

**BBGuy Essentials 077CE:  
Implementing Pathogen-reduced Platelets with Pat Kopko  
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**Pat:** Hi, this is Patricia Kopko from the University of California San Diego, and this is the Blood Bank Guy Essentials Podcast.

**Joe:** Hi everyone. This is episode 077CE of Blood Bank Guy Essentials, the podcast covering the essentials of Transfusion Medicine. My name is Joe Chaffin and I am your host. No, you are not in fact hearing double. If you listened to the previous episode, 076, you might be experiencing a little bit of déjà vu hearing Pat's voice at the beginning. But this is in fact episode 077CE, and it continues my discussion with Dr. Pat Kopko on options to fulfill the recommendations in the September 2019 FDA final guidance on bacterial risk control strategies in platelets. We're going to talk more about that.

But first, you should know that this *is* in fact a continuing education episode. The free continuing education credit is provided by [TransfusionNews.com](http://TransfusionNews.com), and Transfusion News is brought to you by Bio-Rad, who has no editorial input into the podcast. This podcast offers a continuing education activity where you can earn several different types of credit, including: One *AMA PRA Category 1 Credit™*, one contact hour of ASCLS P.A.C.E.® program credit, or one American Board of Pathology Self-Assessment Module (or "SAM") for Continuing Certification. To receive credit for this activity, to review the accreditation information and related disclosures, please visit [www.wileyhealthlearning.com/transfusionnews](http://www.wileyhealthlearning.com/transfusionnews).

So as I said just a minute ago, Pat Kopko joined me for episode 076 to discuss the basics of the FDA final guidance on how we can protect our patients from receiving platelets that are contaminated with bacteria. I really urge you to listen to that episode if you haven't, because it lays the groundwork for this one (and you can find it at [BBGuy.org/076](http://BBGuy.org/076)).

So let me explain what we talked about then....No, there's too much. Let me sum up [*NOTE: Bonus points for anyone who gets the movie reference there!*]. The guidance offers multiple ways to approach this problem, ranging from things that are done in the blood center, like for example culturing a larger quantity sample from the platelet product, or implementing pathogen reduction technology (those are called "single-step" or one step strategies), all the way to things that are done in combination by the blood center and transfusing facility (most likely anyway), and those include, following a culture in the blood center, either adding an FDA approved point-of-issue test within 24 hours of transfusion, which potentially could extend the platelet shelf life up to seven days, or re-culturing the product at either day three or day four of storage. Again, that's just a summary, but you need to check out the episode for more details.

But before that guidance even came out, Pat and her colleague Elizabeth Allen at UC San Diego, as well as Colleen Vincent and David Reeve from the American

Red Cross published a paper in the journal Transfusion on how they implemented pathogen reduced platelets at UCSD. It's really a fascinating paper, and you can check out a link to it on the show page for this episode at [BBGuy.org/077](http://BBGuy.org/077). I urge you to really take a look at this article. In fact, Pat and her colleagues have made this article "open access," so even if you're not a subscriber to the journal Transfusion, you can get a copy of it at the link that you'll find on the show page. But this episode, it really consists of my continued discussion with Dr. Kopko on why she and her team made that pathogen-reduced choice, and what the challenges were along the way.

So, I want to be clear: As I said in the last episode, I am not endorsing any one strategy over another. I can't say that more clearly. In fact, if you remember, I've had Dr. Nancy Dunbar on this podcast before in episode 060CE (and that's [BBGuy.org/060](http://BBGuy.org/060)), and in Nancy's environment for example, the point-of-issue test works wonderfully and she loves it, and that's great. I think the answer is different for different facilities, and my goal here is not to say that everyone should just run out and "jump on the pathogen reduction train," but to show you how Pat and her team did it and why they made the decisions they made.

I introduced Pat in part 1 of this discussion, so I won't repeat it all here, but in short, she is a Loma Linda University School of Medicine graduate for her MD and pathology residency. She did her Blood Bank/Transfusion Medicine fellowship at Cedars-Sinai, and she has been a blood center chief medical officer in the past. She is now in charge of Transfusion Medicine at the University of California San Diego. She's one of my favorite people, and she's really, really, REALLY smart. So let's get right to my interview with Pat on implementing pathogen-reduced platelets. "Implementing Pathogen-reduced Platelets."

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**Joe:** Two episodes in a row with the great Pat Kopko. I am honored. Thank you so much.

