BBGuy Essentials 081CE:
Top Ten Changes in the NEW AABB Standards with Rich Gammon
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Rich: Hi, my name is Dr. Rich Gammon. I'm chair of the AABB Blood Bank and Transfusion Services Standards Committee, and this the Blood Bank Guy Essentials Podcast.

Joe : Hi everyone. This is episode 081CE of Blood Bank Guy Essentials, the podcast that has one simple goal: To help YOU learn the essentials of Transfusion Medicine. My name is Joe Chaffin, and I am, as always, your host.

I am so excited for you to hear this interview today that I conducted with Dr. Rich Gammon. Rich is the chair of the AABB Blood Bank and Transfusion Standards Committee that was responsible for putting out the 32nd edition of the Standards for Blood Banking and Transfusion Services.

We're going to talk more about that in just a moment, but first, you should know that this *is* in fact a continuing education episode. The free continuing education credit is provided by 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.

So, as I mentioned a few moments ago, Dr. Rich Gammon is with me today on the Blood Bank Guy Essentials Podcast to talk through the 10, well, at least what we view, most important changes in the upcoming 32nd edition of Standards. And I say "upcoming" because as of the time that this podcast is released, that is still in the future. You may be listening to this later on, but April 1st, 2020 is when the 32nd edition of Standards becomes effective. If you are an AABB-accredited facility, these are things that you have to follow. And it's also true that if you live in California, these are things that you have to follow. But really, even if you aren't in one of the groups that is kind of required to follow these, there's value in understanding what kind of the "standard practice" is in blood banking, at least according to the Standards Committee. And I think there's a lot of really valuable information here that's going to help you as you look through and see what you may or may not need to implement, or it might be a good idea to implement if you're not an AABB-accredited facility.

Let me tell you a little bit about my guest. Dr. Richard Gammon is a medical director at OneBlood in Florida. His programs provide hospitals with current evidence-based transfusion thresholds, management of transfusion committees, and they emphasize

the importance of appropriate transfusion. Really, Rich really spends a lot of time working on patient blood management initiatives. He's board certified in Blood Banking and Transfusion Medicine, of course, as well as Clinical Pathology. As I mentioned, he's a medical director for OneBlood and Transfusion Medicine Specialists, and he's also an Assistant Professor of Pathology for the University of Central Florida College of Medicine and a Clinical Associate Professor of Pathology at NOVA Southeastern University College of Allopathic Medicine. And just to add another one, he's an Assistant Professor Collaborative Faculty with the Department of Pathology and Cell Biology at the University of South Florida.

Rich serves, as I mentioned, as the chair of the Blood Bank and Transfusion Standards Committee for AABB where he works with a very large group of people coming up with the Standards that you need to be aware of that we're going to discuss today. In January of 2020, Rich and his subchairs, which include Susan Galel, Susan Wilson, and Maureen Beaton (three names that you should know; they did a great job with this), they did an AABB eCast on this very topic where they go into things in a little more detail than Rich and I were able to do today. And I would certainly refer you to that. And you can find old editions of AABB eCasts on the AABB Marketplace; just start at AABB.org.

I do want to thank AABB for their cooperation in helping me make this podcast today, and I just can't wait for you to hear it. So, here is my interview with Dr. Rich Gammon on the top changes in the new 32nd edition of AABB Standards.

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Joe: Hi Rich. Welcome to the Blood Bank Guy Essentials Podcast.

Rich: It's my pleasure to be here, Joe. Glad to be on the podcast today.

Joe: It's really an honor to have you, my friend, and you and I have known each other for a very long time. I'm excited to connect with you in regards to the work that you've done with the upcoming 32nd edition of AABB Standards, and I want to go through kind of the most important changes, at least one or two people's opinions of what the most important changes are.

But before we do that, I wonder if you could just kind of set the context for us a little bit. Could you start by just talking a little bit about the differences between “standards,” that come from organizations like AABB and regulations and guidances that come from people like the Food and Drug Administration.

Rich: Absolutely. That's a great question. So, a few points to be made here. FDA regulations, especially in the code of federal regulations carry the weight of law. FDA guidance documents will often explain how the regulations are to be

followed. AABB Standards are the tools you use to assess a facility that has seeking AABB accreditation.

The AABB Technical Manual and Association Bulletins offer further explanations of the standards, but the facility is not accredited by these documents, only by the Standards.

Joe: So when things like this come out, when new editions of Standards come out, what does that mean functionally to a hospital, Rich? I mean, is this something they're required to follow? I mean, what if a facility, for example, is not AABB-accredited? What's the value of these Standards to them?

