**BBGuy Essentials 046:**
**Top 5 Changes in the NEW AABB Standards with Pat Ooley**
***Released February 6, 2018***

**Joe Chaffin:** This is the Blood Bank Guy Essentials Podcast, episode 046!

**[INTRO MUSIC]**

**Joe:** Welcome! I'm Joe Chaffin, your host.

Just so you know up front, this is not a continuing education episode. Check BBGuy.org and TransfusionNews.com for episodes ending in "CE" to get that kind of credit. CE episodes are provided by Transfusion News, with generous sponsorship from Bio-Rad (who has no editorial input).

This podcast is coming out two days after what can only be considered kind of an "annual tradition" in the United States. The Super Bowl was played on February 4, 2018, and I *guess* I hope all you Philadelphia Eagles fans are happy (but honestly, without my Detroit Lions in the game for the 52nd, that's right I said 52nd year in a row, I didn't care!). Well, there is another "tradition" that happens every OTHER year, on April 1 (and some would say "that is a REALLY appropriate date!"), when the newest version of "AABB Standards for Blood Banks and Transfusion Services" goes into effect. "Standards" represents the latest thoughts on practice and quality in blood banking/ transfusion medicine. This year, we have the 31st edition, and it has some significant changes that you need to understand, if you are one of the literally hundreds of facilities that answer to these Standards in the U.S. and a few other countries (and that includes most of you, whether you know it or not). These are changes required of all AABB-accredited labs.

Fortunately, I feel like I have the PERFECT guest with me to discuss this issue. His name is Pat Ooley, and he is the Senior Corporate Director of Quality for Blood Systems. Pat is also the Chair of the committee that puts the Standards together, the AABB BBTS Standards Committee. He is going to share some "inside" information on just what Standards IS, how Standards are developed, and finally, his thoughts on what he feels are the "Top 5 Changes in the NEW AABB Standards."

Pat knows his stuff, and I think you will really enjoy our discussion, so here is my interview with Pat Ooley!

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**Joe:** Hey Pat! Welcome to the Blood Bank Guy Essentials Podcast!

**Pat Ooley:** Good morning, and thank you for having me on. I'm glad to be here.

**Joe:** I always like to start with just about every guest that I have on, hearing just a little bit about your story and what it is that got you interested in blood banking. How did you move along in your career to get to the point where you are now? Well, I mean actually, let's start at the beginning, what interested you in blood banking to start with, and how has your journey been to get to where you are now?

**Pat:** Yeah, that's a great question, and you know, I don't think about my history very often, so it dates back to maybe about 30+ years ago. I had occasion to visit a laboratory once when I was a kid and was very impressed by people in white jackets, and running tests, and taking blood samples. And so, I knew that was going to be my career path of some sort. So, that led to going to medical technology school, as it was known back in those days, and graduating, which included an internship through the blood bank. And blood banking was always one of those fascinating parts, much more hands on, I think, than other parts of the laboratory, and a lot more risk involved, I think, and making sure you provided compatible blood components to patients.

That turned into working for a blood center. I was in a blood center, and this particular blood center had some regulatory quality issues in the 80s, and there was not something known back then called, the “Quality Plan" or the “Quality System." So, the CEO of the blood center approached me and said, "Hey, why don't you develop a quality plan?" I'm like, "OK! That sounds like a lot of fun!" (had no idea what a quality plan was). First day on the job, the medical director called me and said, "I think we need an audit of our distribution process. Go down and audit them." I'm like, "Fantastic. What's an audit?"

So, that just kind of developed into really understanding, what's the best way to manage a blood donor center? And what are quality elements of a blood bank? And what's important and what's not important? And we really formed a quality system from scratch, not truly knowing what we were doing. This is well before AABB published their "Quality System Essentials" in the 90s. That turned into being familiar with Standards, being familiar with the AABB, and going through AABB assessments and inspections, it was called the “I&A Program," back in those days. And one of our inspections kicked off with the lead inspector physician, who said, "This is how I'm going to write up all your deficiencies." And I thought, "Well, that's an interesting way to start this inspection. You're assuming we're going to have deficiencies. I'm assuming we're going to have NONE!" So, I thought, I need to talk to AABB about how they start their assessment programs. And that turned into me serving on the Accreditation Committee for the AABB. We kind of overhauled the

old I&A program in the early 90s into the accreditation program that has continued to evolve over the years. And that just led from one thing to another, I think, working on committees from the Standards Committee, which I've been on since 2000 (I think the 20th edition was the first edition I worked on), to the Accreditation Committee, to the COI Task Force, and a lot of other groups. It's just been a very enriching and rewarding process to become even more familiar with transfusion medicine and how quality plays an important role in ensuring available blood products are going to be safe for patients.

**Joe:** Well, I think that leads us actually very nicely into what we're talking about today, Pat, so thank you for that. I think that with you in your role as the chair of the blood banks...let's see, I've got to get this committee right! So, it's the "Blood Banks and Transfusion Service Standards Program Unit." Is that correct? Did I get that right?

**Pat:** That is right! It's a good thing you got that right or I might have to end the podcast now! [laughs]

**Joe:** [laughs] Well...I'm wiping the sweat off my brow! That's fantastic! So, obviously this is a group within AABB, that is responsible for putting together the main set of Standards used certainly in the United States and in many other countries for blood banks and transfusion services. We tend to call it "Standards," just flat out "Standards" (there are multiple different ones, but this is the main one). And I wonder if you'd just take us through a little bit, well first, what do we mean when we say, "Standards"? What are people referring to when they talk about that particular set of rules or whatever?

