BBGuy Essentials 080CE:
Is That Donor "Safe?" with Mindy Goldman
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Mindy: Hello, this is Dr. Mindy Goldman from Canadian Blood Services in Ottawa, and this the Blood Bank Guy Essentials Podcast.

Joe : Hi everyone. Welcome to episode 080CE of Blood Bank Guy Essentials, the podcast designed to teach YOU the essentials of Transfusion Medicine. My name is Joe Chaffin and I am your host.

Today on the podcast, I want to give you a "behind the scenes" look at how blood collection organizations make really difficult decisions designed to keep their blood donors AND the people who will receive the blood that they collect, safe, in an interview with Dr. Mindy Goldman from Canadian Blood Services.

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.

Now with that bit of housekeeping out of the way, you should be aware, and I hope you are, that blood collection organizations wrestle *constantly* with two big questions: The first is, of course, "how can I keep these amazing blood donors safe?" We really have to make rules and decisions about who can and can't donate blood, in that case from the perspective of keeping donors from being harmed by what's really an incredibly generous act: Giving blood.

But the second question is probably what came to your mind when I talked about safety, and that's this one: "How can I protect the patients who are going to receive the blood I'm collecting?" We ask our donors, as you know, an incredible array of spectacularly detailed and really, REALLY personal questions, and we're trying to find out about things that put them at higher risk of passing on a transfusion-transmitted infection to a patient.

So, in today's episode, I'm joined by Mindy Goldman, who is the Medical Director of Canadian Blood Services, or "CBS," in Canada (obviously). Mindy and I are going to pull back the curtain on how some of these tough decisions are made, when we discuss two real-world examples. First, we are going to talk about CBS' decision to discontinue the use of an upper age limit for their blood donors, and how Dr.

Goldman and Health Canada decided that their older blood donors would be safe. And second, and somewhat more controversially, we are going to walk through the more recent decision to change the deferral for males who have had sex with other males from 1 year down to 3 months.

So, let's just be honest with each other, OK? I realize that second issue is one that brings up really strong feelings, no matter how you feel about it. I know that some believe strongly that men who have had sexual contact with other men should NEVER donate blood, and others are ok with a timed deferral after male to male sexual contact (like a year or three months), while some believe the entire thing is unfair and discriminatory. And I want to be clear: This interview is NOT meant to be anything but educational! I was interested in the discussion and the "why" behind the decision. I welcome respectful, and I do mean respectful, discussion in the comment section at BBGuy.org/080. And again, I do mean "respectful," if you get my meaning!

Before we start, let me tell you a bit about Dr. Goldman: Mindy is the Medical Director, Donor and Clinical Services at Canadian Blood Services in Ottawa, Canada, and she is an adjunct professor at the University of Ottawa. Mindy is a clinical hematologist with extra training in Transfusion Medicine. Through her career, Mindy has focused on evaluation and implementation of donor eligibility policies to ensure safety for both patients and donors (kind of what we are talking about today), and one her main areas of interest for recipient safety has been the evaluation and evolution of deferral policies for men who have had sex with other men. Mindy is currently on the Board of Directors of the ISBT, and she is active in many international professional societies, including AABB as well as the BEST collaborative. Mindy is a frequent contributor to the medical literature and with Dr. Anne Eder, she is a co-editor of a really, really great book from AABB Press called, "Screening Blood Donors with the Donor History Questionnaire."

OK, let us go! Here's my interview with Dr. Mindy Goldman, "Is That Donor 'Safe?'"

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

Mindy: Nice to be here.

Joe: It's wonderful to have you! I really appreciate you doing this, Mindy, well, for a lot of reasons. I think it's really important and very, very interesting to talk about, first, differences in perhaps how things are done and how decisions are made in Canada as compared to where the majority of my audience is listening from, the U.S., but also to talk about a couple of really, really important decisions/evaluations that you guys have made recently up there in Canada that I think impacts really all of us in the blood world. So as we get started, Mindy, I wonder if you would take us through a little bit how blood is supplied, collected, processed in Canada, in particular in

comparison to how things happen in the United States. Could you just give us a high-level overview of that, please?