Rich: Yeah. That's an excellent point. The value of the Standards, facilities are not required to be AABB-accredited, however, it's basically a high standard that by applying yourself and meeting the requirements of these standards, you're accredited by AABB, which is a world-renowned organization. That means that your practice, anywhere in the world, will match another hospital anywhere in the world that's following the same standards.

So it's a very high standard of care and it's recognized throughout the world. And in fact, if you go outside of the US, a lot of individuals will go to these hospitals that are AABB accredited, especially if they need blood products, because they know, that they're getting the best quality of care.

Joe: That makes sense. Rich, two years ago I did an interview with your predecessor as chair of the committee, Pat Ooley, and everyone that's in BBGuy.org/046. There, we were talking about the 31st edition Standards changes. And now here we are talking about the 32nd and the changes that that you and your committee implemented. I guess the obvious question is what's the deal? How come you guys keep changing these things, for crying out loud?

Rich: Well, blood bank is not static. and you know, there's a, always something going on in blood banking. We're looking at changes to the federal regulations. The AABB always wants to at least meet or exceed what the Food and Drug Administration requires. There's new information that becomes available for research or new technologies.

And then emerging pathogens arise as well, such as Babesiosis and Zika pathogens. You know, there are now requirements, to test for those, relevant transfusion transmitted infections that were not, on the horizon before.

Joe: If you don't mind, Rich, just take us through real quickly the work that you and your team did. I'm sure that there are a lot of people that worked hard on this.

So I'll give the floor to you for just a sec to kind of describe the process that you went through and anybody that deserves some special recognition. Go for it.

Rich: Sure. So the process takes more than a year. There's two face to face meetings at the AABB headquarters in the Washington DC area. There's also two periods for public comment, and finally, it's reviewed by the board of directors, prior to publication. So really a lot of steps in the process that allow for significant review comment before the final decisions are made. there's approximately 50 people on this committee. It really takes a lot of individuals to make this happen.

And, I'd like to recognize our chairs, which is, Susan Galel, Maureen Beaton, and Susan Wilson, who cover the entire Standards. In addition, I want to thank our junior members, public members, and ethicist liaisons representing other AABB committees and representatives from other organizations.

The Standards are meant to be straightforward, less proscriptive, and allow plenty of opportunity for a facility to adopt to their own policies, processes, and procedures.

Joe: The last question I wanted to ask you before we get into the specific changes, which are important and we need to make sure people are aware of, I always like to make sure that people who are somewhat early in their careers, like a lot of the people listen to this podcast, understand the value of serving on committees. Now, obviously someone who's just starting out is not going to be, most likely, involved on the your particular blood bank and transfusion standards committee, but in your career in blood banking, I know you've done a lot with AABB and served on a lot of committees. Can you talk a little bit just about the value that that brings to you, and that it brings to the organization to have people involved in committees with AABB?

Rich: Absolutely. First of all, I would tell anyone that's a member of AABB to volunteer early and volunteer often. It's very rewarding, you'll get to network with individuals from all over the globe, learn best practices, and further your professional development, as well. I can't overstate it enough, the value of being, involved in one of the things, as blood bankers, we're spread out in different cities and different countries across the world.

And, these committees get a chance to get everyone together and, you get a variety of views, from all over the world. And we put this all together into the current edition of the Standards that we're discussing.

Joe: Very cool. And I, again, I congratulate you on the work that you and your committee have done, Rich. I know it was a big, big effort.

So let's talk about some of the most important changes. Now, when I did this with Pat a couple of years ago, Rich, we put them in order, I think we just did the top five. You know, honestly as I look at it this time, I realize that to some people, one particular thing might be more important than others. So we're going to go through about 10 of these, and we're just gonna do them in no particular order. Some of these, folks, might be more important in your setting and others might be important in others.

So let's just start, Rich, with one that I think is super-important no matter what you're doing. But it's obviously most important for donor centers, and that's Standard 5.2.1. It's under iron mitigation strategies. I'll just read a little bit about what has been changed. So, under 5.2.1, Donor Education, one of the subheadings is that "donors are given educational materials regarding the risks of post-donation iron deficiency and mitigation strategies." And that last part is what's been changed, Rich, the "mitigation strategies." Can you talk through what the committee's rationale and what the benefit of that might be?

Rich: Yeah. So the recent studies have indicated that diet alone is not usually sufficient to replace the lost iron from whole blood donation within the eight week whole blood interdonation interval. So the intent of this addition just to inform the donor of measures that the donor can take or the blood bank is taking that may help reduce donor's risk of iron deficiency due to blood donation.

