Colibri Healthcare

Podcast Transcript

Pulse Oximetry: What Impacts Accuracy

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Guest: Donya L. Winters, RN, CLNC

Donya Winters is a Texas-based Registered Nurse and Certified Legal Nurse Consultant with multi-state licensure and over a decade of bedside experience. During the COVID-19 pandemic, she served on the front lines in a small-town Texas hospital, providing acute and end-of-life care under extreme conditions. Her firsthand experience with systemic failures and moral injury has shaped her ongoing advocacy for healthcare equity and reform. Donya currently consults on complex medical-legal cases, including wrongful death, sepsis, and large-scale toxic exposure litigation such as the Camp Lejeune water contamination cases. She is completing her master's degree with plans to pursue a doctorate in Forensic Nursing. She is also the author of The Virus (in submission), a memoir chronicling the emotional toll and ethical battles of pandemic nursing.

Host: Candace Pierce: DNP, MSN, RN, CNE

Dr. Candace Pierce is a nurse leader committed to ensuring nurses are well prepared and offered abundant opportunities and resources to enhance their skills acquisition and confidence at the bedside. With 15 years in nursing, she has worked at the bedside, in management, and in nursing education. She has demonstrated expertise and scholarship in innovation and design thinking in healthcare and education, and collaborative efforts within and outside of healthcare. Scholarship endeavors include funded grants, publications, and presentations. As a leader, Dr. PIERCE: strives to empower others to create and deploy ideas and embrace their professional roles as leaders, change agents, and problem solvers. In her position as the Sr. Course Development Manager for Elite, she works as a project engineer with subject matter experts to develop evidence-based best practices in continuing education for nurses and other healthcare professionals.

Transcript

Candace Pierce: Hello, I'm Dr. Candace Pierce with Elite Learning by Colibri Healthcare, and you are listening to our Elite Learning podcast where we share the most up-to-date education for healthcare professionals.

Welcome to our episode on pulse oximetry: what impacts accuracy? We're going to delve into the hidden truths behind this medical device and its actual impact on patient care. It's actually a critical issue in healthcare. We may not have known that this was a critical issue until just recently, but this is a critical issue: the accuracy of pulse oximeters and their potential bias against patients of color.

Did you know that pulse oximeters, a staple in monitoring oxygen levels, might not be as reliable for everyone? Recent studies have actually shown that these devices can give inaccurate readings based on skin tone, leading to significant clinical consequences.

And I do want to point out that the margin of error for these devices, though it may seem to be small, can actually be clinically significant, especially in critical care settings, and especially if it's you or a family member that experiences the issue. Joining me for this discussion is Donya Winters. Donya, first, thank you so much for being here today for this very eye-opening topic.

Donya Winters: Thank you for having me. I'm really excited to be here. It really is an important topic.

Pierce: Can you share how you became interested in this topic?

Winters: Sure. Actually, I was a frontline COVID nurse, and there were some trends that came about that we kind of noticed at the time, but we didn't really have a lot of time to pay attention to them in the moment because there was so much going on.

But I did notice that, for some reason, some patients' pulse ox readings were not matching their symptoms or their ABG results very well. And I didn't realize that whether it was color oriented. This whole time, I thought it was COVID oriented. I thought it had something to do with the disease, not the skin tone.

It wasn't until after that I started doing some research for a book I'm writing that I found that it's a syndrome, so to speak, called hidden hypoxemia—or occult hypoxemia, silent hypoxemia—and it actually is predominant in African American males, where the pulse oximeter gives a falsely high reading, and that made so much sense when I reviewed clinically what I had seen during those 18 months. So that's how I found out about it. Everybody should know about it.

Pierce: And we're going to really dive into what you were just mentioning as we go through today. But I'm really excited for us to uncover the science, the origins of the problem, and just really talk about a potential path forward toward more equitable care—because what this comes down to is more equitable care.

Winters: Yes. It would seem like this is a small issue, but you know, it's like somebody turning on the light on a much bigger issue that a lot of people don't want to talk about, that we absolutely have to talk about.

Pierce: I agree, absolutely. Now I want to start at the beginning. You know, a lot of us, we walk into our rooms, we put that pulse ox on their finger, we wrap it in the critical care unit—you know, because that's where I spent a lot of my time as well, especially during COVID. But we don't really pay attention to how the pulse oximeters actually work.

It's like a tongue twister today to get all that out, but how they actually work. You know, we just get our reading and we move on about our day to the next thing we have to do, the next patient, and just making sure that our patients are well cared for. But let's start at the beginning. How do these pulse oximeters actually work?

Winters: Well, it can be kind of deceptive because this whole time we think it's actually measuring oxygen, right? But it's not really doing that at all. The pulse oximeter works by measuring two different kinds of light and then doing a bit of math. It doesn't really have a whole lot to do with oxygen in and of itself.

So, for example, oxygenated blood absorbs infrared light. Unoxygenated blood absorbs just red light. So the oximeter—the device—is programmed to take the light frequencies of infrared, the light frequencies of just red, create a ratio, and display that ratio as a percentage.

So let's make it easy. Let's say you've got a patient that's in respiratory distress and you put that pulse ox on them. The pulse ox shows it absorbs four waves of infrared light and one wave of just red light. And that sounds pretty encouraging. It sounds like, okay, we've got four waves of saturated oxygen and one wave of unsaturated oxygen. But that's a one-to-four ratio, right? And one over four is 25%. That means 25% of that blood is unoxygenated, which is going to reflect back on the oximeter as 75%—which means your patient clearly is in respiratory distress. That's how that works. It's just light and math.