Mindy: Sure. So, things are not that different North of the border, but we have two blood suppliers in Canada: Canadian Blood Services and HemaQuébec. The organizations were founded in 1998 after the Krever report of shortcomings in the system when it was run by the Canadian Red Cross and thousands of Canadians were infected with HCV and HIV. And so really the organizations were founded in a very "precautionary principle" sort of way. Canadian Blood Services was responsible for blood collection testing and distribution for all the provinces and territories except for Quebec, and HemaQuébec, as you might guess, is responsible for doing that for the province of Quebec, which is about 25% of the population in Canada. So, these are independent organizations. They're arm's length from government. They have their own boards of directors; however, they are funded mainly by the provincial governments, and the provinces fund according to the blood use in their province. And then blood is distributed, and blood components, to the hospitals according to their needs. We also collect a little bit of source plasma, and we purchase and distribute plasma protein products to all the hospitals, as well. And we do some work in organs and tissues, and we're responsible for the unrelated stem cell registry in Canada and have a Canadian Cord blood bank.

So, if you look at the blood side, we collect about 825,000 whole blood units a year at Canadian Blood Services. Most of our platelets are whole blood-derived using the buffy coat method, so that's a little bit different from the U.S. We do collect some apheresis, but most are buffy coat platelets.

Joe: Mindy, in the United States, as I think most of our listeners will be aware of, there is an overriding government authority, in particular, the Food and Drug Administration, and a lot of blood banks and blood centers in the United States are also, either voluntarily or where I live in California, by law, regulated also by the AABB.

How does that fit in in Canada? Do you have an overriding government organization?

Mindy: We do. We do. So, our equivalent of the FDA is "Health Canada." They're our regulator for both CBS and HemaQuébec. A little nuance compared to the FDA is that we need to submit to our regulator most proposed changes. Any proposed change that might affect recipient health has to be submitted to the regulator prior to implementation.

So that's a bit different than in the U.S. I think it's because we're just two blood suppliers, they're able to do it that way. That does not apply for our diagnostic labs and sort of the "non-core" business, but for the blood components and so on, that all has to be cleared with the regulator before we can make a change.

So if we're talking about a change, a typical change, which is not dealing with an emergent issue, which is a little different, you know, requests for changes can come

in from everywhere. they can be things that people in the field, our staff say, "This is unclear," or, "Do we really need to do things this way?" We get complaints from donors that are being deferred, of "Why am I being deferred?" Nowadays, everyone looks at websites from other organizations. A lot of Canadians go south in the winter and they donate blood in the States, and they challenge us, "How come I was able to donate in Florida and I'm not able to donate here?" That's a good question. And obviously, we ourself go to meetings and learn from our colleagues and think, "Gee, could we do something a bit better here?"

You know, requests for change or thinking about change comes in in many different directions. We have a Donor Selection Criteria Working Group, which is an advisory group that puts together people from Canadian Blood Services and HemaQuébec. It includes both operational people from our collections group as well as quality and regulatory affairs, medical people, of course, both in the field and that head office, our infectious disease specialists. We have a donor representative and a recipient representative on the committee. And so, often, requests for change will start there, and we will think about what we've been asked to do, and, what kind of data we might have or information we might need to make the change. We have a strong epidemiology group, and so often this might mean evaluating some of the data that we have in our donors, or maybe a study that we need to do to get more data to ensure that what we're doing is the right thing.

We often will reach out to international colleagues to see what their data is, what they're doing, and if they performed any studies to assess the safety and efficacy of what they're doing as well.

Joe: So, it's not Mindy sitting on the throne waving her magic wand and saying, "This must change!"

Mindy: Well, that might be the start. Certainly, I sometimes feel like I'm the complaints department, with everybody from, you know, donors who've just come back from Florida to members of Parliament wondering why they're deferred. But then there's, there is no magic wand, I am not the good witch!

Joe: Yeah. Oh, I wasn't implying that! Oh, man! Now I feel badly. All right. Well Mindy, thank you for sharing that. I wonder if we could talk just a little bit about overriding goals. We're going to get into a couple of very specific things that you guys have evaluated recently there in Canada and you've made some decisions on, but before we get there, I think it's important to set the stage a little bit, and, this is certainly universal, whether you're collecting in the United States or the UK or Canada or wherever around the world: When we are considering the criteria, for example, that we use to screen our blood donors for acceptability, whether they're physical criteria, whether they're other criteria that we'll refer to, what are our overriding goals? What are we trying to do when we put in these criteria, either again, behavioral-based or physical criteria-based or age-based, what are we trying to do with that?