**Pat:** It's a pleasure to be here Joe.

**Joe:** Well, it feels like it was just moments ago that we talked about the FDA guidance. Everyone, just a little secret, [whispers] it WAS just moments ago. But I wanted to take the opportunity to talk to you about what we had planned on talking about today, which was your very excellent article, on which you are senior author, and it is currently, as of the time of our recording in "early view" in the journal Transfusion. The article is called "Phased Implementation of Pathogen-reduced Platelets in a Health System Facilitates Increased Manufacturing at the Blood Center." Elizabeth Allen is the primary author on that, also with Colleen Vincent and David Reeve, which I believe are from Red Cross, correct?

**Pat:** Yes. Elizabeth is the associate director of transfusion medicine at UCSD, and I have to give credit where credit is due. Implementing pathogen

reduced platelets was my brainchild, but she's the one who really worked on writing this up. And then, Colleen Vincent and David Reeve from the Red Cross really helped us, Colleen with helping us with the implementation, and David with helping us with some of the statistics and helping us with the description of what they did to significantly increase production.

**Joe:** I think that honestly, especially in light of what has just happened with the guidance being implemented, I think that facilities would do themselves a HUGE favor by getting a copy of this article, which will be linked on the show page, by the way, everyone.

So Pat, let's just talk through this, because I think this is fascinating how you went to a facility that is using a high proportion of your platelets as pathogen-reduced from a facility that wasn't using them at all. So I think the most basic question is, why did you decide that you needed to do this at UCSD?

**Pat:** Well, there's a number of reasons we chose to do this, but first of course is that we really believe in safety. We have really ... At UCSD, we've really been working on implementing a culture of patient safety. And this is a patient safety initiative. Additionally, we had a septic transfusion reaction from platelets.

**Joe:** Uh-oh!

**Pat:** And it doesn't take many of those for people to ask, "Well, how could we have prevented this?" And of course, the answer was, "Well, there is this new technology that at the time, the FDA had just approved that will prevent this." And then it was, "Well, how do we get it?" And then it was, "Well, we have to convince our blood supplier that we will purchase it if you make it."

And one of the big problems here has been the sort of "chicken and egg" thing: Which came first? And that's been one of the big things that we had to do was work with our blood provider to make sure that they knew we were serious, they knew we were going to pay for it, because it is a lot of work and a lot of expense to bring this technology up in a blood center.

**Joe:** I definitely want to get into that, but as you were saying that, Pat, considering the audience that listens to this podcast, which as you know, I'm focused on people that are learning our field, I feel like I would be doing them a disservice if I didn't give you the chance not specifically for your case. I'm not ... No one needs to know the specific details of your case, but just generally speaking, it's my contention that septic transfusion reactions, bacterial contamination reactions, are among the most terrifying things that can happen in our blood bank world. And I don't know if you would agree or disagree with that, but I wonder if you would just give us

the thumbnail on how these things can present and what the consequences can be.

**Pat:** So I will give you some vague details of the patient we had was a liver transplant patient. And they were doing fine, it was maybe two days after the transplant. They needed platelets, we gave them a platelet, and they became highly symptomatic with sepsis very quickly. And fortunately for us, the transplant surgeon figured it out before we ever called her and told her, "Hey, the Gram stain is positive."

**Joe:** Oh wow, uh-huh.

**Pat:** And she ... The patient had been doing so well and then was doing so badly that she had blood cultures drawn and was giving antibiotics by the time we called her.

**Joe:** Wow, wow. That's awesome.

**Pat:** And, well, that is so awesome, because I think the outcome could have been a whole lot worse had she not been so on the ball.

**Joe:** So, again, not speaking necessarily specifically to your case. So when you say highly symptomatic, in general for people with these reactions, we're talking massive temperature increases, blood pressure changes-

**Pat:** Full blown-

**Joe:** Things like that?

**Pat:** Full blown sepsis.

**Joe:** Yeah. Yeah.

**Pat:** Full blown sepsis up to and including death.

**Joe:** Ugh. I'm shuddering just thinking about it. I don't ... Just off the top of your head, Pat, you and I obviously have, we graduated the same year from medical school, so we've both been around for a while. I would say I've probably seen in hospital world three or four of these, and they scared me to death every time. What's your experience been? Have you seen similar numbers or more than that?

