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FDA Regulation of Laboratory Clinical Decision Support Software: Is It a Medical Device?

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Guest: Ronald Jackups is an Associate Professor of Pathology & Immunology at Washington University School of Medicine in St. Louis.

Bob Barrett: This is a podcast from *Clinical Chemistry*, a production of the American Association for Clinical Chemistry. I'm Bob Barrett.

What is clinical decision support software and when should it be considered a medical device? In recent years, many new software tools have been implemented to improve patient care and use of healthcare resources. Some predict disease development, others prevent duplication of testing, while others help translate clinical laboratory results into better patient care decisions.

Which software programs require strict oversight and when is a lower level of scrutiny acceptable? In order to provide clarity for healthcare professionals and software developers, the Food and Drug Administration released guidance in November 2022 defining criteria that must be met in order for clinical decision support software to avoid regulation as a medical device.

An opinion article appearing in the April 2023 issue of *Clinical Chemistry* explores the recent FDA Guidance, discusses implications for healthcare professionals, and proposes next steps for clinical laboratorians. In this podcast, we're excited to talk with the author of the opinion article, Ronald Jackups, who is an Associate Professor of Pathology & Immunology at Washington University School of Medicine in St. Louis.

His clinical and research interests are in clinical informatics and transfusion medicine, with a focus on clinical decision support for laboratory utilization. So Dr. Jackups, what is clinical decision support, or CDS, and how is it commonly used in patient care?

Ronald Jackups: Yeah. So clinical decision support really defines a broad category of tools and processes that use both information technology and communication skills to improve healthcare. A lot of people think it's just those annoying pop-up alerts that show up when they're trying to do something in a patient's chart, but really it's a much wider field that includes

any aspect in the way that clinicians make decisions, such as ordering tests or interpreting tests.

I think that it is right now most well developed in the field of pharmacy and has resulted in, I'd say, hundreds or thousands of different alerts for drug allergies or overdose orders or drug-drug interactions. But we're seeing that expand everywhere. We are seeing that in every clinical specialty in the way that they design their order sets that provide guidance on what to order on different patients depending on indications.

And I also note that, at least in radiology, there are a couple of government requirements that CDS must be shown to outpatient providers in order to bill for certain procedures.

Finally, I think that right now all of the tools are some ways rudimentary or at least require a lot of input from builders to make it work the way it's desired, but I think we're going to see in the future a lot of clinical decision support, or CDS, that relies on predictive analytics to get a much more personalized approach to medicine.

Bob Barrett: I'd like to drill down into this just a little further. How has clinical decision support affected patient care in general and laboratory processes specifically?

Ronald Jackups: Yeah, so I'd say overall, we see an improvement. It really does provide some useful guidance to providers and we know that providers are very busy, only getting busier, and spend unfortunately a lot less time talking to patients and more time in their electronic health record, charting notes and placing routine orders.

And so I think overall, clinical decision support tools have streamlined their workflow and also caught situations where the clinician might make an error that could harm a patient. And so that, as well as the evidence in the literature, does demonstrate that there has been a great improvement in practices, overall clinical practice, with the addition of CDS, but there are problems.

There's definitely a potential for what we call alert fatigue, which is that if you get so many alerts or so many warnings in a short period of time, that you start to ignore all of them, even the ones that may actually be important, and we know this providers are getting hundreds of alerts per day and part of our job is to identify the alerts don't work and pull those out.

Given that context, in the lab, we were little late to the game in developing all the CDS and so I think that we're getting

better. It's definitely growing, the amount of tools that we use.

But we also have to recognize that we're competing with hundreds of different alerts and so we really, right now, are mostly doing proof of concept. We definitely build alerts that prevent duplicate test orders, alerts that warn people about look-alike tests so, the most common one there is 25-hydroxy vitamin D versus 1,25-dihydroxyvitamin D. Those two tests are frequently confused with each other. And a lot of warnings and order builds that encourage appropriate use of red cell or any transfusion, and certain tests, the way that tests are utilized.

And then finally, we build a lot of reflex algorithms in the lab. So instead of, for example, ordering 50 tests to analyze this patient's anemia, why not just order a anemia algorithm single order? And then the lab will run a lot of tests in sequence to determine the cause of the patient's anemia. So I think that we're a little behind; we're growing. I think that we're a little bit limited by the knowledge gaps in the clinicians and how they respond to the CDS that we give them for laboratory utilization, and we're competing with resources.

But at the same time, I've definitely seen some CDS implementations that were surprisingly successful, things that I thought were just a simple little warning that maybe the provider wouldn't notice but we've seen some lasting durable improvements. You never know how it works until you try it out there, and most definitely after you put something out there, you need to keep monitoring it, talk to clinicians and other stakeholders, make sure it's working the way it's intended and then change as needed to make it work.