Mindy: Well, I think the two overriding bedrock goals have got to be recipient safety and donor safety. So, the whole reason we're doing all this is obviously to provide a safe blood component to a patient. And we have to always keep that in mind.

Donor safety has become a more important issue lately, and in terms of a lot of the changes that we do, they invite impact on donor safety as well. So those are the two kind of, I think, basic tenets I have to think about everything.

There are a lot of other kind of areas that are also important in terms of blood availability. For example, you can have a very safe donor, but if that's the only donor that's not gonna work.

So, there's always, you know, we're not an academic institution. It's we have to meet our quotas. Blood availability is an important part of safety. And a lot of things feed into availability, right? Donor satisfaction. We're entirely dependent, as are people in the US and many other countries, on a volunteer blood supply.

So, donors will walk with their feet. They don't like…they're not comfortable with what we're asking us. They think it's too long. It's too invasive. They feel that we are a discriminatory organization, et cetera. So, there are a lot of things that feed into availability.

And then, obviously, operational efficiency is important too, because we're all trying to do the best we can with scarce dollars and make improvements in our system, often with budgets that are not expanding.

So, trying to be more efficient and make the best of the healthcare dollars that are available to us.

Joe: I think what you just said is so important for the learners that are listening to this, to understand, and…yeah, absolutely: Keeping the donor safe, keeping the patient safe, but also being able to strike the balance of not making the criteria so restrictive that we don't have any donors left is, I think, something that learners miss sometimes.

And with that in mind, I would love to take a couple of recent evaluations that you guys have done, as I mentioned, up there in Canada, and just break them down a little bit.

So, let's talk first about the one that, is maybe a little less controversial, and that is whether or not there should be an upper age limit to people donating blood, whether older donors are acceptable and/or just as safe as younger blood donors.

So, Mindy, you evaluated this along with the BEST Collaborative in a paper that was published in April 2019, in “Transfusion” by the way, and that paper was called, "Safety of blood donation by individuals over age 70 and their contribution to the blood supply in five developed countries: A BEST Collaborative group study." Mindy, I wonder if you would talk us through a little bit what led you to be interested in that

paper and further, what's the history in Canada of having an upper age limit with blood donors?

Mindy: The history is that we, like many other blood suppliers, had an upper age limit. We had some pretty complicated criteria actually. So, the upper age limit was the lowest for first time donors. At one point, I think it was as, as low as 61 or 62, which seems ridiculously young now, since I'm in hailing distance! And then, for regular repeat donors, which we had a complicated definition for that, you had to have donated, I think in the last, successfully donated, in the last 2 years, it was a little bit higher, maybe 66. And then, if you were a regular donor, so you were donating regularly, successfully, I believe we dropped you when you hit your 71st birthday.

So, the impetus for change came from a few areas. The first is, we actually had a lot of donors dropping off the edge of that demographic criteria because our whole donor base, our whole population in Canada, as in a lot of other developed countries, is aging. And so, we had quite a few donors who were just being kind of “booted” just because they hit that age limit. And then, as I mentioned, a lot of these people head to Florida in the winter months, and they would successfully donate there. And so, we did get a lot of complaints from these donors, a lot of them very dedicated, you know, multi-gallon donors saying, "I successfully donated in Florida, and now here I am, back in BC. And by the way, this is me winning the marathon in my age group, with a picture from the local newspaper. And, why can't I donate blood here?" It seemed like a good question, to which I really didn't have a great answer!

So then comes the question of, if you want to assess a change, how are you going to get data to support it? Well, one thing is to look at experience in other jurisdictions, and to us that was mainly the U.S. They were really the only place that had either removed the upper limit or had a much higher upper limit. And there were some studies that had been published there. And I also tried to get information from all of my friends and colleagues about what they were doing and how they thought it was working.

The other is to look, if you have any exceptions to your rules, that maybe you can learn from. So, at the time, we had a large autologous donor program, as did a lot of other people, and a lot of those donors were pretty elderly. They had many preexisting medical conditions, and they were on a lot of medications sometimes, or hobbling into the clinic on their cane, at the age of 85 because they were going to have their third hip replacement done, and they tolerated donation rather well.

So, we looked at the, you know, the reaction rate in those donors, which was very low. And we were able to convince our regulator, putting together the U.S. experience, our experience with autologous donors, and a few papers published about the way older adults adjust to hypovolemia (there is literature on that), to convince the regulator that we could increase the upper age limit.