**Pat:** I've probably seen a few more than that, just because of, from the blood center world-

**Joe:** Oh right, yeah.

**Pat:** ...Way back when, and we collected so many platelets. I don't know. Let me ask you a question.

- Joe:** Yeah, go ahead.
- Pat:** Which is scarier to you, an ABO acute hemolytic transfusion reaction or a septic transfusion reaction from platelets?
- Joe:** Yeah, they're both terrifying. I have received that call on several occasions, the, "We transfused Mr. Johnson in bed A's unit to Mr. Jones in bed B, and Mr. Jones is a group O and the unit's group A." Aah! Those are desperately, desperately scary. And as you know, patients crash really badly often with that. I'm not sure ... I mean, I'll put it to you this way: The feeling of helplessness that you get with an ABO hemolytic transfusion reaction is probably a worse feeling. The horrible symptoms from a septic reaction, at least you kind of feel like there's something maybe you can do with antibiotics, et cetera. But there ... I don't know. It's kind of a toss-up to me. Both are awful, let's just put it that way. How do you feel? Which is worse to you?
- Pat:** I think it's pretty much a tie.
- Joe:** Let's avoid them both, right?
- Pat:** Let's avoid them both, because if you think of the scariest things that you have ever encountered in our long careers, and that's what they are. They're the septic transfusion reactions and the acute hemolytic transfusion reactions.
- Joe:** I would say most anything that leads you to have to make that wonderful phone call to the FDA saying that "someone has died in our facility as a result of transfusion." Let's avoid all those things. That's my thought. Let's not go there.
- Pat:** 100%.
- Joe:** Yeah. Okay, well, sorry for that sidelight. So let's talk specifically about what you guys did and how you implemented pathogen reduction. I think some people out there listening to this, Pat, might say, "Well okay, so you decided to do pathogen-reduced platelets. You just called your blood supplier and you started getting 100% PR-platelets, right?" Isn't that how it works?
- Pat:** No, that's not how it works, and that's what I was talking about, the chicken and the egg thing, that I'm hearing all these conversations going on in Transfusion Medicine about, "Well, I can't do it because my blood supplier can't provide me 100% pathogen-reduced platelets. And I can't do it until they can." But the manufacturing for pathogen-reduced platelets is sufficiently complicated and sufficiently different that there is no way that any blood supplier can just "flip the switch" and provide all their platelets as pathogen reduced the day after they start the process. And it literally has become a chicken and egg thing, where, "Well, I can't do it until I

know that I have hospitals that will take it." And the hospital's saying, "Well, I can't take it until I can give it to everyone."

**Joe:** [Laughs] Yes.

**Pat:** Yes.

**Joe:** That's a perfect summary. That is a perfect summary of this. It's almost ... I mean ... Chicken and the egg is the best way to describe it. That's ... it's like who's going to ... almost like a who's going to blink first kind of scenario. So again, how did you get past that? How did you, in the great mind of Pat Kopko, how did you get around that concept to say, "Okay, guys, let me be the voice of reason here and let's move forward."

**Pat:** So as you well know, I can be persuasive when I want to be persuasive. [laughs]

**Joe:** No comment.

**Pat:** As you also know, I am not exactly a shrinking violet.

**Joe:** 100% true. And that's a positive. That's one of my favorite things about you. Don't take that wrong.

**Pat:** And so I ... first of all, it was not much difficulty to convince the hospital we had to do this. I went through our quality council. And in addition to doing this, we had just done the Epic best practice alert for, if you try to order blood for a patient with a hemoglobin greater than 7 [g/dL], it fires and says, "Hey, do you really need this?" If you try to order two units of red cells at a time, it fires and says, "Hey, do you really need this?" and says what best practice is. And guess what? We saved enough money on red cells to pay for all of this.

**Joe:** Look at you. Nice. Nicely done.

**Pat:** So I like to put it this way. We used one safety measure, which was not transfusing red cells that don't need to be transfused, because that is the safest transfusion, to pay for yet another safety measure.

**Joe:** Makes total sense.

**Pat:** So that's how we convinced the hospital. So that part was pretty easy. The second part was convincing our blood supplier. And they were open to it. They just wanted to make sure we were serious and that they weren't going to spend a lot of money on this and then have the hospital change their mind when they started getting the bills for the pathogen-reduced platelets. And we worked with them, and we convinced them, and we were actually the first center in California to start taking pathogen reduced platelets. And so it was a big deal, because this was the first time it was

brought up in California. And they had to go through all the training for manufacturing. They had to bring all the equipment in. They had to get all their procedures in place, and all of that to do this. And nobody's going to do this if they don't have a customer. You cannot afford to do this in the current market if you do not have a committed customer.

**Joe:** And I want to, Pat, explore that for just one second. I mean, our main focus in this discussion is to talk about how you ... the decisions that you made locally, but I think it's fair and I think it's important for people that work in hospitals to maybe have a little clearer picture of what those challenges are for a blood center to implement pathogen-reduced platelets. I have other podcasts that describe the entire PRT process, so we don't need to go through all those details. But from your perspective, what ... Why is it hard? What's the big deal? What is it that you have to do that makes this challenging?

