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Improving Perioperative Medication Safety with Ready-to-Administer Products

Announcer:
You're listening to *Clinician's Roundtable* on ReachMD, and this episode is sponsored by Fresenius Kabi. Here's your host, Dr. Charles Turck.

Dr. Turck:
Welcome to *Clinician's Roundtable* on ReachMD. I'm Dr. Charles Turck, and joining me to share practical approaches for integrating ready-to-administer products into anesthesiology and perioperative workflows is Dr. John Hertig. He's the founder and President of Hertig Healthcare Advising and Adjunct Professor at Purdue University in West Lafayette, Indiana. Dr. Hertig, thanks so much for being here today.

Dr. Hertig:
Well, it's my pleasure. Thank you for the invitation.

Dr. Turck:
Well, to start us off, Dr. Hertig, would you give us an overview of the persistent safety challenges that anesthesiology and perioperative teams face when it comes to medication preparation and administration?

Dr. Hertig:
Of course. And our perioperative and procedural areas are unique. And in short, those persistent safety challenges arise from a variety of factors, including manual preparation, lack of redundancy checks, and really being in a high-stake, high-speed environment. And so, while system-level safeguards like standardization, automation, and technology are improving, many risks remain intrinsic to these areas, and these include a few that I want to mention.

One, anesthesiologists are frequently preparing custom doses on the fly. This can introduce variability, contamination risk, and even mix-ups.

Labeling. As a pharmacist, labeling in the perioperative area is a particular issue, especially when we fail to apply that standardized, legible label. And this can be a problem in all of these settings.

And finally, we have the administration, where it's occurring under time pressure oftentimes and we're multitasking, and that can raise the chance of mis-dosing. So this is really a special environment that does carry significant risk.

Dr. Turck:
Now, there's a lot of talk about the value of ready-to-administer products in high-risk settings. What types of errors are most commonly reduced through their use?

Dr. Hertig:
Well, you're absolutely right, and that level of evidence is mounting. And the thing about ready-to-administer products is there are fewer administration preparation steps. And when there are fewer of these steps, there are fewer opportunities to do those steps wrong. And so we have that reduction in potential errors because of it, and this can primarily reduce dosing calculation errors, dilution and reconstitution errors, those labeling errors that we often see in the perioperative setting, as well as contamination risks and just delays in therapy. Again, fewer steps, fewer opportunities to do those steps wrong.

This then translates directly into reduced adverse events, increased medication safety, and ultimately, better efficiency.

Dr. Turck:
For those just tuning in, you're listening to *Clinician's Roundtable* on ReachMD. I'm Dr. Charles Turck, and I'm speaking with Dr. John Hertig about the role of ready-to-administer products in anesthesiology and perioperative settings.

Dr. Turck:
So Dr. Hertig, let's shift gears a bit and talk about sourcing. What are the core differences between FDA-approved manufacturer-prepared products and 503B compounded alternatives?

Dr. Hertig:
Well, I'm glad you asked that question. This is a really important distinction that definitely the public but even many healthcare professionals do not fully understand.

First, FDA-approved, manufacturer-prepared, ready-to-administer products are rigorously tested, they're standardized, and they're predictable. And they have a few different additional factors. First, they must require demonstration of safety, efficacy, and quality. That's what we want in our products, right, is safe and effective. They're subject to FDA Current Good Manufacturing Practices—we will call that cGMP—that also incur greater inspections. And finally, they require approval from the FDA to be marketed to the public, and this includes strict control of labeling as well as packaging and advertising requirements.

Now, on the other side of this, we have our 503B outsourcer compounder products, which are important as well. They serve an important operational clinical role, but they oftentimes have shorter beyond-use dates, variable formulations, and the safety of them is highly dependent on that individual facility's adherence to good manufacturing practices, and that can be variable.

Both 503B outsourced and FDA-approved manufacturer products do play a central role in perioperative settings, but as a patient safety expert, FDA-approved products are always that gold standard.

Dr. Turck:
Well, as a follow-up to that, when hospitals are deciding between these product types, what operational or regulatory considerations should they be weighing?

Dr. Hertig:
Well, this is a really complex decision for our hospitals and health systems, and oftentimes that decision goes well beyond clinical preference, but instead requires the balancing of operational realities and regulatory compliance.

The simplest answer is that hospitals should always first choose FDA-approved manufacturer-prepared RTA products if they're available. Because, again, it's the most rigorously tested. It requires FDA approval. So if they're available, that's what I would suggest. These products are that gold standard.

But there are other factors that my colleagues and others in hospitals and health systems need to think about—product availability, is it even available? Does it contain accurate and complete labeling? And this may even include RFID capabilities, which is a great technological advancement. Sterility assurance, as well as ultimately, cost, right?

We have to talk about cost here. But it's not just the acquisition cost of a product. We really need to be thinking about the total cost of care. What else is included in purchasing that product? They may be pennies more expensive, but you're incurring these other costs that affect the entire health system.

Worth additional mention is that our hospitals and health systems may have institutional policies as well as pharmacy resources and other limits that play a key role in ensuring that safe integration and quality control that our patients expect and demand.

Dr. Turck:
And if we think about practical implementation for a moment, how might we most effectively introduce ready-to-administer medications into perioperative workflows, especially in anesthesiology?

Dr. Hertig:
Well, it does, like any other change, require diligent planning and cross-disciplinary collaboration. This can be a transformation for an organization, and you have to plan accordingly. So this involves all key stakeholders, including pharmacy, anesthesia, nursing, informational and clinical technology groups, as well as our procurement and buyers—and there might be others too, depending on your hospital and health systems that need to be at the table.

Oftentimes, this type of change requires updates to electronic health records, anesthesia carts, and barcoding systems. So again, being proactive, having a plan, and even doing a failure modes and effects analysis, where you can walk through it and anticipate any

problems, is really essential here.

And finally, plenty of staff education. We really can't overeducate whenever we make this type of operational and/or clinical change.

Dr. Turck:
Now, in the last few moments of our program, Dr. Hertig, what other system-level strategies, from your perspective, could support sustained adoption of ready-to-administer medications?

Dr. Hertig:
Well, much of my work has been focused on assessing waste of these products, operational efficiency, and patient safety implications. And what we've really determined here is we need to look at that cost effectiveness analysis—that total cost of providing care. We know RTA is safer, but how do we then incorporate these other costs that are involved in adopting RTA in our hospitals and health systems? It is well beyond just the acquisition costs of RTA products— labor savings, reductions in waste, reduced diversion risk, and certainly, the most important thing, fewer errors and harm to our patients—all need to be included whenever we make these decisions. And that list goes on and on and on.

No longer should we only be looking at a pharmacy budget and saying, okay, this is a little bit more expensive, so I guess we're not going to do it. Instead, what are all those total costs of care that are incurred by the entire system so that the best possible care can be provided at the best possible cost?

And then, to sustain these changes, like anything else, we need to establish that coordinated and shared governance structure that includes multi-professional decision-making, focusing on that total cost of care, and then finally tracking success. What are those safety metrics? What are those operational metrics? How do we ensure that we're then sustaining that very successful change?

Dr. Turck:
Such insightful comments for us to think on as we come to the end of today's program. And I want to thank my guest, Dr. John Hertig, for joining me to discuss how we can implement ready-to-administer products into anesthesiology and perioperative workflows. Dr. Hertig, it was great having you on the program.

Dr. Hertig:
It was a pleasure. Thank you for having me.

Announcer:
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