At first, we just could do it for these regular repeat donors, and we had to send them to get a permission slip from their physician. The same way when you miss school, you know, "I was out sick," so this was, "I'm not sick!" Although, of course, those physicians don't really know that much about our criteria, but we did do that at first, and then we had a look at the results of that after a year or two of doing that. And we were able to show Health Canada that the donors that were deferred from donation, we would have deferred them anyway by our usual questionnaire. And so, it really was not useful, and it was an extra step for the donor. So, we were able to get rid of it. And then once we gained our own experience and evaluated what was happening in those repeat donors, we were able to gain some courage and drop the upper age limit, even for our first-time donors or the irregular donors. So, it's sort of a gradual process as we learnt ourselves, looking at our own data in Canada.

Joe: Mindy, I think that sets the background really well. Why don't we move ahead in time a little bit to when you were involved with this BEST Collaborative paper, and if you could, just set the stage for the paper, who was involved? What were you trying to look at? What were your goals of that study?

Mindy: So the BEST group is “Biomedical Excellence for Safer Transfusion,” and so it brings together a group of scientists, physicians, researchers and manufacturers to try and pool what we could do together to enhance the safety and efficacy of what we are offering, which is mainly our fresh blood components, a little bit about, also, hospital transfusion practices and diagnostic services. And so, in that group, there's a range of people who have upper age limits for donation. We had done an initial study where we just looked at the demographic characteristics of our general population in our countries and then of our donor population, trying to answer the question about, "Is our donor population aging? And if so, is it aging faster than our general population?" Because of course, looking forward, we're trying to see how we're going to maintain the adequacy of the blood supply when one person in five is getting a senior's discount in Canada.

So, that study highlighted the differences in the upper age limit for donation in many countries and also that individuals over 65 were a very fast-growing segment of the general population in many of our countries, which is a good thing, no? And a lot of these people are very healthy. And so, that kind of gave the idea, "Well, why don't we look more closely at what we're doing on the donor end?"

And I remembered my days trying to change our policy. And one thing I have noticed is that once people have kind of fought their battle and changed their policy, they don't necessarily publish their findings, and they just go on and attack their next challenge, right? And so, that's great on them, but it doesn't really help other jurisdictions that haven't changed look to a nice evidence basis on which to base changes in their policies.

So, as somebody who's always kind of on the outlook for nice studies that I can then send along to Health Canada, I thought that this would be interesting. I also thought that we would probably come up with a better dataset and more solid conclusions by looking at a few different countries that all have sort of different criteria for health considerations, because a lot of medical conditions obviously become more common as people get older, and policies are quite different in different countries about people who have diabetes and are on insulin, or you know, with type two diabetes or people who have heart disease or all those kinds of things. So, it would be more robust if we pulled the data from a few different countries.

So that's what we did in this study. We didn't really want to compare reaction rates or deferral rates between countries, because we know that these are very difficult to compare because of different definitions, different criteria, different ways of gathering the data. So, we decided what would be more valid would be for each country to look at the reactions and the deferrals in their older donors compared to their 24 to 70 year old donors. Why not include the youngest donors? Well, we all know that those donors have the highest reaction rates, and they make up a variable percentage of the blood supply in each country, and the lower age limit is different in different countries. So that's why we came up with that study design.

We invited all BEST members who don't have an upper age limit and were part of kind of large blood centers to participate and there were five countries (quite a few more centers participating than that). And, I think we came up with quite a nice data set showing that at least in repeat donors, it's very safe to continue donating. And these older donors will donate more often than the younger donors. and, are probably the cheapest recruits that you'll find because they, you know, they've "drunk the Kool-Aid," and are eating the cookies, and they're very loyal supporters of the blood system, usually. So, obviously they're a selected group of the older population, but, they're very dedicated and loyal.

And I know that since that paper has been published, I don't want to totally attribute this to the paper, but I know that several other countries in Europe have increased their upper age limit. To me that's like winning the Lotto, you know. That's very gratifying. If you think, "Wow, something that we could do in Canada or in this group could then help others make an informed decision on what to do for their donors to best serve their patients." So that's like, "Jackpot!"

Joe: So going back to that balance that we talked about in the beginning, Mindy, I assume that your conclusion from looking at the information in this paper as well as your personal experience, is that this is, that the balance is not swinging too far towards a lack of safety if you allow older donors to donate. Is that an accurate statement?