**Pat:** Okay, so for all those of you who work in a hospital, when you ask for new equipment, does the hospital just say, "Oh sure, go spend hundreds of thousands of dollars. We don't care."

**Joe:** I'm going to say "no" to that one.

**Pat:** Exactly. And that's the same thing that would go on at a blood center, that you can't purchase all that equipment unless you know you have a customer to eventually help you pay for that equipment. And then when you have to train people to do the manufacturing, it isn't just, "Wave a magic wand and they're trained." You have to take them out of doing the regular production jobs and put them into training. That costs money. Implementing all the SOPs costs money. Every step of it costs money. And blood centers do not have the kind of margin where they can spend the amount of money it takes to implement this without knowing they can get a return.

**Joe:** That's a great summary. I mean, it's absolutely true, and as I said, there are mechanics involved and logistical things from the blood center side as well that we're not going to take the time to go into in great detail. However, you do cover those in your article, Pat, so I would refer everyone to make sure you check that out. Because I think it's really important, as I said, for hospitals to understand that this is not just flip a switch and go. And I'm right there with you, agree.

So Pat, let's go back in time a little bit. So you were ... You're sitting there at UCSD. You've made this decision, you've convinced your supplier that this is something that you want to do. I'm assuming, though, based on what we've already talked about ... I'm more than assuming, I know, that you were hearing, "okay, you're going to get a certain number or a certain proportion," whichever it was, but it was clear to you I'm assuming at that point that you would not be able to do 100% supply, obviously. You've

talked about that. So how did you make the decision back in late 2016, early 2017 when you were about to implement this, on who was going to get them? How did you go through that process?

**Pat:** So before I describe what we did, I'd like to say that there are other ways to do this. Just because this is the way we did it does not make it the 100% right way to do it. Others have done different things and published on different ways they've implemented and decided who gets the platelets. And you have to make a decision based on your situation and your patient population. But for us, the big deal for us was the paper by Hong [Note: See reference on show page at [BBGuy.org/077](http://BBGuy.org/077) for this paper]. What they did was they cultured platelets at the time that they issued them. And they ended up having five septic transfusion reactions that, pretty much, if they had not cultured the product, they would never have known the patient got sepsis from transfusion, because the patients they found them in were patients with hematologic disorders and they developed symptomatic reactions if they had low white counts. And they also developed them with a delayed onset. Four of them were developed within 9 to 24 hours after transfusion. And so if you're doing your classic septic transfusion reaction work-up, that doesn't qualify, does it? Because it's not within, what is it, four or six hours. They never would have known had they not cultured the same organism from the platelet product as they did from the patient that much later.

And if you look at that population, boy, we have a HUGE population like that at UCSD. We have a bone marrow transplant ward. We have an outpatient cancer center. We give a lot of platelets to patients who are neutropenic and outpatient. And if you look at the Hong paper, the patients who had the septic transfusion reactions, the patients who died from the septic transfusion reactions, look a whole lot like where a lot of our platelets go.

And so based on that, we decided, "Well, let's go ahead and start giving these to our patients who are A, outpatient, and if they have a reaction, do not have immediate access to advanced levels of care, and B, patients who are often very neutropenic." And that's how we decided how to start, and we started using them in our cancer center for our outpatients, because one of the things that really impressed me from that prior reaction we talked about was how quickly the patient got treated. And I truly believe that had there been a significant delay in treatment, the outcome may not have been as good as it was, because the patient actually ended up doing fine.

**Joe:** I'm so glad.

**Pat:** But what if it had been a several hour delay? And our cancer center is truly an outpatient environment. We can't call a code. We have to call EMS.



And what if they become symptomatic nine hours later when they're at home?

**Joe:** You'd either never know, or you'd know too late, right?

**Pat:** Yeah.

**Joe:** Neither is good. Okay, so those were your first priority, the patients in your outpatient cancer center. And I believe you called that "phase 1," right?

**Pat:** Yes.

**Joe:** Is that accurate? Okay. So did you ... Before all this started, had you already defined what your phases were going to be, Pat, or did you figure those out as you went along?

**Pat:** We knew what we were going to do before this started based on our previous experience and based on knowing what our population is. We thought that the next group of patients to get these products should be the inpatients on the bone marrow transplant unit. Because they also are neutropenic. And if you think about it, and if you look back at that Hong paper, it kind of makes sense that if you have lower levels of bacteria in your platelet unit, if you transfuse it to somebody who is fully immunocompetent, and has a normal white cell count, then they never get sick. But if you give it to somebody who just had a bone marrow transplant, who has no white cells, it could be a very different outcome.