**Pat:** Yeah, there are multiple versions of Standards from the AABB. The "BBTS," yes, you're right, as we shorten it, is the main set of Standards. And it really outlines the minimum requirements that AABB-accredited facilities (so, blood banks, donor centers, transfusion service) follow. And it's a long-standing tradition for the AABB, and it has a rich history. The very first edition of Standards (I have some trivia for you) was first published in 1958! So that was edition 1, and we are now up to our 31st edition. Interesting, when I was looking back at the 1st edition, it was only 14 pages. It was very simple. Back in the day, when life was easy! But now we're up to the 31st edition, and the Standards really set forth what we believe is the most sound practice in transfusion medicine to ensure donor safety as well as patient safety. And we call them "Standards" because if you've chosen to be an accredited AABB facility, those standards are the minimum requirements that each accredited facility has to follow. So they're mandatory, if you choose to be accredited by the AABB. And in essence they're adopted by other agencies, as well, whether it's Joint Commission, who has similar standards based on what AABB does, or CAP. So anything that's in the Standards is typically worded in one of those legalistic ways with the word "shall." So, if you read a standard and it says, "shall," that means you

have to follow it. There are a handful of standards that say, "may," and those are typically optional, but for the most part, they're the baseline requirements that are developed and published and promulgated, so to speak, to ensure and enhance the quality and safety of our services to donors and to patients.

**Joe:** So, one quick question on that, Pat then, and what you just said is very important when you talk about the, "If you CHOOSE to be AABB-accredited, then these are the minimum standards that you have to follow." However, as you know I happen to live in...I THINK it's the only state in the United States, please correct me if I'm wrong...I live in California, and in California, these Standards are actually state law, isn't that right?

**Pat:** That's absolutely correct and that was a good distinction that you made! In the state of California, it's in the state law that blood banks/transfusion services have to follow the AABB Standards. So, unless you have some exception granted by the state, whatever is published in the Standards, if you reside and work in the state of California, then these Standards are in fact, law.

**Joe:** And there isn't any other state that's done that, is that right?

**Pat:** That's correct. A lot of states have varying degrees of requirements regarding blood banking. Some are pretty extensive. The state of New York is fairly extensive, and some are less so. But, I think California is the only one, to my knowledge, that specifically has it written in as law.

**Joe:** Okay. Well, I find that fascinating, of course, since it impacts me on a daily basis in California! Yes, it's perhaps even more interesting than it will be to everyone else, but let's move on a little bit, and talk about…I think it's important for us to understand how these Standards get developed. I mean, I will admit, and I joke about this, that I imagine the Standards Committee is, you know, ten old dudes sitting in a room, a smoky, cigar smoke-filled room, negotiating..."Yeah! Let's do THAT!" I'm guessing that's probably not as crude as that! So, why don't you tell us what kind of people are the Standards Committee made up of, who's represented? Obviously, just briefly, but how does this process work?

**Pat:** Yeah, there are a group of old people [laughs]…including some of them like me, who have no hair...but it's a pretty large group! We have 38 volunteers that serve on the Standards Committee, plus a handful of AABB staff (national office staff), and it's a wide variety. We try to get a cross-section and multiple disciplines. So we have physicians and pathologists that serve on the Standards Committee. We have a lot of CLS' and med techs that have blood banking experience that sit in on the committee, and we even have an ethicist. So the ethicist...which is a difficult word for me to say..."ethicist," plays a really important role as we're working on wording. It's not as easy as just writing a couple of sentences saying, "Thou shalt

do X." So we have to really think about the way we phrase something, "What's the impact to a donor? What's the impact to a patient? And how will this be interpreted by the population at large and by our members facilities?"

We also have liaisons from a number of other committees. So we have someone from the Accreditation Program Committee from AABB. We have someone from the IS committee from the AABB. We have a TTD (transfusion-transmitted disease committee) who sits on our committee. And then we have reps from a lot of other organizations: The American Red Cross, the American Society for Apheresis. We have a CMS person who helps us stay in line with CLIA regulations. PPTA sits on our committee, CAP has a rep, the Armed Services Blood Program has a rep, Canadian Blood Services has a rep, ICCBA (our ISBT people) are on our committee. The state of California has a representative ("surprisingly" so) on our committee. And lastly, it's the Food and Drug Administration. They are our partners in ensuring that if we do go astray from minimum regulatory requirements, that it was with full knowledge. And as we propose new standards, we rely on the FDA to say, "Is that in concert with what the regulations are?" Or is it not in concert, and if it's not, what would the impact of that be to facilities? So the FDA plays a really important role.

So essentially, when we meet to work on the Standards, it is this humongous group of people that sit around, and the role of the chair, I've always viewed it as "herding the cats," so to speak, and getting the voices to listen to one another. Everyone has an opinion, and they're all valid and good opinions. But the chore is trying to reach consensus and create something that's usable by our membership.

**Joe:** So maybe less cigar smoke than I'm envisioning?

**Pat:** Probably just a little bit less! In fact, AABB...I'm not here, of course, as an *official* AABB representative, but they DO have a no-smoking policy! So whenever I start a Standards Committee meeting, I always have to remind everybody of that.

**Joe:** [LAUGHS] Outstanding! Okay so you mentioned, the 31st edition of Standards is becoming effective April 1...Actually, we may NOT have said that. The 31st edition is the upcoming edition. It IS becoming effective on April 1, 2018. So when did you guys start work on that? Well first, how often are the Standards updated? Is there a "standard" timeline?

**Pat:** Yeah, we have them on a 24-month or two-year cycle. In the past, it used to be an 18-month cycle, but we had a few of our accredited facilities that might get trapped and might not get assessed on whatever the current version was. So we tried to harmonize with other Standards like the Cellular Therapy Standards, Reference Lab Standards, and put everybody on a two-year cycle. We chose the

lucky straw of having ours always be effective on April Fool's Day. I'm not quite sure how that happened, but...