Pierce: I had no idea that math was a part of the internal computer of the meter. I really had no idea there was a lot of internal things in that other than just that red light and then the display that shows me. I had no idea. So that means that light absorption is a central piece to how it functions. Are there different wavelengths? What is the role of different wavelengths?

Winters: Yup, right? It's shocking. It's the infrared versus the red like I talked about. The infrared has a different wavelength than just the red does. So when it's pulling those wavelengths, it basically can tell the difference between an infrared wavelength or just a red one. And then that's how it determines oxygenation versus deoxygenation. So it has to do with how our skin absorbs light, not how oxygenated we actually are. It has to do with how we absorb different wavelengths of different kinds of light.

Pierce: How skin pigmentation should have, in the beginning, played a factor in the wavelengths—because, I mean, you have different colors, and each color has a different wavelength for light. So, and then we have different colors of skin. You would—I guess I'm trying to understand here—how we missed a big piece of light wavelengths.

Winters: Yeah. So if we just look at what we know about basic color—not even medically, not to do with medicine—most people know that white reflects color and dark absorbs color, right? So white is the absence of any color. Dark is the collection of all colors. So, for example, I grew up in Wisconsin. In the wintertime, we need a whole different set of sunglasses than we do in the summertime because the sun reflecting off the snow is blinding. So if you have a device that was tested around Caucasian skin—which is, we call it white, but it's not so white that it's reflective—this device was created to work for Caucasian skin, and it does.

However, you put a darker skin on there that absorbs more color than light-colored skin—because dark absorbs more than white—what's happening is you're getting a false high because all that device is meant to do is count color and create a ratio. That's it. It has nothing to do with actual oxygen.

So it perceives that more light is being absorbed because of the darker skin—because dark absorbs more light—and it's reflecting a higher O2 saturation rate than what the patient of color may actually have. That's a big deal.

Pierce: Absolutely. So how did researchers first discover that these meters were giving inaccurate readings in patients with darker skin? I mean, I know you said through COVID, you started seeing it. But what about researchers—people who should be researching this?

Winters: This makes me really sad. It wasn't discovered until 2020. *The New England Journal of Medicine* published a report in 2020 that noticed those differences and noticed why those differences were happening. But that knowledge never even made it to the bedside. It never trickled down to any of us who were caring for patients at a time when we needed that information. 2020—that's COVID. We needed that information. But what is shameful to me is that it took until 2020 for somebody to start asking those questions about what's going on with this disparity. Because I don't work in respiration. I don't work in ICU. Somebody had to have noticed this before I did in the middle of COVID. I'm not that smart. But it was 2020.

Pierce: 2020 is when, I guess, the first article came out where people started sharing the research into this. But how long have we had the meters?

Winters: That's a good question. That's a question I don't know the answer to. I'm not sure how long pulse ox have existed. I mean, I've been a nurse for many years, and they've always been around as far as I know. And it was just a standard of care.

They don't even, in nursing school, they didn't explain how they worked. They're like, okay, this is what you do. And I know why they were developed. It was financial reasons, right? Because isn't it always, you have a standard set, and nurses generally buy their own oximeters. You have them in the hospital, but we usually have our own, and that doesn't cost the hospital anything. But if you want to run an ABG on a patient, that's going to cost the hospital something. Ten dollars—only ten dollars—but it's going to cost them something. They're going to bill you 200 for it or bill your insurance 300 for it. So I understand why the device was developed and why it seemed like a good idea at the time to save money. But that money that it saved actually cost lives.

Pierce: True. Yes. That's, you know, you're right. In nursing school, nobody ever really talked about it. I've never been taught, never taught anything about pulse oximeters.

But, you know, clinically, we do teach them how to chart it, obviously, how to read what it says, how to put it on. But like you're saying, nobody was ever telling us how these actually work.

And I just find it so interesting that we've had these for a long time—or something like them—for a long time. And it wasn't until 2020 and then, you know, the kickoff of COVID that somebody actually became aware that this was happening. I just—that blows my mind.

Winters: I mean, even when they were developing the science, I would have thought some scientists would have said, "But wait, if this is based on light absorption, what about light absorption for dark-colored skin?" Because that works differently. Why didn't anybody ask that question?

Pierce: Or why didn't they ask that question when they were developing these? You know, we're talking about light, and they're saying in the research how it works. And why was the question never raised early on in the research of, "Light reflects differently"?

I mean, I know, and I live in Florida and I know in the summertime, I do not want to wear a black shirt outside because it's so hot. You're pulling in so much heat from the light that your shirt is absorbing, versus the white shirts, the lighter-colored, where it's, you know, it's a little bit cooler. Okay, so we talked about how skin pigmentation interferes with light absorption in these devices. Now, do you know how much of a margin we're really talking about?

I mean, I know anything that affects patient care from an individual level is going to be clinically significant. It may not be to the research as a whole, but to that person, it is clinically significant—to them and their family. So what is the margin of error that we are really talking about?