Some potential measures are also described in AABB Association Bulletin 17-02. Potential measures could include, but are not limited to taking iron replacement after donating, using ferritin testing to guide iron replacement or donation frequency, increasing intervals between donations, and limiting the number of annual donations.

Joe: Rich, you work in a donor center, as do I. And I know that you and I have certainly realized the fact that people are going about this different ways. And, as you just said, some people are trying to give to give iron, I don't think that's super-common right now, but a lot of people are implementing ferritin testing and the other measures that you talked about. For those that are just learning, who are the types of people that are at the most risk for iron deficiency from donation, or is it just everybody?

Rich: First of all, in the general answer, everybody is at risk of iron deficiency, especially if you donate any more than two times a year. But populations that are specifically at risk are premenopausal females that lose blood every month due to the menstrual cycle in addition to donating blood. They're at risk for iron deficiency.

The second group of individuals are young people generally under 25. Some facilities put that together as 16 to 18 age group or high school donors. And so, you know, again, the data is still in development. There are some concerns that individuals that have iron deficiency that are younger could potentially cause neurological development. More research needs to be done in that area. And that's why a specific standard was not added. For this edition of the standards. But we hope, in conjunction with AABB and the industry, we'll have additional information to make further recommendations for the 33rd edition of the Standards.

Joe: So if I'm reading this correctly, the big change here is, the post donation iron deficiency risk part was there in the 31st edition, but the big change is, we're required now to try and communicate to our donors, "What are some things you can DO about iron deficiency?" Is that a good way to summarize it?

Rich: Absolutely. And, to try to make it clear, yeah, you made a good point, Joe, that most blood centers are not going to be administering iron, because we're really not medical centers, but we certainly have responsibility to ensure the safety and well-being of our donors, and it's certainly reasonable to provide them with a list of mitigation strategies.

Joe: Let's move on to the next one, Rich, and that's, it's actually very close to where we were. This is standard 5.2.2. and this specifically talks about parental permission. So those young donors that you mentioned when we were talking about those that are at risk for iron deficiency. And the Standard says, "When parental permission is required, the collection facility shall have a process to provide information to parents or legally authorized representatives of the donor concerning the donation process." All that was there before, but what's been expanded is that "potential adverse effects related to the donation are required to be discussed."

Why don't you talk us through why the committee felt that that needed to be added?

Rich: Yeah. So, you know, that's a good point. So it just to comment here, it's been expanded to require that when parental permission is required to donate, that the parent or legally authorized representative is made aware of the potential adverse effects of donation. And, you know, this is important because, depending on what state you are, some of these donors are considered minors and so the parents should be notified, because they have responsibility. The second issue is that, you know, as a medical director, you know, I'm sure you get these calls to a donor center that the parents will give a phone call and say, "You know, I didn't realize this was going to happen when my son or daughter

donated." And we don't want that. They should know about this up front, when they make the decision whether or not to let their son or daughter donate. We're not trying to do anything that's not transparent here in the blood bank. Now the other option, the other thing we have sometimes is that sons or daughters will give the parental form to the parents and they don't read it and they sign off on it and then there's a problem and they say, "Well, I didn't know that was in there."

This at least is making sure that the blood bank has that wording in there. It's clearly spelled out. And so, you know, it's the parent's responsibility to read that and sign it. So hopefully this would reduce some of the uncomfortable phone calls we have afterwards, when a parent, you know, may not understand what all the risks and benefits were.

And the parents can always say "no," if they don't want their minor to donate. And their minor, you know, when they become majority age or whatever age they can donate independently in the state that they're in, then they can make their own decisions.

Joe: And that makes sense. I completely agree with that, Rich. I like you have gotten those phone calls from parents saying, "You never told me," and fortunately, I'm usually able to say, "Well, here's the document that you signed." But nonetheless, it's important, absolutely, to make sure that the information is out there.

And I would assume that that potentially includes what we just talked about with iron deficiency, right? I mean, that is that something that you feel, and this is a way from, I know that's not in this standard, but you personally, do you feel like that's something that should be covered in that consent?

Rich: I think surely that could be put in there, but we'd have to word it carefully. you know, we don't want to be overly alarmist. At this point in time, the evidence, if you read the risk-based decision making report that came out from AABB, you know, really, the adverse effects, at most are known to be subclinical in most cases. So we don't want to over-alarm the patients. But we can certainly let them know that it's not a bad idea, you know, if not contraindicated by their doctor, to have their sons or daughters maybe take some iron tablets, or multivitamins with iron, if they're going to be donating, you know, more than two times a year, at their high school.