**Joe:** I am NOT going to touch that one! I'm not commenting!

**Pat:** But it's effective, as you mentioned, on April the 1st of this year [2018]. So we started about a year out. So our first work began in the January-February timeframe of last year, 2017. And we take this large group of 38 people and we break them into three primary work groups. And as many of your listeners may know, the Standards is developed into ten "chapters," and they're based on what AABB terms the "Quality Systems Essentials." Everything from your organization through process control all the way through documents and deviations, etc. So there are ten basic chapters, and so we take those ten chapters and we split them up among three workgroups. Workgroup 1 is focusing on the "donor side" of the house, so they covers sections 5.0 or Chapter 5.0 through 5.10. Workgroup 2 focuses on the "patient or the transfusion side" of the house, and they look at Standards 5.11 through 5.30. So, front-end, back-end. And then workgroup 3 covers everything else, so the basic quality stuff, from training, and personnel, equipment, to documents and records, and those kind of things. So they cover chapters one through four and then six through ten. So in January, we form our workgroups, and then we make assignments. And it starts with, take a look at the current edition of the Standards. Identify what's working, what's NOT working, and then propose edits and changes. There's a lot of evaluation that happens to decide what do we want to do. We don't want to change just to be cruel and unusual. We try to make substantive changes that are meaningful and really facilitate donor-patient safety as well as member understanding.

So some of the things these work groups look at are: Changes in technology, new developments, whether it's a new product type or a new methodology on testing, a new patient safety concern or a new donor safety concern. We look at relevant transfusion-transmitted infections (otherwise known as RTTI's in FDA parlance). We do look at FDA guidances that have come out since our last edition, any new rules or regulations, and how they might impact our Standards. We seek input from our sister committees: TTD, CTMC, the donor history questionnaire task force, others. We look at the circular of information. We ask our accreditation department to tell us what are the most commonly cited issues from assessments, and is it based on the fact that someone's just not complying, or is it based on the fact that maybe the standard isn't crystal clear? We look at member and public feedback. The AABB has a long-standing process of accepting Standards interpretation questions. So a facility, if you're out there, and you're like, "What is the meaning of Standard 1.2.1, or 5.1.5. whatever?" We then evaluate that Standard and provide them guidance on how to interpret the Standard or how to apply it in their facility. So we look at all those past interpretations over the past year or two, and decide, "We've had a lot of questions about a certain Standard. Maybe that Standard isn't as clear as it needs

to be." And then lastly, we look at variance requests. An accredited facility has the ability to say, "I understand what the Standards is stating, but I think MY way is better, and here's WHY I think it's better. Here's what I want to do, and it meets the INTENT of the Standard. Will you allow me to do something different?" And so, we look at them, the variance requests we've received, to decide again, "Do we need to modify the Standards so we're not getting 10 of the same variance requests every year? Maybe we need to modify it to make it better or clear."

So those are some of the things that we consider when we are evaluating what we want to put. So that starts in the January-February timeframe about a year out. But then we go through a series of discussions. So when the workgroups meet, they propose language. Then we get together for a face-to-face evaluation. We spend about a day and a half arguing with one another, trying to decide, "Do you want to make this change? Do we NOT want to make this change?" Sometimes we argue about substantive topics like, "What is the impact on inventory? What is the impact on a patient? What's the impact on donors?" to, "I think we need a comma here because a comma would make this sentence much more clear." So we have those discussions. Then it goes through a technical and a legal and a regulatory review. It goes to AABB's Board of Directors, and then it goes out for public comment. So in this particular edition, the 31st, the public comment period was June through August of last year. And I encourage anybody that has an interest in Standards that when you see the draft Standards come out, please read them and please COMMENT! The committee looks at each and every comment, whether it's 60 comments or 200 comments. And we use that to help influence our decision on clarity and applicability and whether something should truly be a Standard or not. So we get back together in the fall (in this edition, it was in September), we evaluated all those comments, and then we made final changes. It goes back through the process of technical-legal-regulatory, and then board approval. And once it's blessed by the board, it goes for publication, which is about the January timeframe. And then they are mailed out. And for those subscribers to AABB's Standards Portal, the Standards are available on the Portal. And then they're effective on April 1. So that's the long drawn-out explanation.

**Joe:** You know, after hearing that, I can't believe you guys get all that DONE within a two year time frame, Pat! Holy cow!

**Pat:** It's a journey.

**Joe:** I imagine. I mean, especially the "comma arguments," because blood bankers, we're not known for being compulsive or anything, right?

**Pat:** No, not in the SLIGHTEST... [LAUGHS]

**Joe:** [LAUGHS] You did mention one thing in there that I want to make sure that people are aware of. You mentioned that people that are requesting clarification of a standard, or wanting to submit a variance request, that there is a way to do that. Why don't we just go ahead and tell them Pat? There's an email address, right, that people can just use to let you guys know about these things. Why don't you tell us what that is

**Pat:** Yeah! It's pretty common practice to seek information, and AABB is all about providing that guidance. So if you're not quite sure what a Standard means, or you're at a loss to figure out how to implement it in your facility, submitting a request for interpretation or clarification is the easiest way to go about that. And you can email, it's standards@AABB.org. And that goes straight to the Standards department, and based on your question, and which version of the standards; Is it cell therapy, is it IRL, is it BBTS? It's funneled to the right committee. Those always come to the chair and then to one of the workgroup members. We maintain those three different work groups. So if it's a standard on medication for a donor and what the deferral period should be, that would go to workgroup 1. If it's something about retesting a neonate if they've been discharged, that would go to workgroup 2. So it's an excellent way to get information, and it goes through a process in which it goes to a committee member, and a committee member crafts the explanation. It goes back to the committee workgroup and the chair for an evaluation to see if we agree with the interpretation. And then, once we have all agreed, it goes back to the submitter. So that can take probably a few weeks to get through that cycle.

Our committee members are "highly-paid volunteers" [laughs], so we do have to encroach upon their own lives to get them to respond, but they DO respond. And then we make sure it's vetted appropriately and it gets back to you. So I highly encourage people to go to standards@AABB.org if you have a question.