Winters: Well, it depends on what you believe. If you believe the study, the study says it's only 3 to 5%. And that's still significant. But in my particular case, if I had put the pulse oximeter on a white patient that was struggling, that would have come back to me at 75%. It came back to him as 98%. That's a 23% margin right there. I don't believe those numbers are true, and if we only have one study, I don't think we can count on that 3 to 5%. We absolutely have to do more studies, because I'm sure it's way more clinically significant than just 3 to 5%. That's my opinion. The science isn't there to back it up, but my experience was there.

Pierce: Yes. Well, and it makes me think back to taking care of patients where—I mean, how many times have we put that pulse ox on someone's finger who looks like they're struggling, but it shows that their percentage is where it needs to be?

And so we're like, it's anxiety. Let's give them medication. Let's help them slow down their breathing. But looking back—were they really struggling? And is that somebody who, if we would have caught that earlier, maybe they wouldn't have passed away? Or maybe they would not have had to have the care that they ended up needing to have because we didn't catch something earlier. And so now it just leads me to question—go ahead, you're going to say something.

Winters: No, no, it's OK. And I mean, that's the kind of thing that haunts me, especially when I, there was hardly anybody we were saving during COVID anyway, to be frank. And this just haunts me, because that's exactly what we did. So many people had anxiety during COVID. They were so afraid, they couldn't breathe, that a lot of times they would work themselves up into that state, right? So for this particular patient, I was so excited.

Pierce: So many times we sat in patients' rooms with COVID during that time, just trying to get them to slow their breathing down because they were so anxious. They were so worried.

Winters: Yes. So for this particular patient, this was during wave two. And if you worked during COVID, you know during wave two, we really didn't save anyone. We lost just about everybody.

So this guy walked on my floor of his own volition during wave two, which was so exciting for us nurses. We actually had somebody who wasn't on a CPAP or a BiPAP that we could talk to. He was very flirtatious. He was an older man of color. He was really close to the nurse's station too.

So I was in and out quite a bit talking to him because during that time I was just on the phone with families all the time for the most part. Patients weren't very responsive. So I was in and out, and he was doing pretty good. He hit his call light, and I went in there to see what he was doing, and he said he was having a little bit of trouble breathing.

So I put him on two liters—because he wasn't even on any O2 at the time—put him on two liters, checked his O2, but it came back in the upper 90s. So I said, I'm just going to put you on this oxygen for a little bit. We're going to see what happens. I went and made a phone call and in the middle of the phone call, his call light went off again. So I went back in there and he was starting to use accessory muscles. He was starting to sweat. I cranked up his oxygen to four and took his pulse oximetry again and it was still in the mid-90s. So I'm like, okay, he's having some anxiety. So I did the whole thing, please slow down your breathing. I went and pulled some PRN lorazepam, gave it to him. But even by the time I came back to give him the lorazepam, and you know lorazepam takes a while, it's like 30, 45 minutes to peak. He was still, I could see he was just struggling. So I put him on a non-rebreather, turned it way up, and then called respiratory. And they came and I asked them to do an ABG. And they said they need an order for that to do an ABG and I just kind of pointed to him and I'm like he can't wait for an order. I had no idea where the hospitalist was. I'm like just please do it. I'll take the hit for it later. She ran it and he was in the 70s. So I hit. Yeah. So I hit rapid. Hospitals comes down. Starts screaming at me of course for ordering the ABG without him. But we were all so stressed. None of us were acting like ourselves. He normally wouldn't have done that. Just had to have a lot of grace during COVID. But I went up to the ICU, grabbed—yes, right? Later he said, "You did the right thing. That was the wrong thing, and don't do it again." I ran up to ICU. They had one available NIV because somebody had just passed away. I ran down with it, we got him on it, and then he was sent back upstairs to the ICU, and he passed away overnight.

Pierce: I should have been saying thank you.

Winters: So I think this is how wave two went. They walk on your floor, and they die by your next shift. I don't know that we could have saved him. I do know I could have taken the terror out of his eyes by getting him on O2 sooner. That's when I said, okay, we have to do something about this.

At our next department meeting, I asked if nurses could start requesting ABGs when they suspect something like this is happening. They gave us permission to do that for the rest of COVID, so at least we could get them comfortable. I don't think I could have saved his life. But when I went in there with that NIV, he was terrified. It was all over him.

While they were getting him on that, I was holding his hand, telling him we were going to get him more comfortable. I said I would call his wife, because that was all I could do. But I could have had a much bigger head start, and how many patients like that did I have in 18 months?

Pierce: Yes, that we all had in that time. It just brings tears to my eyes. I remember being with one of my coworkers in the ICU, and I couldn't find her for a while. I looked into her room, and she was all dressed out and just holding their hand. When she came out, she said, "I made a promise today. I wasn't going to let anybody die alone."

So as you're talking about it, I can feel just that. I can feel it. It does come back. I don't want to bring that up fully again. It was a lot. But it goes back to the lack of diversity in clinical trials.

Winters: It comes back, doesn't it? Yeah. Thanks for being out there with me, by the way. It was a hard time.

Pierce: That structural bias in device development really contributed to us not being able to identify this earlier. And it took a pandemic to serve as this pivotal moment to bring this issue to the forefront so that we could start having discussions like this on policy and regulatory changes. But in research and in development, we have to start thinking about these types of things.

Winters: We have to do better.

Pierce: We absolutely do, and we're seeing that there is a specific population where this inaccuracy is particularly dangerous. You just described it.

