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### Real-World Data and Quality of Evidence in Reversing Anticoagulation: We Believe!

#### Announcer:

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#### Dr. Dobesh:

So the next - what I want to do for the next few minutes is just kind of discuss - alright, so we have to develop a reversal strategy. And so if you kind of believe that you need to do this, which you do, you know, what are ways to go about it? And so I'm not going to explain at least a lot of detail per se, but really just to kind of give you a kind of 10,000-foot view of, you know, the things you need to think about.

And so if you have an anticoagulation stewardship program in your institution, that's where this lands. And so I walked through the posters yesterday, several good posters on anticoagulation stewardship programs. Actually, I need to reverse this because I think 65% of the pharmacy population now is female. So actually I need to probably move that around there. But yeah, I mean, of the tasks that this kind of this type of a group that handles, right, the tough cases, what are we going to do about reversal? And so one of the things, obviously, to look at are guidelines. Okay? And you've got all of these guidelines here basically saying the same thing, is that use andexanet alfa. If not available, you can use four-factor PCC, into some line or another. And I think there's - I think many people have read this incorrectly. This is not, 'Well, since I don't want to carry andexanet alfa, then I only have four-factor PCC, and that's fine.'

I mean, I have - being an author on these guidelines here, we have a huge debate whether or not to include the four-factor PCC as an option based on the lack of data. And so it's not just like, well pick what you want, right? There's clearly a preference in all of these guidelines, for the most part, to be using andexanet alfa. And at least in the ones that I was involved with, it basically came down to well, we got to give them something. So we try it, if you got nothing. It wasn't like an equal, pick what you want kind of deal here. So you have to look at what the guidelines say. We also, like I said, you don't really have a choice of whether or not you're going to put this together. We know that the Joint Commission looked at the elements of performance and updated them all now to include DOACs. And we know as we look at the patient safety goals, that hospitals have to use approved protocol, evidence-based practice guidelines for reversal of individual anticoagulant reversal strategies. So this is once again, one of the drivers and why we kind of need to move on this.

Now the way that looks can be a variety of different ways. This is an example from one health system basically, that spells out there recommendations for use. It can be more in something more user friendly, I think, like this, which talks about the reversal strategy was interesting, I think, and this one here is that, you know, okay, where critically relevant bleeding, rivaroxaban and apixaban within 18 hours, that's - kind of goes right along with the package label. But that's, you know, that's not how everybody presents.

Right? Bleeders present all kinds of ways. So what are you going to do when they have life threatening bleeding? It's been more than 18 hours, but they're still bleeding. Right? Or someone is going to an emergency surgery. There's no data for that. But they - you've got to develop at least a mechanism that you're going to address that.

And also, really, it's just, how's the patient going to flow through your system? Okay? You know, your patient arrives, there's assessment to give drug, there's a decision to treat, it goes to pharmacy, pharmacy basically prepares the medication, the - reviews the order, prepares the medication. There's got to be a way to get it to the emergency department quickly if that's where it's being given. And basically, then administrate it appropriately. So there's multiple steps that just don't, poof, happen. Right? So we really, you know, people have to - this is where the anticoagulation stewardship programs come in. Someone's got to take the time and spell these out, and try to imagine what roadblocks you might hit and how you're going to get over those. Right? Someone's got to make sure to design how are you actually going to give it. Okay? A number of, you know - we were actually at an institution, we did at the archaic way, we mixed the bolus, got that off, right, and then we use that other time to kind of get the infusion. Now with the larger vial sizes, we kind of

send it all as one. But you've got to have instructions on how you're going to prime the pumps and make sure you get all of the bolus in, in a timely fashion. And so once again, all these things that need to be addressed.

And just like I said, you know, when it comes to establishing hemostasis, the clock ticks differently for some patients, not everyone's the same. Right? You have a trauma or an intracranial hemorrhage, you've got to act extremely quickly. Okay? You've got basically minutes maybe to get this done. Now, if you have bleeding that's leading to hemodynamically compromised, you might have a little bit more time, you might be looking at hours instead of minutes. Of course, and then there's patients that have other types of bleeds that, alright, they're not crashing per se, but they're still bleeding. And so how are we going to manage that? So just to kind of reflect on the fact that not every patient who comes in with a Xa related bleed is going to be this - has got the same sense of urgency. And how are you going to address that within your institution, right?

So stewardship programs, these are just the number of questions, right? So who's going to get the agents? What are you going to carry on formulary? What are you going to do if it's life - if it's not life-threatening bleeding? You know, what are the outcomes that you're going to follow up? What's your medication use evaluation going to be, your MUE? What happens when there's an urgent surgery and someone's on Xa inhibitors? Okay? What are you going to do? You know, and I'm not saying you should use andexanet alfa or four-factor PCC, but you've got to come up with something. You've got to develop a strategy. What kind of labs are you going to do? What labs are your lab - what is your lab going to offer you as far as monitoring if necessary? If you're specifically going to be using andexanet alfa, there's a whole bunch of other questions. Well, what happens if you get transferred - a patient comes transferred from an outside hospital and they already gave four-factor PCC patient? The patient is still bleeding. Right? This is a powder-keg. I hate - you know, this is just - this drives me nuts.

I mean, maybe some of you have gotten through this and think through this differently, but you have to remember right, a patient is bleeding, promotes thrombosis. That's your body's natural response. Okay? You have to remember the patients that we're treating here have a different pathobiology than we do. They have a propensity to clot; hence, they need anticoagulation. So we're stripping that away. Okay? If you gave andexanet alfa, and if you've given them four-factor PCC, you just dumped a whole bunch of firewood on that. And so what are you, what are you going to do in these patients? On the flip side of that, they're bleeding, they're going to - they may die. So you've got to, right - you've got to kind of work through that. What are you going to do for anticoagulation? Are you going to monitor, you're going to get chromogenic Xa levels? What are you going to do, basically, if it's been, you know, outside of 18 hours? And what are you going to do if it's another agent? Right? Somebody, I don't think anybody's probably getting edoxaban, but if you were, patient was getting edoxaban, would you use it? Right? It probably works. Or are you just going to let them die? You just have to think through these things that don't automatically fit, right, into what a package label may tell us.

**Announcer:**

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