Implementation of a Self-Audit Tool Improves Regulatory Compliance for Point-of-Care Respiratory Virus Testing in the Emergency Department

Article:
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Guests: Dr. Ashley Rackow and Dr. Bill Clarke from the Johns Hopkins School of Medicine in Baltimore, Maryland.

Randye Kaye: Hello, and welcome to this edition of *JALM* Talk from *The Journal of Applied Laboratory Medicine*, a publication of the Association for Diagnostics & Laboratory Medicine. I'm your host, Randye Kaye. Point-of-care testing typically allows for simple, rapid laboratory assessments that can support evidence based clinical decision making. The COVID-19 pandemic resulted in a significant increase of point-of-care testing both at home and in hospitals and clinics.

Point-of-care respiratory virus testing, now more common than ever, may offer improved patient flow in emergency departments with the rapid screening and evaluation of patients presenting with respiratory symptoms. However, point-of-care testing also has its challenges. Some of these challenges include maintaining quality and regulatory compliance across diverse and often increasing groups of testing locations and operators. Ongoing quality management and oversight of required steps such as quality control, cleaning and maintenance, and result entry is critical to ensure accurate and effective testing.

The July 2024 issue of *JALM* features an article describing a quality improvement initiative for a point-of-care respiratory virus laboratory within an emergency department. The authors developed a self-audit tool designed to increase transparency between the central pathology point-of-care management office and the emergency department staff. The authors demonstrated how the tool successfully increased and sustained regulatory compliance.

Today, we're joined by two of the article's authors, Dr. Ashley Rackow and Dr. Bill Clarke. Dr. Rackow recently completed a post-doctoral fellowship in clinical chemistry at the Johns Hopkins School of Medicine. She is transitioning to a faculty position at Johns Hopkins, where she'll be Director of Preanalytical, Co-Director of Main Chemistry, and Co-Director of Point-of-Care Testing. Dr. Clarke is a Professor in the Department of Pathology, the Vice Chair of Pathology for Quality and Regulatory Affairs, and the Director of both Point-of-Care Testing and Clinical Toxicology at Johns Hopkins. Welcome Drs. Rackow and Clarke. Let's start with this. How

is point-of-care testing utilized in your emergency department and what tests are currently in use there? Dr. Clarke, we'll begin with you.

Bill Clarke: Thanks. So point-of-care testing is used in the emergency department [ED], often for sort of rapid triage or rapid decision making, right? We use these point-of-care tests to determine which direction, pathway they go in terms of a non-responsive patient or some other diagnosis that requires a laboratory test to start them down the treatment pathway. I think in terms of point-of-care testing, we have limited point-of-care testing in the emergency department. We do have a glucose meter. We have some dipstick type testing. And then the subject of this study is during the pandemic, we incorporated COVID testing, rapid COVID testing so that we could appropriately isolate patients during the pandemic, both for other patient safety and also for the staff safety, so that we could move them into an isolation unit for further evaluation and treatment. And so that's one of the biggest areas we need to focus on in the emergency department today.

Randye Kaye: All right, thank you. Dr. Rackow, can you describe some of the challenges that led to your project focused on respiratory virus testing in the emergency department? And do you think these challenges are unique to your healthcare system?

Ashley Rackow: So, similar to other hospital systems, we experienced a lot of change throughout the pandemic, and many of those, of course, surround respiratory virus testing. So even now, several years after the identification of the pandemic, we have to reestablish how healthcare systems triage respiratory virus testing. And in this case, it really requires strong collaboration between the emergency department and lab medicine. So to increase accessibility and access to rapid results, we deployed point-of-care testing for respiratory viruses in the emergency department, and it's been really helpful. The problem with that is we have to ensure that we are delivering accurate results, and we need to make sure from the pathology standpoint, that regulatory requirements are met, and this is really where our project started.

So at our emergency department, our regulatory compliance based on internal audits was low, and this is something that we see across healthcare systems and it's one of the main challenges of point-of-care, and honestly one of the reasons I really love it. You have to figure out how you're going to fit a very regulated, structured process into an incredibly dynamic environment.

And the ED really is like that, where you have experts that are working in the ED that are constantly changing and adapting to different scenarios and clinical situations. So it's

figuring out how we can monitor and maintain proper testing, things lab medicine is really familiar with. You know, even receiving a specimen, making a positive identification, verifying results within an environment that's super dynamic.

Randye Kaye: That is quite a challenge. Thank you. So, tell us about the intervention, the self-audit tool. What's meant by self-audit and what does it involve?