Winters: Yes.. So, I mean, let's look at the decades prior to the pandemic with the asthmatics, and pulmonary fibrosis, and COPD, and lung cancer. All those patients of color with those diseases were suffering unnecessarily that whole time. And nobody was asking the questions.

Pierce: And all this time, not being able to breathe well also mimics anxiety. So I'm seeing that in my head, and I'm seeing so many of my patients who—because I started out on a cardiac floor and then I worked my way into the ICU—and so I've seen so many patients come in with darker skin who have struggled.

Yes, we've had Caucasian and lighter-colored skin patients come in who've also had the same struggles. So, in my head, I'm thinking, they all seem to probably be anxiety. But how many other patients did I have where I didn't do what they probably needed done because I didn't know better?

I didn't know, potentially, that what I was seeing for their vitals was not actually what was happening in their body. Yes, and we trust a lot of our policies and guidelines. And we're thinking, well, they've done the research. And I know for me, pulse ox readings have been around the entire time I've been on this earth, basically. Why would I doubt that they don't work?

Winters: Yes, exactly. And the tachycardia doesn't tip you off, because you have that with hypoxia and anxiety. So that's not a clue either.

Pierce: Yeah, yeah. So this is not at all to make anybody feel guilty. It does make me think back, and I think it's going to make all of us think back as well. And it's because we care about our patients and we care about their experiences and what they're going through and we should and that's what makes us amazing and great profession and enjoy what we do. But I think it is going to make people think backwards and I just want to throw that out there. This is not to make anybody feel guilty. Nobody knew. Nobody knew that this was happening. Nobody knew that they didn't work the way they say that they're working. We didn't know. We know now. So now

Winters: Yep. We know now, and we have a responsibility to change it because we know.

Pierce: Right. Yes. So now I want to just kind of talk about clinical consequences and the implications that we're seeing. Earlier, you mentioned the occult hypoxemia. So what is occult hypoxemia? Why does that matter clinically?

Winters: So occult hypoxemia is exactly what we've been talking about. You might hear it referred to as hidden hypoxemia or silent hypoxemia. It's when the reading on the device does not match the clinical manifestations of what's going on or the ABG—or both. It's a deceptive reading. It's a false high reading.

And of course, that is significant because your patient is in respiratory distress and you're unaware, and you might be calling it something else and medicating it another way. When a little morphine or some oxygen—or COVID aside, even with COPD or pulmonary fibrosis or lung cancer, when the lungs are full of cancer—that's a whole different route than treating anxiety if your device is wrong.

As a nurse, we're always critically thinking, my device is telling me it's not oxygen, so what else could it be? And you're just ticking through the list. What else could it be? We're going to medicate that. I'm going to call the doctor. I'm going to say, this is what I'm seeing. And they're relying on me to tell them what's going on.

Well, the O2 sat's 95. No, it's not. Let's get an ABG. The O2 sat's 80. That's very clinically significant.

Pierce: Right. And typically, when we're checking our list in our head, if our O2 saturation is good, we're not going to jump to, "Can I get an ABG?" Because we're believing what we're seeing on the monitor. So that's not where my brain immediately goes.

If I've treated everything else that's in my head that I'm checking through, then I'm like, okay, maybe we should get an ABG just to make sure that we're not missing something else. But it's not going to be the first thing I think about if my pulse ox is within normal limits.

Winters: No. I mean, I would have to see cyanosis, diaphoresis, a lot of accessory muscles. I'd have to see that, and there's a great deal of discomfort between here and here. But the earlier signs aren't going to tip me off to that, for sure.

Pierce: And if we get to those later signs that you're talking about, usually our outcome is not going to be as good as it would have been had we caught it earlier, before we started seeing the really bad desaturation symptoms.

And I think that leads us to what are some of the clinical consequences when we are thinking we're seeing an oversaturation—basically, it's an overestimation of the oxygen saturation in their blood. So what are some of those clinical consequences?

Winters: Yeah, those are respiratory distress and, like you said, more poor outcomes, transfers to higher levels of care, death.

Pierce: Bam. Yes, yes, bingo, and if we're having trouble with our hospital administration understanding what we're saying and why we're asking for an ABG even though the pulse oximetry meter is reading high—well, if we're having to increase their level of care, if we're having to put them

in ICU—we've taken ICU beds away. We are now costing you more money trying to care for this patient, had you just let us get an ABG, and we could have caught this early on.

Winters: Yes, and that's kind of how you have to talk to them too. You have to hit them where it hurts, because unfortunately, what hurts us isn't the same as what hurts them.

So yes, if you put it bottom line financially, you're going to be paying more out of pocket because it's going to be a higher level of care. Your mortality rate is going to go up as a hospital, which is not good for them, their numbers. You have to hit them there, because that's what they understand.

Winters: And that's what's hard, because as nurses, we just want to scream about patients and quality of life all day long, but we have to hit them where it hurts them. And that's where it hurts them.

Pierce: And most of us didn't go into nursing strictly for the pay. Yes, we enjoy being paid for our job, but we actually went because we care about our patients—for the majority of us, for our entire profession.

We are one of the most trusted professions for how many years now? That really says something. But then to hear that, as a nurse, I can't trust my devices—how many other devices can I not trust?

Winters: Right. Exactly. I mean, I think a lot of nurses look at that when it comes to things like blood pressure cuffs. If it says 70 over 30 and your patient is sitting up talking and eating, you know to take it on the other arm. You know to get a different cuff. You know things like that.

