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Correlation of Chemical Urinalysis to Microscopic Urinalysis and Urine Culture: Implications for Reflex Urinalysis Workflows.

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Guest: Dr. Allison Chambliss is the Director of Clinical Chemistry and POCT at the LAC USC Medical Center in Los Angeles.

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.

Urinalysis represents one of the most ordered laboratory tests. Urinalysis consists of physical, chemical, and microscopic tests that may aid in the diagnosis of kidney disease or urinary tract infections. Urinalysis reflex approaches are common such that microscopic urinalysis is performed only after a chemical urinalysis yields positive findings. Further, some laboratories have elected to implement reflex urine culture approaches such that urine culture is only performed after an abnormal urinalysis.

Reflex approaches can reduce laboratory burden, improve result turnaround times, and can potentially have implications in antibiotic stewardship. However, reflex approaches may rely heavily on the performance of chemical urinalysis and few studies have evaluated the correlation of the various urinalysis components.

An article on the July 2020 issue of JALM describes the correlation of chemical urinalysis, microscopic urinalysis, and urine culture results in patient samples. The first author of the article is Dr. Allison Chambliss. Dr. Chambliss is an Assistant Professor of Clinical Pathology at the University of Southern California and Director of Clinical Chemistry and Point-of-Care Testing at the LAC USC Medical Center in Los Angeles, California. Dr. Chambliss is our guest for this podcast. Dr. Chambliss, welcome. What led you to conduct this study to correlate chemical and microscopic urinalysis results?

Allison Chambliss:

Well, our authorship team for this article included representatives from our two large medical centers within our county health system. And on that note, I would also like to give a shoutout and thank you to my co-authors, Drs. Holli Mason and Tam Van.

So, at one of our centers, the lab was performing both chemical and microscopic urinalysis, concurrently on all

urines for all urinalysis orders. And at the other center, the lab was using a reflex model for urinalysis. So, they were always performing chemical urinalysis, but they would only perform microscopic analysis if the chemical urinalysis results met certain positive criteria. As a health system, we were looking to standardize to one urinalysis workflow model. And the reflex model is attractive for several reasons, such as decreases in test utilization for the microscopic analysis, and it being less of a labor effort for the lab staff.

But some of us were a bit hesitant about what could potentially be missed diagnostically if microscopic analysis was not always performed. We realized that we didn't really have any good data regarding the correlation between chemical and microscopic urinalysis results, especially since we had been using our current generation of automated urinalysis instrumentation. And further, even though many labs already used reflex approaches, we couldn't find much in the literature in terms of the diagnostic performance of this type of reflex model or what optimal reflex criteria might be.

So, for these reasons, and since we already have the data points of thousands of concurrent chemical and microscopic urinalysis results at our fingertips, we decided to conduct this study. And we also thought that publishing the study might benefit other labs that have not done this robust of a study and it could potentially help them decide upon or refine their urinalysis reflex criteria.

Randye Kaye: All right, thank you. Now, can you summarize the analysis and the results from the correlation of chemical and microscopic urinalysis? What were the major findings?

Allison Chambliss: So, we analyzed just over 9,100 urinalysis orders, each containing results for both chemical and microscopic urinalysis from the same sample. And we predefined our positivity criteria based on what our one urinalysis reflex workflow hospital lab was already using as their criteria for reflex into a microscopic urinalysis.

So, that meant that for chemical urinalysis, the sample was considered positive if the urine had a hazy or cloudy appearance, if it was heme or blood positive, if glucose was greater than or equal to 1,000 milligrams per deciliter, if protein was above trace quantities, or if leukocyte esterase or nitrate was positive.

And for the microscopic urinalysis, the sample was considered positive if there were greater than or equal to four red blood cells or white blood cells per high-powered field, or if there was any detectable presence of bacteria. So collectively, using these positivity criteria and defining the microscopic urinalysis as the reference method, we found that the

chemical urinalysis had a sensitivity of 93 percent and a specificity of about 57 percent for predicting these microscopic elements.