**Joe:** Got it. That is important. OK, Pat, there actually are quite a few changes to the 31st edition. I was fortunate enough to be on an AABB webinar...We're recording this towards the end of January, that was in the MIDDLE of January, the 10th I believe, where you and several of the folks from your committee went over a large number of changes. And if any of you are AABB members, I would strongly recommend that you go to the AABB website if you weren't on the webinar and check that out. We don't have time, certainly, to go through ALL of the ones that you guys went through, but we wanted to do kind of the top five today. "The top five changes or issues in the 31st edition of Standards." There's a whole lot that's going on. But I wanted to start, Pat, with our number five, which interestingly enough, is not really a change, but I found it so important that I thought we should take it as our **number five, and that is the issue of iron depletion prevention in blood donors**. So I wonder if you'd take us through the Committee's rationale on what you guys did or decided NOT to do with iron depletion?

**Pat:** Absolutely. That was a good discussion and kind of a controversial one that we had among the committee members in early 2017. So the issue around blood donor centers establishing policies and procedures and processes to mitigate the risk of iron loss and it's a fairly well-known fact, and there's been a myriad of studies. And I think you've had past podcasts about this topic, so we won't go into the details around each of those studies, whether it's the REDS-II study or the CHILL study or others, but it's known that there is a risk of of iron depletion and potential negative impact on blood donors [NOTE: See Episode 32, "Eat Your Spinach" with Jed Gorlin at BBGuy.org/032 for more on blood donors and iron]. So, as the committee was evaluating that, again, looking at what can be changed to Standards that really enhances or improves both donor and patient safety, we spent a lot of time evaluating that. Ultimately, we opted not to make a change to the standards. We had proposed some language and thought about what we wanted Standards to say. So if you're familiar with Standards, currently there's some reference to this. It's under Standard 5.2.1, donor education. And item number five...and donor education is all about what you need to inform the donor about prior to the donation process...and number five on the list says donors are given educational materials regarding the risks of post-donation iron deficiency. So that's an existing standard and we left that intact.

We spent some time evaluating the AABB Association Bulletin, that's bulletin number 17-02 that came out in 2017, that provided a lot of information about the studies that have been done, and really encourages blood centers to identify and adopt strategies to monitor or limit or prevent iron deficiency in blood donors. Now some background information for your listeners that standards we set earlier are the minimum requirements that we must follow. However, there's guidance and there are Association Bulletins. Association Bulletins and Guidance are merely that, they're “guidance,” you don't have to follow those. So, the Standards Committee evaluated the bulletin about iron depletion and thought, "You know what? It's time to potentially craft a standard."

So, as we were trucking down that road, feeling pretty confident about ourselves, as we often do in the Standards Committee, we realized that at the same time that we were debating this, AABB had formed something called the "risk-based decision making process" to focus SOLELY on iron depletion and strategies to mitigate iron loss in blood donors. The RBDM process (Risk-Based Decision Making Process), is a multidisciplinary group of individuals, includes members of transfusion medicine, includes patient representatives, general population representatives, who are going through a pretty detailed process to really determine what is the right answer.

So, for our top five, the number five is…we did **nothing**. Except to reinforce that your current requirement still applies, that you have to educate donors about the risks of post-donation iron deficiency. Standards doesn't tell you how to do that. We don't tell you what your educational materials should be, that's up to each individual

facility. But, we felt it important to reiterate the current requirement, but wanted to wait until the RBDM process ran its course, which we hope will actually be completed very soon, and we may see some recommendations in the not too distant future from the RBDM group, which their recommendations goes to the AABB Board of Directors, which in turn, makes the final recommendation which will come to the Standards Committee, and then more than likely, we'll formulate some Standard around that once that's all done.

**Joe:** I think that's a great summary. I would completely agree that we are going to hear more about this soon, both from AABB and, unless I miss my guess, from our friends at the Food and Drug Administration, as well, before too terribly long. I think it's not going away, that's for sure, but I understand why you guys chose not to do anything with this particular edition. Okay, so that is number five. Let us move on to number four and that IS a change, so again, we're counting down the Top Five Changes in the 31st Edition of Standards. The **number four change, in our opinion anyway, Pat, is a change to Standard 7.3, and that's regarding classifying adverse events**. So, why don't you tell us what you changed and what the rationale was?

**Pat:** Sure. The standard actually reads: "The BBTS (Blood Bank/Transfusion Service) shall use **nationally recognized** classifications for donor and patient adverse events. The medical director shall participate in the development of protocols used by the staff to identify, evaluate, and report adverse events." So, our big change there was really around the terms "using a nationally recognized classification system." If someone refers to the current 30th edition, which is the one we're following until April 1st, it just stated that "the Blood Bank/Transfusion Service shall use *standardized* definitions," nothing that's nationally recognized. And the change to saying you had to use standardized definitions in the 30th was brand new. So that was a brand new addition to that Standards. We've tweaked that, and it's part of our "master plan," if you will, of helping institutions and establishments be more consistent, and using more universal language to help us classify the kinds of harm that can happen or adverse events that occur, whether it's donor or patient related.

So, we thought the first baby step was the 30th edition of using standardized definitions, the next step is to use something that's nationally recognized. And, the most common question is, you know, “Where in the heck do I get these? What ARE nationally recognized classifications?” And there's a lot of places you can go, whether it's through the AABB…you can contact AABB Center for Patient Safety, they have some really handy reference guides that you can pick up and they can provide you that will tell you a lot about those standard definitions. You can also go to the CDC and the National Healthcare Safety Network, Hemovigilance or the DonorHART Program.

The idea behind this is that, if we all think about and classify adverse events in a consistent way, we eventually will be able to move to better ways to capture these events, to really analyze them, identify trends, and then develop better methods to improve donor safety and improve patient safety. So, it's much easier to identify changes that are needed nationally if we're all speaking the same language. Otherwise, you're comparing apples and oranges and it's very difficult. Even from a quality perspective, you know, when we think about errors and deviations, two different blood establishments or blood banks or transfusion services, could classify their errors differently, which makes benchmarking extremely difficult. But from a patient and a donor safety, we wanted a way to have everyone start to use the same language, and this is a step in that direction.