Joe: We probably shouldn't wade too deeply into that because as you said, there are differences of opinion on the significance of this finding, and let's just leave it there. And I think for interest of, avoiding making some of our colleagues heads explode.

Rich: Fully agree, and stay tuned, I'm sure there'll be more research in that area going forward.

Joe: You bet. All right, well let's move on to the third one, Rich. And that's regarding a product that I'm guessing a lot of my listeners may not be familiar with, and that is cold-stored platelets. And this is actually addressed in two different Standards, Rich. And I'll just summarize them real quick and we'll give you a chance to talk about it in general.

So there's reference standard 5.1.8A, and that's the big list, kind of in the middle of AABB Standards that talks about requirements for storage, transportation, and expiration of all the different blood components. So you guys added a new product in there, platelets, cold stored. More on that in a second.

And then in 5.19.7 under specially selected platelets, you added a new item to include the fact that the use of cold stored platelets should be addressed in transfusion service protocols. So let's just, you know, for those that are going, "Cold-stored platelets, wait a minute, platelets are stored warm! What's going on?" Can you just talk us through that product and what this means?

Rich: Yeah. So, let's talk a little bit about the product itself and some of the changes that are relevant to the Standards. So, cold storage platelets, were used in the past, and kind of fell out of favor, recent times, for platelets that were stored at room temperature, 20-24 degrees Celsius. The idea being that the platelets last longer when the platelets are stored at room temperature. But there are some studies that show that when the platelets are cold, they can be very active, and help in massive bleeding situations, and be effective to create hemostasis in those particular cases, but not be so effective with longer term storage. Also, cold storage does reduce the risk of bacterial contamination. Unfortunately, platelets do have the highest rate of bacterial contamination. The FDA actually issued a guidance document in September of 2009 requiring additional steps for bacterial screening on platelets, to make sure that that risk is mitigated as much as possible.

So a few comments about what we've done with the Standards. If you look at the reference table, 5.1.8A, footnote number 9, the category is stated to include unmodified, modified apheresis and whole blood-derived platelets, and the expiration is according to the manufacturer's written instructions. So there really is no specific date of an expiration of cold-stored platelets. The manufacturer sets that depending on the container that they used. Generally in civilian practice, expiration is three days. In the military practice, there are some additional extensions in storage.

The other comment I wanted to make is, if you look at footnote number 6 of the table, it mentions, "The temperature range decided at the time of manufacture shall be maintained." So the point of this is, and there was a lot of discussion in the Standards Committee to make sure that this was clear. You either produce platelets at 20-24 C, or store them at so-called “room temperature,” or you store them as cold-storage platelets, which are stored at the same temperature as red blood cells, 1-6 C. You can't go back and forth with one product to another. So just wanting to make sure that that was clear.

Joe: That's so important, Rich. It's funny, when I've had conversations with people who become familiar with the fact that there is a cold-stored platelet product out there, and I've heard people in hospitals try to, quote unquote justify platelets being put accidentally into the wrong cooler by saying, "Oh, well, cold stored platelets are okay now!" But what you just said is so important. It's one or the other. You can't have it both ways, right?

Rich: That's exactly right. And we wanted no confusion because if, you know, the Standards are meant to give facilities broad leeway, what they can do, but we didn't want any confusion about someone is just, as you said, that's that's a perfect situation. that, that you mentioned, you can't go back and forth. It's one or the other, because once you've set that stage for the platelets, if you try to go back and forth, the platelets will lose viability and won't be effective.

Joe: Okay, cool. Well, so that was the third one of the 10 that we're going to try to get through today. The cold stored platelet issue. Let's move on to what I would, I guess I would consider the last one on the kind of the manufacturing or donor center side, and that is standard 5.4.1A and that's the medication deferral list and vaccination updates that are in there.

5.4.1A is multiple different requirements for allogeneic donor qualification. So under that table, there's item number nine, I should say, which is drug therapy. I think you guys made a very, very interesting change here. In previous editions of Standards, when you look at that table, you see a fairly long list of different medications and different things that donors can and can't be on, well, can't be on, I should say, and what the deferral would be for those times. But the new edition of Standards simply says that the facilities “shall use the current version of the medication deferral list within six months of the lists effective date.” To those that are going, "the current version of the 'medication deferral list?' What does that mean?" Why don't you talk us through what that actually means in reality?