But we've never had to question that with an oximeter. It just never crossed our minds.

Pierce: Well, and if I don't trust the machine for a blood pressure reading, I'm just going to go take a manual. You know, I can't do that with a pulse ox meter.

Winters: Right. Exactly. It's an ABG. You have to do something else.

Pierce: Right. Yeah, right. But then I have to have an order to be able to do that. I don't have to have an order to go take a manual blood pressure, but I have to have an order to go get an ABG if I don't trust the pulse oxygen machine.

Winters: Right, for an ABG.

Pierce: Isn't that interesting?

Winters: Huh. Yeah. It brings up a lot of stuff. It brings up a lot of stuff medically, and it brings up a lot of stuff ethically, of course. I mean, that's the huge issue. Even medically, like, do nurses need a little more autonomy? Will that help? Yes and no. I mean, we need devices that work, that do their job. We need a device that measures oxygen, not light.

Pierce: So that leads me to ask: how do disparities in readings contribute to broader health inequities that we're seeing?

Winters: Right. So this just leads to some of the big issues that a lot of people just don't want to talk about. You don't have to believe in privilege for it to be true. You don't have to believe in marginalization for it to be true. And they're both true.

When you work in healthcare, you see it all the time. Another problem was—even during COVID—you could see the marginalization, because the African American culture, or the people of color, came in in much worse shape. And that's because they hesitate to come to the hospital. They're often dismissed, or they don't have the kind of healthcare benefits that people not of color more often have.

So a lot of times, they came in in worse shape. This shines a light on some of those issues as well—issues that we talk about, but haven't really been super tackled, that absolutely have to be addressed.

Pierce: Right. And I don't know what year the research was done and these machines were developed. I don't know what year that was. But not that long ago, I did a podcast on gender bias.

Looking at the history of why women were not a part of clinical trials—while I'm not saying that it is right in any way—I did see where it fell more into, "We're trying to protect women." We're trying—what if they're of childbearing age, what if they're pregnant? We're trying to protect them just in case. And so I could see that train of thought for back then, because we didn't have ultrasounds like we do now. You had to wait until you were further along.

So I could make sense of some of that. I don't know the history on when these machines were researched and developed, so I can't say why the research was only done on lighter-colored skin. I don't know what the history is there.

Winters: It still is for the most part. It's always been a very patriarchal-type setting for medical device testing. It always has been. It still is in a lot of ways, and that has to change too. And I get that they said that about trying to protect women. I just think women have been part of the marginalized population—not as marginalized, I'm not saying that at all—for so long that...

Pierce: Right. But in healthcare, they have been. Yeah, for sure.

Winters: Yes. Yes. And a lot of times, women were being treated for anxiety too, when they were in respiratory distress. They're women, they're stressed out, they have anxiety, they're having a panic attack.

So in that way, we belonged in that group. In a lot of ways, we don't belong in the group we're talking about today, but yes, we have been lumped in with that group as well. And it's just a very, like I said, very patriarchal structure, and that needs to change.

Pierce: Absolutely. Are manufacturers doing anything, or are they failing to do anything, to try to fix these issues? Have any manufacturers come out and said, "Hey..."

Winters: No, not really. They're only going to do what they're required to do by the FDA. And unless the FDA makes those changes, changes the regulations for that, it's not going to change. Because for them, it's about money. It's not really about patient care, right?

Pierce: It's not clinically significant yet to them.

Winters: Yeah, and I really don't see the FDA making those kinds of changes anytime soon unless we all start really, you know, banging the drum, which is what we need to do. We've got to start insisting that there be some changes.

And technology—I've been looking into this—technology is so much more forward than anybody realizes. There are potential solutions out there. They're going to cost some investment, but there are solutions that will totally take care of all of this for everybody across the board.

I was researching what's being done, and I had an idea for something. I didn't even know if it was possible, so I started doing research on that—and it is. And once I found out it was possible, I just went ahead and applied for the patent for it. I haven't done anything with it yet, but I'm just really excited that there are things we can do. They're just not being done.

Pierce: Right. Now, what role does the FDA currently play in ensuring device accuracy just in general?

Winters: They're the ones who have all the regulations in place. Device companies—they don't answer to patients, they don't answer to hospitals—they only answer to the FDA. The FDA is in charge of all of that, setting those rules and parameters for them.

And, you know, the FDA is a big part of our government. It would take a lot for them to change what they're doing. They would have to come under a lot of pressure or be threatened to have funding pulled or—you know, then we start getting political, which is unfortunate, because healthcare should not be politics ever. And it is. And that's a big part of the problem.

Pierce: Now, do you think that pulse oximeters maybe should be reclassified as high-risk devices to improve the oversight of them?

Winters: That would help. Right now they're only a class two, which is considered low to moderate risk. But now that we have this information, this is high risk. This is a high-risk device. And we just don't look at it that way.

But it is, because the misreadings are a life-or-death consequence. So bumping them to a class three would certainly help. It would require more rigorous testing. The device companies would have stricter parameters and they would have to go about it differently. But I don't know how... You can't change physics. Physics are what they are. Light absorption is what it is. If you are doing a device based on light absorption and math, that's never going to change. So even moving it to a class three device, I don't know how that would help because science is science. We have to do something completely different, I think. That's just my opinion.

Pierce: You would think the math would change. You would think that the math for lighter skin tone versus darker skin tone would be different. Like there should be two settings—one for light-colored skin, one for... yeah.