**Joe:** So, the listeners that I have in other countries, for example, Canada, the UK, etc., are listening to this and going, "Uh, WHAT? You don't all use the same classifications?" So, I just want to reemphasize what you said there, Pat. Before, with the 30th edition, you were required to use standardized definitions, which basically meant that as long as you were consistent within your own facility, you were fine. But this is more a move to make EVERYONE, as much as possible, consistent to move at least in the direction, more of a unified national hemovigilance approach. Is that a fair way to put it?

**Pat:** That's a very fair way. That's absolutely right.

**Joe:** All right. Good deal. So, that will require potentially some changes for folks. So, I hope everyone listening can just make sure how you're classifying. Obviously, if you're a donor facility, you need to be aware of this, if you're a transfusion service you need to be aware of this. If you're both, you DEFINITELY need to be aware of it! So, take that into account as we move on to our number three…or anything else on number four, Pat?

**Pat:** No, that's it. I think a common question when Standards change is, “What will assessors look for?” You know, the “evil accessors" that come to your facility (I call them "evil" because I am one!). But, I think you will just need to demonstrate what your classification system is and how you know it's compatible or consistent with a nationally recognized system. So, it doesn't mean you can't have something that supplements what you do, but at least your key definitions need to be equivalent to a nationally recognized. So, that's probably what an assessor is going to ask you, how you can demonstrate that.

**Joe:** Got it. Okay. Let us move on to number three. Just for review: Number five was a change that WASN’T made, with iron depletion strategies, number four we just finished, which was using nationally recognized classifications for adverse events. And so, Pat, **number three** is one that I know is very near and dear to your heart, and you and I have interacted about this particular standard for a long time.

**It's reference Standard 5.1.8A, and specifically, it regards platelets and how they are transported**. Now just for background, everyone, as long as I can remember that I've been involved in blood banking, there are some specific guidelines for how platelets have to be shipped, for example, or certainly stored as well, but shipped in particular. And as long as I can remember in blood banking, we have said (the dogma is) that platelets can't go without agitation, they can't sit still for more than 24 hours. So with that background, Pat, why don't you talk us through. What did you guys change in 5.1.8A?

**Pat:** Yeah. It's been a long-standing process, as you said, that platelets can't go without agitation for 24 hours, but we know sometimes, real life happens. And when real life happens, there are situations in which your platelet product could be in a transport kind of mode more than 24 hours. It's very common that there are shipping delays or something along those lines. And we don't want to potentially lose, you know, a highly valuable product, just because we're at 25 hours or 26 hours without agitation. So, many blood establishments would convene a group of quality folks and medical folks and operational folks to really evaluate these, call them "excursions" if you will, when a platelet wasn't stored or transported within a time frame of 24 hours. And, we typically do some evaluation of how does the product look, let's check the pH, etc. Is there any clumping or aggregates forming? Those kinds of things. And nine times out of ten, we would allow the release of those products because the risk to the recipient is pretty low, and the product is pretty good.

So, we brought it up to the committee and did some some evaluation, and we found some reference material. Probably the best reference I can give you is from Transfusion in June 2008 [NOTE: See BBGuy.org/046 for link to this reference], which was a study that talks about the influence of simulated shipping conditions 24 or 30 hours of interrupted agitation on apheresis platelets. There had been studies done on whole blood-derived platelets but there really hadn't been anything on apheresis platelets. And, the conclusion of that study is that pH level 6.2 or higher, which is the minimum pH requirement for a platelet product, was maintained four or five days whenever there was an interruption, whether it was 24 hours or 30 hours. So, we brought that up to the committee and consulted with our FDA colleagues because we know their voice is important, and all agreed that under transport conditions, you can have up to 30 hours (that's your max) of products be out of your normal agitation mode. We did not put it in under the storage side, so the storage just says, "continuous gentle agitation." But, from a shipping perspective if you exceed 24 hours, you can go up to 30 hours and product is still suitable. So, it's kind of a minor change in the Standard itself, but I think it's a very valuable one from a product perspective.

**Joe:** Well and again, as we're recording this, Pat, we're at the end of one of the worst weather months that we have had in different parts of the United States for a

long time. And with planes being delayed, with flights being canceled, and platelet products coming in at just over that 24 hour mark, this is something that really has the potential to have a relatively huge impact on the availability of products, and I think that's, for me, what really strikes me, is the distinction obviously between shipping and regular storage. But this change, especially in the winter months, especially in times of minor delays, really has the potential to allow us to have more products available to patients.

**Pat:** Correct, you're absolutely right.

**Joe:** Okay. All right. Good deal. So that was number three, and Pat, we're going to move on to number two because these last two are really, really interesting, and in particular, the last one, is not only interesting, [whispers] it's a little controversial! So, we want to make sure we get to that! So let's do number two. **Number two is Standard 5.15.1**. And it's something that I have discussed on this podcast previously, in a previous discussion with Dr. Mark Yazer, and that is **the use of low-titer Group O whole blood**. So take us through that, Pat. What did you guys change? There's several places actually where this language has changed, but it starts with 5.15.1.

**Pat:** It does. So 5.15.1 states that "recipients shall receive ABO group-compatible red blood cell components, ABO group-specific whole blood," (and that's unchanged from the current edition of the Standards), "OR" (this is the new part) "or low-titer group O whole blood, for non-Group O or for recipients whose ABO group is unknown." So, that's a long, stiff sentence, and I can tell you it's one that received hours of debate, if not maybe into days and weeks. But nonetheless, that's the standard, and then it cross-references Standard 5.27.1. So, 5.27 is really under the "urgent requirements" section of the Standards. So if you have an urgent need for blood products, and you don't have time to do full compatibility testing, it reads, same thing, "recipients whose ABO group is not known, or has not been confirmed, shall receive Group O red cells, or low-titer group O whole blood." And it references back to 5.14.1/5.14.5. And then 5.27.1.1 states that "if low-titer group O whole blood is used, the BBTS shall define low-titer group O whole blood and shall have policies, processes, and procedures to do the following." First, you have to have a process that says when will you use this? When will you apply and allow for your facility to use low-titer Group O whole blood?. Secondly, what's the maximum volume or the maximum number of units or components that you're allowed to be transfused under this scenario, per event? And then thirdly, patient monitoring for adverse effects. So, if you're going to have a process of allowing the use of low-titer Group O whole blood, what additional, if any, patient monitoring is important to your facility? So your policies need to define all of those things.