Mindy: It is. I mean, we did put, in the discussion in the paper, that most of these donors are repeat donors. So rare is the, you know, first time donor who's over age 70. And so, that's not a deferral in, in most of these, countries that participated, for most of the

blood centers. We talked about if we could split out that data, but unfortunately, we thought that most of the first-time donors in that age bracket would be more first time to that blood center.

You know, people who saw the light and, you know, bailed on Vermont and now live in Arizona, kind of first-time donors, rather than true first-timers. And so, I think the data is probably weaker for actual first-timers and they are rare. There's the odd one, you know. That would be my only caveat there.

Otherwise, for people who have previously donated, who meet the criteria, I think it appears to be a very safe thing to do.

Joe: Let us move on to a topic that is a little more fraught with controversy and this is a topic when we talk about deferrals for men who have had sex with men, this is a topic that is, as I said, fraught with strong feelings, with, in many cases, with a lot of emotion, simply, that has gone into this entire discussion over the years. It's a very big deal, and I think it's very important to understand that we do our very best in blood center world to handle this with as much sensitivity and kindness and grace as we possibly can, but it's a difficult thing to address.

So, we want to take you through a little bit how things have gone internationally, and specifically, how Mindy and her group in Canada have addressed this recently.

Mindy: Definitely. I mean, when you get into a criterion that on the one hand, has been critical in the past for recipient safety, right? Before we had testing for HIV, this criterion was very important in blood safety. And, on the other hand, from a societal perspective, seems to be excluding a whole group of people based on their sexual orientation, a group that has been stigmatized and discriminated in other areas, you can see that the setup is going to be for difficult decisions and difficult to make progress on criteria changes.

Joe: Absolutely. Well, Mindy, you've written about this, in particular in an article in Vox Sanguinis in 2018. Perhaps we should start with just a general look at what strategies blood centers, blood collectors use, both screening and testing, to try and keep the blood supply safe from HIV.

Mindy: Yeah, so we're a very safety-conscious industry, and that of course comes out partly because of the health tragedy in the ‘80s, where so many recipients became infected with HIV and hepatitis C and, you know, in Canada, the Krever report did raise issues where we could have done things better, been more rapid at introducing testing and changing criteria that could have avoided some of this suffering and hardship that we caused.

And so I think that's true in every country, that with the HIV and so-called "Non-A, non-B hepatitis," which your younger listeners will not have a clue, but that was what we called hepatitis C, before what we knew what it was. You know, that is kind of the

background environment of the '80s when the criteria were first put in place, where gay men at first were noticed to be a high-risk group for AIDS. And so, the criteria were put in place to defer first, gay men with multiple partners, because that was clearly a high-risk group. And then, once testing for HIV started, it was noted that even men with just one sexual encounter with another male were at a high-risk group. And so, that's when the FDA, followed by many other regulatory agencies, put in that even once, since 1977 deferral.

And you know, in a regulated environment, it's difficult to make changes in criteria, especially when they come from that kind of background. And there was a paper from Dr. Mike Busch showing that that criterion did make a difference in the epidemic in the U.S., in San Francisco, and decreased transmission of HIV before testing was put in place. So, clearly, before testing was in place, and probably when there was first-generation testing and just antibody testing, right, this criterion was important in maintaining blood safety.

So, you know, at the present time, we have several layers of safety. I think, first of all, we have to recognize that safety begins *before* people come to donate, with public health education, people being able to easily access HIV testing, not coming to the blood center in the "test-seeking mode," and knowing themselves that if they're in certain risk groups, they should not come in to donate.

Then, when people come in, or they look at our website and they're thinking of donation, we all have information in our mandatory pamphlets people are supposed to read, explaining what high risk groups are, what our definition of sex is, what the window period is, and why people should not come in to donate or not donate if they are in these risks groups.

Obviously, all our questionnaires have many questions getting at HIV risks, and one of them is about men having sex with men, or, for women having sex with a male who's had sex with another male. And then, our testing is now improved tremendously, and we are all doing two tests for HIV, so both antibody testing and NAT testing for nucleic acids. And so, our window period when somebody might be infected but not picked up on our tests has become very small, probably in the order of less than a couple of weeks.

So that's kind of the background of where we're at in terms of trying to then think about, criteria changes.