Bob Barrett: Doctor, can you give us a quick summary of the recent FDA guidance on the use of CDS software?

Ronald Jackups: Yeah. So the FDA recently came out with a guidance on the use of CDS software in September of 2022. This is in response to a law, particularly the Cures Act, which dictated how to define software as a medical device. So the FDA, despite being called the Food and Drug Administration, no longer regulates only food and drugs; it also regulates medical devices. We are very familiar with that in the laboratory because all lab test devices that are commercialized require FDA approval.

So the FDA is now increasing their scope to regulate software the same way that they would regulate a benchtop testing device, and they have been trying to define those rules based on laws. So the Cures Act defines certain criteria for how the

FDA will define what is a medical device. What kind of software is a medical device?

This is important because if your software is declared a medical device, you will have a much higher level of scrutiny, particularly as it pertains to how you can advertise the software. So this is primarily for commercial use. The way that I interpret the guidance as it's written is the primary intention, the primary goal behind what the FDA is looking for is: does the CDS software equip providers to make their own clinical decisions by giving them information and explaining why that information is being provided to them, whether it's in the form of an alert or any other informative tool.

What the FDA appears to be more interested in regulating are CDS tools that really tell the doctor what to do, rather than providing them the information that allows them to make their own decision. And this is going to become more important as we increase the scope of CDS to include something more like artificial intelligence or predictive analytics, where the information may be so complex that it may be difficult to provide all that information to the provider so that they understand what they're doing.

And so as soon as your tools get closer to telling a doctor what to do rather than informing them, then it is going to fall under more scrutiny by the FDA.

Bob Barrett: How do you see this guidance affecting the use of CDS related to lab testing?

Ronald Jackups: Yeah, that's a great question because there are a lot of unknowns. We are definitely in a field where we haven't quite figured out, or perhaps the FDA hasn't quite figured out, what they're going to do with all of these. The obvious fear in response to these is that this may stifle innovation.

Anytime something becomes over-regulated, it causes commercial enterprises to fall back on tried-and-true practices rather than trying to come up with something that's riskier that the FDA may ultimately say no to. And that could happen for sure especially, as I said, as these companies try to expand into the area of artificial intelligence and predictive analytics. But there could also be a benefit here, which is that, as I said, the primary goal that I perceive driving this guidance is to increase interpretability, to make sure that the tools really equip clinicians with the information they need to make the right decisions, as opposed to just telling them.

And I think that those interpretations, that information, as long as it is not overwhelming, will enhance the way the providers make decisions rather than slow them down or make things more confusing.

The other thing I see that could happen here is a drive towards more, let's call it lab-developed or homegrown CDS tools, where the institution is either going to have to create their own CDS interventions or take the framework from a commercial enterprise and then adapt it to their own institution, much the same way that we have laboratory-developed tests, which take FDA approved testing devices or tools and then adapts them to the institution's own needs. And that of course falls into more of a murky FDA regulatory environment that certainly has not been explored yet in the field of software to my knowledge.

Bob Barrett: Well finally doctor, how can clinical laboratories adapt to the FDA guidance to maintain compliance and improve patient care?

Ronald Jackups: Yeah, again a very great question. I think right now, there's nothing in the immediate future that's going to inhibit the ability of labs to implement CDS. So that part is good. I think that the FDA still needs some time to process this and decide how they're going to regulate these commercial systems or commercial software coming down the pike.

In the meantime, I would definitely recommend that laboratory experts, particularly those that are involved in information systems, to read the guidance that's publicly available. There are also public comments that anyone can provide. Those are also available so you can read those on the same FDA website with the guidance. You can still add your own comments and the FDA might take those up and change the rule in the future, but that I expect to be a slow process.

As far as what to do at your own institution, when you are reviewing commercial CDS software, keep in mind: how interpretable is this to a clinician? You know, I know from my experience that I don't always get to pick what commercial software gets installed in our institution. Often it's someone else deciding that it needs to be put in and then it's me deciding 'how do I make sure that this is implemented safely and compliantly?' And so I think we need to think about the interpretability of these tools moving forward.

And then finally, if you're interested in CDS, but not really involved in your institution's CDS teams, I'd say get involved now. Use this as a platform to say you need a laboratory expert informing your decisions on how to implement CDS in lab testing in blood product use. And once you're in there, try to develop or adapt your tools in your own institution to meet your stakeholder's needs, and as you develop those, as you get some quick wins, you'll get better buy-in from the

institution on the need for laboratory experts to influence the decisions related to CDS development.

Bob Barrett: That was Dr. Ronald Jackups from Washington University School of Medicine in St. Louis. He wrote an opinion article on FDA regulation of clinical decision support software in the April 2023 issue of *Clinical Chemistry* and he has been our guest in this podcast on that topic.

I'm Bob Barrett. Thanks for listening.