So, these Standards are really important, and it's one that we debated at great length, and it's a good example of relying on public feedback and input, relying on

studies that have been performed, and then we mentioned earlier about the ability for a facility to submit a variance request. We started receiving variance requests for these, and weren't really sure how to handle them, and what we should do about them, because the Standards in the 30th edition doesn't really allow this. It basically only allows group-specific whole blood or group-compatible red cells. It doesn't talk about low-titer group O. And of course, a lot of the controversy around this was, what is "low-titer?" And, how many can you give? And, how do you know if it's safe or not? Well, for those listeners who are long-time blood bankers know that it's not a new concept. It's one that has been around, it's been successfully used in a number of environments. The military has an extensive experience in using low-titer group O whole blood or whole blood transfusions. It's really designed for trauma patients and people who have life-threatening hemorrhaging going on, and there's been a lot of studies. And, as you mentioned, you had Mark Yazer on a previous podcast that went into great detail, and as you know, Mark is pretty passionate about this topic…

**Joe:** [laughs] That's a fair way to put it!

**Pat:** You know, he's the co-chair of the "THOR Group," which is Traumatic Hemostasis and Oxygenation Research. And, just as a comic book lover, I can't tell you how awesome it is to have a committee named “THOR"...

**Joe:** It's the best! [laughs]

**Pat:** It's the best! But nonetheless, he feels very passionately about this thing. He did the Standards Committee a great service by really appealing to us and providing us with a nice SBAR around this topic. You know, evaluating the current situation, the background, what's the assessment of the indications, and then what are some recommendations. And, we took that information, I challenged all of our committee members to really evaluate the studies that have been done and we provided all that information, and then we came to the conclusion that, "Yep. Now was the time. It is the time to add this to the Standard." So, we made that change to the Standards.

Just because it's in The Standards doesn't mean you HAVE to do it, obviously, you can choose NOT to ever transfuse low-titer group O whole blood if you don't want to, but it is an option that you can follow. Just know that with that option, you need to define WHEN; so what's the patient population that you're going to use this for? And then, what's your maximum number of units that you'll allow in any given setting or event? And then, how will you follow up? And of course, part of that definition is knowing what is low-titer? And we talked about writing a standard around that, and decided that sometimes it's important to allow the practice of medicine to prevail. And, what works well in Pittsburgh may not work well in LA. So, we decided that it was appropriate for the facility to define what's right for them. So,

is it a 1:50 or is it 1:250 or is it something else? It just has to be defined in your policy and approved through your normal processes.

**Joe:** Got it. So, listeners, there is a lot more to say about that, as Pat alluded to. And, we mentioned Mark Yazer was on a previous episode. You can find that episode at BBGuy.org/040 and Mark talks quite a bit more. So, we're going to leave it there, Pat, because we've got to get to the number one change. Just for review,

- Number **five** was a NON-change in terms of iron depletion for blood donors
- Number **four** was the use of nationally recognized classifications for donor and patient adverse events
- Number **three** was a change to allow 30 hours without agitation for platelets undergoing transport
- And number **two**, which we just talked about, was the inclusion of low-titer group O whole blood as one of the options for those patients who are in urgent situations and we don't know their blood type.

So, there is much more we can say about that but we've got to do **number one**, Pat. So, this one has caused, and in fact on that conference call, that webinar I should say, on the 10th of January, I know you would agree, the vast majority of questions were regarding this one. So, we need to talk about it. It's **5.14.5, and it is a fairly substantial change that is making some waves with people that are looking at it.** So, I'm not going to preamble it any more than that, Pat, and just give it to you. What did you guys do with 5.14.5?

**Pat:** I am happy to talk about that, and it IS controversial. We had a lot of questions at the seminar on this particular change. It's not uncommon for us to have controversial changes, and at least one with every edition we do. Not to digress too far from this one, but I can remember years ago when we eliminated green soap as an alternative scrub method, because it really isn't very good. And we also eliminated earlobe sticks as a way to check for donor hemoglobin-hematocrit. So we're not immune to doing controversial changes.

So 5.14.5 is titled "Pre-transfusion testing for allogeneic transfusion." And essentially what we did was LIFT a current standard that you can find in the 30th edition known as 5.16.2.2, and move it to the front of the process. Currently, it's only listed under "electronic crossmatch," or under the use of the computer to detect ABO compatibility. But we thought if it's important enough to verify you have the right sample from the right patient, it was important not just from a computer crossmatch perspective but from ANY perspective. And our aim was to really strengthen our practices across the industry to avoid "wrong blood in tube" and to avoid misidentification and mistransfusion as one of the more risky and potentially detrimental outcomes, when you don't have the right sample and you think that you do. So we moved those standards and we tweaked the wording just a little bit.

So I'll read it for your listeners. And it states: "There shall be two determinations of the recipient's ABO group as specified standard 5.14.1. The first determination shall be performed on a current sample, and a second determination by one of the following methods:" And we list three examples. And people have said, Which is better and is one preferred over the other?" And we don't indicate preferences in the standard, but we merely say our requirement is, choose two ways to determine that you have the right patient.

So the first is: "Testing a second current sample." Or number two: "Comparing with previous records" (so you can go on historical type or historical records that you have in your institution). Or number three: "Retesting the same sample if patient identification was verified using an electronic ID system or another process validated to reduce the risk of misidentification."