Joe: I wonder if you would take us a little bit through the history of how you have done deferrals for males having sex with males in Canada. You mentioned in the mid-eighties that Health Canada followed the recommendation from the U.S. FDA to give a permanent deferral for any male who had had sex with a male, even once, since 1977. When did that change and What were the stages that you went through in Canada? And we'll get into the details in a minute. And where are you now?

Mindy: Yeah. So, for many years that did not change at all. There was a lot of social activism on university campuses with "Ban the Ban" campaigns, or sometimes boycott of clinics, to try and put pressure on Canadian Blood Services, and the same thing for HemaQuébec, to change our criteria.

And of course, testing had evolved considerably and was continually improving. We did have a court case, which we, under the charter of rights and freedoms in Canada, that we were being discriminatory. We did kind of "win" the court case, although the judge did say that it was, that we had not proven that we needed to maintain the length of the deferral period, the ever-increasing length of the deferral period. And that's not really what the case was really focused on.

But so, given that, and given the goal of being more inclusive, to have the minimum number of deferrals of both people who are being deferred because they were ineligible, and also people who we would have accepted to donate, but who were kind of allies, and social justice advocates, it's mainly young people, of course, just not wanting to donate in support of people who they thought were being unfairly discriminated against. So, we started having meetings that included both patient groups that needed a high number of transfusions. So, the Canadian Hemophilia Society, Canadian Thalassemia Society, Sickle Cell Anemia, and advocacy groups in Canada, Egale Canada, various other student groups and so on, and trying to get these people together in the room, often with an external facilitator, to have discussions about what we were doing in the blood supply at the time, what we thought the risks were, what possible changes could be made.

And some of these were…some of this was in a consensus conference that was published in the early 2000s, and these were very difficult meetings, difficult conversations, very polarized, and not very successful at finding any kind of a middle ground.

It was clear to us that we were not going to be able to change the criteria with the regulators, since we didn't really have any data to show that it would be safe. Of course, when you're, again, when you're not doing something, you're not going to get any data, and we clearly did not have the support of anybody to move forward in any way.

So, what changed over time was, Australia went to a 12-month deferral. Our testing improved still further. I think, society expectations and understanding improved. We did surveys in our donors that showed that many donors thought that we should accept men who had sex with men, providing that they were “safe,” or if they met all other criteria. I mean, exactly what that's supposed to mean, you can say, “Well, that's not all that clear.” But the donors were clearly open to a different way of doing things and did not think that there should be a lifetime deferral for men who had sex with men.

And so, we started to try and make changes. We again pulled together groups. So, stakeholder participation has always been really vital in this. And this time we were able to get more agreement that a permanent deferral was not necessary, and we could move to a shorter deferral period based on window period for HIV modeling of risk that was done in Canada and in the US and UK of what would happen if we changed our criteria or the experience of Australia.

And so, we were able to move to a five-year deferral. Why five years? I think there was still concern by recipient groups and the regulator about emerging threats, and that may be men who have sex with men would be a high-risk group for emerging pathogens just as HIV had been an emerging threat in the '80s.

So, as we went on, emerging threats, you know, they came up in gardeners who weren't wearing long sleeves and got West Nile virus, or people who traveled to exotic climes, and so on, clearly did not have sexual routes of transmission as their main transmission route. Our testing improved still further. We did not have any increase in HIV in our donors when we moved to a five-year deferral, showing that all the modeling had actually been very conservative.

So, using the same type of logic, both heavy input from high interest groups, patients and community groups, as well as risk modeling analysis of our own epidemiology, and what happened in other countries who changed their criteria, we were able to move from a five-year deferral to a one-year deferral and finally, recently, to a three month deferral for men who have sex with men.

Joe: There's a lot in there that we could talk about and go further into. But in the interest of time, perhaps we should step back just a little bit and we'll come back to your three-month decision and how that entire process went. But before we do that, I think that you've pointed out in previous things that you've written that there are several ways to look at options for deferrals for men who have had sex with other men. And I wonder if you would just take the time to take us through those three main options. In particular, the first two, the time-based deferral and the risk activity-based deferral. Could you take us through kind of the pros and cons of both of those and your views on how both of those have come about?

Mindy: Sure. So, the time-based deferral is basically what we've just been talking about. And that is a pretty blunt instrument, where it's just if a male has had sex with another male, then he will be deferred for a time interval since the last sexual contact. And then, as the testing has improved and so on, the time interval has shrunk.