Winters: True. Yeah, you could, yes, I was going to say you could do a separate setting, sure, absolutely. But you've got people that are in the middle too. It's not just, you know, really black and white.

You've got Hispanics, you've got lighter-colored African American people, and then you've got very dark African American people. And so that spectrum, I just think, allows for a lot of error.

Pierce: Absolutely. The more choices we have, the more opportunity for error. You're exactly right. Great. So what can frontline healthcare providers actually do to compensate for these inaccuracies that we're sort of—

Winters: Yeah, and it's subjective. I think you have healthcare providers that rely too much on medical devices, and you have healthcare professionals that rely a lot on their own brain. So I think we need to really emphasize critical thinking skills even more in nursing and medical school. You have to, in your gut, nurses have nursing guts, we really do. It's a thing. If something is telling you that something's not right, you have to honor that for your patient.

If that means you're pushing the hospitalist or the house supervisor who doesn't want to give you what you need, you just keep going until you get what you need. And I've always been kind of that nurse anyway. It gives me a love-hate relationship with doctors in the hospital, because I will advocate for my patient practically to walking off the floor. But things aren't adding up. There's a reason for that. If you're seeing a lot of this when they're breathing, they're starting to sweat, there's no reason to think that they would be anxious, then that's telling you something. So you have to start looking as the devices as like a helper, not a diagnostician, right? It's there to help with what you already know in your own skillset. It's not there to make decisions for you. You just have to start looking outside of those devices at what else you're seeing in the big picture. I think that's the only thing we can do right this second.

Pierce: Did you know that the meters were classified as low to moderate before you started looking into them? Because it would just—see, no, I didn't either. But I'm thinking, yes, low to moderate.

If we all knew that the risk of these devices could hit in the moderate area, would we have been more likely to be like, this isn't adding up, let me go ahead and get an ABG?

Winters: Nope. I didn't know that in nursing school. I didn’t.

Winters: Possibly. Possibly. And I think they actually need to be high risk. We need to know it's a high risk, and we need to know what that means. It means there's a moderate to high risk if we're depending on those results.

You know, there's a high to moderate risk that that might be wrong. If it's low to moderate and we're not even taught those risks, we're not taught those classifications, and that—I think that would be

something we need to rely on too. Just like we know that the pulse isn't always right, why did we assume the oxygen was right?

Pierce: Great. What documentation practices do you find are useful when we're suspecting there are inaccuracies in our readings?

Winters: So here's where I want everybody to do as I say, not as I do, right? We're taught so much how important documentation is, and it truly is. Now, I won't lie—during COVID, there were times where I sat down after my shift was over, pulled out like six pieces of paper, and did all my documenting for everybody for the whole day.

Pierce: Will you do your COVID. wait a second. I had to do it even before COVID. Let's be real. You had those days.

Winters: Okay, yeah, right. So yes, you do. And that means you're missing trends. You're missing a lot that we should be able to be keeping an eye on. And that's a whole other can of worms that has to do with nurse ratios and things like that. That's a whole different education class.

Pierce: Yeah, workload. That's a whole other—like five different podcasts is what that is.

Winters: Right. Exactly. But I think one of the things that's important for nurses to do when documenting is not just write down what the O2 is, because we don't know that that's true. We know what the SpO2 value is on the oximeter.

So instead of writing "O2 is 90," no—we don't know that that's true. We know that the SpO2 equals 90%. So we're not making a judgment about the oxygen. We're documenting the reading on the device.

Then, "SpO2 = 90%. However, patient is complaining of shortness of breath. Respiratory rate is 24. Patient is diaphoretic, tachypneic." You know, not just the readings. We can't be documenting only the readings. We have to be documenting what they're complaining about, whether we see it or not, what their complaints are, and then what we're seeing as well. And I think if we start getting that specific in charting, which is really difficult to do, but if we do that, then that's going to shine light on some areas that are missing. And if we ever had to testify or whatever, we can say, I said, this is what's happening with the patient. This is what the device was saying. You know, the discrepancy is there but it requires really specific charting, which requires time to really specifically chart.

Pierce: I miss paper charting. You know, in the unit you had—here's this—you flip it this way, flip it, you flip it all these different ways, but everything I needed was right there. I could write exactly what you're saying. I could write long form—exactly what I wanted to say.

So I wish, a lot of times when I'm looking at charting, that I would have my vitals right here at the top of the screen, and then right underneath the screen I would have my note section and I could just type. But, you know, charting today has gone to basically charting by exception, and you're clicking all these things. By the time you're going through 10 pages of clicking, you don't even remember what you wanted to put in your note anymore.

Winters: No, no. And they're kind of teaching you that less is more—but it's not. More is more. And I think a text-to-chart app would be great too. If you could just speak your narrative or real-time talk about what you're seeing as you're seeing it. I mean, that technology is out there. They just don't want to spend the money on it. But talk-to-text has been around for how long?

Pierce: Right, especially if you get called into court.

Winters: A long time. But we need to start creating clearer pictures.

Pierce: I agree, absolutely. And that's for everything—not even just showing that these inaccuracies, that we are seeing these inaccuracies—but it means so much that we document. It should be documented. But we're not. We don't have time to document, or we don't know how to document it, because we've got to go through 10 pages of check marks. I hate—I hate this so much.