**Joe:** Absolutely. So phase 1, outpatient cancer center. Phase 2, inpatient bone marrow transplant ward. What was phase 3 for you?

**Pat:** Phase 3 was the whole hospital.

**Joe:** Okay. That makes sense. Did you have numeric goals? Did you have an idea of what you wanted to do or a proportion of pathogen-reduced platelets for example that you wanted to get to?

**Pat:** We wanted to get over 90% pathogen-reduced platelets in six months, and that was a lofty goal that, if you've ... Since you've seen the paper, you know we did not get there.

**Joe:** But it was a valiant effort, for goodness sake.

**Pat:** It was a valiant effort.

**Joe:** Well, but I think that's, I actually think that's important for us to discuss. So once you got to your phase 3 and you were releasing ... It's pretty much all comers, you, as you said, you didn't get to that 90% within six months. I wonder if you'd take us through what you did get to and what you saw as the "why" you weren't able to get farther.

**Pat:** Okay, so ... Phase 3 started three months after we began, so we began this whole journey in February of 2017. And we were at 53% of all platelets several months in. And we really were not happy with that. We just thought we could do better. So then we worked with the American Red Cross and said, "Hey, look, we're serious. We want a really ... We want 100% of our platelets as pathogen-reduced. Not 53%. We want 100%. But if you can get us to 90, we'll be much happier, because we want to go this direction." And so we worked with them, and they decided that they needed to make some changes in their manufacturing processes.

And what those changes were is it turns out that there's these things called "guardbands," is what they call them. And the FDA has not approved the pathogen reduction process that is approved for ... You can just put any platelet unit into it. It has to meet certain what they call guardbands, which the volume and the number of platelets in the product have to fall within specific ranges. That means not all platelets can go into the pathogen reduction process.

Additionally, there's no triple kit. Yeah, so think about that.

**Joe:** Yeah, as a blood center, that seems a significant issue.

**Pat:** Right.

**Joe:** Because we try to, as you know, we try to make as many of our platelet collections as we can triples, if the donor qualifies.

**Pat:** Yes, and as you know, larger donors with large platelet counts make good triple donors, and so it's just for a number of reasons, we try to make as many of our collections as possible triples. So the Red Cross decided that to get to where they wanted to be and where we wanted to be, they needed to make some changes in their manufacturing processes. And what they did was they optimized the settings of their platelet collection devices to ensure that they were meeting guardbands as much as possible. And then the other thing they did was, they had previously not been treating triples at all, because there was no triple kit. Although there is no triple kit, the FDA has gone on record as saying, "Yes, but you can split the triple into a triple and pathogen-reduce each of them, as long as they meet-

**Joe:** Oh, say that again.

**Pat:** You can split the triple into an actual triple-

**Joe:** Oh, I see.

**Pat:** And pathogen reduce each of-

**Joe:** Each one.

- Pat:** Yes.
- Joe:** Got you.
- Pat:** And so there is no triple kit per se, but the FDA never said, "You can't treat triples."
- Joe:** I see. Big difference.
- Pat:** Big difference. It may sound semantic, but it's not. There were people ... There were blood centers who thought that that meant you couldn't treat triples. And so they worked hard on identifying eligible double and triple platelet products that they could split and pathogen-reduce. And so they made ... In fact, if you look at the graphs, you'll see that there's this period of time where we had sort of increased and then we sort of decrease. And the decrease, the percent decrease, is from when they were optimizing the manufacturing. Because they had to do some retraining, they had to change some things around. But then after they optimized their pathogen reduction process, we were up at over 90% very quickly. And we've pretty much stayed there.
- Joe:** And so roughly how long did that take, until you got over toward your 90% goal?
- Pat:** At about 15 months in, we were over 90%. But remember, we were a really early adopter. I don't think it will take others 15 months.
- Joe:** Why? Why do you think it'll be better in the future?
- Pat:** Well, that's the other thing that we ... You can see in the graphs on the paper, is that when... at first, when they started doing pathogen-reduced platelets, they only had one hospital in all of California who would take the product.
- Joe:** The definition of a limited market, right?
- Pat:** Yeah. So, and you can see we did the statistics here of looking at ... There's a correlation between the number of hospitals that could accept the products and their ability to provide us with pathogen-reduced platelets. And the more hospitals that could accept the products and would accept the products, the more they were able to provide us, because then they didn't have to worry about, "well, literally, if we make one extra platelet that's pathogen-reduced, we have no hospital to send it to. We have no hospital that can even put it into their computer system."
- Joe:** You brought up something that I think is important, and just from the practical perspective, are there things that a hospital transfusion service would need to do, for example, with computer systems, in order to be able to use these products?