The advantage to this is that it has proved very safe. We're very familiar with this approach and we've made all these other changes using this approach. The disadvantage is that you're still deferring any really sexually active gay man, and you are not allowing people who may be in a very low-risk group, for example, people

who have one partner and are in a stable, monogamous relationship for years, from donating.

So that is the problem with that approach. There is a limit to it, when you feel that you're getting pretty close to the window period, plus a little bit of leeway, right? So, that's the time-based approach.

Joe: And Mindy, before you move on from that, can I ask one question that I get asked a lot? When the U.S. went to the one-year deferral for males who had sex with other males, one of the questions that several of the physicians at my hospitals asked me was, “Do we have any idea of whether or not there's complete honesty about how people are answering those time-based deferral questions now?” Is there any data out there about that?

Mindy: So, it's hard to get at that kind of data. The way that organizations have tried to get at it is mainly by doing anonymous donor surveys, looking at people who have recently successfully donated and asking them the same questions or similar questions that should have led to their deferral at the time of donation.

So, doing that, those are called “compliance surveys,” doing that, we see that the compliance rate is very good in our donors of the order of 99%, and that there are a small number that are not compliant with our criteria for MSM. So, it is very reassuring in that the vast majority of donors appear to be answering truthfully.

The other way that you can look at it is look at the donors that are coming up HIV positive, right? And interviewing those donors and finding out, are those people who should have been deferred? And sometimes they are, but I have to say, in Canada, there's a very small number, with from 0 to 5 HIV positive donors a year out of, you know, between Canadian Blood Services and HemaQuébec, over a million donations screened. So that's also an indicator that very high-risk people are not coming in to donate.

Joe: Okay, so let's move on to the risk-activity based questions. And think I said earlier that this is, in a way, something that a lot of people wish that we would be able to get to, where donors are asked about specific activities. Could you give us your perspective on that type of questioning and how feasible it is?

Mindy: Yeah, so that type of questioning is a much more nuanced approach than a “yes/no” answer. It’s not the typical approach that we use to do any kind of donor assessment, to be honest.

So, if you look at our questionnaire, it does tend to be yes/no answers. And it does not tend to be more nuanced risk assessment. And that goes for, criteria related to vCJD risk. We don't accept people who are vegan, even if they insist they didn't eat any meat when they lived in the UK, and on and on.

So that's not our usual, but it is more nuanced, and it can be done in a number of ways. One way would be to still have a capture question about males having sex with males in a given time period. And then, if the answer is yes, trying to drill down with other questions to get a safe subset of people who would be allowed to donate.

Another way, the so-called “gender-neutral” way, is to ask all donors questions to try and get at deferral of those with a high-risk sexual partner, or high-risk sexual behavior, not making the distinction of whether the partner is a same sex or opposite sex partner.

So, the type of questions that could be asked in either way would be our questions about (and it's always in a given time period, you're still focusing on the time period), but it could be asking the donor if they've had a new partner, if they've had more than one partner, if they feel that they and their partner are in an exclusive relationship. Those are the types of questions. They're not really an individual risk assessment, because you're still grouping people in categories, and it's not really true from a risk perspective that a new heterosexual partner in Canada has the same risk of HIV as a new male partner for a male, but it is a more nuanced approach, and it certainly has a certain appeal to it in sounding like a more fair approach, rather than any MSM and you're being deferred for a period of time.

Joe: So, Mindy, that sounds reasonable and it sounds logical. Is anyone actually doing this anywhere in the world?

Mindy: Yes. These gender-neutral approaches are used in Italy and in Spain. They do have quite different blood systems than we do in North America, however. So, they're using physicians to screen the donors, probably allowing for more nuanced questioning and risk assessment. As you know, we use screeners, but we're not asking extra questions of the donors.

If you look at their results, they have not published national data, but what they have published shows a higher rate of HIV in their donors, and more donors that are positive only by nucleic acid testing, so recent infections, than we see in North America. And so, the system is different, so hard to directly transpose to our system.

Joe: OK. Well and and like the, like the time-based deferrals. I know that you've written and talked before about the relative strengths and weaknesses of the risk, activity based deferrals. Could you talk to us about that? What are, what are the good, the good and maybe not so good or more challenging things about assessing things on a risk activity based matter manner.