So just from a personal perspective, I would say it's always good, if you don't have a history on a patient, to get a second current sample. That's the ideal method to ensure that you really have the right sample for the right patient. You can retest IF you have a really robust process that's been validated. So if you have an electronic system, a computer system, and you validated that as part of your methodology to verify you have the right patient, that may suffice. Or, if you have some other kind of validated methodology.

**Joe:** Pat, are we talking like barcodes or barrier systems? Forgive me for interrupting. What you just said and in particular that third thing, retesting the same sample BUT ONLY IF you undergo some fairly robust background...so I guess this is the thing, in my experience, that when I've talked with people about this that has raised the most challenges. So what do you mean when you say an “electronic identification system?” What are we talking about?

**Pat:** Yeah, it could be a variety of methods. It could be the computer system itself. It could be barcode technology. It could be RFID microchips that your facility has employed. It can be some kind of dual labeling process where you're able to verify by more than one methodology that "John Doe" is really "John Doe." The Standards themselves don't get too proscriptive to say what is valid and what's not valid. But, if any of your listeners are subscribers to the Portal, the AABB Standards Portal, the Portal has some advantages that the Standards themselves in hard copy do not, and that is a link to guidance. So many of our standards will have additional information to help supplement that standard to explain the intent, the rationale, the background behind the standard. So for this particular standard, it there is some guidance on this that talks about the importance of the standard to prevent inadvertent transfusion on incompatible blood components. And it gives you some suggestions such as, first, obviously, the separate independently collected blood samples; TWO blood samples NOT collected during the same phlebotomy event

(that's an important distinction). Secondly, looking at historical records, and third, some type of electronic ID verification system. So it could be barcode technology. It could be a number of things. It's whatever your facility is identified as that system. And then if you don't have an electronic system like barcode technology or RFID chips, then there may still be a way for you to really meet the intent of the standard. Some examples might be...one is a computer system, so current samples need to be obtained if you DON't have a computer system, but it could be some other methodology. So some examples could include, a secondary unique banding system, and specimen labeling system. Could be a Blood-Loc safety system, which some people are familiar with. It could be a unique ID band number in addition to the patient's MRN or the patient's account number. So those are just some simple examples. The key is, how do you validate that? How do you ensure that it's robust? And you know the purpose of any validation process is to confirm that you're able to on a consistent basis achieve the intended outcome.

In this case, you want to consistently be able to demonstrate that the patient you have in front of you, the patient whose sample you have, is truly that patient. So you would want to design a test methodology, so to speak, to confirm, not just one time, "Yep, I have these two numbers. It's really this guy." But some ongoing method to identify with repeated consistency that you're able to confirm you have the right person. So I don't know that's helpful or not. Those are just some examples that might apply. The key is to define it and then really test it and validate it to make sure you have the right patient.

**Joe:** So I have a couple of observations and one question...It may just be one observation...I have never been (this is “opinion territory,” everyone, so take this for what it's worth), this is my personal opinion: I have never been a fan of retesting the same sample in general. My feeling on that, Pat, is that if what we're trying to do is to make as sure as we can that we don't have the wrong blood in tube, then retesting the same sample, the only thing that proves, in my opinion, the ONLY thing that proves is that your transfusion service is capable of repeating a test, the easiest test that we have in the blood bank, the ABO and Rh determination, that you can do that twice and get the same result. It doesn't do ANYTHING to prove that it's not the wrong blood in tube. Now, I understand what you're saying in terms of if there's a more robust way of ensuring that it is the right blood in tube, then you can do that. That's fine. But what I've what I've encountered as I've talked to people about this is that because the College of American Pathologists has had the opportunity to retest the same sample as one of their checklist guidances for some time now, I think people may have gotten into the habit of thinking that that is a reasonable thing to do. So again, personal opinion: I'm glad that you guys said that if you're going to retest the same sample, that sample has to live up to a higher standard. I don't know if you have a response to that, but it's basically just my observation.

**Pat:** No, I think it's a great observation. We debated how we wanted this to be in the Standards, and we even debated eliminating the ability to ever retest the same sample, and it had to be a second current sample or comparison with previous records, but we weren't ready to make that move yet. We wanted to be consistent with CAP and others. But we wanted to make sure that it was a robust process. I agree that, ideally, it's always a second current sample is the way to go. And I'm sure people are going to debate, "What is a 'current sample'?"

**Joe:** Yeah. Well, that's my question! Forgive me for interrupting, Pat, but that's exactly where I was going, and you read my mind. Can you walk over to the hematology lab and grab a CBC tube from the same patient, and consider THAT your second sample? Again, we are somewhat entering into the opinion territory, so I want to be clear with everyone listening, Pat. I want you to tell us which part of what you're about to say is your opinion versus something that you can speak for the committee. So I realize we're treading on dangerous ground there, but what about going and grabbing a CBC tube?

**Pat:** Yeah. We'll start with the opinion first, and I don't think that's a good practice. So I would advise against that just from a personal opinion perspective. Lots of questions are around that! How do you know what the methodology was used to collect that sample? Where has that sample been? How do you know if it's truly going to meet your requirements as a blood bank sample versus a chemistry lab sample? I think you have to be very careful about the integrity of that sample and the methodology with which it was collected and how it's been used. So I am not a fan of just grabbing samples from another part of the lab and putting it to use.

However, putting on my "AABB hat," my Standards Committee hat, the first step you need to do is to "define your process." So if you've defined your process that says, "We are going to get or test a sentence current sample in absence of a patient history," and you define "current sample" as any other sample in the laboratory, theoretically, that does comply or conform to the minimum requirements of Standards. As an assessor, I would probably ask you lots of questions around that, such as, "What are the criteria used to identify the patient? Is that criteria uniformly consistent through your whole facility? So is the same rigor that might be applied to a blood sample applied to any other sample in your facility? How do you know how that sample's been maintained? How do you know about the integrity of that sample?" I would ask lots of questions and hopefully you would have all that defined in your policy, and you've had some validation of that process. So those are the kinds of things you would need to put in place.