**Pat:** Of course. As with any product, you can't take it into your computer system unless you've built the appropriate product codes into your system. And so one of the things I would advise pretty much every transfusion service is to go ahead and build the product codes for pathogen reduction. Do it now. Because what if you need a platelet, and the only platelet your blood provider can send to you is pathogen-reduced? What if you need an HLA matched platelet and the only one they have is pathogen reduced? Build the codes now. The other really interesting thing we had to deal with was, all of the issues around irradiation and CMV negative.

**Joe:** Set the stage for us on that Pat. Why is irradiation and CMV an issue or a consideration with pathogen-reduced platelets?

**Pat:** So it turns out that if you think about it, we're pathogen reducing these products to get rid of the bacteria. But they get rid of a whole lot of other things too. If you're worried about things like malaria, Babesia, HIV, HCV, CMV. So if you have a pathogen-reduced platelet, it is equivalent to a CMV-seronegative platelet. So if you're planning on ordering CMV-seronegative, you don't have to do that any more. But how is your computer going to recognize that product as CMV-seronegative?

**Pat:** And it also turns out that the damage that the pathogen reduction process does to DNA and RNA is actually superior to the damage an irradiator does to DNA or RNA [laughs]. And so it can be used in place of irradiation. But how do you get your computer to recognize that the product is irradiated?

So we thought about it a while. We were going to add a PR code and we figured out our computer system wouldn't let us do that and have it equivalent to irradiated or equivalent to CMV-negative. So we tricked our computer into thinking they were the same thing. We changed our codes to ... We used to have "IRR" for "irradiated." We now have "IRRPR." And we used to have "CMV neg" and now we have "CMVPR." And what we did was, we reprogrammed the computer to recognize them as equivalent.

So when a product comes in and it's irradiated, we just put an IRRPR code on it. If it's pathogen reduced, we put an IRRPR code on it. We also put a CMVPR code on it. So then, the computer recognizes it as pathogen reduced or irradiated, or equivalent. And that's a big deal, because without it, you can't release the product.

**Joe:** Right, if it needs to be irradiated and your computer doesn't recognize that product as equal to irradiated, then you're kind of hosed.

**Pat:** And a whole lot of the platelets we issue need to be irradiated. And that's the other thing we did. We were concerned that the nurses would be returning them because they weren't irradiated. And so what we did is, we developed this little sticker that we put on the tag. And it says, "This

product is pathogen-reduced, which is equivalent to irradiated." And, we've not had a single nurse call and say, "Hey, you didn't irradiate my platelet."

**Joe:** That actually brings me to what I wanted to make sure that I asked you. And so you mentioned you did that for your nurses. How did you go about ... I don't want to use the phrase "selling it" to your medical staff, but it's kind of in a way,, did you have discussions with your medical staff prior to implementing this? I assume you did. How did those discussions go? Were there any objections raised?

**Pat:** So I presented this at our quality council, which has medical staff from basically just about every discipline. And they, every one of them, was in favor of doing this, because it was such a patient safety thing. But then the next thing we did was, if you think about who are your thought leaders on what's okay and what's not okay, clinically, for transfusion, and they're your Hematology-Oncology doctors. And so we met with our head of bone marrow transplant, and he said, "Yeah, we need to do this. Yes, this is okay. Yes, it's okay that we don't irradiate." Once your head of bone marrow transplant says what they're doing is okay, your other medical staff are going to believe that. But in addition, we sent out a communication to all medical staff saying we were making this change and these are the changes you would see and some pictures with it of, that the bags look a little different. And we got no complaints. Not one.

**Joe:** I'm not surprised, and my guess is, I mean, again, if your hospital is anything like hospitals I've worked in, my guess is at some point, you had people coming up to you saying, "Hey, when did you start this? This is kind of cool." Did you have conversations like that?

**Pat:** Yes, occasionally. There'd be people who ask, "How long have we been doing this?"

**Joe:** Exactly. So as we close this out, Pat, there's a couple things that I think are really important for us to discuss, and I want to circle back around to what we talked about at the beginning in terms of your phased implementation. Because I think ... And you raised this in the discussion portion of your paper, I think there are some who might argue that there's an ethical issue, a justice-related issue to supplying what can be perceived as a "safer" product to some patients than to others. And your answer to this might be different now that the final guidance has come out and there are requirements for basically every platelet that we transfuse. But how did you work through that ethical argument in your mind and the discussions that you had with others?

