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Guest: Dr. Stacy Melanson is the director of the clinical laboratories at Brigham and Women's Hospital and is an associate professor of pathology at Harvard Medical School.

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. The COVID-19 pandemic continues to burden healthcare infrastructure, including clinical laboratories. Laboratories have faced many challenges during the pandemic including demands for new tests, high-test volumes, and supply chain shortages. While much of the focus has been on testing for the SARS-CoV-2 virus itself, other clinical laboratory areas have been affected directly and indirectly by these challenges. A special report in the May 2021 issue of JALM describes the experiences of the clinical laboratories at a large tertiary care hospital. In the report, the authors described the challenges faced by their labs and the subsequent adaptations they made in various lab sections to combat those challenges. Readers of the article may learn helpful approaches for their own labs to use in facing COVID-19 surges or other future pandemics. The senior author of the report and our guest for this podcast is Dr. Stacy Melanson. Dr. Melanson is the director of the clinical laboratories at Brigham and Women's Hospital and is an associate professor of pathology at Harvard Medical School. Dr. Melanson and her colleagues as described in their JALM article have led their laboratories response to the COVID-19 pandemic. Dr. Melanson, welcome.

Dr. Stacy Melanson: Thank you very much for having me.

Randye Kaye: So, your JALM special report summarizes your laboratory's response to the COVID-19 pandemic. Generally, what can our listeners expect to learn from this article? Why should they read it?

Dr. Stacy Melanson: I'm sure some of the content in the article will ring all too true for many of the readers. Supply shortages, maintaining multiple COVID testing platforms, overworked laboratory staff. We all unfortunately have had very similar struggles. But I'm hopeful that by reading this article, the readers will learn how our responses may have differed from theirs. Maybe get some new ideas and even adjust their approach. The article will also be an important resource as we face another pandemic which we are sure to do. I think the tables

and the figures will help, you know, remind us. Particularly those of us with short memory such as myself, how we prepared and reacted the last time and help inform new decisions for another pandemic. And lastly, it's a great reference to share with hospital leadership and administration to demonstrate the things the laboratory has faced and the many challenges and to even promote the value of the laboratory which I think has been well recognized in this pandemic.

Randye Kaye: All right. Thank you. Of course, the words, you know, another pandemic just terrifies us all but it's yes, you're right. So, we need to be prepared. So, what were some of the key components to your lab's COVID-19 response? Maybe the audience can be able to integrate into their own practices as we do prepare for the possibility of additional cases of COVID-19 or, as you said, another pandemic.

Dr. Stacy Melanson: Sure, I can think of four things off the top of my head that I would suggest for laboratories above all, if they haven't already done them. The first would be that laboratories really work closely with their informatics team to develop dashboards that could be used to monitor testing volumes, turnaround times, staff productivity, and supplies. And then secondly, to build on that, would be that laboratories utilize these dashboards in a productive way. So, use them to develop staffing models to figure out triggers that would say, "Okay, I'm at a point where I can reduce the frequency of this testing" or "I'm at a point where I can start sending out testing." And to go along those lines, I think to support these plans we should have staff ready to and set up to work from home if we need to again reduce density in the laboratory. There should also be a list of tasks readily available for staff to do remotely if that is in fact the case. And then third, along different lines I would strongly encourage laboratories to have a single orderable SARS-CoV-2 PCR test or whatever is applicable to another pandemic in the EHR that builds on clinical questions to route specimens to different platforms which we've had to have during this pandemic and that takes the burden off of the laboratory to have to do it on the back end to determine which platform and what turnaround time is acceptable. And then finally, I think we need to continue to work closely with our clinical colleagues and hospital administration to help inform decisions that we make in the lab and to help determine if we need to request resources. So, a lab may say, "I need project management support, or I need space for assay development. I need money for additional testing platforms or staff to perform additional testing." I think as we continue to discuss this, what's going to become critical kind of in each of these points that were discussing is that, you know, it's our role as laboratory directors to continue to advocate for the laboratory and promote its value.