Rich: Sure. So this, this was a big change to the Standards. And, what happens a little bit of, you know, kind of behind the scenes, is the donor history

questionnaire task force puts together a medication deferral list. And, they have a formal process to do this. They have a pharmacist that's part of the committee, and when they put the list together, they publish it on the AABB website. The issue that was happening is, we do not have a representative sitting on the AABB Blood Bank and Transfusion Standards Committee, and so they would put together a list. The BBTS Standards Committee wouldn't be aware of the changes. And it was a clunky process. You certainly don't want to have, someone, because you are assessed by the Standards and because you're assessed by the medications list, we wanted to, to be the same note, no differences between the two. And so the committee just felt that it was better just to have one group that focuses on the medication deferral list, handle this.

So this way we took the committee out of it. The donor history questionnaire task force now handles the medication deferral list. And we had a lot of discussion about this too, as well, about when they need to be implemented. And we felt that six months was appropriate after there was a change in the medication list giving the institutions enough time to update their list, blood establishment computer systems and deferral practices accordingly.

One other comment that I have is that the medication deferral list is put together by a separate task force that is not open for public comment. And so, you know, these do affect when new medications come out, they do affect donor eligibility and depending on what the medication is and how widespread its used, it could affect, large numbers of donors. So this needs to be looked at very carefully, and the committee just didn't feel comfortable putting in a list that's open for public comment that we really couldn't do anything, we really couldn't modify this list. So you know, again, hopefully this will be one list looked by the donor history task force. We have asked that the task force consider bringing this up for public comment before they make changes to it, but that's really up to the chair of that committee.

Joe: I think that's really helpful, Rich. There's other changes in that Standard, including a couple of additions to the immunizations and vaccinations list, but I think in the interest of time, we'll move on to the next one.

These last six, everyone, are things that primarily are going to impact you in the transfusion service side of blood banking practice. And the first one is one that I explored in great detail with Pat Ooley on the last edition of the Standards update (and that was, again, BBGuy.org/046). 5.14.5 on pretransfusion testing for allogeneic transfusion of whole blood red cell and granulocyte components. I don't want to go into the entire nitty gritty of why Standards is requiring the two determinations of the recipient's ABO type. Everyone, if you want that rationale, we talked 15 minutes on that in the last edition of this, but I specifically want to

hone in on a change that is made in this that has people a little concerned. I'll be frank about this, and I'm sure you're aware of this. So in the ways that people can determine the ABO type for someone, the first determination is, of course, supposed to be performed on a current sample. And the second determination, the standards committee gave several methods, of course, comparison with previous records.

The second one is the one where there's a little bit of controversy: "Testing a second sample collected at a time different from the first sample," that's not a change, but the change is, "including a new verification of patient identification." I can't tell you, Rich, in the time since this came out, how many people have called me to question me, "Exactly HOW do I do that? Exactly how do I verify it?" So I wonder if you would first just kind of take us through the committee's rationale for adding that, and, while I know that it is not your role to give people exact... an exact way to fulfill that ßtandard, I understand that people can do this in different ways, I would just be interested in your general thoughts on that.

Rich: Yeah. So, you know, and that's a good point. There was a lot of discussion about this within the committee, because certainly the issue about the second sample, we really want to avoid wrong blood in tube, because the outcomes can be morbidity or even mortality in worst case scenarios.

So, the individuals reviewing this shouldn't get too hung up on when we say, the committee put, "a new verification of patient identification," all we meant was that when a second sample is collected, the patient needs to be re-identified again. That's all. So we didn't want someone kind of trying to buck the system, collecting one tube, and then collecting another tube right afterwards.

Believe me, you can get 50 people in the room and blood bankers, our minds always go to the worst case scenario, all that, that just means, just go through the process twice, whatever time period you want in between the tubes, it's up to your facility.

Joe: Okay. That's about as straightforward as it can possibly be. I will tell you what I have said to people is just what you're saying, the whole idea is for patient safety and wrong blood in tube is potentially so catastrophic that whatever we can do to avoid that, I stand behind that 100%.

In terms of how exactly people verify that their staff are doing that, as you said, I think that's up to the facility, but maybe don't get incredibly crazy about that level of detail. I don't know. Again, I don't want to minimize it cause I think it's hugely important, but that doesn't mean that you're going to be out there looking over everybody's shoulders when they do a verification sample, right?

Rich: Well, that's true. However, I would encourage facilities to do periodic audits, and it's up to your facility, how often you want to schedule them, but to have someone go up and audit a specimen tube collection, and just make sure that the nursing staff is, or the phlebotomy staff is collecting this appropriately. You know, you have to have two things, good policies and procedures, and then you've got to have people following those. So it doesn't hurt to audit it and just make sure the process is working as expected.