**Pat:** Well, for us, because we use so many platelets, and so many of them go to outpatients who have low white counts, that Hong paper was just instrumental for us in saying, some centers have done first in, first out and just mixed them with everything else, and taking care of the justice issue

by saying, "You have an equal chance of getting the pathogen-reduced platelet as everyone else." And had we not had the unique circumstance of our cancer center and the infusion center there is physically separated from our hospital, I may have done that. But that Hong paper made such an impression that the patients who are most at risk were the outpatients with low white counts. And so we decided to go for where we knew we as a medical center had a risk and give them to who we knew from this documentation and that paper, they were at the highest risk.

Now, had that infusion center been in the hospital, I might not have made the same decision. And I think it's really important when you make these decisions, you have to look at what you have in your organization and what best fits your organization and your patient population.

**Joe:** I could not agree more with that statement. You're absolutely right, and that actually brings me to the next question, which I'm going to ask you for your interpretation of this or your feeling on this with the acknowledgment that your answer may not be the right answer for everyone, and it's a practical question. And again, you raised this in the discussion section. Say you have a pathogen-reduced platelet that it's about to expire, and you have another product that is potentially a better ABO group match for the patient. How do you make the decision on which product to choose in that scenario, and what are the pros and cons of each?

**Pat:** So one of the things about our pathogen reduced platelets is they're all in PAS, so we don't have as much of the ABO issues.

**Joe:** Help everyone understand that, Pat. Why is that less of an issue?

**Pat:** Because 65% of the plasma is replaced with platelet additive solution, which means you have 65% less plasma in these products. And so for us, that's probably not as big an issue. But every patient is unique, and if I was asked that question, I'd have to look at it in balance, "Okay, which do I think is a better product for this patient?" And fortunately, you brought something up: "If I have one that's about to expire." Honestly, that doesn't happen to us that much, and the reason is, this is the other thing I really wanted to talk about, we work with our blood provider, and we have two hospitals. We have one that is next to downtown. And that's where our trauma center and our burn unit is. And so if you can imagine, we have to have a lot of platelets on the shelf for the trauma center. But our cancer center and our bone marrow transplant unit is 13 miles from there. Now you can imagine we have to have a really lot of platelets on the shelf for them. And so we worked with our blood provider that when the platelets get to to day four, they pick them up and take them to the other hospital for us.

**Joe:** Oh, interesting.

- Pat:** Yes, and so that's really helped us with our platelet supply. And so we don't end up in that situation that much, because we use so many platelets. But if you think about other hospitals, that's not necessarily... And we're urban. So if you think about other hospitals, I think Nancy Dunbar's been on your podcast...
- Joe:** She has.
- Pat:** She talks...they do it completely different at Dartmouth. But they're a completely different organization than we are. They're rural. They are a long way from getting restocked. It snows there! [laughs]
- Joe:** [laughs] Wait, what? Snow, no.
- Pat:** It snows there!
- Joe:** We're Californians now, Pat. We don't talk about that.
- Pat:** And so if you look at what they've done, and extending platelets to six and seven days, that makes a whole lot of sense for them. It doesn't make as much sense for us as an urban center that really uses a lot of platelets and does not outdate many at all. Our biggest problem is, "Hey, we need more!" [laughs]
- Joe:** Right.
- Pat:** "Hey, we're down to eight. We're panicking!"
- Joe:** Yes, yes, I hear you. And so everyone, Pat mentions the great Dr. Nancy Dunbar and her protocol at Dartmouth. You can hear about that, just sidebar for a second Pat, on [BBGuy.org/060](http://BBGuy.org/060), that's episode 60 of this podcast, and in the last part of it, Nancy talks about the choices that she and Dartmouth made for platelets that are, as you said, different than the decisions that you've made.
- And I think that's really important for us as we close this down, Pat, for people to understand, and we've emphasized it, we emphasized it in the previous episode talking about the guidance, and we're emphasizing it again now and we've already done so: The answers are not the same. There's no one size fits all, right? I mean, people have to figure this out for themselves.
- Pat:** Yes, and let me just tell your listeners, if you haven't heard that podcast, it's well worth the time. It's a really good podcast, and she discusses why they've made the decisions they've made, which are completely different decisions than what we've made at the University of California San Diego. But they are still very valid and well thought out decisions.
- Joe:** I would expect no less from Nancy, right? She's-

**Pat:** Right.

**Joe:** Yeah, well... Anyway, so Pat, again, as we close this out, what are the things that you want to leave us with? I guess as you leave us, I wonder if you would also discuss, how does the guidance being finalized impact what you're doing and what you're planning to do. As you said, and in fact you mention this in the early view version of your paper, when you wrote it, the guidance obviously wasn't out yet. With what you know now, does that change anything for you?