Winters: Yep. And yeah, I'm a certified legal nurse consultant as well. And I'll tell you what, that lack of charting will get you in trouble in court every time. You'll lose your license.

Pierce: I overchart because I worry about that. So I'm like, no, I'm checking all the things. They're like, no, you just have to check what you didn't see—charting by exception or whatever it is that they say. No, no, no. I'm charting all the things.

Winters: Yes, especially if I saw something and asked for something and it was denied.

Pierce: Right. Yeah, put that in there as well. Now, newer meters—are we seeing any better ability to address skin tone disparities in any of the newer machines that are coming out?

Winters: No, not really. Some of them say they're working on it, but they haven't offered up any proof of concept, or I haven't found any real trials out there. It's like either the information isn't being presented to these device companies yet, or they don't care because the FDA regulations aren't out there. I'm not sure which it is. It could be both.

Pierce: It's getting huge—the responsibility to fix this. True, very true. And you know, I don't really see a lot, in the different hospitals I've worked in. You'll see new meters come out for sugar—for checking your sugar—but I do not see a lot of new SpO2 monitors coming out. I don't see them buying them. I just see the old ones.

Winters: And just following your ABCs—your ABCs, you know. The airway is more important than blood sugar. So those oximeters should be at least as important as that.

The way we track blood sugars is crazy to me anyway. How often we do it and for everybody—and especially since stress causes higher sugar levels—so that's not really real either. But the oximeter should at least be held to that standard.

Pierce: Absolutely. Now I want to look at just some broader implications of this bias that we're seeing. Are there other biometric devices that also show racial or skin tone biases, like facial recognition devices or wearable devices?

Winters: Yes. Yes. Anything that's sensor-based—sensor-based tech works on light, works on wavelength. So yes, there's like a 35% discrepancy, I think, on face sensors in African American women of color.

Yeah. So all of those things need to change. It's like the testing that goes on for devices globally seems to think that the world is white. And we are actually an extremely narrow margin of global color. Yet everything that we develop—all our tech—is based on white male patriarchy.

It's insane to me. And I mean, that's not just the United States. It's happening everywhere. It's happening in countries of color. And I just can't make that make sense in my head. I don't know why that's happening, but that's exactly why all of this is happening—because our tech is built around and by both. It's tested and developed by mostly white men. And that's a problem.

Pierce: Yeah. Why do you think that the algorithmic and hardware bias that we're seeing is so widespread in medicine? I mean, I know I talked about gender bias and the thoughts way, way back in the day when things first started. But again, back then it was a patriarchal—patriarchal, not patriotic. I'm combining multiple words together.

Winters: Yep, patriarchal. Yeah, I know what you mean. They thought they were the same back then anyway.

I think it's just—nobody's really sat down and said, hey, is this still working for us? And it's just been passed forward and forward and forward. Here's our test groups. Here's the people who are designing it.

Pierce: Yeah, I think so.

Winters: And nobody's ever stopped to question it. "Hey, this isn't our patient population. I don't have only white male patients on my floor." I just don't think anybody's asked, "Is this still working for us?"

And I think the population of color is so tired of banging the drum for everything and not being listened to or paid attention to. Pulse oximeters are the least of their concerns, quite frankly, I'm sure. They have much bigger fish they're trying to fry. And that makes me terribly sad.

It just shouldn't be. Our technology development and testing needs to be as inclusive as our population is. White testing subjects should actually be in the minority of testing subjects, because as a global people, we're in the minority.

And I think it's just, "This is the way we've always done it." How much do we see that in medicine all the time? We do it because this is the way we've always done it. It's not working anymore.

Pierce: So much. Yes. Now, how can we advocate for more inclusive and equitable medical device development? Where do we start?

Winters: I think now that we know better, now that the information is out there—especially healthcare providers of privilege like we are—I think we are the ones who have to start pushing that forward.

We have to start putting pressure on administration. We have to start putting pressure on the FDA. We have to start putting pressure on other regulatory bodies of government—legislature, Congress. We just have to start.

There are a lot of other things like that being created right now. There's a lot of movement out there. So it makes a difference. It can be done. But I think it's going to have to come from what's considered the privileged group.

I imagine the other populations are not only tired, but they have a history of just not being represented well. And I think, you know, it was Maya Angelou who said, "Once you know better, you do better." And I think having that knowledge, we are absolutely responsible for trying to press for that change. I think that lies on us.

Pierce: Absolutely. And as we've been talking today, some of the things that I've thought about are, from a leadership perspective, if you're in a hospital or a facility that uses these devices—which the majority of our facilities do, from clinics to hospitals to rehabs—it just seems that we might could start with changes to our guidelines.

Changes to the guidelines in the sense that, if we know the symptoms we are seeing and observing do not match what the pulse ox reading—the SpO2 reading—actually shows, we can push for getting an ABG. Can we? Where do we start with that?

I think it starts with education. Until changes are made, I think we need to advocate for education for all healthcare providers that this is happening. And then we need to push for accountability and being able to take care of our patients. "Hey, this patient needs an ABG. Yes, it might read that it's a 95% SpO2 reading, but they do not match that."

Winters: Yeah, take the $10 out of my check. I'll pay for it if I have to, right? Just give me the ABG. Yes, exactly. If I'm wrong—yeah.

Pierce: I mean, if I'm wrong, right. So I see that as being a start that also helps us to advocate and push for more inclusive technology design as well. My priority—my head immediately goes to, how do I take better care of my patient now that I know this?