The other thing I would recommend as chair of the Standards Committee and working with Standards for a long time is that, if you have a process and you don't want to wait until you're assessed or inspected by the AABB, and you want to know right away that's right or not right or robust enough, send it into the AABB. You can

use that same process, the Standards interpretation process, and submit that. Submit a comment or question that says, "I'm trying to apply standard 5.14.5. Here is the way my current process works. Does this meet the intent of the Standards?" And then the committee will evaluate it, and then they'll give you some feedback on whether it does meet the intent to Standards or not. Then when you're inspected by someone, an assessment team or assessor team comes in, provide that evidence that, "This is my process, this is how I know it works, and I've vetted it through the Standards Committee." So that's always an option to facilities.

**Joe:** OK, So a couple more, very quick, probably more "opinion questions" for you Pat. If, for example, you have decided you're going to try to do that "grab the CBC tube thing," if you go over and you grab the CBC tube, and it is time-stamped the exact same time as your blood bank sample, my opinion is that would not meet the definition of a "second current sample," if it was drawn at the same time. Would you agree with that or disagree?

**Pat:** I would agree with that. The idea is a separately, independently collected blood sample. So not two blood samples that were collected during the same phlebotomy event. Again, Standards doesn't go to that level of detail, but that's the intent.

**Joe:** Understand. Again, we're in "opinion territory," everyone, so hang with us. I have been asked this question (in fact I was just asked this at a conference this weekend). I'll throw it to you (and I know Standards doesn't define this): Would a facility be wise, in your opinion, to set a minimum time between samples? In other words, sample 1 comes down and it is drawn at 12:01, and then you tell them you need sample 2, and, "Oh look! It was drawn at 12:02!" There obviously may be some gaming of the system there, I get that, but again, in your opinion, should facilities set a minimum time between samples?

**Pat:** Yes that's a tough question, actually because…

**Joe:** It is.

**Pat:** …the short answer is, "Yes." You should define for your facility, what do you mean by a "second current sample that's not part of the same phlebotomy event"? So if you define it that way, that it can't be the same phlebotomy event, maybe one that's ten minutes later is fine, if it's collected by a different phlebotomist or a different event than when the first sample was drawn. I would probably shy away from saying, "The minimal amount of time between samples is 4 minutes," because you will have someone come in and say, "Oh this one was done at three minutes and 59...."

**Joe:** We call that "setting yourself up for failure," right?

**Pat:** Yes, exactly. I would shy away from being that proscriptive, but I would add clarity and definition around what you mean by a "second current sample" and what you mean by a "separate phlebotomy event." That could even be in your policy document, it could in your training material, it could be in something in your facility that really defines what you mean by that. I think if you do that, you'll have to defensible process.

**Joe:** Okay and one last one, Pat. I'm putting you on the hot seat here, buddy.

**Pat:** I'm sweating now!

**Joe:** [LAUGHS] Well, the one that always, always comes up, and I'm sure you've heard this, and I'm sure it was debated, is: What to do in emergencies? So let me ask first, did you guys consider loosening this standard in emergencies or not? And then if you want to go into opinion territory, do you feel like it could or should be loosened in emergencies?

**Pat:** I think it can be. Sometimes in urgent situations and cases of mass casualty/ mass trauma events, you have to know when it's okay to deviate from the norm. The first thing I would say is just think about Section 5.27 of the Standards, which is about urgent requirement for blood and blood components. Now it does say you shall have a process for the provision of blood and blood components before completion of tests required. And of course among those is Standard 5..14.5. So you can vary from that and have a different process away from those two independently collected samples for determining recipient ABO type. However, I would NOT say you can use that as a convenient way to not adhere to this standard. So, in other words, "I'm going to give O negative red cells all the time, so it doesn't matter if I get that that second sample or not." That's probably the wisest use of resources, first of all, of something that's not readily available. So I think you can deviate from the practice as long as you define what your process is.

**Joe:** Right. Okay. Well, Pat, I think we have...You know, I guarantee someone is going to have a different question than what I had. So folks, just again a reminder that if you go to the show page for this episode which is BBGuy.org/046. You will find, at the bottom of the page, a comment section, and feel free to hit us with your comments and tell us what you think about this. I will do my best, I certainly read every question that gets asked, and anything that I need Pat's help on which is very likely...

**Pat:** I doubt that.

**Joe:** ...I will ask his opinion on those as well. So, we have hit the top five changes in the 31st edition of Standards, and, Pat, I think this has been really, really helpful. Thank you so much for doing this with me!

**Pat:** You're very welcome. I was glad that you asked, and just really pleased to be able to be a part of your program and your podcast. So thanks for the invitation, and I hope that was useful to your listeners.

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**Joe:** I hope you enjoyed that, but more importantly, I actually hope you maybe got a little annoyed! If so, that means you are thinking about this, and that's what everyone affected by these changes (most of us) needs to do. Please let me know how you feel, especially about the "two-specimen" requirement (because that is a big thing that in many cases will require some significant changes). You can do that at the show page for this episode at BBGuy.org/046. On the show page, you can also find the transcript for this episode. You can also find some references for things that we talked about in this episode. I promise I will read everything that is submitted there! You can also now email me directly at comment@bbguy.org. Please give the show a rating on Apple Podcasts or iTunes when you have a chance.

Thanks for listening! The next episode will feature Dr. John Roback from Emory on Transfusion-transmitted CMV (I don't want you to miss that one), and I've got more fun topics coming as I count down to my landmark 50th episode in April with the amazing Sue Johnson discussing the essentials of pretransfusion testing!

Until then, I hope as you go through your day that you smile, and have fun, and above all, never EVER stop learning, you guys! We'll see you next time.