Ashley Rackow: So, within pathology, our point-of-care coordinators do a great job of visiting test sites. They do inspections and they perform audits. So that's what we call a normal audit. They're just going in and checking regulatory requirements to make sure that the testing that we're performing, we're doing under the best case scenario. And for better or for worse, they're often viewed as enforcers of lab regulations. And I do want to emphasize our point-of-care coordinators, they're experts in lab regulation, but we also want to make sure that our clinical staff in the ED feel empowered to be able to make changes in their areas, because in this case, it's ED nursing that runs this lab. So we wanted to create a system that equally enables both point-of-care and the ED to become regulatory experts. And that's when we developed this self-audit tool.

So the self-audit tool is something that ED nursing uses. So they can use this tool to walk through the lab and view the ED area as a pathologist, and have a little bit of that training, that background, so that they can walk into a space that they work in and say, hey, this meets requirement, this doesn',t and these are the changes we can make before point-of-care even comes in, before pathology comes in, so that we can make sure we're performing the test to the best of our ability. So that's what you see in the paper, is these kind of dual audits. One, which is the data that the paper shows, is our normal point-of-care audit. But what's happening behind the scenes is ED nursing is also coming through and doing their review. So that way, we're kind of catching it on both sides.

Randye Kaye: All right, thank you. So, following the intervention, what were the most significant improvements that you observed?

Ashley Rackow: So, I think, first and foremost, we saw that there was a significant improvement in the level of engagement, and people that work in point-of-care know that this is a big deal. Getting involvement and engagement from the clinical unit is really important, and having a good working relationship between point-of-care and whatever clinical unit is utilizing that test is incredibly important. And that working relationship really allowed us to be able to be joint decision makers and come in to reestablish a process that really worked on the side of both pathology and the ED. So some of the things that we saw from this, not only was that increase

in engagement, but it was also a better understanding of regulatory requirements and from an outcome standpoint, we noticed better use of PPE, which is really important in a COVID area, that we had some negative swipe test findings, meaning that all the testing was done in a clean way. And that's really important for employee safety. We also saw, with some targeted education, improvements in the performance of QC. And I think, really fundamentally, that comes from a better understanding of how lab medicine works, why we have certain requirements in place, and how that supports patient care.

Randye Kaye: All right, thank you. Finally, there are other healthcare systems that are facing similar challenges in the oversight of point-of-care testing. So what advice would you give to them?

Ashley Rackow: So, first, I would say the majority of point-of-care projects and any quality improvement projects, really, they're all iterative so they'll ebb and flow as lots of other factors change: engagement, staffing, leadership. So none of these challenges are truly, like, completely fixed. Many similar challenges will continue to appear, and that could be in the ED, it could be in another unit. So, I think that's important to remember as we think about how we monitor these interventions and having a continuous data monitoring plan in place.

The other thing I want to emphasize is this project, and projects like these are really collaborative, and I think it's important that every unit feel a sense of ownership. So often the hardest part of projects like these is getting buy-in from that other clinical unit that you are trying to work with and in that way, every case is going to be unique. The problems or challenges may be the same, but the way that you engage and collaborate with that unit is going to be different. All of those units have different needs, and I think in pathology, it really is our job to meet them where they are and ensure that we can effectively communicate and that we're on the same team.

And I think it's that positive communication and collaboration that's the most important, because once that's established, it's easy to pitch a pilot, even if you say in the short term, we're going to try this and see if it works, and it does, if it doesn't work for you, then we'll backpedal, reassess, and try something else. Point-of-care has a lot of challenges in that, and it's both in process and in these incredibly dynamic environments, working with other people, understanding different workflows, and understanding the regulation component. But I think with that said, it's one of the most fun, engaging, interactive areas of the lab. And in my institution, I'm fortunate to really work with some great

people both in my department and external to my department to make sure that we are providing services and implementing systems that really support patient care.

Randye Kaye: All right, thank you so much. Dr. Clarke, anything to add to all this, or as Dr. Rackow pretty much covered it now?

Bill Clarke: I think Ashley has covered it well, and she did a great job on this project, and hopefully this is something that more people can use at their own institution.

Randye Kaye: All right, well, thank you, both of you, for joining us today.

Bill Clarke: Thank you.

Randye Kaye: That was Drs. Ashley Rackow and Bill Clarke describing the *JALM* article, "Implementation of a Self-Audit Tool Improves Regulatory Compliance for Point-of-Care Respiratory Virus Testing in the Emergency Department." Thanks for tuning in to this episode of *JALM* Talk. See you next time. And don't forget to submit something for us to talk about.