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James H. Nichols, Ethan S. Brandler, Corinne R. Fantz, Kimberley Fisher, Michael D. Goodman, Gary Headden, Debra Hoppensteadt, Ryan Matika, W. Frank Peacock, John Rodrigo, Andre Schützenmeister, Jonathan R. Swanson, Cristina Canada-Vilalta, Gabrielle Miles, and Nam Tran

A Multicenter Evaluation of a Point-of-Care Blood Glucose Meter System in Critically Ill Patients.

J Appl Lab Med 2021; 6:4 820-33. <https://doi.org/10.1093/jalm/jfab005>

Guest: Dr. Nam Tran is a professor of clinical pathology at UC Davis School of Medicine and Associate Professor in the Departments of Pathology, Critical Care Medicine, and Clinical and Translational Science at the University of Pittsburgh School of Medicine.

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.

Accurate monitoring of blood glucose is an important aspect of care for critically ill patients. They commonly experienced hyperglycemic and hypoglycemic episodes. In intensive care units, bedside point-of-care testing for glucose can be advantageous relative to routine laboratory-based testing because it enables more rapid, frequent and less invasive monitoring. However, not all point-of-care glucose monitors are approved by the US FDA for use in critically ill patients. There remains a need for studies which investigate the accuracy of point-of-care glucose monitoring in critically ill patient populations.

The July 2021 issue of JALM include such a study. It investigated the use of the Accu-Chek Inform II system for point-of-care glucose monitoring in a large population of critically ill adult pediatric and neonatal patients across 10 US hospitals. The study investigated the analytical accuracy of the point-of-care glucose device relative to a reference method as well as clinical performance and implications for insulin dosing. On today's podcast, we're joined by the senior author of the article, Dr. Nam Tran.

Dr. Tran is a professor of clinical pathology at UC Davis School of Medicine. He received his PhD in comparative pathology from UC Davis and completed his postdoctoral training under the UC Davis Point-of-Care Technologies Center funded by the National Institute of Biomedical Imaging and Bioengineering. Welcome Dr. Tran. Let's start with this. What are the challenges to point-of-care blood glucose monitoring in critically ill patients?

Nam Tran: Oh that's a great question, a question that we've been obviously dealing with for quite a long time. Point-of-care

glucose testing obviously extremely convenient, been around of ages, but the challenges in the critically ill population is well the patients are sick, right? So they have many medications on board. At our institution our burn unit had patients that average 10 to 20 medications each day and some of these medications can interfere with certain glucose meters out there. So that's one aspect that you have to address with these devices.

The other aspect is that sometimes the samples may not be of sufficient quality if you're doing a finger stick for example for someone who is critically ill, they may not provide you with sufficient amount of blood to plasma ratio to give you an accurate result. These devices were developed to measure glucose under conditions that may not be represented in people who are very sick. And then of course those that are special populations neonates, pediatrics who are sick and of course children are not smaller versions of adults, that can contribute to inaccuracy so really fundamentally the challenges of point-of-care blood glucose monitoring in critically ill is the fact that it poses challenges to devices to give an accurate results which translates to providing accurate dosing of things such as insulin which is a very dangerous drug if used incorrectly.

Randye Kaye: All right, thank you. That makes a lot of sense. So in this patient population, are there particular factors that confound glucose monitoring? Anything other than what you've already mentioned?

Nam Tran: Even high doses of something as innocuous as vitamin C or at least we suspect as innocuous or we want to believe is innocuous, right? Some glucose meters out there can be greatly affected by high doses of vitamin C and where that comes in is there's lots of discussions: should we use vitamin C to deal with sepsis? There's even talks of it for COVID-19. So something like that, something vitamin C that we're taught as children that is a good thing, maybe a bad thing that could affect our tests out there.

Randye Kaye: So why is this so important? Accurate blood glucose monitoring, why is that so important in critical care?

Nam Tran: So, years ago, there are studies that show that if you keep a critically ill patient's blood glucose close to as normal as possible, right? And just by analogy you want a person who's diabetic to keep their glucose as normal as possible. They tend to do better and are able to get out of the ICU more quickly, they are more likely to survive and so forth. And this is connected to all of the studies and science out there that shows that high glucose levels some of which could be due to diabetes, some of which could be due to stress such as

following injury. It's not really a good thing for your immune system, wound healing, and all these other factors.

So keeping glucose normal, which is facilitated by many of these institutions, is facilitated by giving insulin. Insulin lowers your blood glucose level and the challenge though is if you give too much insulin, you're going to perhaps starve all of our cells and you know that's detrimental to the patient, and could even die. So you need to rely on very accurate glucose measurements what the body is seeing and give the right amount of insulin that is proportional to how much you want to lower it to a level that is hopefully normal and is conducive to survival.

Randye Kaye: Okay it is a very delicate balance from what I understand. So let's talk about your study. Can you summarize the findings of the study? How did the Accu-Chek Inform II system for point-of-care glucose monitoring? How did it perform in this multicenter evaluation?

Nam Tran: Yeah so for the most part, it showed that these devices perform well and there's some areas and questions that do come up from the study. The study of about 476 arterial samples spread between the pediatric adults as well as neonates, 375 venous samples and even 100 neonatal heel stick samples. So all these across multiple institutions, all these patients were considered critically ill, so 10 hospitals were involved in this case as well as the ER and so on and we found that when compared against a higher-order reference method (in this case a perchloric acid hexokinase in comparator method) we found that these devices work well.

So in the case of actually looking at criteria where they should fall within these boundaries so greater than equal, greater than 95% of results within plus or minus 12 mg per deciliter of glucose. I don't want to get too laborious in terms of the technical stuff but these devices tend to do well. In this case we found that 96% and 98% of venous samples actually fell within these criteria, these two levels of criteria, for that specimen type. However, when you start looking at other populations, for example neonatal arterial samples, there were a little bit of differences and it did not meet some of these criteria and some of those questions that come up is: what are these factors that actually influence the accuracy in the special population? So in our case there are two criteria it needs to meet equal or greater than 95% and equal or greater than 98% within these criteria. We found that for the neonatal arterial samples 84% or 98% only fell within those criteria respectively. So that one kind didn't make the cut but I just emphasize that these special populations do differ in amongst ICU patients they do differ as well. So these are hard matrices to work with.

Randye Kaye: Okay so some challenges but some promising results. What do you think is the future of critical care glucose monitoring? What challenges still remain for you?

Nam Tran: There's probably three areas I personally feel are the remaining challenges, right? We still need to have more accurate measurements and accurate measurements that are less affected by these interfering substances, right? So there's going to be more medications that patients are given. We need them to be robust against these drug base as well as physiologic factors that can alter accuracy. The second component is addressing how we can measure more frequently and frequently meaning that should we look at continuous glucose monitoring so that we can trend the data more accurately. Right now most places are testing every hour. That's actually as frequent as it usually gets. Other places may not depending on how sick the patients are and the third component is really going to a new area which isn't discussed in the paper but really looking at predictive analytics, right? Machine learning, how can we use all this data perhaps glucose trends and values and they have to be accurate of course but also perhaps other variables that we measure in the lab to predict where this patient is going and perhaps make things more personalized or at least more precise for insulin dosing.

Randye Kaye: All right. Dr. Tran, thank you so much for joining me today.

Nam Tran: Thank you, appreciate it.

Randye Kaye: That was Dr. Nam Tran discussing the JALM article "A Multicenter Evaluation of a Point-of-Care Blood Glucose Meter System in Critically Ill Patients." 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.