**Pat:** Well, it doesn't change a lot. We still want 100% pathogen-reduced platelets, because honestly, between you and me, I think we're eventually going to get there. I think-

**Joe:** Between you and me and the four or five other people that listen to this podcast, right?

**Pat:** Yes, between you and me your occasional listener, I think that's where we're going. But we can't get there tomorrow. So, I recognize that on occasion, we're going to get a platelet that is not pathogen-reduced. And in those circumstances, I am okay with anything in this guidance. However, as you know, I've spent a long time at a blood center. And now I've spent a long time in a transfusion service. I firmly believe manufacturing as much as possible should be done by the donor center. So therefore, I am going to let our donor center know that we would really like them to do the manufacturing.

**Joe:** And we'll just leave it there. As I said, we're not here to recommend one particular thing or the other, but that's ... I hear you loud and clear. I think that's going to be a fairly common answer, but as you said, for others, they might come to a completely different conclusion-

**Pat:** Right-

**Joe:** And that's fine.

**Pat:** But you know what? That also has to do with where you're at. Because in California, we have to use, for all of the [two-step] ways that you can extend the life of your platelet or even get it to five days with an early culture, you have to use licensed clinical laboratory scientists.

**Joe:** That's a big thing, big, big thing.

**Pat:** And for California, that's a big thing. We don't have an excess of those highly trained, highly intelligent people. And so for us, that's part of the cost equation too, is the labor and even being able to find those people and hire those people. And that may be a different calculation in different parts of the country. Can I add one thing?



**Joe:** You can.

**Pat:** Something everyone needs to know about the pathogen-reduced products. The bags are bigger. Now, you think, "So what?" Well, if your platelet incubator is crowded already, they're not going to fit and you need to buy a second one. Just something to think about.

**Joe:** That is a very practical tip. That is important for people to know.

**Pat:** So at one of our hospitals, we have two very large platelet incubators, so it's not a problem. The other hospital, the one that doesn't do the bone marrow transplantation has a single platelet incubator, and we're going to have to buy another one.

**Joe:** Well Pat, I can't thank you enough for doing this. Not just for talking about this with me, but for the paper that you and your group have put out, which as I said everyone, you can find that paper on the show page for this episode. There's a ton of great information in there that I think people, especially in light of the guidance being finalized, can use to, again, guide them in a way that may make sense for them to go the way you've gone, or may make sense for them to do something different. But I think it's a really valuable contribution to everyone, as is your time with me, Pat. I appreciate both so much.

**Pat:** Thank you Joe. It's been a pleasure to be on the podcast.

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**Joe:** Hi, it's Joe with just a couple of quick closing thoughts. I hope that this conversation and the one that preceded this one in episode 076 stimulated some thoughts for you regarding how if you practice in the United States, you're going to approach the recommendations and the FDA Guidance from September 2019. As I have mentioned, I think multiple times, I think each facility should read the guidance, start a conversation internally and with your blood supplier, and start to form a plan. Your plan may be different from someone else's and certainly may be different from what Pat and her team decided, and that's okay. There are options, and you really need to explore them.

I do want to mention again, this is a continuing education activity, so if you are a physician or a laboratorian, don't forget to visit [wileyhealthlearning.com/transfusionnews](http://wileyhealthlearning.com/transfusionnews), to get your hour of totally free continuing education credit. My thanks for that, as always, to Transfusion News, to Bio-Rad who brings you Transfusion News, and to Wiley Health Learning.

I want to thank, again, Transfusion News assistant editor Dr. Daniela Hermelin from St. Louis University. Daniela helped me very much with the continuing education materials for this episode, so thank you so much, Daniela.



I've mentioned in the past that I have a terrific interview coming with one of the inventors of pathogen reduction technology, Dr. Ray Goodrich. I felt like we needed to address the FDA guidance right away, though, so that episode will be coming soon. In addition, I'm excited for you to hear from Dr. Mindy Goldman from Canadian Blood Services about choices she and CBS have made in Canada regarding donor and patient safety. I also have coming soon a round table discussion with some laboratory science leaders in Transfusion Medicine, including one of my heroes, Sue Johnson from Versiti Wisconsin. In that round table, we talk about how lab science students and practitioners should understand why blood banking is a fantastic career choice! I can't wait for you to hear that one, and it'll be out before the end of 2019.

But until that day, my friends, as always, I hope that you smile, and have fun, and above all, never, EVER stop learning. Thank you so much for listening. I'll catch you next time on the Blood Bank Guy Essentials Podcast.