Mindy: Well, I think I've pointed out the weakest. I didn't mean not. Afford the same degree of safety for recipients, at least as performed in Italy and Spain. In terms of adequacy of supply, if you ask these questions to all donors, so if you do do a gender-neutral approach, you could be losing a lot of very safe donors because these are not rare activities.

And so, I think you have to look in a more detailed way at that side of things, in terms of the specificity of the question is it's very low, right? And you will be losing a lot of currently donating safe donors. So, I think it's hard to just transpose what's happening there and say, well, why don't we do the exact same thing here?

It doesn't mean that one couldn't develop a more nuanced approach, but it's hard to just do a cut and paste of something that's currently out there.

Joe: I hear what you're saying. I mean, I think that the idea of course, is that doing things that way has the potential to gain back the gay men who are in monogamous steady relationships with another. In theory anyway, that seems like that would be a fairly safe group of men.

And I think that's been the concern that has been expressed in that population is that we're discriminating against those in monogamous relationships, but it doesn't come without some potential other complications. Is that a fair way to interpret it?

Mindy: I think it is, and it could be that the first way that this will be implemented is with an additional manufacturing step that would ensure safety. So, for example, with a quarantine on plasma, or with processing of plasma in the source plasma situation, or with pathogen reduction with platelets. And so there would be an extra step that would be there in addition to all the things that we're currently doing to ensure safety.

Joe: So, Mindy, just in the interest of time, as we close out our time together, I wanted to give you the chance to talk through a little bit, as you mentioned, you very recently, at the time of this recording, it's just been a couple of months, so, in June of 2019, Canada moved to a three month time-based deferral for males who have had sex with other males. So I wonder if you'd just share with us as we finish this, what kind of reception has that change received? Has there been resistance on either side, either from the perspective of the donor safety side or the, well, primarily from the recipient safety side. Has there been any pushback to that? And how do you plan to monitor going forward how well this is going for you?

Mindy: So in terms of recipient groups, we really included them in the whole process of modifying the criteria. And many of them wrote letters of support to our regulator, Health Canada, to show that they agreed with the change, as did MSM advocacy groups. So they knew this was coming. They were part of the process and we have not had any kind of negative feedback from them.

In terms of MSM groups, LGBTQ advocacy groups, I mean, for them, this is maybe a step in the right direction, but obviously not where they want to end up. So, we're continuing to work with them in many research studies. The federal government has given a lot of money to do more research projects to try and move to a more nuanced, risk-based policy.

How we're going to assess the safety of what we've done? We will again, look at the HIV rates in our donors. We will do another anonymous compliance survey to see if that has changed at all. And, we will of course monitor the adequacy of the supply and see if there are donors that have previously been referred who are now coming back to donate. We might get a few donors back that way.

Joe: Well, Mindy, this has been a wonderful experience for me. I am so grateful to you for sharing the thoughts. If I can refer back to the beginning of our talk, maybe sharing the thoughts of the wizard with the wand upon the throne, okay, maybe not… But to hear your thoughts on how all this is happening and how all this has happened has been really terrific for me and I'm sure for my audience as well. So thank you so much for doing it. Thank you so much for being here.

Mindy: Well, thank you so much for taking the time, and I don't think the "wizard analogy" is a very good one because as you see, changing donor criteria is a collaborative process and not a dictatorial one. So, you know, maybe for Halloween it might be a good costume, but I don't think that's the best way to make policy in our society.

Joe: I think you're absolutely right. Thank you so much, Mindy. You take care.

Mindy: You're welcome. Thank you, Joe.

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Joe: Hi, it's Joe with just a couple of quick closing thoughts. I hope that you end our time together today with a better understanding of how blood collection organizations make difficult decisions for both donor and patient safety. And again, I am more than happy to welcome respectful discussion in the comment section at BBGuy.org/080.

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

My next episode is coming very soon, hopefully next week, and it will feature an interview with Dr. Rich Gammon, chair of the AABB Blood Bank and Transfusion Service Standards Committee. Rich and I will discuss the top ten changes in the new, 32nd edition of AABB Standards (and if that sounds exciting, it IS! It's awesome!), and that edition of AABB Standards, by the way, becomes effective in April 2020. Even if you don't work in an AABB-accredited facility, maybe you live, like I do, in California; it's applicable to you whether you are AABB-accredited or not. But, you definitely won't want to miss that interview!

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