Now, how can we start pushing for inclusive technology design from the start?

Winters: Yeah, exactly. Inclusive technology—that's when you have to start pushing government regulatory bodies. But I agree with you, absolutely. I agree it starts with educating our institutions that this is going on.

What kind of policy and procedure changes can we make in-house to cover that? Can we give nurses a little more autonomy?

And now, as you know, you have nursing students rotating through your units all the time. The education can start there. If they're not getting it in school, it's our job as senior nurses to pass that on.

So if you get an example of that, if they're on with you—I love that when that happens—you're like, "OK, do you see? Do you see how he's struggling and we have 95% here? What do you think that could mean? What should we do next?" Get them thinking that way.

So the next generation of nurses that come up are already kind of in that mindset. But you're right. Before we can make the bigger changes—because that takes so long—it needs to start in-house.

Pierce: And I love what you said about documentation. We don't actually necessarily know what their O2 saturation is, but we can tell you what the SpO2 reading is—what the value is on the machine. That does not necessarily mean it is correct, but I can tell you what it said, and I can tell you what other things I saw and observed with the patient. And I can tell you what they complained of. I think that is so important, too. So I'm glad you pointed that out.

Now I want to ask you: if you had the ear of the FDA—or any major medical device company, for that matter—what would you ask them to change first?

Winters: I would ask them to kind of start from scratch. Get rid of that technology altogether.

What I want to see—and this is what I applied for the patent for, so I can talk about it because it's already covered—but there's technology that's available that can be put into, like, you know those Listerine strips that are dissolvable? Little sensors can be put in those and placed on the patient's tongue, and the oxygen can actually be detected through saliva.

You can get an O2 reading. You can get a pH level. You can get a glucose level. And they're digestible sensors. You can't even see them. They're small, and it dissolves on the patient's tongue and transmits wirelessly to a monitor.

You have to actually measure oxygen. You can't measure light. We have to measure oxygen. So that's what I would say to a device company. What if we just started from scratch?

Winters: With what we know about the body and what we know about technology, if we could just start over—how can we do this differently? And then color and gender are not an issue. It's chemistry.

Pierce: And I also think that if we could have the ear of the FDA to say, let's go back and look at our regulatory requirements for research. How do we make sure that it is equitable for everybody?

Color, gender, short, tall, big, small, age, young, old—how do we make it more equitable across the board so that we're not continuously running into these issues?

We run into these issues with women. We run into these issues with skin tone. Now think about the woman with a darker skin tone. That—you can continue to step on all of the inequalities from age to skin tone.

How can we make this equitable so that we can take better care of our patients?

Winters: Yep. That's exactly, yes. And that's the question that they all need to start from.

Pierce: Yeah. How can this conversation we're having today spark broader changes in research, education, and clinical practice?

Winters: I just hope that whatever students or nurses listen to this podcast are as astounded as we were by some of the things that we found and get just as indignant and righteous as we feel about it. Because I think once we start coming together as a global community, start asking for change in our clinics and our hospitals and things like that, then you get a movement started. Then things really start to change. It just starts with conversations.

Pierce: And the data is out there. If you want to take this down, if you want to go to your leadership—I will say, most of the time when you want to see a change in an organization, you have to show them how it's going to hurt them financially. They don't really dwell on it as much as we do about the patient as a person. To them, it is the big numbers. But there is data, there is research out there that you can take to your leadership. You have to find it though—you have to dig for it. And it might be that you have to do the research yourself in your facility.

So maybe you set up a small study in your facility to try to show these discrepancies firsthand and how they're happening, because there is not a lot of research happening about this. This was just determined. And so it's been kind of quiet, but maybe you could help the voice get louder and louder to show that this is an issue and we need to fix it.

Yes, absolutely. Because it's our patients. We need to take care of our patients.

Well, Donya, as we come to the end of our time together, is there anything that you just want to make sure that you covered? Anything you want to remind the listeners as we come to the close?

Winters: Right. Yes. Absolutely. I agree. And if anybody's going to do it, it's going to be a group of nurses. I just want to remind everyone that once you become aware of something and have that knowledge, you therefore have a responsibility to do something about it. Because if you don't, then silence is complicity—and we've had enough of that. So once you're in possession of knowledge, you're just as responsible as anybody else for making that change.

Pierce: Absolutely. I agree completely. Thank you so much, Donya, for joining me on this discussion to just really uncover and address these biases in places we didn't even realize they existed.

Winters: Thank you, Candace, for inviting me. I mean, we could talk about this subject for probably a week and never cover it all, but I hope we've uncovered enough that really opens some people's eyes, because this was all very astounding to me when I did my own research and found out about it. So I'm hoping it just really opens people's eyes.

Pierce: Yes. And to our listeners, as you're seeing disparities in our care for gender as well as color—and maybe not intentionally when these devices were developed—I don't know the full history of

how the meters were developed. But you can check out our podcast that we released on gender bias to hear some of that history and how we got to where we are.

Now we are learning the importance of skin tone and how it's relevant to research. As we take time to learn more, we get to correct and we get to do better moving forward.

It takes us being together to really push for change and ensure that healthcare technology and healthcare research in general serve everyone equally. To our listeners, thank you for joining us. And I encourage you to explore many of the courses we have available on EliteLearning.com to help you continue to grow in your careers and earn CEs.