships where you can actually manage these discrepancies.

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Dr. Robert Moran: In my mind, that's absolutely critical. Having a handle on a problem before it's a problem always makes it easier to solve.

Randye Kaye: Yes, it definitely does. If someone is going to ask for references for any further insight or learnings regarding this subject, what do you recommend?

Dr. Robert Moran: I think the best thing for the laboratorian, whether they be a clinical chemist or hematologist, is of course the CLFI reference standards especially those focused on evaluating products. These are developed over--and have been developed over--time by experts, both clinical experts or I should say all three: clinical experts, governmental regulators and other experts, as well as people from industry. So there's a real balance there in terms of their recommendations.

That's always a good start. I think the issue there sometimes might be and that's something that you would read before bedtime before they're exciting but they definitely tell you how to approach evaluations and doing it in a way that you can make valid comparisons if you've done it right. The trouble is they really do tend to be more focused for those that focused on doing evaluations, the real experts. And that can be a problem for us ordinary clinical chemists and hematologists because we might look at it is as "Well, we've got a job to do. We can't read through all of that." And often it gets to be a terminology issue too. So I guess the thing that I would recommend although again, it's not great reading material from the standpoint of classic novel, and that is the book by the ASQC Statistics Division, the *Glossary and Tables for Statistical Policy Control*. They've got some good definitions in there, readily accessible and by reading it, you're preparing yourselves to talk to the non-analytical folks that you're more likely to find in the care unit. After all, they've got their expertise that us analytical folks don't have. And we need to do some translating sometimes when we do talk to them without overwhelming them. You got to be careful of that.

Randye Kaye: That makes a lot of sense and again, under management and relationship. You may have already answered this next question but I just want to make sure if you may have something to add to it. Who are the typical players or personnel that should be involved in the process of evaluating instrument performance, and instrument to instrument variation?

Dr. Robert Moran: Well, the typical ones, you have those -- I shouldn't say they're on the periphery but a way they are -- and that's the clinician, the one that is actually directly treating patient. While they are on the periphery, they're definitely involved

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since they're the ones that are most likely to complain to whoever is nearby. I think the laboratorian needs to understand and I've been in this position myself getting those kinds of complaints. You have to understand the stress that is in the care units at certain times and one thing the clinician or anyone directly treating that patient, one thing they don't need is a question mark. They have enough of them clinically as it is in that acute care situation. And if the question mark happens to be the result from an analytical system, that is problematic. Everything flows downhill from there really so clearly you need to get their input either directly or indirectly and then responsible folks from the care units, including operators of the systems and other ancillary personnel, for example respiratory therapist, pulmonary physiologist and so on. Then of course the key people in the lab, whether it be hematology or clinical chemistry.

It's almost sounds like we're going to need to rent Yankee Stadium to have a meeting, and that's another part of the management, isn't it? You need to address "Okay, who are the key people that we absolutely need here, and solicit their input and the input of others by saying to them "Look, we need to get together and address this, but you need to find out from those others in your group that might have some insight here." Because the way I would see the meeting that might be pulled together here would be to get all the issues on the table and this goes into kind of two parts. One part would be if you've already got a good rapport established with the care unit, then you can get down to the real facts of the case. If you have not established that rapport ahead of time, then you're going to need to have a meeting where all kinds of stuff gets brought up, including bunch of things that have no relevance to the issue at hand at all. You can't just ignore those things. You really need to write down everything that happens at this initial meeting with these various players to make sure that they know that you're going to address all of them. Maybe not all of them right away but first thing first, that address the issue at hand, but make sure that they know you're going to take care of the other issues too.

Randye Kaye: Thank you. So you really have to lay the foundation for the teamwork and to quantify it and then you want to make it right but laying that teamwork foundation really helps. Is this particular phenomena limited to point of care versus laboratory testing or are there other instances as well?

Dr. Robert Moran: Oh, no. It happens in so many things. In fact, thinking about this, I recalled a situation that happened with me personal--strictly anecdotal--but let me just explain. I routinely go to a large internationally recognized clinic and hospital in the Boston area for my health needs. Years ago

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during early visits, I would be weighed at each position of a clinical office. This could be multiple times within a short interval of couple of hours, because I went into the different offices. I saw differences of my own personal weight of anywhere from two to fourteen pounds. I had began to remark on it over the years, but I kept observing it until shortly after the facility went to real-time data entry when I began to notice certification seals on each of the scales, and the results all of a sudden started agreeing. Yes, it's in areas other than just laboratory and point of care.

Randye Kaye: Wow, very interesting. Well, anything else you need to add? That pretty much answers my questions. Is there anything we've left out that you feel is important?

Dr. Robert Moran: I think the key thing really is getting into that very first part, and that's the management. If you as a laboratorian, and this doesn't need to be an official thing, shouldn't be really. But as a laboratorian, if you get out to the care unit frequently on an informal basis, not an inspection tour, but bring him a cup of coffee or whatever, and just talk to not only the supervisor but the others in the area, make yourself available to solve the little problems and they will make sure that you know when there's an issue that crops up unexpectedly.

Randye Kaye: That was very good parenting advice too, what you gave. It's like you got to lay the foundation of teamwork and community in order to get your kids to cooperate with you.

Dr. Robert Moran: The thing is, this whole issue when it came up and I began to write an article on this one, the original one was much longer than the one that's being published. But I was thinking to myself, "Gee, I remember having this problem 40 years ago, and 30 years, and 20 years ago." Because it's one of those things that keeps on cycling and I don't know if things like this are not taught in school or what, but there's the two components: of the management, and then there's the technical issue.

You have sample handling issues, sure, they've always been around and you have to be aware of those but you also have fundamental issues of instrument calibration; interesting thing, and I use that hemoglobin as my example because that's the one that seems to show up a lot even though technically hemoglobin is a measurand that is very well-controlled at such, certainly throughout the U.S. and Europe and there aren't any fundamental issues with it. That's the one that on these enhanced blood gas systems, you will find most likely to show up discrepancies like this. The reason is other than the fact that it's the only that's measured both at point of care and in the lab primarily but

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also it is subject to that phenomenon that I mentioned, the separating out of the cell. The other analytes aren't affected by that.

Randye Kaye: Interesting.

Dr. Robert Moran: Yeah.

Randye Kaye: That is very important information. Thank you so much for joining us today.

Dr. Robert Moran: Well, thank you for having me.

Randye Kaye: That was Dr. Robert Moran from Wentworth Institute of Technology. He's talking about the JALM article "Point-of-Care vs Central Lab 'Discrepancies': Getting the Message Across" for this podcast. Thanks for tuning in for "JALM Talk." See you next time, and don't forget to submit something for us to talk about.

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