Because again, as you mentioned, Joe, like the consequences of just a wrong blood in tube can be catastrophic. And you know, there's been loads of cases, they have gone back or even phlebotomist working years at a facility that didn't follow the procedures.

Joe: Completely agree. and do want to mention at this point, Rich, something that Pat had pointed out, and I'm assuming that you would support as well, and that's that, folks, if you're in a facility and you're not sure with any of these that we're talking about, you're not sure that what you're doing is quote unquote meeting Standards, there is an email, standards@aabb.org that those emails go to people at AABB, and Rich, I'm not sure how involved you are in those, or your committee is involved in those, but there's certainly a way to get some feedback on your particular process. Is that still applicable now, Rich?

Rich: Yes. So, I'll make comments on two sources individuals can rely on. First thing I would do is encourage them to go to either the guidance, if they have the Standards Portal or there's a special, separate publication you can buy that has explanations of each of the Standards. We have the Standards, and those have to be followed for the assessment. But realizing that there's different ways to do things, the Standards Committee has put down some additional documentation or guidances to help explain how to follow the Standards.

If an individual reviews that and still has additional questions, they can contact AABB. I'm involved with that as well as the committee chair. AABB will draft a response. I will review that along with the committee chair and we'll send it back. And believe me, there should be no hesitation about sending in a question. There's no stupid questions. There's only, It's only stupid if you don't ask a question and then you get a nonconformance on the assessment. So we're here to help. That's what I wanted to get across.

Joe: That's awesome. And again, is that still standards@aabb.org; is that correct, Rich?

Rich: That's correct.

Joe: Okay. Got it. Okay. Everyone. So let us move on to the last five, and these, again, are primarily transfusion-service based. And these will go fairly quickly, so we'll just kind of cruise through them, Rich.

Number six that we'll hit is standard 5.15.2.1, specifically addressing Rh-positive red cell containing components being given to Rh-negative recipients. And what was added at the end of that Standard is that what should be addressed is "including during times of critical inventory levels." Can you talk us through that change to the Standards?

Rich: Yeah. And so this came about as a result of AABB Association Bulletin 19-02, which focused on the overuse of group O red cells. If you look at, for example, O negatives, 6.9% of the U.S. population of donors is O negative. But the usage continues to increase, going between 9 and 10% and even higher in certain areas.

So it's very difficult to have group O, or especially O negative blood that's available. The committee felt that this is just adding to make sure that there's good stewardship of the blood supply, both during standard times and times during critical inventory levels.

Why are they "critical inventory levels?" That could be because there's a blood shortage. There are not enough donations coming in. It could also be because of some natural or manmade disaster that's using a lot more blood products as well. But again, this just asks facilities to focus on that issue and make sure that they have a policy in place, because these issues do come up, and the committee felt that it's better to have a policy to say, for example, "After four units of O negatives, if the patient is not a female of childbearing age, go ahead and switch over to O positives." It's much better to have in place than trying to make arbitrary decisions, when sometimes there's an urgent need for blood.

Joe: I completely agree with that, Rich. I tell people all the time that time to make those tough choices or to set up your protocols for those tough choices is not in the heat of the battle. It's before, so everybody knows what's going to happen and that your and your staff in your hospital knows what's going to happen as well, right? That's really crucial to me.

Rich: Absolutely.

Joe: Okay. Well, I completely agree with that and I think that's a very important addition. Everyone again, Rich gave an example, but this is something that facilities have to decide on locally and decide exactly how you're going to handle that. The point is, have a policy.

So, let's move on to the next one, number seven, which is 5.19.3, the washed cellular products policy. And, quite frankly, I'm not sure how we didn't have this before, to be honest! And so 5.19 is the general header for a group that goes under, "Selection of blood and blood components in special circumstances."

And there's a lot of things in there, Rich, as you well know, about leukocyte reduction and cytomegalovirus and prevention of TA-GVHD, things like that. The committee chose to add that "The blood bank and transfusion service needs a policy regarding the use of washed cellular products." Again, I'm not sure how we missed that in the past, but talk us through that and what that means.

Rich: Washed products was always listed under one of the reference tables. As you mentioned, Joe, there's a variety of products, CMV-negative, irradiated, and then washed just wasn't there, so we've added it in there. It's really nothing new.