Randy Kaye: All right, thank you. So, four important things. But you also mentioned the need to constantly adapt during a pandemic. So, since you wrote this article, have there been any further adaptations that our listeners need to know about?

Dr. Stacy Melanson: Yes, absolutely and we do continue to adapt. Some of the things that we have done or where we actually validated additional testing platforms. Particularly those with a rapid turnaround time which was the clinical need and continues to be the clinical need. Specifically, getting results back within less than one hour. Thankfully, our supplies have also stabilized a bit and we were able to expand our indications for rapid testing. For us that's been to include all of labor and delivery to include urgent OR cases and to help assist with bed management. And so, since writing the article, we now have six COVID testing platforms. You know, the other thing that we have done since writing it is after many requests and after pages and calls to the laboratory, we've developed an application outside of the EHR to display cycle threshold values for some of the SARS-CoV-2 PCR assays and we have guidance on how to interpret them in conjunction with infectious disease and infection control. And that has really helped the clinicians in taking some of the burden off and calls away from the laboratory.

Randy Kaye: Okay, great. Always learning. Always adapting. Let's talk about vaccines for a minute. Now, of course, the availability has brought some promise but also increasing concerns about the COVID variants and the vaccine efficacy. How has the distribution of the vaccine and the emergence of these variants impacted testing in your laboratory?

Dr. Stacy Melanson: Yeah, great question. Couple things here. One, since the summer we've offered serology testing and at the time that was anti-nucleic acid which never really at least in our laboratory increased significantly in volume. But then more recently, we validated the anti-spike assay which as, you know, is the target of the vaccine. And now what we're focusing on is the clinical utility of patients that have been vaccinated particularly those immunocompromised. Is this serology testing valuable? And not only that, you know, how can you guide patient management? So, if they have a certain antibody level that's low enough, does that trigger a vaccine booster? And so we continue to work on that as related to the vaccine. And also, with related to the variance, we're working with infection control and others to determine when and if we should get sequencing results to determine if that patient had a variant of concern and the patient populations that we're looking at doing these sequencing for variance would be patients maybe that has tested positive for COVID after vaccination or patients that acquire infection during hospitalization.

Randy Kaye: All right, thank you. Let's look into the future a little bit. We can't predict it, but in the next six months, we obviously want to remain responsive to COVID-19. So, in the near future based on what we do know now, what are your plans for your laboratories?

Dr. Stacy Melanson: Yeah, and again, that theme emerges that throughout this we need to continue to celebrate our successes and to promote the value of the laboratory and our invaluable laboratory staff has really allowed us to get through this, you know. On that note, I hope everyone recently enjoyed the well-deserved lab week celebration, but I think be more specific. As we can't look into the future, I think we need to think about obviously testing volumes, how that will change from where we are now in spring and summer to the fall and not only COVID testing volumes but additional respiratory testing that we may want to bring back into the fold. Many laboratories aren't seeing really any fluent RC positive. Will that change in the fall? What workflow and staffing change may we need to do based on those testing volumes that we see changes to? Right now, you know, we're kind of seeing a stable volume of COVID testing. So, we're thinking in the near-term future do we need six different COVID testing platforms, or should we be diverting those resources to other COVID initiatives, or even non-COVID initiatives? And then we will also continue to optimize patient care particularly related to COVID. So, in the next few months, we'll be looking at what additional patient populations we can transition from nasopharyngeal swabs to anterior nares and many of you may personally know that anterior nares is a much more patient-friendly swab but there's some debate about the sensitivity and specificity of that. So, you know, where can we balance with clinical and patient needs? And where will we go with that? We will determine over the next few months.

Randy Kaye: All right, thank you so much. As you said, always adapting, always learning, and the labs have been such an important part as we get our way through this crisis. Thank you so much for your work and for joining us today.

Dr. Stacy Melanson: Sure. Thanks, Randy.

Randy Kaye: That was Dr. Stacy Melanson from Brigham and Women's Hospital describing the JALM special report, "How SARS-CoV-2 Transformed the Clinical Laboratory: Challenges and Lessons Learned." 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.