And we were considering a reflex model of chemical with reflex to microscopic analysis, so we were most concerned about having a high sensitivity rather than the specificity. So, we really wanted to make sure to detect as much as possible and be highly sensitive in that first chemical urinalysis step. So overall, we felt that our sensitivity was fairly high and that the reflex model could be appropriate. And by our results, implementation of a chemical with reflex to microscopic urinalysis workflow would yield a 34% reduction in the number of microscopic tests needing to be performed in our lab.

Randy Kaye: Now, what about the correlation of urinalysis results to urine culture results? Why did you conduct that analysis and what did you find there?

Allison Chambliss: Well, we really wanted to learn with this study was what we might be missing diagnostically by implementing a reflex model. Our hospitals were also interested in adopting urinalysis with reflex to urine culture workflows, on top of this chemical reflex for microscopic urinalysis workflow. So, we were particularly curious about that other 7 percent missing from the 93 percent sensitivity. These were the samples that were negative by our chemical analysis, but positive by microscopic analysis. So, these were samples that had significant microscopic elements, but they would have never been reflex to microscopic analysis by our predefined criteria.

So, in diving deeper into those which we called our false negatives, we noticed that most of them had trace amounts of bacteria. And urinalysis can detect bacteria that is clinically significant, such as in urinary tract infections. But it can also detect contamination and other bacteria that is not considered clinically significant. So, this led us to perform a further correlation study of urinalysis results to urine culture results, to really get at what true clinically significant bacteria we might not be catching with our reflex model.

Not all of our urinalysis study samples also had urine culture ordered by the provider and performed by the microbiology lab, but we were able to correlate urinalysis and urine culture results for just over 3,100 samples, so about a third. We found that of the samples negative by chemical urinalysis only about 6% of them had clinically significant positive urine culture results.

Randy Kaye: Well, were there any limitations or caveats of the study that you would like to share with us?

Allison Chambliss: Yes, absolutely. So first, I'd like to mention that it could be debated as to whether missing 6 percent of clinically significant positive urine culture results is acceptable.

It is important to note that clinical guidelines recommend performing full urinalysis, including microscopic analysis for a certain patient population, and this includes pregnant women, neonates, and immunocompromised patients. So regardless of the chemical urinalysis findings, microscopic analysis should be performed for those patients. Our study did not investigate for or exclude those patient populations. So, we are optimistic that we would actually miss less than 6% of infections in real-world scenarios if providers can still direct order microscopic urinalysis for those patients.

I'll also note that we predefined our positivity criteria for the chemical and microscopic urinalysis in the study based on what was commonly used elsewhere. So, we did not tweak those criteria to optimize diagnostic performance and other institutions may wish to do so. And finally, our results are specific to our own automated urinalysis system. While we'd anticipate that automated urinalysis systems from other vendors might perform similarly, other institutions using other platforms would have to verify this.

Randye Kaye: All right. Thank you. Now, let's just put it all together. Can you summarize some key take-home points for our audience and bottom line, would you recommend that laboratories implement urinalysis reflex models?

Allison Chambliss: Our studies show that with our urinalysis system and our selected parameters, correlation between chemical urinalysis, microscopic urinalysis, and urine culture findings was fairly strong.

So, this indicated to us that our proposed reflex model was appropriate and that we could improve test utilization and decrease labor requirements in the lab without sacrificing diagnostic performance. So, we would certainly recommend that other labs could consider adopting urinalysis reflex models if they have not already done so. Keeping in mind that they may need to perform their own correlation studies, specific to their analyzer system. They should also consider the needs of their specific patient populations and should discuss the urinalysis workflow with relevant clinician stakeholders, as well as the microbiology lab if reflex to urine culture workflows are under consideration.

Randye Kaye: All right. Thank you so much for joining us today.

Allison Chambliss: Thanks for having me.

Randy Kaye:

That was Dr. Allison Chambliss from the University of Southern California, describing her JALM article, "Correlation of Chemical Urinalysis to Microscopic Urinalysis and Urine Culture: Implications for Reflex Urinalysis Workflows." 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.