The only comment I want to make about using washed cells is, we sometimes get requests for this. Well, if you look at the Technical Manual, up to 20% of red cell yield and or 33% of platelet yield may be lost during the washing procedure and may increase product wastage. Red cells expire in 24 hours, and washed platelets expire in four hours, so we certainly want to add that, make sure that everyone knew that was an available product,

Joe: Rich, just, again, for those that are learners, and folks, we're not proscribing what you need to specify as reasons for washing, but Rich, in your practice in Florida, what are the kinds of things that people ask you to wash blood products for?

Rich: Yeah, I mean, there's really three of them. The first one is, individuals with IgA deficiency, and possibly anti IgA antibodies. That's kind of the highest profile, but those cases don't come up that often. A much more common one, in fact, the one I'm dealing with today even, is an individual that has allergic reactions to products containing plasma. So just platelets, or red cells, and they're refractory to medical treatment. The third is if a mother wants to donate for her newborn, and the baby has platelet antibodies. The mother can be a good donor. The antibodies are to the father. So, we want to make sure that we wash the plasma of the mother before we give those platelets.

Joe: If I can circle back to what you said before you listed those three, I think it's important for people to understand, again, for the learners out there, that washing is not just completely benign. There is absolutely loss of product and there's some consequences.

Now I know our friend Neil Blumberg would argue with me about this, but the truth is washing, to me, for limited circumstances, for a limited indication, like a mild allergic reaction, for example, I'm sure you get those requests, as do I. I always have a conversation with people about, do you really want to do this? It's like bringing a bazooka to meet something that a little rubber band could take care of. Am I overstating that Rich or do you share that?

Rich: No, I do. And you know, in the community practice, especially where I'm located, and especially, I'm sure for many of the listeners, a lot of these hospitals don't wash cells anymore. They just don't have the need for it. So the blood center does it.

And I can tell you some of our areas with the platelets, we're washing them, we're having them on the highway and just about making them to the hospital within the four hours. So again, this is something that if there's any question about the request, as blood bank medical directors, we may give the hospital a call and just make sure this is the best use of a product. There may be other options that we could explore.

Joe: Okay, let's move on and hit the last three real quick, Rich, and the first is 5.27.1.1 and that is regarding the use of low titer, group O whole blood. This standard itself was implemented in the 31st edition, but there's been a slight change in that there was a number three previously, saying that patients who received low titer, group O whole blood, that those patients needed to be monitored for adverse effects, and the committee chose to remove that. And what was the rationale for that, Rich?

Rich: Sure. The idea was that now there's...when the 31st edition came out, the use of whole blood for massive transfusions was fairly new. With this edition to the Standards, it's been in place now and much more widely used. And there's been multiple publications and hospital experience that's really showing that this is safe.

And the committee did not feel that an additional step asking facilities to monitor for adverse events by laboratory values, for example, was needed. Of course, that doesn't exclude the possibility that if an individual has a transfusion reaction, that that should not be investigated because it should. But we just felt that the laboratory, doing these laboratory tests added little value. And, you know, of course, with anything, if you add it as a Standard and someone doesn't do it, it can result in a nonconformity.

Joe: And obviously I'm sure I can speak for you and the committee by saying that doesn't mean to just ignore the possibility right? But it removes it as a specific requirement that people could be cited for.

Rich: That's exactly right. If there's a concern about a transfusion reaction, then a formal transfusion should be called not just running laboratory values.

Joe: Great. Okay. So number nine is standard 5.29.1, and again, this is a change to a preexisting Standard. And, I'll just summarize it. 5.29, this is a section that talks about the patient's medical record and things that need to be documented in the medical record. 5.29.1 specifically, talks about a bunch of things that need to be documented during transfusion, but specifically what the committee added, or modified slightly, is to specify that vital signs should be taken at facility-defined intervals, including pretransfusion, during the transfusion, and post transfusion. I think that's probably fairly standard in most places, Rich, but why did the committee feel the need to specify that?

Rich: There's really two reasons. One, we wanted to make it consistent with the CAP standard TRM .41000, that requires vitals be taken during the transfusion. Secondly, the current standard of practice is to obtain vitals within the first 5 to 15 minutes of the transfusion, to make sure that the patient does not experience any adverse events. And then at that point, it's standard of care to start the transfusion slowly, to run it up to regular speed. So you know, this is really a safety issue. It's a very important issue that the patient be monitored during those first 15 minutes. And we didn't feel that the committee didn't feel that the Standard specifically addressed that. So that's been added in.

But just to be clear to the listeners, that's up to their facility to determine when they want to do the monitoring during the transfusion. You can do it before, 15 minutes, afterwards. You can do it every hour. However you decide to define it in your policies and procedures is how you'll be assessed.

Joe: I guess that's where "facility defined intervals" comes in, right?

Rich: Absolutely!

Joe: OK. Alright, Rich, so we've come to the last one that we're going to talk about today, and everyone, just to be clear, these are not the ONLY changes in the 32nd edition of Standards, but these are ones that we felt like would be valuable to talk about.

And this one is Standard 8.2, and that's utilization review. It's tucked all the way back, almost on the last page of Standards, and 8.2, under "Utilization Review," talks about how "transfusing facilities shall have a peer review program that monitors and addresses transfusion practices for all categories of blood and blood components."

And it gives a list of multiple things that need to be monitored. And one of the things that has been on there before includes monitoring appropriateness of use. Of course, I think everybody does that. But the committee added, including the use of group O and O RhD-negative red cells and AB plasma. And I think I know why committee did that, Rich, but why don't you just make sure that that's clear to everyone?

Rich: Sure. Again, we mentioned in an earlier Standard, this was kind of expand on AABB Association 19-02, to make sure that there's judicious use of group O blood, especially group O negative within the facility, and AB plasma, which is also a scarce resource. There are no specific national numbers that say, you know, "so much percent should be above or below this threshold." It's what you define as your facility, or your hospital organization.

You know, I think a good rule of thumb would be to kind of watch this and see if it's increasing. That might be an opportunity to explore that within your facility to see, why is it increasing? Are we getting more patients or is there just more ordering of O negatives and possibly take an action on that?

So that was really, again, the intent of the committee, to just ask that there'd be another layer of oversight in your peer review process.

Again, just one additional comment on 8.2: There is no requirement to have a formal transfusion committee, although many facilities do. The point is to make sure you have peer review of a variety of items that are listed in the Standard, and this will just add to the list, that you're looking at the scarce resources of group O positive, O negative, and AB plasma.

Joe: Rich, you're fantastic for saying that because actually, my next episode is an interview with Dr. Carolyn Burns on building the perfect transfusion committee. So, man, didn't tell you to say that, but that you, gave me a segue to my next episode. Nice job !

Rich: That's why you brought me on!

Joe: Well Rich, this has been great. Is there anything that you'd like to leave our listeners with, as we close our time together?

Rich: I just want to say it's a pleasure to be here, Joe, today, and I encourage everyone, again, review the Standards, look at the guidances, and if you have any further questions, email AABB, we'll review your question and we'll get back to you in a timely fashion.

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Joe: Hi, it's Joe with just a couple of quick thoughts before I let you go. You know, you could look at an episode like that as a “to-do list,” in other words, things that you've *got* to do in order to be AABB-compliant if you're an AABB-accredited lab, or if you live in California. But really, I prefer to think about it as kind of a “best practices” type of scenario. In other words, what are the things that you could and should be thinking about to make sure that you're giving your patients the best possible care? That's the way really that I would prefer to look at this, and I hope that you look at it the same way. I hope that was really useful to you, and it's given you some things to really think about as you move forward.

I do want to mention again that this is a continuing education activity. So if you're a physician or a laboratorian, don't forget to visit wileyhealthlearning.com/transfusionnews to get your hour of totally free continuing education credit. Just a reminder, my thanks for that, as always, to Transfusion News, to Bio-Rad who brings you Transfusion News, as well as to Wiley Health Learning.

For the next episode, well, I have to admit, in this episode, I fibbed just a little bit. I said that the next episode was going to be an interview regarding transfusion committees, but actually, the next episode will be an interview with three wonderful and brilliant blood bankers that I really am excited to introduce you to. One of the three you already know. Her name is Sue Johnson, and she's been on the podcast a couple of times. She's magnificent. But I also am excited to introduce you to Laurie Gillard and Jay Slayten. All three of them joined me late last year for an interview that I call, “So You Want to be a Blood Banker?” and it's really designed for those of you that are early in your career and you're thinking about different possibilities for what you want to do with your life. And we want to tell you why being a blood banker is an excellent, excellent idea! So that's coming up next week.

A couple of weeks from now, the interview that I mentioned in the episode, with Dr. Carolyn Burns regarding “Building the Perfect Transfusion Committee.” That's a great interview. Tons of practical tips in that one. And again, I'm so excited for you to hear that.

But until that time, my friends, I hope that you smile, and have fun, tell the ones that you love that you do, and above all, never, EVER stop learning. Thanks very much for joining me on the Blood Bank Guy Essentials Podcast. We'll catch you next time.